ORAL ARGUMENT NOT YET SCHEDULED

No. 07-7062

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION,

Appellant,

v.

DISTRICT OF COLUMBIA and ADRIAN FENTY,
in his official capacity as Mayor of the District of Columbia,

Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA, No. 04cv01082,
Honorable Ricardo M. Urbina, United States District Judge

BRIEF FOR AMERICA'S HEALTH INSURANCE PLANS, INC. AND THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AS *AMICI CURIAE* IN SUPPORT OF APPELLANT

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RULE 26.1 CORPORATE DISCLOSURE STATEMENT AND CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to D.C. Circuit Rules 27(a)(4) and 26.1, *amici*[1] state that America's Health Insurance Plans, Inc. ("AHIP") and the Chamber of Commerce of the United States of America ("the Chamber") are not-for-profit corporations with no parent company; no publicly-held company has a 10% or greater ownership interest in either AHIP or the Chamber.

Pursuant to D.C. Circuit Rules 27(a)(4) and 28(a)(1), *amici* state that, except for the Chamber, all parties, intervenors, and *amici* appearing before the district court and in this Court are listed in the Brief of Appellant. References to the ruling at issue appear in the Brief of Appellant. This case has previously been before this Court, *see Pharmaceutical Care Management Ass'n v. District of Columbia*, No. 05-7007. *Amici* are aware of no related cases pending before this Court or any other court in the District of Columbia.

Dated: October 2, 2007

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Jonathan D. Hacker

[1] The Chamber's motion for leave to participate as *amicus* accompanies this brief, so the Chamber is only a proposed *amicus*. For the sake of simplicity, however, this brief refers to AHIP and the Chamber collectively as "*amici*."

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[3] All applicable statutes are contained in the Brief of Appellant.

INTEREST OF *AMICI CURIAE*

This brief is submitted on behalf of America's Health Insurance Plans, Inc. ("AHIP") and the Chamber of Commerce of the United States of America ("the Chamber") as *amici curiae* in support of appellant Pharmaceutical Care Management Association. This Court granted AHIP's motion for leave to file an *amicus* brief on September 13, 2007. The Chamber's motion for leave to join AHIP's *amicus* brief accompanies this brief.

AHIP is a national trade association whose membership consists of approximately 1300 companies that administer and/or insure benefits including disability, long-term care, supplemental coverage, health, and pharmaceutical coverage to more than 200 million Americans, the great majority of whom are participants in, or beneficiaries of, employee benefit plans under the Employee Retirement Income Security Act of 1974 ("ERISA"), 29 U.S.C. § 1001, *et seq.*

The Chamber is the nation's largest federation of business companies and associations, with an underlying membership of more than 3,000,000 business and professional organizations of every size and in every sector and geographic region of the country. An important function of the Chamber is to represent the interests of its members by filing *amicus curiae* briefs in cases involving issues of national concern to American business. The vast majority of the Chamber's members sponsor employee benefit plans governed by ERISA, many of which employ third

parties to provide non-fiduciary but essential services to administer their plans. Such essential third parties include pharmacy benefit managers employed by many Chamber members to administer prescription drug benefits.

This case is of significant interest to *amici* because the District of Columbia ("District") law at issue substantially interferes with the ability of *amici*'s members to establish beneficial terms for the employee prescription drug benefit plans they sponsor and administer. More broadly, the district court's decision threatens to undermine the relationship between employee-benefit plans and the vast network of third-party service providers that facilitate the provision of benefits. And the district court's unrestrained view of collateral estoppel jeopardizes the ability of national associations like *amici* to defend their interests nationwide. *Amici* are uniquely positioned to explain the practical effect of the District's law, and the need to reverse the decision below.

SUMMARY OF ARGUMENT

The decision of the district court should be reversed for several reasons.

I. The court's collateral estoppel holding is both erroneous and unsound as a matter of public policy. Rulings on pure questions of law are not entitled to preclusive effect, and the district court's contrary decision will impede the development of the of law on questions of national importance.

II. The AccessRx Act of 2004, D.C. Code §§ 48-831.01 *et seq.* undermines employers' ability to administer prescription drug benefits efficiently, and thus has the perverse effect of increasing the cost of providing prescription drugs. And because the statute interferes with the efficient administration of prescription drug benefit plans governed by ERISA, it relates to such plans and is therefore preempted.

For these reasons, as well as those articulated by appellant Pharmaceutical Care Management Association, the decision below should be reversed.

ARGUMENT

I. THE DISTRICT COURT'S COLLATERAL ESTOPPEL RULING IS LEGALLY INCORRECT AND UNSOUND AS A MATTER OF PUBLIC POLICY

The district court below gave preclusive effect to the decision of the First Circuit in *Pharmaceutical Care Management Association v. Rowe*, 429 F.3d 294 (2005), holding that a Maine law similar to the District statute at issue here was not preempted by ERISA § 514, 20 U.S.C. § 1144. That application of collateral estoppel was in error. The *Rowe* court ruled as a matter of *law* on the preemption question before it, and it is clear that such legal rulings are not entitled to preclusive effect in subsequent litigation. *Cf. Montana v. United States*, 440 U.S. 147, 162 (1979) ("Where . . . a court in deciding a case has enunciated a rule of law, the parties in a subsequent action upon a different demand are not estopped

from insisting that the law is otherwise, merely because the parties are the same in both cases.").

The district court's legal error is amply documented by appellant. *See* Appellant's Br. 19-35. *Amici* instead focus on the practical consequences of that error, which are extremely troubling for the development of the law on matters of national importance. It is often the case that a national legislative agenda will lead to adoption of similar statutes in many states. When that happens, national associations like *amici* may seek to challenge those statutes in a number of jurisdictions. On the district court's logic, however, the first ruling in any one of those challenges will be preclusive in all future association litigation – so that the first local court to issue a final ruling will effectively decide for the entire country the lawfulness of a national legislative agenda.

There is no reason why a single court, by virtue of an accident of timing, should be vested with the authority to settle for all jurisdictions a legal question of national import. Application of collateral estoppel in that context short-circuits full development of the law. *See, e.g.*, *Envtl. Def. v. U.S. Envtl. Protection Agency*, 369 F.3d 193, 203 (2d Cir. 2004) ("applying collateral estoppel in public cases involving geographic breadth 'would substantially thwart the development of important questions of law by freezing the first final decision rendered on a particular legal issue'" (quoting *United States v. Mendoza*, 464 U.S. 154, 160

(1984))). And while Supreme Court review is theoretically available to correct any error in the initial judgment, the fact that only one case – the first – will properly present the question for review sharply limits the opportunity for Supreme Court intervention.

The impact on litigants and their strategies is likely to be counter-productive, as well. Under the district court's rule, giving preclusive effect to whichever ruling is first in time, litigants will have every incentive to forum-shop, jockeying for quick decisions in favorable fora and using delay tactics to slow decisions in less favorable fora. And to avoid application of collateral estoppel, association members may abandon collective litigation through their associations, and instead sue individually – leading to more (and more repetitive) lawsuits, taxing the resources of the courts, and depriving them of the benefits of associational expertise and resources. For all these reasons, *amici* submit, the district court's decision is not only wrong as a matter of law, but unsound as a matter of public policy.

II. THE DISTRICT'S LAW DIRECTLY INTERFERES WITH THE RELATIONSHIP BETWEEN PBMs AND EMPLOYERS IN A WAY THAT IS PREEMPTED BY ERISA AND UNDERMINES THE ABILITY OF HEALTH PLANS TO PROVIDE ACCESS TO EFFECTIVE AND AFFORDABLE PRESCRIPTION DRUG BENEFITS

If this Court agrees that the district court was wrong to give issue-preclusive effect to the First Circuit's ruling on Maine's pharmacy benefit manager ("PBM")

law, it should decide for itself the question of law on which this case turns: whether Title II of the AccessRx Act of 2004, D.C. Code §§ 48-831.01 *et seq.* ("AccessRx Act"), is preempted by federal law.

Almost every ERISA-governed employee benefit plan that covers prescription drugs relies on a PBM to administer those benefits. Indeed, absent the services PBMs provide, most of the employers *amici* represent would not be able to provide access to any meaningful prescription drug benefit at all. PBMs perform a variety of essential functions, virtually all of which result in substantial savings in the costs of covering prescription drugs. *See generally* Federal Trade Commission & U.S. Department of Justice, *Improving Health Care: A Dose of Competition*, ch. 7, at 10-18 (July 2004) ("FTC/DOJ Healthcare Report").

By pooling the purchasing power of many different employer- and plan-clients, PBMs can negotiate significant discounts and rebates from drug manufacturers for the drugs their clients will purchase. *Id.* at 11-12. PBMs often administer drug benefit plans by processing benefit claims, providing access to retail pharmacy networks, and managing mail-order pharmacy services. PBMs also often work with employers to design benefit structures that provide quality benefits at a reasonable cost. These structures include "formularies" (i.e., lists of prescription drugs approved for coverage under a client's pharmacy benefits plan) and creation of "tiered" copayments (i.e., the assignment of lower co-pay levels for

lower-cost but therapeutically equivalent drugs to encourage their use). *Id.* at 12-13. PBMs also provide drug utilization review services to ensure the efficacy and safety of the drugs included on plan formularies. *Id.* at 14.

The District law at issue seeks to alter the contractual relationship between PBMs and their customers by transforming PBMs into "fiduciaries" of employers' ERISA plans and dictating key terms on which PBMs may administer prescription-drug plan benefits. Contrary to the *Rowe* decision treated as preclusive by the district court, a state's direct interference with the employer-PBM relationship is preempted by ERISA § 514. Section 514 preempts any state law that "relates to" ERISA plans, which includes any state law that regulates "employee benefit structures or *their administration*," *N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 658 (1995) (emphasis added). As explained below, it is difficult to see how the District law does not meet that standard – indeed, the law's entire purpose is to regulate the terms on which employers and other plan sponsors may contract with PBMs to administer their prescription-drug benefits.

What is more, the restriction imposed by Title II on PBM-employer relationships directly impedes *amici*'s members' ability to provide prescription-drug benefits to the nation's employee beneficiaries as efficiently as possible. Title II is a badly misguided attempt to protect the interests of health plans as well as

employers and other benefit plan sponsors – all rendered "covered entities" by Title II – from the supposedly pernicious commercial self-interest of PBMs. But as we explain below, *amici*'s members strongly disclaim any need for the protection of such laws. Indeed, it is the view of *amici* – as well as of the federal government's primary competition authorities – that such laws seriously undermine their ability to make quality prescription drug benefits available at reasonable cost.

A. Title II Undermines Employers' Ability To Administer Prescription Drug Benefits Efficiently

Title II of the AccessRx Act makes PBMs fiduciaries to their clients and requires PBMs (1) to provide to the health benefit plan sponsor, on request, information about the quantity and cost of drugs purchased by the sponsor, as well as "all financial terms and arrangements for remuneration of any kind" between the PBM and drug manufacturers; (2) to "transfer in full to the covered entity any benefit or payment received in any form by the [PBM] as a result of a prescription drug substitution"; and (3) to "pass . . . on in full to the covered entity" any payment or benefit from a drug manufacturer "based on volume of sales or market share." D.C. Code § 48-832.01(a), (b)(2), (c)(1), (c)(2), (d)(3).[4]

The aim of Title II is to give employers and others who provide health

[4] Section 48-832.01(b)(2) allows a covered entity to agree by contract to return "*a portion*" of the benefit to the PBM. *Id.* (emphasis added).

benefits in the District a special advantage over PBMs in arms-length negotiations for PBM services, thereby reducing (the theory goes) the cost of providing prescription drug benefits. *See id.* § 48-831.01(2); *cf. Rowe*, 429 F.3d at 298-99 (Maine's Title II equivalent aspires to "plac[e] Maine health benefit providers in a better position to determine whether PBMs are acting against their interests"). In fact, as we demonstrate below, by interfering with the free – and highly competitive – market for PBM services, laws such as Title II actually increase the cost of providing prescription drug benefits.

1. *Increasing Prescription Drug Expenditures Strain The Ability Of Employers And Other Plan Funds To Provide Prescription Drug Benefits*

The financial strains on the employer-provided health insurance system prevalent in the United States are already widely recognized. Despite the improvements in cost containment made possible by managed-care techniques, national spending on health care has reached 16% of gross domestic product ("GDP") and continues to grow. *See* U.S. Department of Health & Human Services, Centers for Medicare & Medicare Services, *National Health Expenditure Projections 2006-2016*, at 4, Tab. 1 (2005) ("*Health Expenditure Projections*"). And because "national health spending growth is forecast to outpace GDP growth each year during the next decade," health care spending is expected to reach nearly 20% of GDP by 2015. C. Borger et al., *Health Spending Projections Through*

2015: Changes on the Horizon, Health Affairs Web Exclusive, Feb. 22, 2006, at W61; *see Health Expenditure Projections* at 4, Tab. 1.

Increases in prescription drug expenditures have been a critical driver in overall heath care cost increases. Between 1995 and 2000, "prescription drugs were by far the fastest growing category of health spending." B. Strunk & P. Ginsburg, *Tracking Health Care Costs: Trends Stabilize But Remain High in 2002*, Health Affairs Web Exclusive, June 11, 2003, at 4. Spending on prescription drugs has quadrupled since 1993, growing from $51 billion that year to $201 billion in 2005. *See* Borger et al., *supra*, at W62 Ex. 1; *Health Expenditure Projections* at 5, Tab. 2. These figures reflect an increase in usage (the number of prescriptions increased 71% from 1994 to 2005, while the U.S. population grew only 9%); increases in retail prescription prices; and a shift toward newer, higher-priced name-brand drugs. Kaiser Family Foundation, *Prescription Drug Trends* 2 (May 2007). Overuse of antibiotics alone "results in as much as $5 billion in unnecessary expenditures each year." Midwest Business Group on Health, *Reducing the Costs of Poor-Quality Health Care Through Responsible Purchasing Leadership*, at iii (2003). Prescription drug spending is expected to continue to grow annually by 7% to 10% every year for the foreseeable future. *See Health Expenditure Projections* at 14, Tab. 11.

Increasing prescription drug costs pose a serious challenge to employers, other plan sponsors, administrators and insurers. *See* Kaiser Family Foundation & Health Research and Educational Trust, *Employer Health Benefits 2007 Annual Survey* 182 (2007) ("*Kaiser 2007 Survey*") ("The factor most often cited by firms as contributing 'a lot' to higher health insurance premiums is higher spending for prescription drugs (66%), followed by higher spending for hospital care (60%) . . . ."). While the rate of increase has slowed in recent years, it still greatly exceeds inflation and earnings growth, and premiums for employer-sponsored health insurance increased by a robust 6.1% between 2006 and 2007. *Id.* at 14; *see id.* at 11 (noting that the rise observed in 2007 was "lower than the 7.7% increase for 2006 but still much higher than the overall rate of inflation (2.6%) or the increase in workers' earnings (3.7%)."). "[P]remium growth continues to outpace growth in the economy and workers' incomes by a wide margin, making health care benefits increasingly unaffordable for employers and employees alike." B. Strunk et al., *Tracking Health Care Costs: Declining Growth Trend Pauses in 2004*, Health Affairs Web Exclusive, June 21, 2005, at W5-286; *see* P. Ginsburg et al., *Tracking Health Care Costs: Continued Stability But at High Rates in 2005*, Health Affairs Web Exclusive, Oct. 3, 2006, at w488 ("Health care spending outpaced overall economic growth by a wide margin again in 2005, despite a robust increase of 5.4 percent for the U.S. economy . . . ."). Employees are now

paying a high percentage of plan costs, as well as larger deductibles and co-payments, *see Kaiser 2007 Survey* at 68, 97-98, 112-14, and the increase of health insurance premiums is clearly linked to the growing ranks of the uninsured, Strunk et al., *supra*, at W5-294.

2. *PBM Practices Enhance The Efficiency Of Health Benefit Plan Administration While Reducing Employers' Cost Of Providing Prescription-Drug Benefits And Assuring Safety*

Although prescription-drug expenditures have been rising rapidly, a recent study by the Centers for Medicare and Medicaid Services ("CMS") shows that growth in spending on prescription drugs began slowing in the last few years. The CMS study specifically attributes the spending-growth slowdown to the expanding use of tiered benefit structures developed and administered by PBMs. *See* Cynthia Smith et al., *National Health Spending in 2004: Recent Slowdown Led by Prescription Drug Spending*, 25 Health Affairs 186, 192-94 (2006); *see also* Ginsburg et al., *supra*, at w491 (attributing the continued stability of drug price trends in 2005 in part to "market responses to continuing growth in cost-sharing differences across the payment tiers for generic, preferred brand, and other brand drugs."). A wealth of additional empirical evidence confirms that PBMs have constrained the growth of employers' prescription-drug expenditures and costs, through a variety of administrative functions that vastly improve the efficiency of prescription-drug benefit plans. *See generally* Robert F. Atlas, *The Role of PBMs*

in Implementing the Medicare Prescription Drug Benefit, Health Affairs Web Exclusive, Oct. 28, 2004, at W4-506-W4-508. The cost-saving efficiencies PBMs provide, which are elaborated below, explain why *up to 95% of all employer-provided health benefit plans with prescription drug benefits rely on PBMs to manage those benefits*. *See* John Richardson, Health Strategies Consultancy, Remarks at the Federal Trade Commission/Department of Justice Hearings on Health Care and Competition Law and Policy: Mandated Benefits, at 6 (June 26, 2003).

The primary mechanism PBMs use to reduce employers' prescription drug benefit costs is obtaining large-scale discounts and rebates from pharmaceutical manufacturers. PBMs can obtain discounts unavailable to individual employers because PBMs can pool the purchasing power of many different clients simultaneously. *See* Letter from Fed. Trade Comm'n to Virginia House of Delegates Member Terry G. Kilgore, Oct. 2, 2006, at 5-6 ("FTC Kilgore Letter"); *see also* Order at 2, *Pharm. Care Mgmt. Ass'n v. District of Columbia*, No. 04-cv-1082 (Mar. 6, 2007). In 2000-2001, for example, PBMs administered the expenditure of $121 billion of prescription drugs – or 80% of total U.S. spending on prescription drugs. Richardson, *supra*, at 9; *see also* Atlas, *supra*, at W4-506 (estimating that the three largest PBMs managed more than one-third of the estimated $208 billion in U.S. drug spending in 2004). Pharmaceutical

manufacturers in turn provide PBMs deep price discounts in exchange for guaranteed volume purchases resulting from inclusion of their drugs on PBM formularies. *See* Federal Trade Commission, *Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies* 10 (Aug. 2005) ("FTC Conflict of Interest Study"). Empirical studies have indicated that PBMs obtain discounts amounting to between 5% and 7% on brand name drugs. *See* U.S. Department of Health & Human Services, *Report to the President on Prescription Drug Coverage, Spending, Utilization and Prices* 105 (Apr. 2000) ("HHS Study"). On aggregate, pharmaceutical manufacturer discounts obtained by PBMs reduced total annual drug spending between 3% and 9% from 1998 to 2001. *See* U.S. General Accounting Office, *Federal Employees' Health Benefits: Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies* (Jan. 2003) ("GAO Report"). And a 2002 Congressional Budget Office study concluded that by using all their available tools PBMs "could save up to 30 percent in total drug spending relative to unmanaged purchases of prescription drugs." Atlas, *supra*, at W4-508 (citing Congressional Budget Office, *Issues in Designing a Prescription Drug Benefit for Medicare* (Oct. 2002)).

PBMs further reduce drug benefit plan costs by reducing administrative costs in the physical delivery of drugs to plan members. PBMs establish networks of retail pharmacies to deliver prescriptions to plan members. Typically, PBMs

contract with 90% to 95% of the retail pharmacies in the geographic regions they serve. *See* FTC Conflict of Interest Study at 4. Retail pharmacies actively compete to join PBM networks by offering discounts on both ingredient cost reimbursements and prescription dispensing fees. *Id.* Health benefit plans and their members directly benefit from this competition through lower drug prices and improved access to pharmacies. For example, the Department of Health and Human Services estimates that PBMs pay retail pharmacies 13% to 15% less than the average wholesale price for brand name drugs. *See* HHS Study at 103.

PBMs also promote the use of less-expensive and more efficient mail-order pharmacies. *See generally* FTC/DOJ Healthcare Report; *see also* FTC Conflict of Interest Study, at vii ("[P]lan sponsors often secure[] more favorable pricing for mail dispensing than for retail"). In a study of the price effects of PBMs on federal employee benefit plans, the Government Accounting Office concluded that PBMs achieved "significant discounts for drugs purchased at retail pharmacies and offered even greater discounts through their mail-order pharmacies." GAO Report at 9. PBM prices for prescription drugs were 18% less than average retail pharmacies and 47% less than average consumer cash prices for four selected generic drugs. *Id.* at 4. Likewise, PBM mail order prices were 27% and 53% below average retail pharmacy prices for selected brand name and generic drugs, respectively. *Id.*

The GAO concluded that these cost savings "were . . . passed on to enrollees in the form of premiums that were less than they otherwise would be." *Id.* at 19. Identifying similar cost-savings generated by mail-order pharmacies, the Department of Health and Human Services attributed the reduction in annual spending growth on prescription drugs from 14.3% in 2000-2002 to 8.2% in 2004 to a shift to greater mail-order dispensing. *See* U.S. Department of Health & Human Services, Centers for Medicare & Medicaid Services, *National Health Expenditure Data*, *Highlights* (2004).

Finally, PBMs help lower prescription drug benefit costs for employers and assure safety through a range of intervention techniques and drug utilization review services that identify opportunities to substitute less expensive, but equally effective, drugs to plan members. Specific intervention techniques include therapeutic interchange (encouraging the substitution of less expensive formulary brand name medications considered safe and effective for more expensive nonformulary drugs within the same drug class); the substitution of generic drugs for name brands; and step therapy (the practice of beginning drug therapy with the most cost-effective and safest therapy and progressing to other, more costly or risky therapy if necessary). GAO has estimated that these programs lower health benefit plan costs between one and nine percent. GAO Report at 12, 4. And in its analysis of 2005 national health expenditure data, the Department of Health and

Human Services attributed the slowing growth of prescription drug spending in part to "a shift in use toward generic drugs," as well as "the proliferation of tiered-copayment benefit plans." *See* U.S. Department of Health & Human Services, Centers for Medicare & Medicaid Services, *National Health Expenditure Data, Highlights* (2005). The PBMs' techniques have clearly produced tangible change.

In short, it cannot be doubted that employer-provided ERISA plans' reliance on PBMs to provide and administer prescription drug benefits has reduced the cost of those benefits significantly.

3. *Locally-Imposed Disclosure And "Transfer" Rules Undercut Many Of The Benefits PBMs Currently Provide To Health Benefit Plans*

Title II makes PBMs fiduciaries to ERISA plans, requiring them specifically to disclose to such plans proprietary financial information and to transfer to the plans any benefit of any kind received by the PBM as a result of prescription drug substitution or sales volume. D.C. Code. § 48-832.01(a), (b)(2), (d)(3). In purpose and effect, these requirements statutorily alter the terms of the arms-length contracts that currently exist between plans and PBMs. Laws like Title II are motivated by a perception that PBMs fail to pass on to plans the discounts and rebates they negotiate, and do not adequately disclose to plans the discounts they obtain, thereby denying employers and other plan sponsors all the benefits that might possibly be obtained from PBMs. *See id.* § 48-831.01(2); *Rowe*, 429 F.3d at

298-99. Title II assumes that employers and other PBM customers, including Taft-Hartley plans, lack sufficient bargaining power to negotiate adequate disclosures and pass-throughs themselves, and thus are inevitably victimized by PBMs in the bargaining process, causing plans to pay higher prescription-drug benefit prices than they otherwise would.

Amici and their members can attest, however, that the core empirical assumption underlying Title II is false: employers are not powerless victims in the market for PBM services. To the contrary, as the FTC has pointed out, the market to provide PBM services to plans is exceedingly robust: between 40 and 50 PBMs compete vigorously for health plan business. *See* FTC Conflict of Interest Study at 2. Employers and other plan sponsors "typically procure PBM service through a bidding process," involving multiple bids submitted in response to requests for proposals. FTC Kilgore Letter at 6; *see* Letter from Fed. Trade Comm'n Bureau of Competition to California Assembly Member Greg Aghazarian, Sept. 7, 2004, at 7 ("FTC Aghazarian Letter"). Sponsors pay close attention to bidders' price guarantees, treatment of rebates, claims-processing fees, customer service promises, and any prior experience with the PBM, including its market reputation.

The FTC has found the market for PBM services to be highly competitive, and has pointed out that employers have ample power to negotiate concessions from individual PBMs for more extensive disclosures and more extensive

discounts, as each individual sponsor sees fit. *See* FTC Kilgore Letter at 7; (competition among PBMs is "vigorous"); FTC Aghazarian Letter at 10 ("There do not appear to be any significant barriers to negotiation between health plan sponsors and PBMs over the terms of their agreement, including how PBMs are to be paid for their services and the disposition of any rebates."). Indeed, plan sponsors bargaining with PBMs in this competitive environment often *intentionally allow* PBMs to retain manufacturer rebates in whole or in part, in exchange for lower administrative fees, lower participant out-of-pocket costs or improved administrative services. *See* FTC/DOJ Healthcare Report, ch. 7, at 16-17; FTC Conflict of Interest Study at vii. As the FTC has observed, "some plan sponsors want to receive all payments from manufacturers, while others seek to negotiate deeper discounts on list prices by allowing the PBM to retain these payments – and many plan sponsors fall somewhere in-between." FTC Kilgore Letter at 6. In short, "[m]arket forces are operating to give covered entities the desired disclosures and negotiated terms and conditions for PBM services." William G. Schiffbauer, PCMA v. Maine, *The First Circuit Blesses a 'Shotgun Wedding' Between Business Interests and State Government*, 4 Pharm. L. & Indus. 1, 4 (Jan. 13, 2006).

A recent government study confirms the efficacy of those market forces, showing that *70% to 90% of manufacturers' rebates are already passed along*

directly to health benefit plans. HHS Study at 105. Even more significant, the federal government's two competition enforcement agencies reviewed the data and concluded unequivocally that the existing competitive market for PBM services works much better to ensure adequate disclosures, sufficient discount pass-throughs and low benefit prices, than interventionist regulations such as Title II:

> Vigorous competition in the marketplace for PBMs is more likely to arrive at an optimal level of transparency than regulation of [disclosure] terms. Vigorous competition is also more likely to help ensure that gains from cost savings are passed on to consumers of health-care services, either as lower premiums for health insurance, lower out-of-pocket costs . . . or improved services. . . . Just as competitive forces encourage PBMs to offer their best price and service combination to health plan sponsors to gain access to subscribers, competition also encourages disclosure of the information health plan sponsors require to decide on the PBM with which to contract.

FTC/DOJ Healthcare Report, ch. 7, at 17; *see* FTC Aghazarian Letter at 10.

Title II interferes with these properly functioning market forces in ways directly detrimental to the very plan sponsors it is supposed to protect. First, by requiring PBMs to "transfer in full . . . any benefit or payment received in any form" by the PBM in connection with prescription drug substitution, Title II curtails the flexibility of PBMs and their customers to jointly design products tailored to specific needs and circumstances. As the FTC has found, PBMs already "compete on both price and non-price dimensions to serve . . . varying client needs," considering not just financial terms like administrative fees and

manufacturers' payments to plan sponsors based on formulary drugs utilized, but also non-price elements such as benefit design and the quality of mail-order service. FTC Conflict of Interest Study, at 8-9.

Second, the FTC has determined that mandatory PBM disclosure laws "may increase the cost of pharmaceuticals and health insurance premiums by attenuating competition between pharmaceutical companies." FTC Aghazarian Letter at 12. The FTC believes that "[p]ublic disclosure of proprietary information can . . . undercut vigorous competition on drug pricing," since "[k]nowledge of rivals' prices can dilute incentives to bid aggressively and can facilitate tacit collusion, which increases prices." FTC Kilgore Letter at 13-14.[5] Title II's disclosure requirements undermine healthy competition among pharmaceutical manufacturers, as manufacturers are likely to respond to the new law by reducing price concessions to any particular PBM, thereby preventing employers from obtaining lower individually negotiated prices. Letter from Fed. Trade Comm'n Bureau of Competition to Rep. Patrick McHenry re: N.C. House Bill 1374, July 15, 2005.

In short, PBMs "achieve the best cost efficiencies in the prescription drug industry when left unregulated." Thomas P. O'Donnell & Mark K. Fendler,

[5] The harm caused by disclosure is not mitigated by the fact that Title II applies only to contracts executed in the District or with covered entities who are in the District, *see* D.C. Code § 48-832.02. The information, once released, will spread, not least because many of the covered entities operate regionally or nationally.

Prescription or Proscription? The General Failure of Attempts to Litigate and Legislate Against PBMs as "Fiduciaries," and the Role of Market Forces Allowing PBMs To Contain Private-Sector Prescription Drug Prices, 40 J. Health L. 205, 235 (Spring 2007); *see also id.* (collecting economic data to that effect, including a study concluding that "PBMs save the State of Texas an estimated $180 million per year in prescription drug costs" and that Title II-like regulation of PBMs "would result in a decrease in spending in the Texas economy by almost $1.6 billion per year"). Of course, an increased cost of benefits is "likely to undermine the ability of some consumers to obtain the pharmaceuticals and health insurance they need at a price they can afford." FTC Aghazarian Letter at 12. And "when costs are high, people who cannot afford something find substitutes or do without. . . . The higher the cost of pharmaceuticals, the more people skip doses or do not fill their prescriptions." FTC Kilgore Letter at 15 (quoting William Sage et al., *Why Competition Law Matters to Health Care Quality*, 22 Health Affairs 31, 35 (Mar./Apr. 2003)).

In addition to these specific consequences, Title II will create a general upward pressure on prescription-drug benefit costs. This is so for at least two reasons.

First, the law imposes general fiduciary duties on PBMs, and creates a cause of action for money damages by making a violation of Title II a violation of the

District's consumer protection laws. *See* D.C. Code §§ 48-832.01(a), 48-832.03. This new litigation threat will increase PBMs' cost of doing business with District employers and other plan sponsors exponentially – costs that are inevitably passed on to sponsors through prices for PBM services. Not only does Title II create a damages action where none existed before, but that action brings with it the added cost of significant uncertainty: much conduct that would be fully acceptable in a standard, private, arms-length market arrangement may not be permissible under the one-way fiduciary responsibilities established by the law. Because PBMs cannot easily distinguish *ex ante* the commercial actions that will create monetary liability from those that will not, they will be forced to increase prices generally to insure against the possibility that a given decision will result in significant monetary payout.[6]

Second, benefit costs will be adversely affected by the law's interference with the efficient market forces already governing PBM services. As noted above, there is no evidence whatsoever of any failure in the market for PBM services. Government regulation of that highly competitive market thus can have only one effect – increased prices or reduced output, in terms of either the quantity or

[6] By allowing a private action for damages by any person injured by a Title II violation (damages that will ultimately be borne by the plans), Title II effectively supplements the remedies already provided by ERISA § 502(a) and is preempted for that reason. *Amici* discuss why Title II is preempted by ERISA for further reasons in Part B, *infra*.

quality of the services provided. Title II may mandate that District benefit plans receive something they currently must bargain for, but the law cannot mandate that plans receive these gains for nothing. Because bargaining in this market is otherwise unimpeded, plans' legally mandated gains will necessarily come at some price elsewhere in the economic relationship. That price will either be more expensive benefits, less attractive benefits, or no benefits at all. In a competitive market, that outcome is unavoidable.

B. Title II Is Preempted By ERISA § 514 Because It Regulates The Administration Of Health Benefit Plans

As the previous section demonstrates, Title II harms the interests of the very employers and benefit plans it is supposed to protect. Those harmful effects are symptomatic of another, deeper problem with the law: Title II directly relates to benefit plans and so is preempted by ERISA § 514(a), 29 U.S.C. § 1144(a).

A law "relates to" employee benefit plans under § 514 when it regulates "employee benefit structures or their administration." *N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 658 (1995). As discussed above, Title II easily satisfies that test because it specifically regulates the terms on which plans may contract with PBMs to provide and administer prescription-drug benefits. Under the District law, for example, the requirement that benefits of drug substitution be passed along to the covered entity will limit plan sponsors' ability to negotiate for other contractual concessions.

Whether in technical or common-sense terms, it is impossible to see how such a law does not "relate to" employee plans. Indeed, the explicit purpose and intended effect of the law is to protect employee benefit plans from PBMs, to ensure that plans and their beneficiaries pay lower prices for prescription drugs. The previous section demonstrated that the law will actually increase rather than reduce prescription-drug benefit costs, but either way, Title II obviously "relates to" the very benefit plans it was explicitly enacted to protect.

The Supreme Court has already recognized that a state law regulating the terms of an ERISA plan's contract with a third party to provide or administer benefits is law that "relates to" the plan within the meaning of § 514. *See Ky. Ass'n of Health Plans, Inc. v. Miller*, 538 U.S. 329 (2003); *Rush Prudential HMO, Inc. v. Moran*, 536 U.S. 355 (2002). *Miller* and *Rush Prudential* both addressed state laws that, like Title II, regulated the terms of third-party provider contracts. *Miller* is especially on point. That case involved a state "any willing provider" ("AWP") law, which required health maintenance organizations ("HMOs") to allow any willing health care provider to join HMOs provider-networks. The AWP law thus effectively precluded employee benefit plans from contracting with HMOs to provide benefits through more limited networks. Because they directly regulated the terms on which plans could contract with HMOs to administer health

benefit plans through provider networks, such laws plainly related to plans under § 514.

The Supreme Court in *Miller* ultimately found that state AWP laws are not preempted under § 514, but *only* because of § 514's "insurance savings clause," which saves from § 514 preemption those laws that "relate to" ERISA plans but also "regulate insurance." *See* 29 U.S.C. § 1144(b). In other words, although AWP laws *did* "relate to" ERISA plans by regulating the contractual relationship between plan and third-party service provider, they were saved from § 514 preemption because they (1) were targeted at insurance companies and (2) directly affect the "risk pooling" arrangement between insurer and insured. *Miller*, 538 U.S. at 342.[7]

Title II likewise directly regulates the contract between plan and third-party service provider, with the avowed purpose of bestowing on plan sponsors seeking to offer prescription-drug benefits a bargaining advantage vis-à-vis the third-party providers – PBMs – that make such benefits available. Title II therefore is within the ambit of § 514 preemption, like AWP laws, but unlike such laws, it is obviously *not* a law that "regulates insurance" under the two-part test articulated in

[7] Likewise, in *Rush Prudential*, the Supreme Court addressed a state law requiring HMOs to provide for independent physician review of "medical necessity" determinations. The Court ultimately held that the law was saved from the force of § 514 preemption because it "regulate[d] insurance," but nobody doubted that the law fell within the ambit of § 514, inasmuch as it effectively mandated a term (independent physician review) of the contract between plan and HMO.

Miller. Title II is not "specifically directed toward entities engaged in insurance," *id.*, but instead toward PBMs, which do not insure against risk and are not treated as insurers under any state's law. And of course the law does not "substantially affect the risk pooling arrangement between the insurer and the insured," *id.*, since its targets are not insurers and its subject (disclosures and rebates) have nothing to do with risk-pooling. Accordingly, unlike in *Miller*, the § 514 savings clause is irrelevant here – what is relevant is § 514's basic preemption rule, which applies by its own terms, and requires preemption of Title II.

In according estoppel effect to the First Circuit's holding in *Rowe*, the district court cast an entirely uncritical eye on that court's contrary preemption decision and allowed its profoundly wrong analysis to govern as to Title II. But the First Circuit's conclusion that Maine's Title II counterpart falls outside the ambit of § 514 cannot withstand even minimal scrutiny. That court reasoned that the Maine law does not relate to ERISA plans because, though such plans "can re-evaluate their working relationships with the PBMs if they wish" in light of Maine's law, "nothing in the [law] compels them to do so." *Rowe*, 429 F.3d at 303. But that makes no sense: laws like Title II need not compel plans to "reevaluate" their working relationships with PBMs because *the law itself reorganizes those relationships directly*, by dictating the terms of the relationships regarding confidential information and rebate pass-throughs that plans may not

want or need, *see supra* at 7-8, and for which they have neither negotiated nor paid. It is equally wrong to say that "[i]n no way does the [Maine law] circumscribe the ability of plan administrators to structure or administer their ERISA plans." *Rowe*, 429 F.3d at 303. Title II and its Maine counterpart do exactly that, by imposing substantial burdens (both legal and financial) on the very third parties on which the vast majority of employers and other sponsors rely to provide and administer prescription drug benefits.

This reasoning in particular threatens adverse legal consequences that go beyond even the negative consequences for prescription drug benefits. In concluding that a state law regulating a plan's relationship with third parties does not "relate to" the plan, the First Circuit characterized the Supreme Court's preemption decisions in *Alessi v. Raybestos-Manhattan, Inc.*, 451 U.S. 504 (1981), and *Egelhoff v. Egelhoff*, 532 U.S. 141 (2001), as limiting the scope of § 514 to state laws mandating *specific benefit structures*. *Rowe*, 429 F.3d at 302-03. It is thus irrelevant, the court concluded, that these laws attempt "to dictate the terms of contracts between ERISA plans and PBMs" and "to regulate plans' relationships with PBMs when PBMs perform administrative functions for such plans." *Id.* at 303.

If sanctioned in the District, that reasoning would allow the District to impose burdensome restrictions of all kinds on the benefit-plan-related

administrative functions of third-party providers. Notably, the First Circuit's logic is not limited to the activities of PBMs – *any* service provided by a third party to a benefit plan, including a welfare or pension benefit plan, is potentially subject to onerous state-by-state regulation. And because, as shown above, burdens on the third-party provider services plan sponsors receive are effectively burdens on the plan sponsors themselves, the decision to uphold the District's restrictions on PBM service activities could have much broader negative consequences for welfare and pension benefit plans nationwide, and for the employers who establish them in this time of rising healthcare costs.

The district court's estoppel ruling was wrong. If this Court agrees, *amici* respectfully suggest that the Court should then decide that Title II is, as a matter of law, preempted by ERISA.

CONCLUSION

For the foregoing reasons, and for the reasons stated by appellant, the judgment of the district court should be reversed.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE WITH RULE 32(a)

This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because it contains 6744 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii). This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word 2003 in 14-point Times New Roman.

Dated: October 2, 2007

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on October 2, 2007, I filed the foregoing Brief for America's Health Insurance Plans, Inc. and the Chamber of Commerce of the United States of America as *Amici Curiae* in Support of Appellant by hand delivery with the Clerk's Office of the United States Court of Appeals for the D.C. Circuit, and also caused a copy of this brief to be delivered by FedEx to:

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