

051297 APR 10 2006

No. 06- OFFICE OF THE CLERK

---

IN THE

**Supreme Court of the United States**

---

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION,  
*Petitioner,*

v.

G. STEVEN ROWE, IN HIS OFFICIAL CAPACITY AS  
ATTORNEY GENERAL OF THE STATE OF MAINE,  
*Respondent.*

---

**On Petition for a Writ of Certiorari to the  
United States Court of Appeals for the First Circuit**

---

**PETITION FOR A WRIT OF CERTIORARI**

---

BARBARA A. LEVY  
General Counsel  
Pharmaceutical Care  
Management Association  
601 Pennsylvania Ave, NW  
Suite 740  
Washington, DC 20004

GLEN D. NAGER  
*(Counsel of Record)*  
TRACI L. LOVITT  
KATE BUSHMAN  
JONES DAY  
51 Louisiana Ave., NW  
Washington, DC 20001  
(202) 879-3939  
*Counsel for Petitioner*

---

## **QUESTION PRESENTED**

Whether § 502(a) or § 514(a) of the Employee Retirement Income Security Act of 1974 (“ERISA”), 29 U.S.C. §§ 1132(a), 1144(a), preempts a state law that regulates the conduct of ERISA non-fiduciaries, such as pharmacy benefit managers, that is functionally part of the administration and management of ERISA-covered employee benefit plans.

**PARTIES TO THE PROCEEDING**

Petitioner, the Pharmaceutical Care Management Association, is a national trade association of pharmacy benefit managers. Respondent is the Attorney General of the State of Maine, acting in his official capacity.

**TABLE OF CONTENTS**

	<b>Page</b>
QUESTION PRESENTED .....	i
PARTIES TO THE PROCEEDING .....	ii
TABLE OF AUTHORITIES .....	iii
OPINIONS BELOW .....	1
JURISDICTION .....	1
CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED .....	1
STATEMENT .....	2
REASONS FOR GRANTING THE WRIT .....	11
I. THE FIRST CIRCUIT’S DECISION IS INCONSISTENT WITH THE DECISIONS OF NUMEROUS OTHER COURTS OF APPEALS .....	12
II. THE FIRST CIRCUIT’S NON- PREEMPTION CONCLUSION IS ERRONEOUS.....	17
III. THIS COURT’S IMMEDIATE REVIEW IS ALSO NEEDED IN ORDER TO PREVENT INTERFERENCE WITH THE FEDERAL GOVERNMENT’S ONGOING EFFORTS TO CONSTRAIN PRESCRIPTION DRUG PRICES THROUGH SUPPORT OF PBMs.....	24
CONCLUSION.....	28

---

## TABLE OF AUTHORITIES

Page

## Cases

<i>Aetna Health Inc. v. Davila</i> , 542 U.S. 200 (2004).....	5, 18
<i>Alessi v. Raybestos-Manhattan, Inc.</i> , 451 U.S. 504 (1981).....	3
<i>Custer v. Pan Am. Life Ins. Co.</i> , 12 F.3d 410 (4th Cir. 1993).....	13
<i>District of Columbia v. Greater Wash. Bd. of Trade</i> , 506 U.S. 125 (1992).....	3, 4
<i>Egelhoff v. Egelhoff</i> , 532 U.S. 141 (2001).....	21, 27
<i>Garren v. John Hancock Mut. Life Ins. Co.</i> , 114 F.3d 186 (11th Cir. 1997).....	13, 16
<i>Gerosa v. Savasta Co.</i> , 329 F.3d 317 (2d Cir. 2003).....	12, 19
<i>Gibson v. Prudential Ins. Co.</i> , 915 F.2d 414 (9th Cir. 1990).....	13
<i>Harris Trust &amp; Sav. Bank v. Salomon Smith Barney Inc.</i> , 530 U.S. 238 (2000).....	5, 19, 23
<i>Howard v. Parisian, Inc.</i> , 807 F.2d 1560 (11th Cir. 1987).....	13, 16
<i>Ingersoll-Rand Co. v. McClendon</i> , 498 U.S. 133 (1990).....	4, 5
<i>Mass. Mutual Life Ins. Co. v. Russell</i> , 473 U.S. 134 (1985).....	3
<i>Mertens v. Hewitt Assocs.</i> , 508 U.S. 248 (1993).....	5, 18, 20
<i>NGS Am., Inc. v. Barnes</i> , 998 F.2d 296 (5th Cir. 1993).....	13, 14, 15
<i>Nachman Corp. v. Pension Ben. Guaranty Corp.</i> , 446 U.S. 359 (1980).....	3
<i>Penny/Ohlmann/Nieman, Inc. v. Miami Valley Pension Corp.</i> , 399 F.3d 692 (6th Cir. 2005).....	13
<i>Pilot Life Insurance Co. v. Dedeaux</i> , 481 U.S. 41 (1987).....	4, 18

**TABLE OF AUTHORITIES**  
(continued)

	<b>Page</b>
<i>Rush Prudential HMO, Inc. v. Moran</i> , 536 U.S. 355 (2002).....	5
<i>Shaw v. Delta Air Lines, Inc.</i> , 463 U.S. 85 (1983).....	21
<i>Smith v. Provident Bank</i> , 170 F.3d 609 (6th Cir. 1999).....	13, 15, 20
 <b>Federal Statutes and Regulations</b>	
U.S. Const. art. VI, cl. 2.....	1
28 U.S.C. § 1254(1).....	1
28 U.S.C. § 1291.....	1
28 U.S.C. § 1331.....	1
Employee Retirement Income Security Act of 1974 ("ERISA") 29 U.S.C.....	3
§ 1001(b).....	3
§ 1002(14).....	4
§ 1002(21).....	3
§ 1106(a).....	4
§ 1109(a).....	3
§ 1132(a)(1)(B).....	<i>passim</i>
§ 1144(a).....	2, 4
 <b>State Statutes and Regulations</b>	
D.C. Code Ann. §§ 48-832.01-48-832.03 (2004).....	27
Ga. Code Ann. § 26-4-110.1 (2004).....	27
5 Me. Rev. Stat. Ann. §§ 209, 213.....	8
Unfair Prescription Drug Practices Act (22 Me. Rev. Stat. Ann.)	
§ 2699(1).....	7
§ 2699(2).....	7, 8, 20, 21
§ 2699(3).....	21
Md. Code Ann. Ins. § 15-10B-20 (2005).....	27
N.D. Cent. Code §§ 26.1-27-01.1, <i>et seq.</i> .....	27
S.D. Codified Laws §§ 58-29E-1—58-29E-10.....	27

**TABLE OF AUTHORITIES**  
(continued)

**Page**

**Miscellaneous**

Jane Brierton, Office of Legislative Research, Connecticut Gen. Assembly, <i>Regulation of Pharmacy Benefit Managers</i> No. 2004-R-0071 (Jan. 15, 2004).....	27
Department of Labor, <i>FAQ's About the Benefit Claims Procedure Regulation</i> (Jan. 12, 2006).....	23
ERISA Litig. Rep. 16 (Dec. 2005).....	17, 20
Federal Trade Commission, <i>Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies</i> (Aug. 2005).....	6
Federal Trade Commission & U.S. Department of Justice, <i>Improving Health Care: A Dose of Competition</i> (July 2004) .....	6, 24
Government Accountability Office, <i>Federal Employees Health Benefits: Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies</i> , GAO-03-196 (Jan. 10, 2003).....	25
Letter from the Federal Trade Commission to California Assembly Member Greg Aghazarian (Sept. 3, 2004).....	7, 26
Letter from the Federal Trade Commission to North Carolina Representative Patrick T. McHenry (July 15, 2005) .....	7
RIA Pension & Benefits Library, <i>Benefits Analysis</i> (2006).....	6
William G. Schiffbauer, <i>PCMA v. Maine: The First Circuit Blesses a "Shotgun Wedding" Between Business Interests and State Government</i> 4 PHARM. LAW & INDUS. 1 (Jan. 13, 2006).....	16, 21

## OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a–33a) is reported at 429 F.3d 294. The district court’s opinion (Pet. App. 38a–87a) is not reported but is available at 2005 WL 757608.

## JURISDICTION

The district court exercised jurisdiction under 28 U.S.C. § 1331, and entered a final judgment on April 13, 2005. The court of appeals asserted jurisdiction pursuant to 28 U.S.C. § 1291, and entered judgment on November 8, 2005. The court of appeals subsequently entered an order denying a timely-filed petition for rehearing and for rehearing *en banc* on January 9, 2006. Jurisdiction in this Court exists under 28 U.S.C. § 1254(1).

## CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The Supremacy Clause of the United States Constitution, U.S. Const. art. VI, cl. 2, provides in pertinent part:

This Constitution, and the Laws of the United States which shall be made in Pursuance thereof . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

Section 502(a) of the Employee Retirement Income Security Act of 1974 (“ERISA”), 29 U.S.C. § 1132(a)—the statute’s civil enforcement provision—states in pertinent part:

(a) Persons empowered to bring a civil action. A civil action may be brought (1) by a participant or beneficiary (A) for the relief provided in sub-section (c) of this section, or (B) to recover benefits due to him under the terms of his plan, to enforce his rights under the terms of the plan, or to clarify his rights to future benefits under the terms of the plan . . . .

---

Section 514(a) of ERISA, the Act's express preemption provision, 29 U.S.C. § 1144(a), provides in pertinent part:

(a) Supersedure; effective date. Except as provided in subsection (b) of this section, the provisions of this subchapter and subchapter III of this chapter shall supersede any and all State laws insofar as they may now or hereafter relate to any employee benefit plan described in section 1003(a) of this title and not exempt under section 1003(b) of this title.

#### STATEMENT

This case squarely presents an important and recurring federal question that is in need of immediate resolution by this Court—whether ERISA preempts state regulation of the conduct of ERISA non-fiduciaries where the conduct is functionally part of the administration and management of an ERISA-covered employee benefit plan. Maine has enacted a law regulating the conduct of pharmacy benefit managers (“PBMs”) that requires PBMs to function as fiduciaries toward ERISA plans, disgorge certain profits to ERISA plans, and disclose to ERISA plans their arrangements with drug manufacturers. Although they are ERISA non-fiduciaries, PBMs provide services to ERISA plans that are functionally part and parcel of employee benefit administration—namely, negotiating drug prices and purchases from pharmaceutical manufacturers, providing drug utilization review, and developing pharmacy networks to fulfill the plan's function of providing pharmaceutical benefits. The First Circuit—contrary to the precedents of other courts of appeals and this Court—erroneously held that Maine's law is not preempted by ERISA because it regulates only ERISA non-fiduciaries. In doing so, the court of appeals ignored the well-developed law of other circuits holding that laws regulating non-fiduciaries in their function as part of plan administration and management are also subject to ERISA's preemptive scope. Thus, the First Circuit's decision creates a judicial conflict on an important

federal question. In addition, the First Circuit's decision, if allowed to stand, will undermine the federal government's important ongoing efforts to constrain escalating prescription drug costs by encouraging the use of PBMs.

1. ERISA is a "comprehensive system for the federal regulation of private employee benefit plans," *Dist. of Columbia v. Greater Wash. Bd. of Trade*, 506 U.S. 125, 127 (1992), the declared policy of which is to protect participants in employee benefit plans "by providing for appropriate remedies, sanctions, and ready access to the Federal courts." 29 U.S.C. § 1001(b), (c). ERISA generally leaves to potential plan sponsors the decision whether to establish an employee benefit plan and, if so, the substantive terms of the plan. *See Alessi v. Raybestos-Manhattan, Inc.*, 451 U.S. 504, 512-13 (1981). But once an employer decides to establish a plan, ERISA imposes requirements for reporting and disclosure relating to the employee benefit plan. *See* 29 U.S.C. §§ 1021-1031.

As one part of this "comprehensive and reticulated" scheme, *Nachman Corp. v. Pension Ben. Guar. Corp.*, 446 U.S. 359, 361 (1980), ERISA establishes standards of conduct for, and the duties of, plan "fiduciaries," 29 U.S.C. §§ 1101-1114, which ERISA defines as any person who "has any discretionary authority or discretionary responsibility in the administration of [an employee benefit] plan." *Id.* § 1002(21)(A)(iii). A fiduciary's duty to the plan includes "the proper management, administration, and investment of [plan] assets, the maintenance of proper records, the disclosure of specified information, and the avoidance of conflicts of interest." *Mass. Mut. Life Ins. Co. v. Russell*, 473 U.S. 134, 142-43 (1985). A breach of any of these duties renders fiduciaries personally liable and subject to suit for damages, restitution, as well as "such other equitable or remedial relief as the court may deem appropriate." 29 U.S.C. § 1109(a).

---

ERISA also regulates certain conduct of non-fiduciaries. For example, third-party administrators who provide services related to the management or administration of an ERISA plan may be “part[ies] in interest” under ERISA. *See* 29 U.S.C. § 1002(14)(B) (defining a “party in interest” to include “a person providing services to [an ERISA] plan”). Parties in interest cannot engage in certain transactions with an ERISA plan, such as the sale of real property, *id.* § 1106(a); *see also id.* § 1108(b)(2), and must disgorge assets and profits obtained through participation as parties-in-interest in those transactions.

To guarantee the uniform administration of employee benefit plans, ERISA preempts state laws in two ways: (i) the express preemption clause in ERISA § 514(a), and (ii) the set of comprehensive remedies in ERISA § 502(a), which completely preempt state law remedies that supplement or supplant ERISA’s civil enforcement scheme. *See Ingersoll-Rand Co. v. McClendon*, 498 U.S. 133, 138-44 (1990) (discussing ERISA’s preemptive scope).

First, § 514(a) provides that ERISA “shall supersede any and all State laws insofar as they may now or hereafter *relate to* any [covered] employee benefit plan.” 29 U.S.C. § 1144(a) (emphasis added). This Court has recognized that a state law “relates to a covered employee benefit plan for purposes of § 514(a) if it has a connection with or reference to such a plan.” *Greater Wash. Bd. of Trade*, 506 U.S. at 129 (internal quotation marks omitted); *see also Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. 41, 47-48 (1987) (holding same).

Second, § 502(a) preempts state laws that supplement or supplant ERISA’s civil enforcement remedies. Specifically, § 502(a) authorizes a participant, beneficiary, or fiduciary to bring suit “to recover benefits due to him under the terms of his plan, to enforce his rights under the terms of the plan, or to clarify his rights to future benefits under the terms of the plan,” or generally “to enjoin any act or practice which

violates any provision of [Title I of ERISA] or the terms of the plan.” 29 U.S.C. § 1132(a)(1)(B), (3). Under this provision, an ERISA fiduciary is personally liable for monetary damages, restitution, and equitable relief.

ERISA § 502(a) also defines a remedy against non-fiduciaries. As this Court has held, § 502(a)(3) authorizes a plan “participant, beneficiary, or fiduciary” to bring a civil action for “appropriate equitable relief” against a non-fiduciary service provider in certain circumstances. *See Harris Trust & Sav. Bank v. Salomon Smith Barney Inc.*, 530 U.S. 238, 241 (2000). A non-fiduciary is not, however, subject to monetary damages under ERISA unless it “cross[es] the line from advisor to fiduciary.” *Mertens v. Hewitt Assocs.*, 508 U.S. 248, 262 (1993). Because Congress intended it to function exclusively, § 502(a) completely preempts state law causes of action that add to or alter the remedies created under this section. *See Ingersoll-Rand*, 498 U.S. at 144-45; *Rush Prudential HMO, Inc. v. Moran*, 536 U.S. 355, 377-81 (2002).

Considering ERISA’s preemption provisions, this Court has held that a plan beneficiary cannot seek compensatory damages against ERISA non-fiduciaries for assisting a fiduciary’s breach of fiduciary duty. *See Mertens*, 508 U.S. at 255-59. In addition, the Court has held that state tort law claims against non-fiduciaries for improper claims processing are preempted, because such claims arise “from the particular rights and obligations established by the benefit plans.” *Aetna Health Inc. v. Davila*, 542 U.S. 200, 213 (2004).

2. Petitioner Pharmaceutical Care Management Association (“PCMA”) is a national trade association of PBMs. PBMs facilitate the provision of prescription drug benefits to over 200 million American consumers covered by ERISA and non-ERISA health plans, self-insured employers, union-sponsored plans, and government purchasers, including the federal government. They do so by

---

functioning as intermediaries between the demand side (health care benefit providers) and the supply side (pharmaceutical manufacturers and retail pharmacies) of the prescription drug industry. See RIA Pension & Benefits Library, *Benefits Analysis* ¶ 137,623.1 (2006) (“*Benefits Analysis*”).

In general, PBMs “manage” the prescription drug insurance benefits of health benefit plans. Federal Trade Commission, *Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies*, at i, available at [www.ftc.gov/reports/pharmbenefit05/050906pharmbenefitrpt.pdf](http://www.ftc.gov/reports/pharmbenefit05/050906pharmbenefitrpt.pdf) (Aug. 2005) (“*FTC Report*”) (last visited April 4, 2006). For example, “PBMs assemble networks of retail pharmacies so that a plan sponsor’s members can fill prescriptions easily and in multiple locations by just paying a co-payment amount.” *Id.* In addition, PBMs negotiate reduced drug costs by contracting for rebates from manufacturers on bulk purchases, as well as drug-specific discounts for drugs on the PBM’s formulary. See *Benefits Analysis*, at ¶ 137,623.1. PBMs perform drug utilization review tasks, such as suggesting cost-effective alternatives to the drug prescribed, as well as recommending less expensive generic alternatives. *Id.* PBMs also perform prescription benefit claims processing and review individual prescriptions for possible dangerous drug interactions or dosage levels. *Id.*

“[B]y pooling substantial numbers of health benefit providers,” PBMs can negotiate concessions from the manufacturers that individual providers would otherwise be unable to obtain. Pet. App. 3a. “[T]o date, most empirical evidence suggests that PBMs have lowered costs for health plan sponsors.” Federal Trade Commission & U.S. Department of Justice, *Improving Health Care: A Dose of Competition*, ch. 7, at 1 (July 2004), available at [www.ftc.gov/reports/healthcare/040723/healthcarerpt.pdf](http://www.ftc.gov/reports/healthcare/040723/healthcarerpt.pdf) (last visited April 4, 2006) (“*FTC/DOJ Report*”). As a consequence, numerous agencies of the federal government

have sought to promote the use of PBMs by, for example, opposing state laws that seek to impose disclosure, fiduciary and other requirements on PBMs. *See, e.g.*, Letter from the FTC to California Assembly Member Greg Aghazarian 14 (Sept. 3, 2004), *available at* <http://www.ftc.gov/be/Vo40027.pdf> (“*Aghazarian Letter*”) (last visited April 4, 2006); *see also* Pet. App. 123a-143a (Letter from the FTC to North Carolina Representative Patrick T. McHenry (July 15, 2005)).

3. In 2003, the State of Maine nonetheless enacted the Unfair Prescription Drug Practices Act (“UPDPA” or the “Act”), 22 ME. REV. STAT. ANN. § 2699, to place restrictions on the nature and scope of the contractual relationships between PBMs and “covered entities,” which UPDPA defines as “a nonprofit hospital or medical service organization, insurer, health coverage plan or health maintenance organization,” *id.* § 2699(1)(A). It is undisputed that UPDPA applies to contracts between PBMs and ERISA-covered employee benefit plans. *See id.*; Pet. App. 7a.

UPDPA provides that a “[PBM] owes a fiduciary duty to a covered entity and shall discharge that duty in accordance with the provisions of state and federal law.” 22 ME. REV. STAT. ANN. § 2699(2). PBMs are required to discharge this duty “with care, skill, prudence and diligence and in accordance with the standards of conduct applicable to a fiduciary in an enterprise of a like character and with like aims.” *Id.* § 2699(2)(A). As part of this fiduciary duty, PBMs must “notify the covered entity in writing of any activity, policy or practice of the pharmacy benefits manager that directly or indirectly presents any conflict of interest” with the imposed fiduciary duty. *Id.* § 2699(2)(C).

In addition, UPDPA requires PBMs to disgorge certain profits to employee benefit plans and other covered entities. For example, the Act requires PBMs to transfer “any payment or benefit . . . based on volume of sales for certain

---

prescription drugs [in Maine].” *Id.* § 2699(2)(F). Where the PBM offers a substitute for a prescribed drug, moreover, it must “transfer in full to the covered entity any benefit or payment received in any form by the [PBM] either as a result of a prescription drug substitution . . . or as a result of the [PBM’s] substituting a lower-priced generic and therapeutically equivalent drug for a higher-priced prescribed drug.” *Id.* § 2699(2)(E)(3).

Finally, UPDPA compels PBMs to disclose information to covered entities regarding (i) all financial information related to the PBMs servicing of the covered entity, *id.* § 2699(2)(D); (ii) fee arrangements between PBMs and pharmaceutical manufacturers or labelers, *id.* § 2699(2)(G); and, (iii) fees accruing to PBMs for drug substitutions, *id.* § 2699(2)(E).

The Act reaches broadly to “all contracts for pharmacy benefits management entered into in [Maine] or by a covered entity in [Maine].” *Id.* § 2699(3). Sanctions for violations include damages, equitable relief, and fines of up to \$10,000. *Id.* § 2699(4). UPDPA may be enforced by the Attorney General of Maine or by private citizens, who in most instances would be plan beneficiaries. *Id.*; *see also* 5 ME. REV. STAT. ANN. §§ 209, 213.

4. In September 2003, PCMA commenced this action in the United States District Court for the District of Maine to challenge the enforceability and constitutionality of UPDPA and to enjoin the Act’s enforcement. Pet. App. 4a. The district court (Judge Woodcock) preliminarily enjoined the enforcement of the Act, finding that UPDPA was likely both preempted by ERISA and an unconstitutional taking. *Id.* at 88a-120a. After brief discovery (and Judge Woodcock’s recusal), however, the district court later granted summary judgment to respondent. *Id.* at 36a-37a.

Specifically, the district court adopted in full the report and recommendation of the overseeing magistrate judge.

Pet. App. 37a. With respect to ERISA preemption, the court held, adopting a magistrate judge's report and recommendation (Pet. App. 38a-87a), that UPDPA had no "connection with" an ERISA plan, because the Act did "not restrict the freedom of employee benefit plans to administer or structure their plans in Maine precisely as they would elsewhere." *Id.* at 52a. In addition, the district court concluded that "UPDPA does not impermissibly refer to an ERISA plan." *Id.* at 53a. In the court's view, UPDPA "neither acts immediately and exclusively upon ERISA plans nor depends on the existence of ERISA plans in order to have meaning." *Id.* Finally, the court found that "UPDPA does not impermissibly intrude upon the remedial scheme Congress devised to govern the relationships among ERISA entities," because "it is not designed to regulate or afford remedies against entities that provide services to plans." *Id.* at 55a.

5. On appeal, the United States Court of Appeals for the First Circuit affirmed. Pet. App. 1a-33a. The court of appeals first rejected PCMA's argument that UPDPA impermissibly converts PBMs into ERISA fiduciaries, *id.* at 6a-8a, reasoning that, although "[t]he UPDPA requires PBMs to be fiduciaries of the covered entities with which they contract," PBMs are not "fiduciaries under the definition of a fiduciary provided in ERISA." *Id.* at 7a. Rather, in the court's view, "these are duties imposed under state law." *Id.*

Next, the court of appeals considered whether ERISA preempts UPDPA. It concluded that "[s]ince the PBMs regulated by the UPDPA are not fiduciaries under ERISA, there can be no preemption in this instance." Pet. App. 8a.

With respect to whether ERISA § 514(a) preempts UPDPA, the court observed that "a particular state law 'relates to' an employee benefit plan [within the meaning of § 514(a)] 'if it [i] has a connection with or [ii] a reference to such a plan'." Pet. App. 9a (quoting *Cal. Div. of Labor*

---

*Standards Enforcement v. Dillingham Constr., N.A., Inc.*, 519 U.S. 316, 324 (1997)). The court of appeals then determined that UPDPA does neither.

Relying exclusively on the fact that UPDPA regulates only PBMs, not ERISA fiduciaries, the court concluded that “UPDPA does not have an impermissible ‘connection with’ ERISA plans,” because it does not “compe[l]” ERISA plans to do anything. Pet. App. 12a. Rather, according to the court of appeals, UPDPA regulates only PBMs and does not directly bind “plan administrators . . . to a particular choice of rules.” *Id.* The court rejected PCMA’s argument that UPDPA regulated ERISA plans by effectively dictating the terms of their contracts with PBMs and by regulating the relationship between PBMs and ERISA plans; in the court’s view, “[t]he fact that the UPDPA requires *PBMs* to engage in certain ‘required practices’ in Maine, such as divulging the terms of contracts with pharmaceutical manufacturers and labelers,” does not make UPDPA a regulation of ERISA plans. *Id.* at 11a (emphasis added).

The court of appeals also found that UPDPA contained no impermissible reference to an ERISA plan, because even “[i]f the reference to employee health plans was deleted from the text of the UPDPA, the statute would still be operable.” Pet. App. 13a-14a. To the court, UPDPA “operates to regulate PBMs that contract with employee health plans—some of which may happen to be ERISA plans—it also operates upon the state Medicaid program and on insurance companies.” *Id.* at 13a.

Finally, the court of appeals held that UPDPA is not preempted under ERISA § 502(a) as a state law that supplies an “alternative enforcement mechanism to ERISA.” Pet. App. 15a. The court based this conclusion solely on the fact that PBMs are not ERISA fiduciaries, observing that PBMs are not within “the intricate web of relationships among the principal players in the ERISA scenario (*e.g.*, the plan, the administrators, the fiduciaries, the beneficiaries, and the

employer).” *Id.* The court found that this fact, without more, precluded ERISA preemption, reasoning that “[a]lthough ERISA prescribes the duties that are owed by ERISA entities to one another, and prescribes remedies for their breach, it is not designed to regulate or afford remedies against entities that provide services to plans.” *Id.* (internal quotation marks omitted).

Finally, the court affirmed the district court’s judgment with respect to PCMA’s other constitutional claims, which are not at issue here. Pet. App. 2a.

6. On January 9, 2006, the First Circuit denied a timely petition for rehearing and rehearing *en banc*. Pet. App. 121a-122a.

### **REASONS FOR GRANTING THE WRIT**

The First Circuit’s decision dramatically departs from the preemption precedents of those other federal courts of appeals that have considered the question presented. Contrary to the First Circuit—which held that UPDPA is not preempted because it regulates and imposes obligations on only ERISA non-fiduciaries—the Second, Fourth, Fifth, Sixth, Ninth, and Eleventh Circuits have all concluded that ERISA preempts state laws that regulate the conduct of ERISA non-fiduciaries where the conduct is functionally part of ERISA plan administration and management—that is, where the non-fiduciary is functioning to assist the plan in its management or administration of benefits. This Court’s immediate review is required not only to resolve this judicial conflict and reverse the error of the court below, but also to prevent states like Maine from undermining the federal government’s ongoing efforts to constrain escalating prescription drug costs by, among other things, promoting the use of PBMs. The Federal Trade Commission (“FTC”), the Department of Justice (“DOJ”) and the Government Accountability Office (“GAO”) have all warned that laws such as UPDPA, regulating PBMs as ERISA fiduciaries, are

---

anti-competitive and have the paradoxical effect of increasing already-high prescription drug prices. In addition, numerous states have either passed, or are looking to the First Circuit's decision as they consider, legislation akin to UPDPA. Accordingly, every factor that the Court typically considers when deciding whether to grant a writ of certiorari applies here, and each demonstrates that this Court's immediate intervention is necessary.

**I. THE FIRST CIRCUIT'S DECISION IS INCONSISTENT WITH THE DECISIONS OF NUMEROUS OTHER COURTS OF APPEALS.**

Contrary to the First Circuit's holding, the uniform precedents of the courts of appeals hold that ERISA preempts state laws that regulate ERISA non-fiduciary conduct that is functionally part of the management or administration of an ERISA plan. Rather than looking at the *label* affixed to the regulated party, all courts—except the First Circuit—look to the *function* that is being regulated, because just as a state cannot regulate an ERISA plan in its non-fiduciary administrative functions, it cannot regulate the performance of those same plan administrative functions by employees or contractors hired by the plan. This Court's intervention is necessary to resolve the judicial conflict.

The Second, Fourth, Fifth, Sixth, Ninth, and Eleventh Circuits have uniformly concluded that there is a distinction between (i) state laws that regulate the conduct of ERISA non-fiduciaries that is functionally part of the management and administration of an ERISA-covered plan, and (ii) “garden variety” state laws of general applicability (such as state bar requirements) that regulate persons who happen to be working for plans but do not regulate essential ERISA functions. Contrary to the First Circuit here, those courts have held that ERISA preemption applies to the former kind of state laws but not to the latter kind of state laws. *See, e.g., Gerosa v. Savasta Co.*, 329 F.3d 317, 323-24 (2d Cir. 2003) (holding that “ERISA does not preempt ‘run-of-the-mill’

state law professional negligence claims against non-fiduciaries,” but does preempt state laws regulating non-fiduciaries “that would tend to control or supersede central ERISA functions—such as state laws affecting the determination of eligibility for benefits, amounts of benefits, or means of securing unpaid benefits”); *Custer v. Pan Am. Life Ins. Co.*, 12 F.3d 410, 418-19 (4th Cir. 1993) (holding state law claim seeking to recover benefits from non-fiduciary preempted and observing that “the generalized contention that there should be some form of action available against non-fiduciaries is insufficient to overcome the specified language of [ERISA] which provides for preemption of any claim that relates to an employee benefit plan”); *NGS Am., Inc. v. Barnes*, 998 F.2d 296, 300 (5th Cir. 1993) (holding that a state law regulating the non-fiduciary administrator of an ERISA plan was preempted where the law “impose[d] significant burdens on administrators of ERISA-governed employee benefit plans” in their role as plan administrators); *Penny/Ohlmann/Nieman, Inc. v. Miami Valley Pension Corp.*, 399 F.3d 692, 702 n.5 (6th Cir. 2005) (observing that state law claims addressing issues within § 502(a) are preempted and that “[t]his principle holds true even where the suit is brought against a non-fiduciary”); *Smith v. Provident Bank*, 170 F.3d 609, 613, 617 (6th Cir. 1999) (holding state law that effectively converted ERISA non-fiduciaries into state law fiduciaries was preempted, but state laws that generally regulated professional service of non-fiduciary were not); *Gibson v. Prudential Ins. Co. of Am.*, 915 F.2d 414, 417 (9th Cir. 1990) (observing that, because “section 502(a)(3) of ERISA allows equitable relief against both fiduciaries and non-fiduciaries,” “[t]he existence of some remedy for misconduct by nonfiduciaries suggests that Congress intended to include their behavior under ERISA”); *Garren v. John Hancock Mut. Life Ins. Co.*, 114 F.3d 186, 187-88 (11th Cir. 1997) (holding that where the state law claim brought against a non-ERISA entity affects the relationship between the ERISA entities, the state law

---

claim is preempted); *Howard v. Parisian, Inc.*, 807 F.2d 1560, 1565 (11th Cir. 1987) (holding that § 514(a) “preempts all state laws insofar as they relate to employee benefits plans and is not limited to state laws as applied only to plan fiduciaries”) (emphasis in original). In the words of the Fourth Circuit, with respect to state laws that regulate a non-fiduciary’s plan administration or management related services, all “courts of appeals that have considered the question agree that state causes of action asserted against nonfiduciaries are preempted by ERISA. They disagree only on the extent to which ERISA provides its own remedies against nonfiduciaries.” *Pan Am. Life*, 12 F.3d at 419.

In contrast, in this case, the First Circuit focused on the identity and label of the entities that UPDPA regulates, not on the functions that they perform for employee benefit plans, concluding that “[s]ince the PBMs regulated by the UPDPA are not fiduciaries under ERISA, there can be no preemption in this instance.” Pet. App. 8a. The court held that UPDPA had no “connection with” an ERISA plan because it places “fiduciary duties and administrative burdens on *PBMs*” but does not directly “circumscribe the ability of plan administrators to structure or administer their ERISA plans.” *Id.* at 10a, 11a (emphasis added). That is, the court rejected preemption because nothing in UPDPA “compel[led]” ERISA plans to do anything. *Id.* at 12a. Similarly, the Court held that the preemptive effect of § 502(a) was not implicated simply because “UPDPA targets the PBMs, which, as stated above, are not ERISA fiduciaries.” *Id.* at 15a. Finally, the court below had no issue with Maine converting PBMs into fiduciaries in connection with their plan administration related conduct, because the change did not alter the ERISA fiduciary definition. *Id.* at 7a-8a. These conclusions—based on PBM’s non-fiduciary label, rather than the functions that PBMs performed for employee benefit plans—cannot be squared with the uniform holdings of the other courts of appeals described above.

Indeed, the First Circuit's decision conflicts directly with both the Fifth Circuit's decision in *NGS American* and the Sixth Circuit's decision in *Provident Bank*. In *NGS*, the Fifth Circuit considered whether a Texas law that imposed disclosure and audit obligations, as well as fees, on non-fiduciary plan administrators was preempted by ERISA. See 998 F.2d at 299-300. Unlike the First Circuit, the Fifth Circuit did not pause to consider the non-fiduciary status of the entities governed by the Texas statute. Instead, it examined the burdens imposed by the law as they related to plan administration functions. The court found that the Texas provision "impose[d] significant burdens on administrators of ERISA-governed employee plans" that related to their "role as administrator" for the plan. *Id.* at 300. The court concluded that "[i]t is these burdens of complying with conflicting state regulations that Congress sought to eliminate by enacting ERISA." *Id.*

Similarly, in *Provident Bank*, 170 F.3d at 613, the Sixth Circuit considered a state law that broadly defined a fiduciary to include entities that would not otherwise fall within ERISA's fiduciary definition and held the state law preempted because it supplanted ERISA's definition of fiduciary. The court reasoned that, through ERISA, Congress "standardize[d] the administration of employee benefit plans, including the duties and liabilities of fiduciaries," *id.*, such that state law could not add to, or detract from, ERISA's definition of fiduciary. It was of no moment, moreover, that the state fiduciary duty law increased the scope of fiduciary liability. In the court's view, it was "not a valid argument against preemption to say that the state seeks to impose greater obligations than Congress did." *Id.* "If [defendants] do not meet ERISA's definition of a fiduciary, neither can be liable for breach of fiduciary duty with respect to management of an ERISA plan." *Id.* The First Circuit's contrary holding flatly conflicts with *Provident Bank*.

---

In addition, the First Circuit's analysis directly conflicts with the analytical approach adopted by the Eleventh Circuit with respect to claims against ERISA non-fiduciaries who are performing functions that are part of the administration or management of an employee benefit plan. In *Garren*, the Eleventh Circuit considered a state law claim of tortious interference against a non-fiduciary for alleged wrongful denial of a benefit claim. Contrary to the First Circuit, the Eleventh Circuit concluded that ERISA preemption is *not* precluded by the mere fact that the defendant was "neither a party to the agreement nor the plan administrator." 114 F.3d at 188. The court explained, "[t]he proper focus is *not on the relationship* between the parties *but on the relationship between the alleged conduct*" and the benefits plan. *Id.* (emphasis added). And, in *Howard v. Parisian, Inc.*, the same court held that state law claims against an ERISA non-fiduciary for improper claims processing are preempted by ERISA. 807 F.2d at 1565. The court observed that "[a]dmittedly ERISA does not regulate the duties of non-fiduciary plan administrators." *Id.* at 1564. Nonetheless, the court reasoned that § 514(a) "preempts *all* state laws insofar as they relate to employee benefit plans and is not limited to state laws as applied only to plan fiduciaries." *Id.* at 1565 (emphasis in original). Otherwise, the court concluded, "[a]llowing plan beneficiaries to assert state law claims against non-fiduciary plan administrators for the wrongful termination of benefits would upset the uniform regulation of plan benefits intended by Congress." *Id.*

Not surprisingly, much has been written about the First Circuit's extreme departure from existing ERISA precedents. One ERISA practitioner has called the First Circuit's decision "a major leap backwards in precedent under [ERISA] insofar as preemption analysis and 'fiduciary' status have been interpreted by the courts" and has observed that the court's "rationale introduces a new and pernicious distinction into ERISA preemption analysis." William G. Schiffbauer, *PCMA v. Maine: The First Circuit Blesses a*

*“Shotgun Wedding” Between Business Interests and State Government*, 4 PHARM. LAW & INDUS. 1, 3 (Jan. 13, 2006). Other commentators discussing the First Circuit’s decision, have observed that “there is something disturbing to ERISA eyes about a state statute that creates a fiduciary duty to ERISA plans . . . , requires that duty to be discharged ‘in accordance with state and federal law,’ and then spells out that duty with a conscious parroting of the language of ERISA’s prudence standard.” 13 No. 5 ERISA Litig. Rep. 16, 16 (Dec. 2005).

This conflict in ERISA preemption precedents will not resolve itself over time but will worsen. There is no reason to expect that the First Circuit will reconsider its decision in this case. The court denied a motion to rehear the case *en banc*. The precedents of the courts on the other side of the preemption issue, moreover, are long-standing and well established. This Court’s review is thus necessary to resolve the judicial conflict.

## **II. THE FIRST CIRCUIT’S NON-PREEMPTION CONCLUSION IS ERRONEOUS.**

The Court’s intervention is also necessary to correct the serious error committed by the court below. Applying the proper preemption analysis set forth in this Court’s decisions, it is clear that state laws like UPDPA, imposing disgorgement, disclosure, and ERISA fiduciary obligations on PBMs, are preempted.

Contrary to the precedents of this Court, the First Circuit incorrectly held that, because PBMs are non-fiduciaries, ERISA preemption principles cannot apply. This Court has repeatedly approved application of ERISA preemption principles to non-fiduciary conduct—such as the processing of benefit claims by third-party non-fiduciaries. Indeed, this Court has twice held that state law claims against insurers were preempted in cases where the conduct allegedly giving

---

rise to the claim was *not* a fiduciary act but a non-fiduciary act pertaining to plan management or administration.

In *Pilot Life*, the Court held that a beneficiary's common-law breach of contract and tort causes of action for improper claims processing were preempted, even though in processing the claims the insurer was *not* acting as a fiduciary, because ERISA's preemption "clause is not limited to state laws specifically designed to affect employee benefit plans." See 481 U.S. at 47-48 (internal quotation marks). And, in *Aetna Health Inc. v. Davila*, 542 U.S. 200 (2004), the Court held that a third party's denial of benefits could not form the basis of a state law claim even though the third party's acts were not fiduciary in nature. See *id.* at 206 n.1. The Court concluded, notwithstanding the respondent's non-fiduciary character, that petitioners' claims were essentially "about denials of coverage promised under the terms of ERISA-regulated employee benefit plans" and thus were preempted under ERISA. *Id.* at 211, 212-13.

In addition, in *Mertens v. Hewitt Assocs.*, 508 U.S. 248, 250 (1993), the Court explained why state law cannot expand the remedies against non-fiduciaries. There, the Court considered whether a non-fiduciary who knowingly assists in a breach of an ERISA fiduciary duty is liable to the ERISA plan for compensatory damages. The Court held that compensatory damages were not available against the non-fiduciary under ERISA, because no provision in ERISA "explicitly require[d] [non-fiduciaries] to avoid participation (knowing or unknowing) in a fiduciary's breach of fiduciary duty." *Id.* at 254. The Court explained that ERISA "allocates liability for plan-related misdeeds in reasonable proportion to respective actors' power to control and prevent the misdeeds." *Id.* at 262. Specifically, ERISA provides for damages against only fiduciaries and "defines 'fiduciary' not in terms of formal trusteeship, but in *functional* terms of control and authority over the plan," which "expand[s] the universe of persons subject to fiduciary duties." *Id.*

(emphasis in original). Thus, the Court ruled that, under this scheme, non-fiduciaries “become liable for damages when they cross the line from advisor to fiduciary.” *Id.* State law could not expand the universe of liability, the Court concluded, because doing so “would impose high insurance costs upon persons who regularly deal with and offer advice to ERISA plans, and hence upon ERISA plans themselves.” *Id.* See also *Harris Trust & Sav. Bank*, 530 U.S. at 241 (holding non-fiduciaries participating in ERISA prohibited transactions are liable under ERISA for “appropriate equitable relief”).

Because it failed to properly analyze how ERISA preemption principles apply to non-fiduciaries like PBMs, the First Circuit failed to recognize the numerous reasons why UPDPA is preempted.

*First*, applying the correct preemption analysis, it is clear that the First Circuit erred, first and foremost, because UPDPA regulates PBMs in a way that directly relates to their administrative-related functions. Under the correct preemption analysis, state laws cannot regulate non-fiduciaries in a way that would tend to “control or supersede central ERISA functions.” *Gerosa*, 329 F.3d at 323-24. Thus, in *Davila*, this Court held preempted a state law claim against a non-fiduciary third party performing utilization review conducted for an ERISA plan. See 542 U.S. at 211-13.

Here, there is no question that PBMs function as part of plan management and administration. They are hired by plans to manage prescription drug benefits. See *FTC Report*, at i. Indeed, absent a contract with a PBM, the plan must, itself, do the tasks performed by PBMs; the plan could not provide drug benefits without someone performing these functions. UPDPA regulates these very ERISA-related functions, in particular the manner in which PBMs negotiate with pharmaceuticals, the prices PBMs must charge for prescription drugs, and ultimately the PBM’s formulary.

---

But, just as a state cannot regulate an ERISA plan's performance of these non-fiduciary administrative-related functions, it cannot regulate these functions when they are performed by a third-party PBM on behalf of the plan.

*Second*, UPDPA impermissibly supplants ERISA's definition of "fiduciary." Under ERISA, an ERISA "fiduciary" is defined, in relevant part, as a person who, in connection with an employee benefit plan, exercises discretionary authority or discretionary control over plan management, plan assets, or plan administration. It is well established that a state cannot alter the scope of ERISA's fiduciary duties by expanding state law fiduciary provisions as they relate to an ERISA plan. *See Mertens*, 508 U.S. at 261; *Provident Bank*, 170 F.3d at 613. By its terms, however, UPDPA alters ERISA's definition of "fiduciary" by converting PBMs into fiduciaries—regardless of whether they exercise the requisite discretionary control—for purposes of "state *and federal law*." 22 ME. REV. STAT. ANN. § 2699(2) (emphasis added). As the Sixth Circuit held in *Provident Bank*, such a state law is preempted because "it is the nature of the claim—breach of fiduciary duty—that determines whether ERISA applies, not whether the claim will succeed." 170 F.3d at 613.

The First Circuit erroneously backhanded the argument that UPDPA impermissibly expands the scope of ERISA's fiduciary definition, reasoning that the Act altered only state law requirements, not federal law requirements. The First Circuit missed the point, however, that state fiduciary law cannot operate more broadly than ERISA with respect to ERISA plans. As one commentator has observed, "[t]he 1st Circuit conclusion that the [fiduciary] duty created [by UPDPA] is a state law duty has to be true in the sense that state law cannot create a federal law duty. If so, however, how can state law create a duty to an ERISA plan and what is the meaning of [UPDPA's] express reference to a duty under 'federal law'?" ERISA Litig. Rep, *supra*, at 16.

*Third*, UPDPA impermissibly binds ERISA plans in their contractual relations with PBMs and in their relations with beneficiaries. As this Court has observed, state law cannot “bind[] ERISA plan administrators to a particular choice of rules” for plan management or administration. *Egelhoff v. Egelhoff*, 532 U.S. 141, 147 (2001). By its terms, however, UPDPA dictates the terms an ERISA plan must have in its contract with a PBM by requiring specific provisions “in all contracts for pharmacy benefits management entered into . . . **by a covered entity** in this State,” which includes ERISA plans. 22 ME. REV. STAT. ANN. § 2699(3) (emphasis added). Thus, in the State of Maine, an ERISA plan *cannot* enter into a contract with a PBM that is inconsistent with UPDPA’s requirements. No state law could more directly “relate to” an ERISA plan. *See Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 96-98 (1983).

Indeed, UPDPA binds ERISA plans in several specific ways. Through the requirement that PBMs operate as fiduciaries, “UPDPA *binds* ERISA plan administrators to outsourcing prescription drug benefits under a ‘fiduciary’ arrangement with a PBM.” Schiffbauer, *supra*, at 4 (emphasis in original). ERISA plans “[no] longer have the flexibility to contract with PBMs on the basis of specific needs and cannot contract as a ‘non-fiduciary’ for ‘ministerial’ claims administration only, because state law requires PBMs to always act as ‘fiduciaries’.” *Id.* In addition, UPDPA mandates that PBMs “shall transfer in full” to ERISA plans “any benefit or payment received in any form by the [PBM]” as a result of a prescription drug substitution. 22 ME. REV. STAT. § 2699(2)(E)(3). By so requiring PBMs to hand over their profits to ERISA plans, (among others), UPDPA will inevitably impact PBMs’ formularies and thus the mix of drug benefits provided by ERISA plans.

*Fourth*, the First Circuit erroneously refused to apply § 502(a) preemption principles, but under those principles,

---

UPDPA is preempted due to the ERISA-based remedies available to beneficiaries.

Where a plan beneficiary has a remedy under § 502(a), a state law cause of action for a different remedy “fall[s] within the scope of ERISA” § 502(a) and is “therefore completely preempted by ERISA § 502.” *Davila*, 542 U.S. at 214 (internal quotation marks omitted). It is irrelevant, moreover, that ERISA does not contain the precise claim authorized by state law because “an alternative remedy to those provided by the ERISA civil enforcement mechanism conflicts with Congress’ clear intent to make the ERISA mechanism exclusive.” *Id.* at 214 n.4.

Here, plan beneficiaries and fiduciaries have an avenue of recourse under ERISA if they believe that a PBM or a benefit plan has mis-priced a prescription drug or co-pay, or has wrongly required the use of a brand-name, instead of a generic, drug as part of its formulary—which are the wrongs UPDPA is designed to address. Specifically, § 502(a)(1)(B) provides a cause of action “to *recover benefits* due . . . under the terms of . . . plan, to *enforce . . . rights* under the terms of a plan, or to *clarify . . . rights* to future benefits under the terms of the plan.” 29 U.S.C. § 1132(a)(1)(B) (emphasis added). Participants aggrieved by a final co-pay determination may sue under this provision to enforce their asserted right to pay the lower co-pay, or to clarify their right to pay a lower amount in the future. *See Davila*, 542 U.S. at 211-12 (federal court is authorized to issue preliminary injunction to enforce plan rights). If a participant has already paid the higher co-pay, the participant may seek reimbursement of the overpayments under § 502(a)(1)(B). *See id.* at 211 (“respondents could have paid for the treatment themselves, and then sought reimbursement through a § 502(a)(1)(B) action”).

In addition, because prescription drug benefits are usually contractual rights to obtain particular drugs on a formulary developed by the plan sponsor in exchange for a particular

co-pay amounts, participants have the right to appeal an alleged erroneous co-pay assessment. *See* U.S. Dep't of Labor, *FAQ's About the Benefit Claims Procedure Regulation*, at C12 (Jan. 12, 2006) available at, [http://www.dol.gov/ebsa/faqs/faq\\_claims\\_proc\\_reg.html](http://www.dol.gov/ebsa/faqs/faq_claims_proc_reg.html) (DOL internal appeal regulation "permits claimants to challenge whether, for example, the plan applied the wrong co-payment requirement or deductible amount") (last visited April 4, 2006). If the participant is dissatisfied with the plan fiduciary's final decision on a coverage claim, ERISA § 502(a) provides the exclusive judicial recourse.

Plan fiduciaries and beneficiaries can also seek "appropriate equitable relief" against a non-fiduciary under § 502(a). *See* 29 U.S.C. § 1132(a)(3). Thus, a non-fiduciary engaged in ERISA prohibited acts can be enjoined under § 502(a)(3). *See Harris Trust*, 530 U.S. at 246-49.

UPDPA purports to alter ERISA's remedies by conferring on beneficiaries a right to sue PBMs for damages in the event that the beneficiary overpays for a drug or does not receive a preferred drug as a result of perceived flaws in the ERISA plan-PBM relationship. The entire point of § 502(a) preemption, however, is to bar state-law claims that provide remedies beyond those that Congress chose to make available in the "carefully balanced" § 502(a) remedial scheme. "Congress' intent to make the ERISA civil enforcement mechanism exclusive would be undermined if state cause[s] of action that supplement the ERISA § 502(a) remedies were permitted, even if the elements of the state cause[s] of action did not precisely the duplicate the elements of an ERISA claim." *Davila*, 542 U.S. at 216. The First Circuit's contrary conclusion can only now be corrected by this Court.

**III. THIS COURT'S IMMEDIATE REVIEW IS ALSO NEEDED IN ORDER TO PREVENT INTERFERENCE WITH THE FEDERAL GOVERNMENT'S ONGOING EFFORTS TO CONSTRAIN PRESCRIPTION DRUG PRICES THROUGH SUPPORT OF PBMs.**

The Court's immediate review is also needed in order to prevent interference with the federal government's ongoing efforts to constrain escalating prescription drug prices through support of PBMs. Numerous agencies of the federal government have studied the impact of PBMs on prescription drug costs and have concluded that PBMs substantially reduce those costs. The FTC, moreover, actively discourages states from adopting laws, like UPDPA, that regulate PBMs on the ground that such laws have the paradoxical effect of increasing drug costs to consumers. These federal efforts will be frustrated if the Court does not intervene.

Numerous federal government agencies have concluded that PBMs have a beneficial impact on prescription drug prices. In a joint 2004 study on health care competition in the United States, the FTC and DOJ both concluded that the growth of PBMs is "an important development in providing consumer access to prescription drugs," because "consumers with prescription drug insurance administered by a PBM save substantially on their drug costs as compared to cash-paying customers." *FTC/DOJ Report*, ch. 7, at 11. In addition, the GAO found in a 2003 study that PBMs "achieved savings for . . . participating health plans by using three key approaches: obtaining drug price discounts from retail pharmacies and dispensing drugs at lower costs through their mail-order pharmacies; passing on certain manufacturer rebates to the plans; and using intervention techniques that reduce utilization of certain drugs or substitute other, less costly, drugs." *See GAO, Federal Employees Health Benefits: Effects of Using Pharmacy*

*Benefit Managers on Health Plans, Enrollees, and Pharmacies*, GAO-03-196, at 4 (Jan. 10, 2003), available at [www.gao.gov/new.items/d03196.pdf](http://www.gao.gov/new.items/d03196.pdf) (last visited April 4, 2006). The GAO study further noted that the average price that PBMs negotiated on behalf of federal workers for brand-name drugs from retail pharmacies “was about 18 percent below the average cash price customers would pay” for select brand-name drugs and “47 percent below the average cash price” for select generic drugs. *Id.* Other non-governmental studies have reached similar conclusions. For example, one study found that two large PBMs saved consumers over \$1 billion in 1997 alone. *See* Br. of PCMA to 1st Cir. at 4-5. And yet another study, in Maine, estimated that PBMs saved Maine benefit providers between \$20,000 and \$600,000 annually. *See id.*

Agencies of the Executive Branch have also concluded that state regulations of PBMs are unnecessary and counterproductive. In 2003, recognizing the pivotal role that PBMs play in the prescription drug industry, Congress requested that the FTC study whether health benefit plans are adequately protected against PBMs’ potential conflicts of interest in retaining some discounts and rebates from drug manufacturers, as well as the competitive impact of PBM regulation—the supposed conflict UPDPA purports to address through its disgorgement and fiduciary requirements. Pursuant to this congressional mandate, the FTC recently completed a landmark study that analyzed voluminous data concerning how PBMs assist with the design and administration of prescription drug benefits. *See FTC Report* at v, 2, 19. In the study, the FTC concluded that the PBMs’ practice of retaining some portion of drug manufacturer rebates—a practice prohibited by UPDPA—is in the interest of health benefit plans:

It may be in the interest of both PBMs and plan sponsor clients to have contracts that provide that the PBMs will retain a substantial share of manufacturer payments, while

including other contract terms that benefit plan sponsor clients. Such an arrangement would give the PBMs an incentive to negotiate aggressively with manufacturers for formulary and other payments, to the benefit (through other contract terms) of their plan sponsor clients.

*Id.* at 60. The FTC also found that “nearly all” of the 26 plan sponsor contracts that it reviewed granted the sponsor some form of audit rights to verify formulary and market-share payment sharing, ranging from general audit rights to quarterly reports from the PBMs. *Id.* at 56, 58.

Unsurprisingly, in light of these studies, the FTC has concluded that laws like UPDPA, which regulate PBMs as fiduciaries and force PBMs to give cost savings to benefit plans and to disclose to plans information about their negotiations with drug manufacturers, have an anti-competitive impact in the market for prescription drug benefits. When the terms of private contracts and cost-saving methodologies are disclosed to PBMs’ customers and suppliers, as well as to the pharmaceutical manufacturers with which the PBMs negotiate, the result is that prices tend to become standardized at a higher level (a pricing “floor”). *See generally FTC Report; FTC/DOJ Report.* The FTC has thus actively discouraged the passage of laws like UPDPA, because such statutes are “more likely to undermine competition than promote it” and “are likely to undermine the ability of some consumers to obtain the pharmaceuticals and health insurance they need at a price they can afford.” *See Aghazarian Letter* at 12.

While these federal initiatives favoring PBMs and opposing state regulation of PBMs are widespread and growing, numerous states are nonetheless currently considering legislation similar to UPDPA. In addition to Maine, the District of Columbia, Georgia, Maryland, North Dakota, and South Dakota have passed laws regulating, to varying degrees, the operation of PBMs within each State. *See D.C. CODE ANN. §§ 48-832.01-48-832.03 (2004); GA.*

CODE ANN. § 26-4-110.1 (2004); MD. CODE ANN. INS. § 15-10B-20 (2005); N.D. CENT. CODE §§ 26.1-27-01.1, *et seq.* (2006); S.D. CODIFIED LAWS §§ 58-29E-1—58-29E-10. In addition, during the last several years, there has been a staggering increase in the number of PBM-regulating bills introduced in State legislatures. In 2002, only 8 legislatures entertained bills to regulate PBMs; that number nearly tripled in the following year, with 22 legislatures considering PBM regulations. Janet Brierton, Office of Legislative Research, Connecticut Gen. Assembly, *Regulation of Pharmacy Benefit Managers* No. 2004-R-0071 1 (Jan. 15, 2004) (Pet. App. 145a-146a). Currently, Alabama, New Jersey, Pennsylvania, Rhode Island, South Carolina, and Tennessee are all considering similar legislation, and dozens of other legislatures are debating “fiduciary” legislation applicable to PBMs, all with an eye toward the First Circuit’s decision. Only this Court can resolve the growing tension between the federal government, on the one hand, and the state governments, on the other hand, in the area of PBM regulation.

That resolution cannot wait. As the Executive Branch agencies have concluded, the proliferation of laws imposing state-law fiduciary status on PBMs will adversely impact the financial stability of employee benefit plan assets by increasing the cost of plan administration and forcing plan sponsors, insurers and administrators to master the relevant laws of 50 States and to contend with litigation pertaining to PBM regulation. This state of affairs obviously “undermine[s] the congressional goal of minimiz[ing] the administrative and financial burden[s] on plan administrators—burdens ultimately borne by the beneficiaries.” *Egelhoff*, 532 U.S. at 149-50 (internal quotation marks omitted; second and third brackets in original). In light of the substantial practical and legal importance of the question presented, the First Circuit’s departure from this Court’s precedents and the uniform

---

precedents of the Courts of Appeals, and the First Circuit's clear error, this Court's immediate review is essential.

**CONCLUSION**

The petition for a writ of certiorari should be granted.

Respectfully submitted,

BARBARA A. LEVY  
General Counsel  
Pharmaceutical Care  
Management Association  
601 Pennsylvania Ave, NW  
Suite 740  
Washington, DC 20004

GLEN D. NAGER  
*(Counsel of Record)*  
TRACI L. LOVITT  
KATE BUSHMAN  
JONES DAY  
51 Louisiana Avenue, NW  
Washington, DC 20001  
(202) 879-3939

April 2006

*Counsel for Petitioner*