United States Court of Appeals For the First Circuit

No. 05-1606

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION,

Plaintiff, Appellant,

v.

G. STEVEN ROWE, in his official capacity as ATTORNEY GENERAL OF THE STATE OF MAINE,

Defendant, Appellee.

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MAINE [Hon. D. Brock Hornby, <u>U.S. District Judge</u>]

Before

Boudin, <u>Chief Judge</u>, Torruella, <u>Circuit Judge</u>, and Dyk,^{*} <u>Circuit Judge</u>.

<u>William J. Kayatta, Jr.</u>, with whom <u>John J. Aromando</u>, <u>Catherine</u> <u>R. Connors</u>, <u>Pierce Atwood LLP</u>, <u>Paul J. Ondrasik</u>, <u>Jr.</u>, <u>Martin D.</u> <u>Schneiderman</u>, and <u>Steptoe & Johnson LLP</u>, were on brief, for appellant.

Andrew L. Black, Assistant Attorney General, with whom <u>Paul</u> <u>Stern</u>, Deputy Attorney General, <u>G. Steven Rowe</u>, Attorney General, and <u>Ronald W. Lupton</u>, Assistant Attorney General, were on brief, for appellee.

November 8, 2005

^{*} Of the Federal Circuit, sitting by designation.

Per Curiam. The panel unanimously affirms the district court's grant of summary judgment for defendant on all claims. On the ERISA preemption, due process, and Commerce Clause issues, the panel unanimously adopts Judge Torruella's reasoning. As to the association standing, Takings Clause, and First Amendment issues, the joint concurring opinion of Chief Judge Boudin and Judge Dyk represents the opinion of the court.

Affirmed.

"Opinion follows."

TORRUELLA, <u>Circuit Judge</u>. This appeal arises from an attempt by plaintiff-appellant Pharmaceutical Care Management Association ("PCMA") to challenge the provisions of Maine's Unfair Prescription Drug Practices Act ("UPDPA"), Me. Rev. Stat. Ann. tit. 22, § 2699 (2005). PCMA brought suit against defendant-appellee G. Steven Rowe, Attorney General of the State of Maine, seeking to obtain an order enjoining enforcement of the UPDPA. The parties issued cross-motions for summary judgment, and the district court denied PCMA's motion and granted the motion of the Attorney General. PCMA now appeals this decision. For the reasons hereinafter stated, we affirm the decision of the district court.

I. Factual Background

PCMA is a national trade association of pharmacy benefit managers (PBMs). PBMs are major players in the delivery of health care in the United States. They act as middlemen in the lucrative business of providing prescription drugs. They serve as intermediaries between pharmaceutical manufacturers and pharmacies on the one hand (as the district court noted, the "supply" side of the trade) and health benefit providers (e.g., insurers, selfinsured entities, health maintenance organizations, and public and private health plans) on the other (the "demand" side). The services that PBMs extend are designed to facilitate the provision of prescription drug benefits to the people who utilize the services of the health benefit providers.

-3-

For example, PBMs often provide health benefit providers with access to an established network of pharmacies, where customers of the health benefit providers can obtain drugs at certain set prices. PBMs negotiate volume discounts and rebates with drug manufacturers by pooling substantial numbers of health benefit providers. This pooling gives the PBMs tremendous market power to demand concessions from the manufacturers. PBMs also provide drug utilization review services and "therapeutic interchange programs" (in other words, substituting a drug for the one actually prescribed by a doctor).

In this role as intermediary, however, PBMs have the opportunity to engage in activities that may benefit the drug manufacturers and PBMs financially to the detriment of the health For example, in cases of "therapeutic benefit providers. interchange," a PBM may substitute a more expensive brand name drug for an equally effective and cheaper generic drug. This is done so that the PBM can collect a fee from the manufacturer for helping to increase the manufacturer's market share within a certain drug Similarly, a PBM might receive a discount from a category. manufacturer on a particular drug but not pass any of it on to the health benefit provider, keeping the difference for itself. The health benefit provider, however, often has no idea that a PBM may not be working in its interest. This lack of awareness is the result of the fact that there is little transparency in a PBM's

-4-

dealings with manufacturers and pharmacies. As the district court noted, "[w]hether and how a PBM actually saves an individual benefits provider customer money with respect to the purchase of a particular prescription drug is largely a mystery to the benefits provider." <u>Pharm. Care Mgmt. Ass'n</u> v. <u>Rowe</u>, No. 05-1606, 2005 U.S. Dist. LEXIS 2339, at *6 (D. Me. Feb. 2, 2005).

With the aim of placing Maine health benefit providers in a better position to determine whether PBMs are acting against their interests, and correspondingly, to help control prescription drug costs and increase access to prescription drugs, the Maine Legislature enacted the UPDPA in the spring of 2003. The UPDPA imposes a number of requirements on those PBMs that choose to enter into contracts in Maine with "covered entities" -- meaning health benefit providers and including, in part, insurance companies, the state Medicaid program, and employer health plans. Such PBMs are required to act as fiduciaries for their clients and adhere to certain specific duties. For example, they must disclose conflicts of interest, disgorge profits from self-dealing, and disclose to the covered entities certain of their financial arrangements with third parties. Me. Rev. Stat. Ann. tit. 22, §§ 2699(2)(A-G) (2005). The disclosures made by the PBMs to the covered entities are protected by confidentiality. None of the disclosures are available to the public.

-5-

PCMA, on behalf of its member PBMs, challenges the UPDPA on five separate grounds. First, it claims that the Maine law was preempted by either the Employee Retirement Income Security Act of 1974 ("ERISA") or the Federal Employee Health Benefits Act ("FEHBA"). PCMA's second argument is that the UPDPA violates the Takings Clause of the Fifth Amendment because it conditions doing business in Maine upon the forced disclosure or taking of proprietary information. Third, PCMA states that the provisions of the UPDPA violate due process because they provide no predeprivation hearing. Fourth, the association claims that the UPDPA disclosure provisions violate the First Amendment by compelling commercial speech in the context of a voluntary business relationship. PCMA's final argument is that the UPDPA violates the Commerce Clause, either through its "extraterritorial reach" or by excessively burdening interstate commerce.¹

In the proceedings below, the parties issued crossmotions for summary judgment. The magistrate judge responsible for the case recommended to the district court that summary judgment be

¹ PCMA also alleges a violation of 42 U.S.C. § 1983 (2000), claiming that the UPDPA subjects PCMA's member PBMs to the deprivation of "rights, privileges, or immunities secured by the Constitution." The district court entered summary judgment in favor of the appellee on this claim. It reasoned that since the UPDPA did not run afoul of any of the federal rights raised by PCMA, summary judgment was proper on PCMA's § 1983 claim. PCMA raises this same § 1983 claim on appeal but provides no additional discussion on the matter. Because we also find that the UPDPA is not violative of any federal rights, we think the district court was correct in disposing of this claim on summary judgment.

entered in favor of the Attorney General on all claims. The district court agreed with this recommendation and upheld the UPDPA against all of PCMA's challenges. Upon careful review, we now affirm.

II. <u>Discussion</u>

A. Standard of review

We review a district court's ruling on cross-motions for summary judgment <u>de novo</u>. <u>Calero-Cerezo</u> v. <u>Dep't of Justice</u>, 355 F.3d 6, 19 (2004).

B. Preemption claims²

ERISA is "a comprehensive statute designed to promote the interests of employees and their beneficiaries in employee benefit plans." <u>Shaw</u> v. <u>Delta Airlines</u>, 463 U.S. 85, 90 (1983). The statute includes a broadly-worded preemption provision, 29 U.S.C.

² In addition to its claim that the UPDPA is preempted by ERISA, PCMA argues that the UPDPA is also preempted by FEHBA. FEHBA authorizes the Office of Personnel Management to negotiate contracts with private carriers to provide health benefits for federal employees, retirees, and their dependents. The statute includes an express preemption provision, 5 U.S.C. § 8902(m)(1) (2000), that is nearly identical to ERISA's preemption provision. Therefore, we look to ERISA precedent in determining the scope of the preemption provision under FEHBA. See Botsford v. Blue Cross <u>& Blue Shield of Mont., Inc.</u>, 314 F.3d 390, 393-94 (9th Cir. 2002) (noting that the FEBHA preemption provision closely resembles ERISA's preemption provision and that "precedent interpreting the ERISA provision thus provides authority for cases involving the FEHBA provision"). Because both parties here, as they did before the district court, agree that "whether the FEHBA preempts the UPDPA depends on essentially the same analysis as the question of whether ERISA preempts the UPDPA," we confine our discussion here to examining the scope of the ERISA preemption provision. Pharm. Care Mqmt. Ass'n, 2005 U.S. Dist. LEXIS 2339, at *29.

§ 1144(a) (2000), that Congress included "to afford employers the advantages of a uniform set of administrative procedures governed by a single set of regulations." <u>Fort Halifax Packing Co.</u> v. <u>Coyne</u>, 482 U.S. 1, 11 (1987). PCMA here claims that the UPDPA is preempted by ERISA.

1.

In examining PCMA's preemption claim, a threshold issue we must confront is whether the PBMs act as ERISA fiduciaries.³ This is an issue with high stakes, for classification as a fiduciary or a nonfiduciary renders a defendant liable for different types of damages. For example, under sections 409 and 502(a)(2) of ERISA, 29 U.S.C. §§ 1109(a), 1132(a)(2), an ERISA fiduciary is personally liable for monetary damages, for restitution, and for "such other equitable or remedial relief as the court may deem appropriate." 29 U.S.C. § 1109(a). A nonfiduciary, however, is not subject to monetary damages in a suit brought under ERISA. <u>See Mertens</u> v. <u>Hewitt Assocs.</u>, 508 U.S. 248, 262 (1993) (noting how "[p]rofessional service providers such as

³ Although the district court noted that "PCMA's member PBMs are not ERISA fiduciaries," <u>Pharm. Care Mgmt. Ass'n</u>, 2005 U.S. Dist. LEXIS 2339, at *16, and the parties state that they agree to this fact, we feel it necessary to explore this issue in some depth here, both because our subsequent analysis relies on its outcome and because the briefs of the parties belie their mutual contention that they are in agreement as to the status of PBMs under ERISA.

actuaries become liable for damages when they cross the line from adviser to fiduciary").⁴

Under ERISA, a fiduciary is one who exercises discretionary authority or control in the management and administration of an ERISA plan. 29 U.S.C. § 1002(21)(A). See also Mertens, 508 U.S. at 251, 262. The Attorney General argues that since PBMs do not exercise discretionary authority or control in the management and administration of ERISA plans, they are not fiduciaries under the definition provided for under ERISA. PCMA, in contrast, claims that the UPDPA makes PBMs fiduciaries in performing administration activities for ERISA plans. The UPDPA, after all, targets PBMs that contract with "covered entities" -insurance companies, the state Medicaid program, and employer health plans -- some of which may be ERISA plans. The UPDPA requires PBMs to be fiduciaries of the covered entities with which they contract. Therefore, when a PBM contracts with a covered entity that happens to be an ERISA plan, the PBM is a fiduciary of that ERISA plan.

Although the UPDPA does impose certain fiduciary duties on the PBMs, these are duties imposed under state law. The key

⁴ In <u>Mertens</u>, the Supreme Court expressly reserved the question as to whether ERISA provides for a cause of action against nonfiduciaries who assist in a fiduciary's breach of duty. The Court, however, did resolve the question as to whether a nonfiduciary in such a suit would be subject to monetary damages. <u>See Mertens</u>, 508 U.S. at 253-54.

issue here, however, is whether the PBMs are fiduciaries under the definition of a fiduciary provided in ERISA. Our review of the requirements imposed on the PBMs under the UPDPA lead us to believe that the PBMs do not exercise "discretionary authority or control in the management and administration of the plan." 29 U.S.C. § 1002(21)(A). For example, the UPDPA provisions requiring disclosure of conflicts of interest and payments from drug manufacturers are administrative provisions involving no discretion on the part of the PBMs. Such duties are purely ministerial and simply not sufficient for us to find that the PBMs are acting as fiduciaries under ERISA.

2.

With that threshold matter disposed of, we are now able to confront the main issue at hand: Is the UPDPA preempted by ERISA? PCMA claims that ERISA does preempt the UPDPA because ERISA preempts all state laws that "relate to any ERISA covered employee benefit plan," 29 U.S.C. § 1144(a), regardless of whether an entity is acting as a fiduciary or not. The state, in contrast, argues that the UPDPA is not preempted by ERISA because ERISA only preempts state laws relating to acts performed by ERISA fiduciaries. Since the PBMs regulated by the UPDPA are not fiduciaries under ERISA, there can be no preemption in this instance.

-10-

To answer the question of what exactly ERISA preempts, we first turn to the statute itself. ERISA's preemption provision states explicitly that ERISA "shall supersede any and all State laws insofar as they may now or hereafter relate to any employee benefit plan." 29 U.S.C. § 1144(a) (2000). Looking only at the face of the statute, then, it appears that PCMA is correct. With its broad and expansive language, the ERISA preemption provision seems to say that all state laws that in any way "relate to" any ERISA-covered employee benefit plan are preempted.

The Supreme Court, however, has stated that the language of the ERISA preemption provision is not as broad as it seems. The Court has emphasized that the expansive language of the provision is still subject to "the starting presumption that Congress does not intend to supplant state law" and has warned "that, unless congressional intent to preempt clearly appears, ERISA will not be deemed to supplant state law in areas traditionally regulated by the states." <u>New York State Conf. of Blue Cross & Blue Shield</u> <u>Plans v. Travelers Ins. Co.</u>, 514 U.S. 645, 654, 661 (1995); <u>Carpenters Local Union No. 26</u> v. <u>U.S. Fid. & Guar. Co.</u>, 215 F.3d 136, 139-40 (1st Cir. 2000).

Realizing, then, that the exact scope of the ERISA preemption provision is imprecise and that the provision cannot be read literally, the Court has developed a two-part test to determine exactly what state laws ERISA preempts. The test

-11-

established by the Court begins with reference to the preemption provision itself. As already stated, ERISA expressly preempts "any and all State laws insofar as they . . . relate to any employee benefit plan." 29 U.S.C. § 1144(a) (2000). "[T]he incidence of ERISA preemption turns on the parameters of the phrase 'relate to.'" <u>Carpenters Local Union No. 26</u>, 215 F.3d at 139. The Court has stated that a particular state law "relates to" an employee benefit plan "if it [1] has a connection with or [2] a reference to such a plan." <u>California Div. of Labor Standards Enforcement</u> v. <u>Dillingham Constr., N.A., Inc.</u>, 519 U.S. 316, 324 (1997); <u>Carpenters Local Union No. 26</u>, 215 F.3d at 140. We use this test to determine whether the UPDPA is preempted by ERISA.

a) The "connection with" prong

The Supreme Court has stated that when determining whether a state law has a "connection with" ERISA plans, a court must avoid an "uncritical literalism" and look instead to "the objectives of the ERISA statute as a guide to the scope of the state law that Congress understood would survive, as well as to the nature of the effect of the state law on ERISA plans." <u>Eqelhoff</u> v. <u>Eqelhoff</u>, 532 U.S. 141, 147 (2001) (citing <u>Travelers</u>, 514 U.S. at 656 and <u>Dillingham</u>, 519 U.S. at 325) (internal quotation marks omitted). According to the Court, "[t]he basic thrust of the preemption clause . . . was to avoid a multiplicity of regulation in order to permit the nationally uniform administration of employee

-12-

benefit plans." <u>Travelers</u>, 514 U.S. at 657. State laws that impede this goal of national uniformity will be preempted. Therefore, we must determine here whether the UPDPA, in placing fiduciary duties and administrative burdens on PBMs operating in Maine, thereby precludes the ability of plan administrators to administer their plans in a uniform fashion.

In several different cases, the Supreme Court has found this goal of "national uniformity" to be compromised (and therefore the state law was preempted). For example, in Alessi v. Raybestos-Manhattan, Inc., 451 U.S. 504, 526 (1981), the Court invalidated a New Jersey law that prohibited offsetting worker compensation payments against pension benefits. "Since such a practice [was] permissible under federal law and the law of other States, the effect of the [state] statute was to force the employer either to structure all its benefit payments in accordance with New Jersey law, or to adopt different payment formulae for employees inside and outside the State." Fort Halifax, 482 U.S. at 10 (discussing the holding in Alessi). Similarly, in Egelhoff, the Supreme Court found that "[u]niformity [was] impossible" with regard to a Washington statute that provided that the designation of a spouse as the beneficiary of a nonprobate asset was revoked automatically upon divorce. Egelhoff, 532 U.S. at 148. The Court held that the statute was preempted by ERISA because "[p]lan administrators [could not] make payments simply by identifying the beneficiary

-13-

specified by the plan documents. Instead, they [had to] familiarize themselves with [specific] state statutes so that they [could] determine whether the named beneficiary's status [had] been 'revoked' by operation of law." Id. at 148-49.⁵

In contrast to the state laws at issue in <u>Alessi</u> and <u>Egelhoff</u>, the goal of national uniformity poses no problems in the instant case. In no way does the UPDPA circumscribe the ability of plan administrators to structure or administer their ERISA plans. As the district court stated, "[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

Alessi and Egelhoff are not the only cases in which the Supreme Court has encountered a state law that "created the prospect that an employer's administrative scheme would be subject to conflicting requirements." Fort Halifax, 482 U.S. at 10. For example, in Shaw, the Court found that two New York laws were preempted by ERISA. One of those laws, New York's Human Rights Law, prohibited "employers from structuring their employee benefit plans in a way that discriminated on the basis of pregnancy." Shaw, 463 U.S. at 97. The second, New York's Disability Benefits Law, required "employers to pay employees specific benefits." Id. The Court held that these laws were preempted by ERISA because they "could have been honored only by varying the subjects of a plan's benefits whenever New York law might have applied, or by requiring every plan to provide all beneficiaries with a benefit demanded by New Travelers, 514 U.S. at 657 (discussing the holding in York law. Shaw). Similarly, in FMC Corp. v. Holliday, 498 U.S. 52 (1990), the Court discussed a Pennsylvania law that prohibited plans from "requiring reimbursement [from the beneficiary] in the event of recovery from a third party." Id. at 60. The law was likewise preempted by ERISA because the law "require[d] plan providers to calculate benefit levels in Pennsylvania based on expected liability conditions that differ from those in States that have not enacted similar antisubrogation legislation, [thereby] frustrat[ing] plan administrators' continuing obligation to calculate uniform benefit levels nationwide." Id.

and labelers does not restrict the freedom of employee benefit plans to administer or structure their plans in Maine precisely as they would elsewhere." <u>Pharm. Care Mqmt. Ass'n</u>, 2005 U.S. Dist. LEXIS 2339, at *23-24. This is simply not a case where "uniformity is impossible . . . [because] plans are subject to different legal obligations in different States." Egelhoff, 532 U.S. at 148.

In attempting to demonstrate that the UPDPA would require employee benefit plans to implement unique measures in Maine, PCMA points to the way in which the UPDPA attempts "to dictate the terms of contracts between ERISA plans and PBMs, including by redefining the duties and liabilities of PBMs to such plans, their sponsors and participants." PCMA also points out how the UPDPA "attempts to regulate plans' relationship[s] with PBMs when PBMs perform administrative functions for such plans." Although the ERISA plans can re-evaluate their working relationships with the PBMs if they wish in light of the UPDPA, nothing in the UPDPA compels them to do This is not an instance, such as that confronted by the so. Supreme Court in Egelhoff, where the plan administrators were bound to a particular choice of rules -- rules mandated by the state for determining beneficiary status. The plan administrators here have a free hand to structure the plans as they wish in Maine. We find, therefore, that UPDPA does not have an impermissible the "connection with" ERISA plans.

-15-

b) The "reference to" prong

A state law is preempted by ERISA by virtue of an impermissible "reference to" an ERISA plan "[w]here a State's law acts immediately and exclusively upon ERISA plans . . . or where the existence of ERISA plans is essential to the law's operation." Dillingham, 519 U.S. at 325.

In Carpenters Local Union No. 26, when explaining the scope of this test in light of the Supreme Court's decisions in Travelers and Dillingham, we discussed two prior precedents of our own: McCoy v. Mass. Inst. of Tech., 950 F.2d 13 (1st Cir. 1991) and Williams v. Ashland Eng'q Co., 45 F.3d 588 (1st Cir. 1995). McCoy dealt with a Massachusetts mechanics' lien statute that, "by its terms, inured to the advantage of 'the trustee or trustees of any fund or funds, established pursuant to section 302 of the Taft Hartley [Act].'" Carpenters Local Union No. 26, 215 F.3d at 142 (noting also that any plan that grants benefits under section 302 is by definition an ERISA plan). Williams, in contrast, dealt with a bond statute covering public works projects. Id. at 143. We noted that this bond statute differed from the mechanics' lien statute in McCoy in that the "bond statute makes no direct reference to section 302" (and hence, no direct reference to ERISA) and in that the language of the bond statute was not at all "ERISAspecific." Id. The relevant language in Williams stood "at the end of a long list of items," most of which had "nothing whatever

-16-

to do with ERISA." <u>Id.</u> In <u>Carpenters Local Union No. 26</u>, we noted that the specific reference to an ERISA plan in <u>McCoy</u> was what gave rise to ERISA preemption. <u>Id.</u> at 142.

We think the UPDPA is similar to the state law at issue in <u>Williams</u>. The existence of ERISA plans is not at all essential to the operation of the UPDPA. The UPDPA applies regardless of whether PBMs are serving ERISA plans. The law applies with respect to a broad spectrum of health care institutions and health benefit providers, including but not limited to ERISA plans. "Covered entities" under the UPDPA includes health plans, labor union plans, association plans, insurance companies, HMOs, medical service organizations, and the state Medicaid program. Me. Rev. Stat. Ann. tit. 22, § 2699(1)(A).

PCMA, in support of its proposition that ERISA plans are essential to the UPDPA's operation, cites to <u>Dist. of Columbia</u> v. <u>Greater Washington Bd. of Trade</u>, 506 U.S. 125 (1992). In that case, the law at issue required an employer who provided health insurance coverage to its employees to provide equivalent coverage to injured employees eligible for workers' compensation benefits. The coverage for injured employees was "measured by reference to 'the existing health insurance coverage' provided by the employer," which the Court found to be a "reference to" an ERISA plan and therefore preempted under ERISA. <u>Id.</u> at 130.

-17-

As we pointed out in Carpenters Local Union No. 26, however, the law at issue in Greater Washington contained a specific reference to an ERISA plan. See Carpenters Local Union No. 26, 215 F.3d at 144 n.7. Such a law would be completely inoperable if the reference to the ERISA plan were omitted. Ιt relied on the reference for its operation. The UPDPA, in contrast, has no such deficiency. Although the UPDPA does operate 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. If the reference to employee health plans was deleted from the text of the UPDPA, the statute would still be operable.⁶ As we have stated previously, "[a] state law that applies to a wide variety of situations, including an appreciable number that have no specific linkage to ERISA plans, constitutes a law of general application for purposes of 29 U.S.C. § 1144." Carpenters Local Union No. 26, 215 F.3d at 144-45 (adding that "state laws of general application are safe from ERISA preemption").

⁶ We also note that in <u>Dillingham</u>, the Supreme Court faced a similar situation with apprenticeship programs. Since the Court found that the "approved apprenticeship programs [in that case] need not necessarily be ERISA plans," it refused to find that the California law at issue there "ma[de] reference to" ERISA plans. <u>Dillingham</u>, 519 U.S. at 325.

c) Alternative enforcement mechanism

PCMA, therefore, is unable to show that the UPDPA "relates to" an employee benefit plan under either the "connection with" or "reference to" prongs of the test prescribed by the Supreme Court. PCMA, however, offers an alternative argument. It states that the UPDPA's remedial scheme (i.e., the UPDPA's enforcement provision in Me. Rev. Stat. Ann. tit. 22, § 2699(4) (2005)) conflicts with the "exclusive" remedial scheme set forth by Congress in ERISA (in 29 U.S.C. § 1132 (2000)) and is therefore preempted.

The civil enforcement provision of ERISA, 29 U.S.C. § 1132 (2000), provides a mechanism by which plan participants, beneficiaries, fiduciaries, and the Secretary of Labor can sue to enforce rights expressly guaranteed by ERISA. 29 U.S.C. § 1132 (2000) (ERISA § 502(a)). Accordingly, "ERISA preemption proscribes the type of alternative enforcement mechanism that purposes to provide a remedy for the violation of a right expressly guaranteed and exclusively enforced by the ERISA statute." <u>Carpenters Local</u> <u>Union No. 26</u>, 215 F.3d at 141. In <u>Ingersoll-Rand Co.</u> v. <u>McClendon</u>, 498 U.S. 133 (1990), the Supreme Court specifically recognized that a state law can be preempted as an alternative enforcement mechanism to ERISA § 502(a).

ERISA, however, does not preempt state laws that "touch upon enforcement but have no real bearing on the intricate web of

-19-

relationships among the principal players in the ERISA scenario (e.g., the plan, the administrators, the fiduciaries, the beneficiaries, and the employer)." <u>Carpenters Union Local No. 26</u>, 215 F.3d at 141. Here, the UPDPA targets the PBMs, which, as stated above, are not ERISA fiduciaries. As such, they are outside of the "intricate web of relationships among the principal players in the ERISA scenario." <u>Id.</u> The district court correctly noted 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." <u>Pharm. Care Mgmt. Ass'n</u>, 2005 U.S. Dist. LEXIS 2339, at *28-29. Therefore, we hold that the UPDPA does not provide an alternative enforcement mechanism to ERISA's civil enforcement scheme and is not preempted.

PCMA, however, points to the Supreme Court's recent decision in <u>Aetna Health, Inc.</u> v. <u>Dávila</u>, 124 S. Ct. 2488 (2004). PCMA argues that in <u>Dávila</u>, the Court held that state causes of action purporting to supplement ERISA §502(a) are preempted "even if the elements of the state cause of action [do] not precisely duplicate the elements of an ERISA claim." <u>Id.</u> at 2499-2500. In that case, however, the plaintiffs were plan participants and beneficiaries who brought suit "only to rectify a wrongful denial of benefits promised under ERISA-regulated plans" and who did not attempt to remedy any violation of a legal duty independent of

-20-

ERISA. <u>Id.</u> at 2492-93, 2498. In other words, all the parties in that case were part of the "intricate web of relationships among the principal players in the ERISA scenario." <u>Carpenters Union</u> <u>Local No. 26</u>, 215 F.3d at 141. That was the reason that the state remedy in that case was preempted. Therefore, PCMA's use of <u>Dávila</u> is misplaced.

C. Takings claim

Under the UPDPA, PBMs are required to disclose to their customers in Maine information concerning the discounts and other contract terms that they are able to negotiate with drug manufacturers and pharmacies. According to the PCMA, this information is confidential and proprietary and is to be considered a "trade secret." Because the UPDPA requires PBMs to disclose these trade secrets as a condition of doing business in Maine, PCMA contends that the UPDPA effects a regulatory taking, and this requires "just compensation" under the Fifth Amendment. "Α regulatory taking transpires when some significant restriction is placed upon an owner's use of his property for which 'justice and fairness' require that compensation be given." <u>Philip Morris Inc.</u> v. Reilly, 312 F.3d 24, 33 (1st Cir. 2002) (quoting Goldblatt v. Hempstead, 369 U.S. 590, 594 (1962)).

1.

Before we reach the merits of such a claim, however, we first must assess whether PCMA has standing to bring a takings

-21-

claim here. The district court held that PCMA did not have standing. Standing decisions are reviewed by this court <u>de novo</u>. <u>Donahue</u> v. <u>City of Boston</u>, 304 F.3d 110, 116 (1st Cir. 2002); <u>Nyer</u> v. Winterthur Int'1, 290 F.3d 456, 459 (1st Cir. 2002).

"[A]n association has standing to bring suit on behalf of its members when: (a) its members would otherwise have standing to sue in their own right; (b) the interests it seeks to protect are germane to the organization's purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." <u>Hunt</u> v. <u>Washington State Apple</u> <u>Adver. Comm'n</u>, 432 U.S. 333, 343 (1977). The third factor of this test is prudential. <u>United Food and Commercial Workers Union Local</u> <u>751</u> v. <u>Brown Group, Inc.</u>, 517 U.S. 544, 557 (1996). PCMA here has the burden to prove it has standing. <u>Harvey</u> v. <u>Veneman</u>, 396 F.3d 28, 34 (1st Cir. 2005); <u>Donahue</u>, 304 F.3d at 116.

The main point of conflict in this case regards the third, prudential, prong of the <u>Hunt</u> test: "Neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." The district court concluded that the third factor for associational standing had not been met because at least one PBM would have to participate in the suit to prove that property was being taken. Also, the court noted that because some PBMs might not be affected if they did not possess trade secrets (because they had already contracted away access to

-22-

this information), the claim would require member-by-member scrutiny. We disagree.

PCMA is indeed required to introduce evidence "pertaining to how, inter alia, one or more of its members develops, and maintains the secrecy of, its information and how one or more of its members would be injured by disclosure." <u>Pharm. Care Mgmt.</u> <u>Ass'n</u>, 2005 U.S. Dist. LEXIS 2339, at *39. However, in <u>Playboy</u> <u>Enters., Inc.</u> v. <u>Pub. Serv. Comm'n of Puerto Rico</u>, 906 F.2d 25 (1st Cir. 1990), we noted that "just because a claim may require proof specific to individual members of an association does not mean the members are required to participate <u>as parties</u> in the lawsuit." <u>Playboy Enters.</u>, 906 F.2d at 35. (emphasis in original). We think that to be true here. Even though a takings inquiry is intensely fact specific and PCMA will be required to introduce proof of specific PBM practices and effects of the UPDPA on specific PBMs, we see no reason that PCMA's member PBMs would be required to participate as parties in this litigation.

In <u>Playboy Enters.</u>, we discussed the Supreme Court's holding in <u>Warth</u> v. <u>Seldin</u>, 422 U.S. 490 (1975). <u>Playboy Enters.</u>, 906 F.2d at 35. In <u>Warth</u>, the Court held that an association had no standing to sue on behalf of its members when seeking monetary relief to compensate for its members' injuries. <u>Warth</u>, 422 U.S. at 515-16. In <u>Playboy Enters.</u>, we noted that "the crucial reason [in <u>Warth</u>] for <u>requiring the members' participation as parties must</u>

-23-

have been so that the members [rather than the association] could recover their own damages, should they prevail." <u>Playboy Enters.</u>, 906 F.2d at 35 (emphasis in original). The association in that case was not entitled to be compensated for the various injuries suffered by its members. "The members' participation <u>as parties</u> was necessary so that judgment could be entered in their favor." <u>Id.</u> at 35-36 (emphasis in original). In the instant case, however, there is no similar claim for monetary damages. PCMA requests only equitable relief. Such a remedy would, if granted, "inure to the benefit of those members of the association actually injured." <u>Warth</u>, 422 U.S. at 515. There is, in other words, no need here for the member PBMs to participate as parties. As such, PCMA does have associational standing to assert its claim.

2.

With the disposal of that threshold jurisdictional issue, we can now address the merits of PCMA's takings claim. Here, PCMA brings a facial challenge to the UPDPA, asserting that the UPDPA violates the Takings Clause of the Fifth Amendment because it conditions doing business in Maine upon the forced disclosure or taking of proprietary information.

In the takings context, a facial challenge is usually ripe "the moment the challenged regulation or ordinance is passed." <u>Suitum</u> v. <u>Tahoe Reg'l Planning Agency</u>, 520 U.S. 725, 736 n.10 (1997). To succeed on a facial challenge to a statute, however, is

-24-

very difficult. As we have noted before, a plaintiff wishing to bring a facial challenge "face[s] an uphill battle." <u>Reilly</u>, 312 F.3d at 52 (Lipez, J., dissenting) (quoting <u>Keystone Bituminous</u> <u>Coal Assn.</u> v. <u>DeBenedictis</u>, 480 U.S. 470, 495 (1987)). "A facial challenge to a legislative Act is . . . the most difficult challenge to mount successfully, since the challenger must establish that no set of circumstances exists under which the Act would be valid." <u>Pharm. Research & Mfrs. of Am.</u> v. <u>Concannon</u>, 249 F.3d 66, 77 (1st Cir. 2001) (internal quotation marks omitted). Here, this would mean that PCMA has the burden to prove that <u>every</u> disclosure under the UPDPA, if uncompensated, would result in an unconstitutional taking.

PCMA, however, has not met this burden. This is a result of the differing circumstances of PCMA's member PBMs. There are certain PBMs that have already disclosed extensive information to their clients, pursuant to contract or in the context of annual audits. The state writes, for example, about how

> . . . Medco [a PBM] allows United Healthcare [a client] virtually unfettered access to Medco's contracts, contract terms, rebates, records and information; virtually complete audit rights; and even the ability to participate in negotiations with the drug manufacturers. Appellee Br. 31-32.

All of this information is now also required to be disclosed under the UPDPA. <u>See</u>, <u>e.g.</u>, Me. Rev. Stat. Ann. tit. 22, § 2699(2)(D) (2005) (requiring disclosure of all financial and utilization

-25-

information requested by a covered entity relating to the provision of services to that covered entity).

None of this information, however, can in any way be considered a trade secret. Under Maine law, a trade secret is "information . . . that . . . [d]erives independent economic value . . . from not being generally known to and not being readily ascertainable by proper means by other persons who can obtain economic value from its disclosure or use and . . . is the subject of efforts that are reasonable under the circumstances to maintain its secrecy." Me. Rev. Stat. Ann. tit. 10, § 1542(4) (2005). <u>See also Ruckelshaus</u> v. <u>Monsanto Co.</u>, 467 U.S. 986, 1002 (1984) ("Because of the intangible nature of a trade secret, the extent of the property right therein is defined by the extent to which the owner of the secret protects his interest from disclosure to others.").

The information disclosed as a result of these client contracts, however, is readily available. The record is replete with evidence demonstrating that the PBMs that made these contracts have taken no special steps to protect their information. For example, Timothy Wentworth, the group President of National Accounts for Medco, stated that he was not aware of any written security policy prohibiting the removal of client contracts at Medco. Other PBMs keep these client contracts in unlocked cabinets

-26-

"in public areas such as hallways." Therefore, such information -at least under Maine law -- cannot be considered a "trade secret."

Given that there are no trade secrets involved with these client contracts, there is no "property" subject to the Takings See Monsanto, 467 U.S. at 1002 ("If an individual Clause. discloses his trade secret to others who are under no obligation to protect the confidentiality of the information, or otherwise publicly discloses the secret, his property right is extinguished."). Hence, many disclosures required from the PBMs under the UPDPA would not be considered unconstitutional takings. Therefore, PCMA cannot show that every disclosure under the UPDPA will result in an unconstitutional taking, for there are clear and obvious circumstances when disclosures under the UPDPA are not unconstitutional takings. We therefore hold that PCMA's facial takings claim fails on the merits.

D. Due Process claim

As the district court recognized, this claim "tags along" with PCMA's takings claim. In <u>Zinermon</u> v. <u>Burch</u>, 494 U.S. 113, 132 (1990), the Supreme Court held that due process requires that "[i]n situations where the State feasibly can provide a predeprivation hearing before taking property, it generally must do so regardless of the adequacy of a postdeprivation tort remedy to compensate for the taking." As we have already discussed, however, PCMA has not been able to show that the UPDPA effects a taking. Since there is

-27-

no taking and no deprivation, it follows that no predeprivation hearing is required. The district court was therefore correct to grant summary judgment in favor of the state on this claim.

E. First Amendment claim

The district court also found that the provisions of the UPDPA do not violate the First Amendment. PCMA claims that the UPDPA violates the First Amendment because it compels PBMs to engage in speech -- in the form of mandated disclosures -- as a condition of doing business in Maine. In a number of different cases, the Supreme Court has recognized that compulsion to speak may be as violative of the First Amendment as prohibitions on speech. <u>See, e.g., Zauderer</u> v. <u>Office of Disciplinary Counsel of the Supreme Court of Ohio</u>, 471 U.S. 626 (1985); <u>Wooley v. Maynard</u>, 430 U.S. 705 (1977); <u>Miami Herald Publ'g Co.</u> v. <u>Tornillo</u>, 418 U.S. 241 (1974). We agree with PCMA that a compelled disclosure, such as the one here, does indeed implicate the First Amendment.

In assessing whether the disclosures mandated by the UPDPA are violative of the provisions of the First Amendment, the initial question we must confront is the nature of the speech. The degree of protection afforded by the First Amendment depends on whether the speech here is commercial speech or noncommercial speech.⁷ "'[C]ommercial speech' is entitled to the protection of

⁷ The district court simply assumed that the speech at issue here is "commercial speech." We, however, think that the classification of speech in this case is not at all clear and deserves a full

the First Amendment, albeit to protection somewhat less extensive than that afforded 'noncommercial speech.'" Zauderer, 471 U.S. at 637; <u>see also Ohralik</u> v. <u>Ohio State Bar Ass'n.</u>, 436 U.S. 447, 456 (1978) ("[W]e . . . have afforded commercial speech a limited measure of protection, commensurate with its subordinate position in the scale of First Amendment values, while allowing modes of regulation that might be impermissible in the realm of noncommercial expression."); <u>Bolger</u> v. <u>Youngs Drug Prods. Corp.</u>, 463 U.S. 60, 64-65 (1983) ("[t]he Constitution accords less protection to commercial speech than to other constitutionally safeguarded forms of expression.").

If the speech here is of a commercial nature, there is a reduced burden on the state to justify the UPDPA. <u>See Zauderer</u>, 471 U.S. at 650-651; <u>Riley</u> v. <u>Nat'l Fed'n of the Blind of North Carolina, Inc.</u>, 487 U.S. 781, 796 n.9 (1988) ("Purely commercial speech is more susceptible to compelled disclosure requirements."). If, however, the speech is of a noncommercial nature, the compelled disclosure will be subject to "exacting First Amendment scrutiny." <u>Riley</u>, 487 U.S. at 798. In such a case, the state, to justify its law, would have to advance a compelling state interest and also show that the means chosen to accomplish that interest are narrowly tailored. <u>See id.</u> at 795 (noting that a statute that mandates speech "that a speaker would not otherwise make necessarily alters

analysis.

the content of the speech" and that such a statute is therefore considered a content-based regulation of speech); <u>Madsen</u> v. <u>Women's</u> <u>Health Ctr.</u>, 512 U.S. 753, 790-91 (1994) (noting that content-based regulations receive strict scrutiny).

We have stated that commercial speech is defined as "expression related solely to the economic interests of the speaker and its audience." El Día, Inc. v. Puerto Rico Dept. of Consumer Affairs, 413 F.3d 110, 115 (1st Cir. 2005) (citing Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of New York, 447 U.S. 557, 561 (1980)). Although it is a close question, we think that the speech mandated by the UPDPA meets this definition. Many of the UPDPA's provisions are overtly geared at the economic interests of the PBMs and the covered entities. See, e.g., Me. Rev. Stat. Ann. tit. 22, § 2699(2)(F) (requiring PBMs to disclose and disgorge any payment or benefit based on volume of sales or classes or brands of prescription drugs). Even those provisions of the UPDPA that are on their face less related to "economic interests" -- e.g., id. § 2699(2)(C) (requiring PBMs to disclose conflicts of interest) -are aimed at eliminating certain PBM practices that unnecessarily increase the cost of prescription medications.

We discuss this case, therefore, on the basis that commercial speech is at issue. In <u>Zauderer</u>, the Supreme Court held that "[b]ecause the extension of First Amendment protection to commercial speech is justified principally by the value to

-30-

consumers of the information such speech provides," a party who was faced with a disclosure requirement had only a minimal interest in withholding the information requested of him by law. <u>Zauderer</u>, 471 U.S. at 651. The Court also held that the party's rights are adequately protected "as long as disclosure requirements are reasonably related to the State's interest in preventing deception of consumers." <u>Id.⁸</u>

Applying these principles here, we find that the UPDPA disclosure provisions do not run afoul of the First Amendment. PCMA's member PBMs only have a minimal interest in withholding the information the UPDPA requires from them, especially given Maine's interest in ensuring that its citizens receive the best and most cost-effective health care possible. The information disclosed under the UPDPA will help the "covered entities" that are responsible for paying for medications in Maine ensure that they and their customers are not adversely affected by the abuses and self-dealing of certain PBMs. Furthermore, we think it obvious that the UPDPA's disclosure requirements are "reasonably related" to Maine's interest in preventing deception of consumers and increasing public access to prescription drugs. Id. As the district court noted, these disclosure requirements are

⁸ In its reply brief, PCMA states that the holding in <u>Zauderer</u> is "limited to potentially deceptive advertising directed at consumers." Appellant Reply Br. 28. None of the cases it cites, however, support this proposition, and we have found no cases limiting <u>Zauderer</u> in such a way.

designed to create incentives within the market for the abandonment of certain practices that are likely to unnecessarily increase cost without providing any corresponding benefit to the individual whose prescription is being filled and that appear to be designed merely to improve a drug manufacturer's market share.

Pharm. Care Mgmt. Ass'n, 2005 U.S. Dist. LEXIS 2339, at *82-83.

PCMA argues that the PBMs' interest in not disclosing, rather than being minimal, is acute. This is because "the compelled speech takes their valuable property." Appellant Reply Br. 28. Aside from the fact that PCMA offers no proof supporting this contention, we have already held that PCMA failed to show that the UPDPA effects a taking of the PBMs' property. We do not see how the situation is any different in the First Amendment context. We think, therefore, that the district court was correct in holding that UPDPA's provisions do not contravene the First Amendment.

F. Commerce Clause claim

The district court held that the UPDPA was not in violation of the Commerce Clause. The Commerce Clause provides that Congress shall have the power "to regulate Commerce . . . among the several States." U.S. Const. art. I, § 8, cl. 3. It has long been understood, however, that this affirmative grant of authority to Congress necessarily encompasses a limitation on the power of states to enact legislation that burdens the flow of interstate commerce. This restriction on the states, known as the dormant Commerce Clause, is not absolute and in the absence of

-32-

conflicting legislation by Congress, "the States retain authority under their general police powers to regulate matters of legitimate local concern, even though interstate commerce may be affected." <u>Maine</u> v. <u>Taylor</u>, 477 U.S. 131, 138 (1986) (internal quotation marks omitted).

PCMA argues that the UPDPA violates the dormant Commerce Clause on two grounds. First, it claims that the UPDPA has "extraterritorial reach." A state statute is per se invalid under the dormant Commerce Clause when it "regulates commerce wholly outside the state's borders or when the statute has a practical effect of controlling conduct outside of the state." <u>Pharm.</u> <u>Research & Mfrs. of Am.</u>, 249 F.3d at 79. A statute has this impermissible extraterritorial reach if it "necessarily requires out-of-state commerce to be conducted according to in-state terms." <u>Id.</u> (quoting <u>Cotto Waxo Co.</u> v. <u>Williams</u>, 46 F.3d 790, 794 (8th Cir. 1995)).

The Supreme Court has discussed "extraterritorial reach" in a number of cases. PCMA, for example, invokes <u>Edgar</u> v. <u>MITE</u> <u>Corp.</u>, 457 U.S. 624, 640-43 (1982), a case involving an Illinois law that sought to regulate tender offers for the stock of Illinois corporations. The law required that all such offers be registered in advance with the Illinois Secretary of State. Under the terms of the statute, a Delaware corporation soliciting the shares of an Illinois corporation from a resident of Arkansas would be required

-33-

to register with the state of Illinois. The Supreme Court, however, struck down the statute under the dormant Commerce Clause, noting that the law "directly regulates transactions which take place across state lines, even if wholly outside the State of Illinois." Edgar, 457 U.S. at 641.

The district court, similarly, discussed Brown-Forman Distillers Corp. v. New York State Liquor Auth., 476 U.S. 573 (1986). In that case, the Supreme Court invalidated a provision of the New York Alcoholic Beverage Control Law that required liquor distillers and producers doing business in New York to affirm that their prices were no higher than the lowest price at which the same product would be sold in any other state during the month. The Court determined that this was extraterritorial reach violative of the Commerce Clause because during the period that the affirmation was in effect, New York made it illegal, without prior permission from state authorities, for a distiller or producer to reduce its price in other states. Thus, the New York law effectively regulated the price at which liquor was sold in other states. As the Court stated, "[f]orcing a merchant to seek regulatory approval in one State before undertaking a transaction in another directly regulates interstate commerce." Brown-Forman, 476 U.S. at 582.

PCMA draws here on this idea of "extraterritorial reach" and attempts to apply it to the UPDPA. It argues that if a PBM operating outside of Maine enters into a contract outside of Maine

-34-

with a national insurer similarly operating beyond the state's borders but licensed in the state, the PBM would have to comply with the UPDPA's disclosure requirements. "This is exactly the sort of extraterritorial reach condemned in <u>Edgar</u> v. <u>MITE Corp.</u>," says PCMA.

We beg to differ. There is a key difference between the UPDPA and the laws in <u>Edgar</u> and <u>Brown-Forman</u>. In <u>Edgar</u> and <u>Brown-Forman</u>, the state laws at issue gave the state power to determine whether a transaction in another state could occur at all. For example, the law in <u>Edgar</u> gave the Illinois Secretary of State power to determine whether to allow a tender offer by a Delaware corporation for stock held by an Arkansas resident. Similarly, the New York law in <u>Brown-Forman</u> gave the New York State Liquor Authority power to determine whether a liquor distiller or producer would be permitted to reduce its price in other states. It was this sort of "extraterritorial reach" that led the Court to invalidate the statutes at issue in those cases.

The UPDPA, however, does not give Maine any such authority. Under the UPDPA, a transaction outside of Maine between two parties -- for example, between PCMA's hypothetical out-ofstate PBM and insurance company -- can take place regardless of whether Maine consents or not. Maine law does not "regulate . . . [the] out-of-state transaction, either by its express terms or by its inevitable effect." <u>Pharm. Research & Mfrs. of Am.</u>, 249 F.3d

-35-

at 81. Maine does not dictate the terms of such a transaction. Nor is Maine in any way "project[ing] its legislation" into those other states. <u>Baldwin</u> v. <u>G.A.F. Seelig, Inc.</u>, 294 U.S. 511, 521 (1935). It simply requires that PBMs, should they choose to do business <u>within</u> Maine, provide "covered entities" with certain information about their business relationships. In other words, the UPDPA does not require out-of-state commerce to be conducted according to in-state terms. It requires only that in-state commerce be conducted according to in-state terms. <u>See</u> Me. Rev. Stat. Ann. tit. 22, § 2699(1)(B), (3) & (5) (2005) (showing that the UPDPA covers only contracts entered in Maine with respect to covered entities in Maine). In light of this distinction, we think that the UPDPA cannot properly be said to have an extraterritorial reach violating the Commerce Clause.

Alternatively, PCMA argues that the UPDPA violates the Commerce Clause under the more lenient test set out by the Supreme Court in <u>Pike</u> v. <u>Bruce Church, Inc.</u>, 397 U.S. 137 (1970). Under that test -- to be used when the state statute at issue regulates evenhandedly and has only incidental effects on interstate commerce -- courts employ a balancing approach whereby they examine whether the state's interest is legitimate and whether the burden on interstate commerce clearly exceeds the local benefits. <u>Pike</u>, 397 U.S. at 142. Since we have held that the UPDPA is not per se invalid because it does not effect any "extraterritorial reach,"

-36-

and because the Maine statute does regulate evenhandedly and has only incidental effects on interstate commerce, we employ here the <u>Pike</u> balancing test to assess the constitutionality of the UPDPA.

In <u>Pharm. Research & Mfrs. of Am.</u>, we noted that the <u>Pike</u> test involves three separate steps. First, we are to evaluate the nature of the putative local benefits advanced by the statute. Second, we must examine the burden the statute places on interstate commerce. Finally, we are to consider whether the burden is "clearly excessive" as compared to the putative local benefits. Pharm. Research & Mfrs. of Am., 249 F.3d at 83-84.

The putative local benefits of the UPDPA are clear. The aim of the UPDPA is to reduce the costs of, and increase the public's access to, prescription drugs. The law was designed to deal with "one of the serious problems of our time." <u>Id.</u> at 80. PCMA, for its part, thinks these benefits are not likely to materialize as a result of the UPDPA. It is not the place of this court, however, to pass judgment on the wisdom of the policies adopted by the Maine legislature. <u>See Kassel</u> v. <u>Consol.</u> <u>Freightways Corp.</u>, 450 U.S. 662, 679 (1981) (Brennan, J., concurring) (stating that courts should refrain from attempting to "second-guess the empirical judgments of lawmakers concerning the utility of legislation"). Furthermore, as the district court points out, under <u>Pike</u>, it is the <u>putative</u> local benefits that

-37-

matter. It matters not whether these benefits actually come into being at the end of the day.

On the "burden" side of the Pike balancing equation, PCMA only asserts that as a result of the UPDPA, certain PBMs will no longer do business in Maine. PCMA states that "the extraordinary restrictions imposed [by the UPDPA] on the business operations of pharmacy benefit managers (PBMs) will make it virtually impossible to establish or maintain a prescription drug program that relies on a for-profit PBM for administrative services." In Pharm. Research & Mfrs. of Am., we said that "[a]rquably, the only burden imposed on interstate commerce by the . . . Act [in that case] is its possible effects on the profits of the individual manufacturers." Pharm. Research & Mfrs. of Am., 249 F.3d at 84. We think the same to be true here. However, as we noted in Pharm. Research & Mfrs. of Am., such a burden is not violative of the Commerce Clause because the Clause "protects the interstate market, not particular interstate firms, from prohibitive or burdensome regulations." Id. (quoting Exxon Corp. v. Governor of Md., 437 U.S. 117, 127-28 (1978)).

Even if such a burden was cognizable under the Commerce Clause, at the very least the burden on interstate commerce in this instance would not be "clearly excessive" as compared to the local

-38-

benefits provided by the UPDPA.⁹ <u>Pharm. Research & Mfrs. of Am.</u>, 249 F.3d at 84; <u>see Edgar</u>, 457 U.S. at 643 ("[F]or even when a state statute regulates interstate commerce indirectly, the burden imposed on that commerce must not be excessive in relation to the local interests served by the statute."). "[T]he burden of proving 'excessiveness' falls upon the [plaintiff], not the state," <u>N.H.</u> <u>Motor Transp. Ass'n</u> v. <u>Flynn</u>, 751 F.2d 43, 48 (1st Cir. 1984), and PCMA here has clearly failed to carry that burden.

Given the set of competing concerns we are presented with here, we think the district court was correct in asserting that PCMA "failed to provide the court with any great weight to place on the excessive burden side of the scale." <u>Pharm. Care Mqmt. Ass'n</u>, 2005 U.S. Dist. LEXIS 2339, at *73-74. When measuring PCMA's concern about its members' profits against the increased access to prescription drugs for Maine citizens, the local benefits clearly outweigh any incidental burden on interstate commerce. Accordingly, PCMA's Commerce Clause claim fails under the balancing test set forth in <u>Pike</u>.

III. <u>Conclusion</u>

For the reasons set forth above, we \underline{affirm} the decision of the district court.

"Concurrence follows."

⁹ It is not the case, as the appellants claim, that "the UPDPA must fall if <u>any</u> burden is imposed on interstate commerce."

BOUDIN, <u>Chief Judge</u>, and DYK, <u>Circuit Judge</u>, Concurring. The association standing question in this case is difficult. There is no well developed test in this circuit as to how the third prong of the <u>Hunt</u> test--whether "the claim asserted [or] the relief requested requires the participation of individual members in the lawsuit," <u>Hunt</u> v. <u>Wash. State Apple Adver. Comm'n</u>, 432 U.S. 333, 343 (1977)--applies in cases where injunctive relief is sought. This prong of the test is prudential rather than constitutional in nature, <u>United Food & Commercial Workers Union Local 751</u> v. <u>Brown</u> <u>Group, Inc.</u>, 517 U.S. 544, 555 (1996), and there exists some latitude in case-by-case judgments.

That only injunctive relief is sought here distinguishes this case from damages cases; in those, association standing is precluded where the damages turn upon the varying circumstances of the individual plaintiffs. <u>See Warth v. Seldin</u>, 422 U.S. 490, 515-16 (1975). Where only injunctive relief is sought, an association may sometimes be allowed to sue even if some proof from individual non-party members is required; on the other hand, plenty of injunction cases have been dismissed because of the need for individualized proof.¹⁰

¹⁰ <u>E.g., Ga. Cemetery Ass'n.</u> v. <u>Cox</u>, 353 F.3d 1319, 1322 (11th Cir. 2003); <u>Rent Stabilization Ass'n.</u> v. <u>Dinkins</u>, 5 F.3d 591, 596-97 (2d Cir. 1993); <u>Kan. Health Care Ass'n.</u> v. <u>Kan. Dept. of Soc. & Rehab.</u> <u>Svcs.</u>, 958 F.2d 1018, 1022-23 (10th Cir. 1992).

There is one decision in this circuit upholding association standing in a case dealing with injunctive relief. <u>Playboy Enters.</u> v. <u>Pub. Svc. Comm'n of P.R.</u>, 906 F.2d 25 (1st Cir. 1990), <u>cert. denied</u>, 498 U.S. 959 (1990). In that case, however, the impact on individual members necessary for injunctive relief was readily established as to at least one member. Furthermore, the challenged law in <u>Playboy</u> was a state statute regulating expression; in such cases, courts are generally more inclined to permit <u>jus tertii</u> claims. <u>See Osediacz</u> v. <u>City of Cranston</u>, 414 F.3d 136, 140 (1st Cir. 2005). <u>Playboy</u> is not an open door for association standing in all injunction cases where member circumstances differ and proof of them is important.

Sensibly, the Third Circuit in <u>Pennsylvania Psychiatric</u> <u>Society</u> v. <u>Green Spring Health Services, Inc.</u>, 280 F.3d 278 (3d Cir. 2002), <u>cert. denied</u>, 537 U.S. 881 (2002), did not adopt an all-or-nothing test. The court there stated that it would allow for association standing if proof as to member circumstances were "limited," but it noted that "conferring associational standing would be improper for claims requiring a fact-intensive-individual inquiry." <u>Id.</u> at 286-87. This is not a complete compendium of relevant considerations, but it is a useful start.

In this case, putting to one side their generic weakness, individual takings claims could in principle be significantly strengthened or weakened by the particularized circumstances of

-41-

each individual member. Furthermore, there appears to be considerable variation in each member company's particular circumstances--for example, whether a member already discloses the information in question to its customers, the methods by which it stores copies of its contracts, and so on. The district court acted reasonably in concluding that in this case the association should not be allowed to sue as to the takings claim and that individual members should bring their own cases.

However, as we are dealing with a matter of prudential standing, the limitation has no Article III implications. Because at least some members could doubtless show that their materials were not disclosed and were well protected, the district court sensibly went on to forestall individual actions that would inevitably follow a dismissal of the association's takings claim on standing grounds. It correctly held that even if association standing were assumed to be adequate, such takings claims fail on the merits.

Putting aside a separate threshold concern,¹¹ the Supreme Court in <u>Ruckelshaus</u> v. <u>Monsanto</u>, 467 U.S. 986 (1984), made clear that trade secrets--as defined by state law--can constitute

¹¹ Typically, no injunctive relief claim based on taking would be ripe until state compensation remedies were exhausted, <u>Williamson</u> <u>County Reg'l Planning Comm'n</u> v. <u>Hamilton Bank of Johnson City</u>, 473 U.S. 172, 195 (1985), but because there may be some circumstances that avoid this bar, <u>see Philip Morris, Inc.</u> v. <u>Reilly</u>, 312 F.3d 24 (1st Cir. 2002) (en banc), we do not address this issue.

property interests for Takings Clause purposes. <u>Id.</u> at 1003-04. It is far from clear that the Maine courts would find the information required to be disclosed here to represent a trade secret under Maine law. However, as there is no definitive state court judgment on this issue, it is possible that the information sought to be disclosed could potentially represent a valid property interest for Takings Clause purposes.

Nevertheless, even assuming a property interest, the Maine statute does not work a full taking. It does not confiscate the supposed trade secret in the conventional sense; at most, it requires limited disclosure to customers of transactions possibly adverse to the customers' interests, which may reduce the value of the trade secret to the PBM. PBMs may still negotiate rebate contracts with drug companies, but their plan customers may--as a result of PBMs' disclosures--look elsewhere for benefits management.

In this context, a takings claim is far from straightforward. In <u>Penn Central Transportation Co.</u> v. <u>City of New</u> <u>York</u>, 438 U.S. 104 (1978), the Supreme Court--while noting that such analyses are "essentially ad hoc, factual inquiries"--outlined three relevant factors in determining whether a regulation effects a taking: (1) "the extent to which the regulation [would] interfere[] with distinct investment-backed expectations"; (2) "[t]he economic impact of the regulation on the claimant"; and (3)

-43-

"the character of the governmental action." <u>Id.</u> at 124. Given the absence of a full-scale taking and the presence of a traditional regulatory interest, it is enough to defeat the takings claim that no reasonable investment-backed expectation is present at all. <u>See Good v. United States</u>, 189 F.3d 1355, 1363 (Fed. Cir. 1999), <u>cert.</u> denied, 529 U.S. 1053 (2000).

Under the terms of the statute, the PBMs' disclosure requirements run only to their "covered entity" customers and apply only to contracts entered into or renewed after the statute's effective date, namely, September 13, 2003 (three months after the statute was enacted). As the district court noted, PBMs and drug manufacturers typically negotiate their rebate terms on an annual basis. More than two years have elapsed since the statute gave warning of the new regime (in June 2003), so one-year rebate contracts negotiated before that date have expired or have been renewed in the teeth of the statute, and any rebate contracts first entered into after June 2003 would have been made with knowledge of the statute's requirements. There is no basis for forward-looking injunctive relief with respect to rebate contracts entered into after the statute's effective date.

Even as applied to trade secrets arising before the statute's effective date, the statute would not constitute a taking. "A manufacturer or vendor has no constitutional right to sell goods without giving to the purchaser fair information of what

-44-

it is that is being sold." <u>Corn Prods. Ref. Co.</u> v. <u>Eddy</u>, 249 U.S. 427, 431 (1919). PBMs should therefore have expected the possibility that they would have to disclose to their covered entity customers information needed to forestall what could reasonably be deemed abusive control. PBMs are undoubtedly aware of the heavily regulated nature of the healthcare industry; in fact, as the district court noted, they are already subject to extensive regulation under federal and state law.

If PBMs truly assumed that they would be free from disclosure requirements of the sort set forth in the Maine law here, this would be more wishful thinking than reasonable expectation. Whether or not the law strikes the right economic balance between competing producer and consumer interests, it is no more a taking than the requirement that public corporations disclose private corporate information about financial prospects to the public through regular SEC filings.

Lastly, PCMA's First Amendment claim is completely without merit. So-called "compelled speech" may under modern Supreme Court jurisprudence raise a serious First Amendment concern where it effects a forced association between the speaker and a particular viewpoint. <u>See</u>, <u>e.g.</u>, <u>Wooley</u> v. <u>Maynard</u>, 430 U.S. 705 (1977) (requiring all New Hampshire drivers to display "Live Free or Die" on their license plates); <u>Miami Herald Publ'g Co.</u> v.

-45-

<u>Tornillo</u>, 418 U.S. 241 (1974) (requiring newspapers to afford political candidates a right to reply to editorial critiques).

What is at stake here, by contrast, is simply routine disclosure of economically significant information designed to forward ordinary regulatory purposes--in this case, protecting covered entities from questionable PBM business practices. There are literally thousands of similar regulations on the books--such as product labeling laws, environmental spill reporting, accident reports by common carriers, SEC reporting as to corporate losses and (most obviously) the requirement to file tax returns to government units who use the information to the obvious disadvantage of the taxpayer.

The idea that these thousands of routine regulations require an extensive First Amendment analysis is mistaken. Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626 (1985), makes clear "that an advertiser's rights are adequately protected as long as disclosure requirements are reasonably related to the State's interest in preventing deception of consumers." <u>Id.</u> at 651. This is a test akin to the general rational basis test governing all government regulations under the Due Process Clause. The test is so obviously met in this case as to make elaboration pointless.

-46-