

UNITED STATES DISTRICT COURT
DISTRICT OF MAINE

PHARMACEUTICAL CARE)
MANAGEMENT ASSOCIATION,)
)
Plaintiff,)
)
v.)
)
G. STEVEN ROWE, IN HIS OFFICIAL)
CAPACITY AS ATTORNEY GENERAL)
OF THE STATE OF MAINE,)
)
Defendant.)

Civil No. 03-153-B-H

RECOMMENDED DECISION ON CROSS-MOTIONS FOR SUMMARY JUDGMENT

The plaintiff, Pharmaceutical Care Management Association (PCMA), is a national trade association representing pharmaceutical benefits management companies (PBMs).¹ PCMA brings this action on behalf of its members to obtain an order enjoining enforcement of Maine's Unfair Prescription Drug Practices Act (UPDPA), as amended, 22 M.R.S.A. § 2699. According to PCMA's complaint, the UPDPA may not be enforced because it, by count:

- (1) is preempted by the Employee Retirement Income Security Act;
- (2) is preempted by the Federal Employee Health Benefits Act;
- (3) would effect a regulatory taking of industry trade secrets;
- (4) would effect a regulatory taking of revenues and other contractual rights and violates Due Process;
- (5) violates the Contracts Clause;
- (6) violates the Commerce Clause;

¹ (Docket No. 94, ¶ 1.)

(7) violates free speech rights; and

(8) subjects PCMA's members to the deprivation of "rights, privileges and immunities secured by the Constitution," in violation of 42 U.S.C. § 1983.

Now before the court are cross-motions for summary judgment. In its motion, PCMA moves the court to enter summary judgment against the Maine Attorney General with respect only to its ERISA preemption claim and takings claim. (Docket No. 85.) In his motion, the Attorney General moves the court to enter summary judgment against all of PCMA's claims, with the exception of the claims related to takings of revenues and other contractual rights and alleged violation of the Contracts Clause (counts 4 and 5), both of which have been waived by PCMA. (Docket No. 88.) I recommend that the court enter summary judgment in favor of the Attorney General on all claims.

FACTS²

PCMA is a national trade association representing PBMs. (Docket No. 104, ¶ 1.) The parties are in agreement that it is the business of PBMs to act as transactional intermediaries or "middlemen" in the multi-billion dollar trade in prescription drugs. Among their customers are insurance companies, health maintenance organizations and private and public health plans and programs (collectively, what I will call "benefits providers"), including employee benefit plans subject to the Employee Retirement Income Security Act (ERISA), 29 U.S.C. §§ 1001-1461. Generally speaking, the services that PBMs extend to these benefits providers are designed to facilitate the provision of prescription drug benefits to the benefits providers' insureds, participants or subscribers. For example, a PBM might provide its benefits provider customers with access to an established network of pharmacies, including mail order pharmacies, or with

² The facts set forth herein are drawn from the parties' Local Rule 56 statements of material facts in accordance with the local rule.

certain formulary services, all of which permit the benefits provider customers to obtain drugs at established prices.³ (Docket No. 94, ¶ 4; Docket No. 89, ¶ 164.) Conceptually, by pooling the prescription drug purchasing power of a number of benefits providers, a PBM can negotiate substantial volume discounts and rebates from drug manufacturers and pharmacies, and thereby not only provide its customers with savings on prescription drugs and other pharmaceutical products, but also ensure a profit for itself and its shareholders or stakeholders. (Docket No. 89, ¶ 165; Docket No. 94, ¶ 4; Docket No. 101, ¶ 4.) Additional services that a PBM might extend to a benefits provider include "drug utilization review services" and "therapeutic interchange programs." (Docket No. 94, ¶ 4.)

As intermediaries, PBMs provide services to pharmacies and drug manufacturers (the supply-side of the trade) as well as to benefits providers (the demand side of the trade). (Docket No. 89, ¶¶ 8-20.) In particular, when it comes to drug utilization services and therapeutic interchange programs, PBMs are as apt to be serving pharmacies and manufacturers as health benefits providers. For example, "therapeutic interchange" refers to the practice of substituting a drug for the one actually prescribed by a doctor. This may involve substituting an equally efficacious and cheaper generic drug for a brand name drug, which might benefit a provider. On the other hand, the practice may involve substituting a more expensive brand name drug for the benefit of the manufacturer, a pharmacy and/or the PBM. Thus, for instance, a brand name drug might be substituted so that a pharmacy or PBM can obtain a "reward" or "incentive" from the manufacturer for helping increase the manufacturer's market share within a certain drug category. (Docket No. 89, ¶¶ 37-38, 42-44, 83.) Similarly, a PBM might be paid a rebate or fee by a drug manufacturer in exchange for including a drug on the PBM's formulary or for

³ Except when operating mail order pharmacies, PBM's do not actually acquire or handle prescription drugs. (Docket No. 89, ¶ 166.)

"featuring" or "preferring" that drug, sometimes to the exclusion of others. (Docket No. 89, ¶¶ 12, 39-41.)

Whether 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. To illustrate the concern raised by the lack of transparency that typifies the PBMs' dealings with drug manufacturers and pharmacies, the Attorney General offers expert testimony from Stephen W. Schondelmeyer, a professor at the University of Minnesota's College of Pharmacy. (Id., ¶ 123-125.) I credit this testimony, over PCMA's foundation objection. The objection is not briefed and the foundation objection was not preserved during the deposition questioning, which was conducted by PCMA's counsel. According to Professor Schondelmeyer, it is difficult for a benefits provider to know whether it is getting a lower net cost for a drug received through a PBM due to a lack of transparency in the PBM market. (Id., ¶ 124, citing Ex. O at 52.) For instance, if a drug manufacturer provides a higher rebate to a PBM on a \$100 drug than it does on a \$20 drug and the PBM shares the rebate with the benefits provider, it may appear to the benefits provider as though it is saving money. However, it is just as likely that the amount of rebate received by the benefits provider does not make up for the higher base price of the more expensive drug, so that the net economic effect to the benefits provider is a loss. (Id., ¶ 123, citing Schondelmeyer Deposition, Exhibit O, at 50-51.) This lack of transparency also has a tendency to undermine a benefits provider's ability to determine which is the best proposal among competing proposals from PBMs. For example, if a benefits provider had proposals from three different PBMs for pharmacy benefits management services, each guaranteeing a particular dollar amount of rebate per prescription, the PBM proposal offering the highest rebate for each prescription filled could actually be the worst proposal as far as net cost savings are concerned,

because that PBM might have a deal with the manufacturer that gives it an incentive to sell, or restrict its formulary to, the most expensive drugs. (Id., ¶ 125, citing Ex. O at 58.) In other words, although PBMs afford a valuable bundle of services to benefits providers, they also introduce a layer of fog to the market that prevents benefits providers from fully understanding how best to minimize their net prescription drug costs.

In an effort to help control prescription drug costs and increase public access to prescription drugs (Docket No. 94, ¶ 17), the Maine Legislature enacted into law what is now known either as "An Act to Protect Against Unfair Prescription Drug Practices" or the "Unfair Prescription Drug Practices Act," 22 M.R.S.A. § 2699 (UPDPA). The UPDPA regulates "pharmacy benefit managers" (PBMs) and "contracts for pharmacy benefits management." Id.⁴ The UPDPA imposes on PBMs certain fiduciary duties and "required practices," which duties and obligations are owed to the PBMs' benefits provider customers, whom the UPDPA labels "covered entities." Id., § 2699(1)(A) & (2)(A). Among other duties, the UPDPA requires that PBMs "shall 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

⁴ The UPDPA defines pharmacy benefit management as follows:

E. "Pharmacy benefits management" means the procurement of prescription drugs at a negotiated rate for dispensation within this State to covered individuals, the administration or management of prescription drug benefits provided by a covered entity for the benefit of covered individuals or any of the following services provided with regard to the administration of pharmacy benefits:

- 1) Mail service pharmacy;
- 2) Claims processing, retail network management and payment of claims to pharmacies for prescription drugs dispensed to covered individuals;
- 3) Clinical formulary development and management services;
- 4) Rebate contracting and administration;
- 5) Certain patient compliance, therapeutic intervention and generic substitution programs; and
- 6) Disease management programs.

22 M.R.S.A. § 2699(1)(E).

duties imposed by this subsection." Id., § 2699(2)(C). The UPDPA also compels PBMs to disclose the following information to covered entities:

(1) "[A]ll financial and utilization information requested by the covered entity relating to the provision of benefits to covered individuals through that covered entity and all financial and utilization information relating to services to that covered entity," id., § 2699(2)(D);

(2) "[T]he cost of both drugs and any benefit or payment directly or indirectly accruing to the pharmacy benefits manager as a result of the substitution," in the event that the PBM "makes a substitution in which the substitute drug costs more than the prescribed drug," id., § 2699(2)(E)(2); and

(3) "[A]ll financial terms and arrangements for remuneration of any kind that apply between the pharmacy benefits manager and any prescription drug manufacturer or labeler, including, without limitation, formulary management and drug-switch programs, educational support, claims processing and pharmacy network fees that are charged from retail pharmacies and data sales fees," id., § 2699(2)(G).

The first category of information need be disclosed only upon request by a covered entity. Id., § 2699(2)(D). The latter two categories of information must be disclosed even in the absence of a request. Id., § 2699(2)(E)(2) & (2)(G). In the event of any disclosure under the first or third category, the PBM may designate the information disclosed as confidential. Id., § 2699(2)(D) & (2)(G). "Information designated as confidential by a pharmacy benefits manager and provided to a covered entity . . . may not be disclosed by the covered entity to any person without the consent of the pharmacy benefits manager" or in the absence of a court order or an investigative demand made by the Attorney General in an effort to police compliance with the UPDPA. Id. A violation of the UPDPA "is a violation of the Maine Unfair Trade Practices Act, for which a fine of not more than \$10,000 may be adjudged." Id., § 2699(4). In addition to compelling the disclosure of such information, the UPDPA requires PBMs to pass on, in full, to covered entities "any payment or benefit" that is received "based on volume of sales for certain prescription drugs or classes or brands of drugs within the State," id., § 2699(2)(F), as well as for drug substitution,

including substitution of "a lower-priced generic and therapeutically equivalent drug for a higher-priced prescribed drug," id., § 2699(2)(E)(3).

In support of its regulatory takings claim, PCMA offers evidence relating to four (now three through a merger or other combination) of its ten PBM members (a small sample in a market occupied by 40-50 PBMs). Those members are Express Scripts, Inc., Medco Health Solutions, Inc., and Caremark Rx, Inc. (Docket No. 94, ¶ 2.) To illustrate the confidentiality of PBM contracts and the uniqueness of each PBM's contract with a given manufacturer or pharmacy, PCMA even more narrowly offers a contract from each of its three representative PBMs, all of which contracts were entered into with one manufacturer, Pfizer, in either 2003 or 2004. (Id., ¶ 20.) Relying on this evidence, PCMA maintains that the terms of all PBMs' agreements with pharmacies and drug manufacturers constitute trade secrets, the forced disclosure of which would constitute a regulatory taking of the PBMs' property. In my view, it is impossible for the court to make a finding as to the practices of the entire PBM market when it comes to keeping secret the terms of agreements with pharmacies and manufacturers based on this limited evidence.⁵ However, the Attorney General appears willing to concede that contracts between PBMs and pharmacies or manufacturers generally include provisions that are designed to avoid transparency, so that the PBMs' provider customers are incapable of ascertaining the full extent of the discounts, rebates and drug substitution incentives PBMs negotiate or otherwise obtain and, by extension, the extent to which PBMs retain or generate revenues from discounts, rebate and drug substitutions above and beyond what they pass through to their benefits provider customers in the way of savings. (Docket No. 94, ¶ 18; Docket No. 101, ¶ 18.) According to

⁵ The Attorney General asserts in his statement of material facts, and PCMA admits, that PCMA maintains that the discovery of trade secret information from all of PCMA's members was not relevant to the claims or defenses of any party and that PCMA objected to any discovery beyond information related to its three member representatives (Medco, Caremark and ESI). (Docket No. 104, ¶¶ 172-174.)

PCMA, confidentiality provisions in such contracts are also designed to ensure competition and prevent one PBM from learning about another PBM's "unique" agreement with a given manufacturer or pharmacy. (Docket No. 94, ¶ 20.) That any given manufacturer or pharmacy actually preserves the secrecy of one PBM's contract terms when dealing with another PBM is something the court is apparently supposed to assume. PCMA offers only that PBMs endeavor to maintain the secrecy of their agreements. (Docket No. 94, ¶¶ 6-8.)

PCMA offers additional statements that are designed to have the court enter a finding that enforcement of the UPDPA would either destroy competition among PBMs in the marketplace or else enable the PBMs' larger benefits provider customers to essentially cut the PBMs out of the market and deal directly with the pharmacies and manufacturers. (Id., ¶ 19.) In addition, PCMA would have the court find, as a material fact, that "PBMs are likely to cease doing business in Maine and with Maine covered entities to the extent necessary to avoid application of the UPDPA." (Id., ¶ 23.) As to the likely implications of the UPDPA on the PBM market, the Attorney General offers numerous statements designed to support a finding that entrance into the PBM market is not as simple as knowing a PBM's drug costs, financial and utilization data and how it arranges for direct remuneration from manufacturers and pharmacies for the services it provides. (Docket No. 89, ¶¶ 26-34.) Moreover, there is a contract in the record that expressly prohibits the manufacturer from entering into rebate agreements directly with the PBMs' benefits provider customers. (Docket No. 89, ¶ 86.) On the issue of market impact, neither party has marshaled the kind of evidence that would reliably, in PCMA's words, "speak to the ability [let alone the likelihood] of any individual plan, employer or other PBM customer to self-provide or provide to others certain PBM services." (Docket No. 104, ¶¶ 26-34.) As to the admonition that PBMs are "likely" to withdraw from the Maine market, I make no finding. The statement

offered by PCMA is inherently speculative and, in the context of PCMA's motion for summary judgment, the court is constrained to infer that any given PBM is equally likely not to withdraw from the market. Moreover, although disputed by the Attorney General, this is not the sort of fact that is readily susceptible to trial on the merits or, for that matter, even material to the disposition of this motion. For the same reason, I decline to make any finding on broader health care policy questions or, with respect to competing expert opinions, on the UPDPA's likely impact on the prescription drug market in Maine. (See, e.g., Docket No. 89, ¶¶ 118, 123-130, 170; Docket No. 104, ¶¶ 118, 123-130, 170; Docket No. 94, ¶ 19 (last sentence), ¶ 20 (last paragraph) & ¶¶ 21-22; Docket No. 101, ¶¶ 19-22.)

PCMA's member PBMs do not exercise any discretionary authority or discretionary control respecting the management of employee benefit plans. (Docket No. 89, ¶ 159.) PCMA's member PBMs do not exercise any discretionary authority or discretionary control respecting management or disposition of the assets of employee welfare benefit plans. (*Id.*, ¶ 160.) PCMA's member PBMs do not have any discretionary authority or discretionary responsibility in the administration of employee welfare benefit plans. (*Id.*, ¶ 161.) PCMA's member PBMs are not ERISA fiduciaries. (*Id.*, ¶ 162.) PBMs enter contracts with drug manufacturers that require the manufacturers to supply drugs to the PBMs' benefits provider customers. (*Id.*, ¶ 163; Docket No. 104, ¶ 163.) PBMs enter contracts with pharmacies whereby the pharmacies agree to charge certain prices to the customers of the PBM. (Docket No. 89, ¶ 164.) PBMs enter contracts with health plans that allow the health plans' members to obtain drugs at certain prices and that provide financial rebates to the health plans based on volume of utilization. (*Id.*, ¶ 165.) Except when operating mail order pharmacies, PBMs do not actually acquire or handle prescription drugs. (*Id.*, ¶ 166.) PBMs do not make final determinations of whether health plan

members are entitled to receive drug benefits under the plan. (Id., ¶ 167.) PBMs may perform ministerial tasks associated with the processing of drug claims under a health plan. (Id., ¶ 168.)

Facts Submitted Under Seal⁶

⁶ I have included this portion of the facts separately because the documents from which these facts are drawn are confidential business records that were filed under seal. I have placed these material facts under seal until such time as the court has an opportunity to rule upon any objections to this recommended decision. I would recommend that this section be unsealed after review by the court.

DISCUSSION

I. ERISA Preemption

In its motion for summary judgment, PCMA maintains that the UPDPA is preempted by ERISA because it "attempts to dictate the terms under which . . . ERISA plans and their sponsors may contract with PBMs to administer [prescription drug benefit] programs and to define the duties and liabilities of PBMs to such plans, their sponsors and participants." (Docket No. 85 at 4.) According to PCMA, the UPDPA undermines the congressional goal of "establishing a uniform regulatory scheme" (Id. at 7) because it adds an additional layer of regulation to important administrative functions that PBMs perform for, among other entities, ERISA plans and plan sponsors (Id. at 6-7) and because it would afford plans and plan sponsors rights and remedies against PBMs that Congress did not speak of in ERISA (Id. at 11). For his part, the Attorney General argues that the UPDPA is not preempted because it applies to all entities providing pharmacy benefit management services in Maine, regardless of whether such benefits arise out of a plan subject to ERISA (Docket No. 88 at 9), because PBMs are not ERISA fiduciaries or entities (which the Attorney General refers to as "primary" ERISA entities) and because the only burdens the UPDPA imposes fall on PBMs, whom the Attorney General describes as "merely third-party service providers," rather than on any ERISA fiduciary or entity (Id. at 10). According to the Attorney General, acceptance of PCMA's logic would mean that ERISA preemption would foreclose state regulation of any service enterprise that is necessary to the provision of ERISA benefits (such as medical, legal, and accounting services), even though the market for such services extends beyond the ERISA universe. (Id. at 12-13.)

Both parties analyze the preemption issue through the three lenses prescribed by the Supreme Court: (1) whether the UPDPA has a "connection with" an ERISA plan or plans; (2)

whether the UPDPA "refers to" an ERISA plan or plans; and (3) whether the UPDPA's remedial scheme conflicts with the "exclusive" remedial scheme set forth by Congress in ERISA. See Carpenters Local Union No. 26 v. United States Fid. & Guar. Co., 215 F.3d 136, 139-40 (1st Cir. 2000) (outlining the development of ERISA preemption doctrine based on the Supreme Court's interpretation of the "relates to" language of ERISA § 1144(a)); Hampers v. W.R. Grace & Co., 202 F.3d 44, 49-51 (1st Cir. 2000) (discussing circumstances in which a state law cause of action may be deemed to impermissibly conflict with ERISA's exclusive remedial scheme). I follow their lead.

A. "Connection with"

Whether a state law is preempted by ERISA by virtue of an impermissible connection with an ERISA plan or ERISA plans, is determined by judicial interpretation of congressional intent. New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645, 656-57 (1995). Essentially, the inquiry is whether a state law would interfere with the congressional purpose to "avoid a multiplicity of regulation in order to permit the nationally uniform administration of employee benefit plans." Id. at 657. Thus, state laws that prescribe specific benefits that an employee benefit plan must afford are preempted, as are state laws that restrict the ability of an employee benefit plan to use or enforce terms in plans or plan documents or state laws that would prevent plans from using a uniform set of rules or formulae for computing benefits. See id. at 657-58 (discussing the holding of Shaw v. Delta Air Lines, Inc., 463 U.S. 85 (1983), and FMC Corp. v. Holliday, 498 U.S. 52 (1990)). In such cases, state laws are said to be preempted because they "mandate[] employee benefit structures or their administration." Id. at 658. In contrast to such cases are state laws that would impose an indirect cost on plan administration in a given state, but would in no way circumscribe the ability of plan

administrators to structure or administer their ERISA plans in that state. Id. at 658-59. Thus, in Travelers, the Supreme Court held that a New York law that "requires hospitals to collect surcharges from patients covered by a commercial insurer" and that "subjects certain health maintenance organizations (HMO's) to surcharges that vary with the number of Medicaid recipients each enrolls," id. at 649, does not have an impermissible connection with ERISA because the law "does not bind plan administrators to any particular choice and thus function as a regulation of an ERISA plan itself" and does not "preclude uniform administrative practice or the provision of a uniform interstate benefit package if a plan wishes to provide one." Id. at 659. In concluding on the issue, the Court observed:

In sum, cost uniformity was almost certainly not an object of preemption, just as laws with only an indirect economic effect on the relative costs of various health insurance packages in a given State are a far cry from those "conflicting directives" from which Congress meant to insulate ERISA plans. See [Ingersoll-Rand Co. v. McClendon, 498 U.S. 133, 142 (1990)]. Such state laws leave plan administrators right where they would be in any case, with the responsibility to choose the best overall coverage for the money. We therefore conclude that such state laws do not bear the requisite "connection with" ERISA plans to trigger preemption.

Id. at 662.

The question presented by the instant litigation is whether the UPDPA, in placing fiduciary duties and administrative burdens on PBMs operating in Maine, thereby precludes the ability of employee benefit plan administrators to administer their plans in a uniform fashion. PCMA contends that it does because it: "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" (Docket No. 85 at 4); "attempt[s] to regulate [plans'] relationship[s] with PBMs when PBMs perform administrative functions for such plans" (Id. at 6); and "attempt[s] to supplement ERISA's fiduciary duty and disclosure provisions" so that plan

administrators cannot "predict the legality of proposed actions without the necessity of reference to varying state laws" (Id. at 7, citation omitted). The Attorney General rejects these arguments. According to him, the UPDPA does not undermine the congressional goal of uniform plan structure and administration because it does not mandate benefits and because PBMs are not ERISA entities. (Docket No. 88 at 10.) I agree with the Attorney General on this issue.

The UPDPA imposes fiduciary and reporting obligations exclusively on PBMs, not on plans, plan sponsors or plan participants and their beneficiaries.⁷ And with respect to the provision of prescription drug benefits by employee benefit plans, the UPDPA "does not bind plan administrators to any particular choice and thus function as a regulation of an ERISA plan itself" and does not "preclude uniform administrative practice or the provision of a uniform interstate benefit package if a plan wishes to provide one." Id. at 659. The 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 restrict the freedom of employee benefit plans to administer or structure their plans in Maine precisely as they would elsewhere. Nor does it obligate any plan to act upon, or even consider, any of the information that might be disclosed pursuant to the operation of the UPDPA. Because the UPDPA leaves ERISA plans, sponsors, participants, beneficiaries, and the duties and obligations running among them untouched, and because the record does not permit the court to ascertain whether or in what ways the UPDPA would require employee benefit plans to implement unique measures in Maine in connection with plan structure or administration, I conclude that the UPDPA does not have an impermissible "connection with" ERISA plans or plan administration.

⁷ PCMA dismisses any suggestion that PBMs serve as ERISA fiduciaries in the performance of their services. (Docket No. 104, ¶¶ 159-162; see also Docket No. 85 at 4, 6-7, 13.)

B. "Reference to"

A state law is preempted by ERISA by virtue of an impermissible "reference to" an ERISA plan "where 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." Cal. Div. of Labor Standards Enforcement v. Dillingham Constr., 519 U.S. 316, 325 (1997). See also Carpenters Local, 215 F.3d at 143. PCMA argues that the "reference to" test is met here because the UPDPA "purports to regulate the relationship between health benefit plans, plan sponsors and PBMs . . .[,] relationships that cannot exist without the plans themselves." (Docket No. 85 at 9.) In addition, PCMA argues that the UPDPA impermissibly refers to ERISA because "[a]ll of these provisions depend on the existence of health benefit plans." (Id. at 10.) The Attorney General argues that the Dillingham standard makes the "refers to" issue an easy one to call because the obligations imposed on PBMs under the UPDPA apply irrespective of whether PBMs are serving ERISA plans. (Docket No. 88 at 8.) I conclude that the UPDPA does not impermissibly refer to an ERISA plan or plans because it applies with respect to pharmacy benefits management services supplied to a broad spectrum of health care institutions and health care benefits providers, including but not limited to employee benefit plans, see 22 M.R.S.A. § 2699(1)(A),(B) & (E), and, therefore, neither acts immediately and exclusively upon ERISA plans nor depends on the existence of ERISA plans in order to have meaning. PCMA's invocation of District of Columbia v. Greater Washington Board of Trade, 506 U.S. 125 (1992), does not dissuade me from this conclusion. In that case, the Supreme Court affirmed a finding that ERISA preempted a singular section of a District of Columbia workers' compensation amendment that required employers providing health insurance coverage to their workers to obtain insurance that would extend health insurance coverage for up to 52 weeks while a worker

was receiving workers' compensation benefits. Id. at 128. The statute thus exclusively concerned employee benefits (the District of Columbia did not even contest that the statute related to ERISA) and also mandated specific benefits. See id. at 130 (finding that the only health insurance programs the statute applied to were ones "subject to ERISA regulation"). The same distinction is applicable to the statute at issue in Mackey v. Lanier Collection Agency & Service, Inc., the other opinion primarily relied upon by PCMA in support of its position. See 486 U.S. 825, 829 (1988) ("The Georgia statute at issue here expressly refers to—indeed, solely applies to—ERISA employee benefit plans."). The UPDPA is not of the same species.

C. Remedial conflict

In addition to impermissible connections and references, a third category of ERISA preemption applies to state laws that would have the effect of affording to an ERISA entity, most commonly an ERISA beneficiary, an "alternative enforcement mechanism [or] remedy for the violation of a right expressly guaranteed and exclusively enforced by the ERISA statute." Carpenters Local, 215 F.3d at 141 (citing Ingersoll-Rand v. McClendon, 498 U.S. 133, 145 (1990)). Preemption of this sort does not extend to state laws that merely "touch upon enforcement but have no real bearing on 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. (citing Woodworker's Supply, Inc. v. Principal Mut. Life Ins. Co., 170 F.3d 985, 990 (10th Cir. 1999)).

PCMA argues that the UPDPA runs afoul of the exclusive enforcement/remedy test because it "purports to create a new fiduciary breach cause of action against a specific category of ERISA plan service provider," when no ERISA remedy would be afforded against [them] under ERISA. (Docket No. 85 at 13.) For his part, the Attorney General argues that conflict

preemption does not arise because the UPDPA has "no real bearing on the intricate web of relationships among the principal players in the ERISA scenario" and because "PCMA's member PBMs are not ERISA fiduciaries." (Docket No. 88 at 15.) I agree with the Attorney General that the UPDPA does not impermissibly intrude upon the remedial scheme Congress devised to govern the relationships among ERISA entities. Although 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. Furthermore, PCMA has failed to present any set of circumstances in which enforcement of the UPDPA's "required practices" against a PBM would undercut ERISA's civil enforcement scheme. Finally, it seems to me that there is no logical basis to infer that Congress intended for ERISA to foreclose state regulation of third-party pharmacy benefits management services engaged in by non-ERISA fiduciaries or to preclude ERISA plans from employing state-created remedies against PBMs on an equal footing with other consumers of such services.

II. FEHBA Preemption

PCMA maintains that the UPDPA is preempted by the Federal Employee Health Benefits Act (FEHBA). (Docket No. 85 at 14-15.) The Attorney General argues that it is not. (Docket No. 88 at 16-18.) Both agree that whether the FEHBA preempts the UPDPA depends on essentially the same analysis as the question of whether ERISA preempts the UPDPA. (Docket No. 85 at 15; Docket No. 88 at 18.) Based on the parties' concessions that the analysis would be redundant, I conclude that the FEHBA does not preempt the UPDPA for the same reasons I set forth with regard to ERISA preemption.

III. Regulatory Taking

According to PCMA, information concerning the discounts and other contract terms that PBMs are able to negotiate with drug manufacturers and pharmacies are "classic trade secrets." (Docket No. 85 at 19.) Because the UPDPA requires PBMs to disclose these trade secrets to their benefits provider customers in Maine, PCMA contends that the UPDPA requires PBMs to surrender trade secrets as a condition of doing business in Maine. (Docket No. 85 at 18-19.) For his part, the Attorney General does not categorically argue that information and terms developed through contract negotiations are never trade secrets.⁸ Instead, the Attorney General argues that PCMA's takings claim is misconceived at a fundamental, jurisdictional level because it seeks injunctive relief rather than just compensation. (Docket No. 88 at 20-26.) On a somewhat related note, the Attorney General argues that whether or not a trade secret exists or is taken depends on a number of individualized findings that cannot be made in the context of a lawsuit brought by a trade association, as opposed to a lawsuit brought by one or more PBMs individually. (Docket No. 88 at 19-32; Docket No. 100 at 8-10.) In addition to this concern over PCMA's associational standing to pursue its takings claim, the Attorney General argues that PCMA's facial challenge to the constitutionality of the UPDPA cannot succeed because PCMA cannot prove that there is no set of circumstances under which the UPDPA would be valid – because PCMA has offered evidence pertaining only to three existing PBMs and because that evidence suggests that the information that would be disclosed under the UPDPA is not always secret. (Docket No. 88 at 32-33; Docket No. 100 at 9-10.) Finally, the Attorney General argues that the confidentiality protections afforded by the UPDPA "inoculate" the disclosure provisions. (Docket No. 88 at 33-42.) Before addressing the merits of the takings claim, I pause to address the jurisdictional and prudential concerns raised by the Attorney General.

⁸ The Attorney General does not concede that they are, either. (Docket No. 88 at 33 n.15.)

A. Ripeness

The Attorney General contends that this court does not have jurisdiction to enjoin enforcement of the UPDPA before there has been an effort to enforce it against a PBM or, at least, before a PBM can demonstrate that state law remedies are inadequate to redress any alleged injury to the PBM's interests in its trade secrets. (Docket No. 88 at 20-26.) As the court observed in its order granting preliminary injunctive relief, the current controversy is ripe for adjudication because PCMA brings a "facial" takings claim rather than an "as applied" takings claim. Pharm. Care Mgmt. Ass'n v. Rowe, 307 F. Supp. 2d 164, 180 n.17 (D. Me. 2004). However, as discussed below, the scope of a facial takings claim must be restricted to the theory that the challenged regulation does not substantially advance a legitimate state interest, or that recourse to state procedures for obtaining just compensation would be futile. Yee v. City of Escondido, 503 U.S. 519, 534 (1992) ("As this [facial challenge] does not depend on the extent to which petitioners are deprived of the economic use of their particular pieces of property or the extent to which these particular petitioners are compensated, petitioners' facial challenge is ripe."); Sinclair Oil Corp. v. County of Santa Barbara, 96 F.3d 401, 406-407 (9th Cir. 1996), cert. denied, 523 U.S. 1059 (1998) (discussing Williamson County Reg'l Planning Comm'n v. Hamilton Bank, 473 U.S. 172 (1985) and Yee, supra, and explaining the different kinds of facial takings claims at issue in each); Daniels v. Area Plan Comm'n, 306 F.3d 445, 458 n.13 (7th Cir. 2002) ("Litigants are not required to meet the Williamson County ripeness requirements when solely mounting a pre-enforcement facial challenge to the constitutionality of a statute under the Fifth Amendment."); See also Philip Morris, Inc. v. Reilly, 312 F.3d 24, 52 (1st Cir. 2002) (Lipez, dissenting) (discussing the stringent burden placed on plaintiffs presenting only facial

takings claims). Whether the takings claim that PCMA advances in its memoranda of law actually adheres to this limitation is an interesting question.

The real focus of the Attorney General's jurisdictional objection goes to PCMA's request for injunctive relief. According to the Attorney General, "[n]o court prior to this case has . . . found" that there exists such a thing as a "facial per se takings claim for which there was no adequate state compensatory remedy and thus the claim was ripe for federal court equitable relief." (Docket No. 88 at 23.) In response, PCMA assures the court that it need not be concerned over this issue because PCMA "challenges the UPDPA's generic condition, without exception and applicable to PBMs as a class, requiring surrender of property rights in return for the ability to do business in Maine." (Docket No. 103 at 15.) According to PCMA, the First Circuit recognized an "unconstitutional condition" doctrine in Philip Morris, Inc. v. Reilly that bars state legislation that attempts to impose a taking as a quid pro quo for access to state markets. (Id. at 17.) Thus, PCMA cites a footnote in Justice Torruella's primary opinion to the effect that it creates an "unconstitutional condition" when a state puts the sellers of products in the "untenable position of having to choose between relinquishing their valuable trade secrets or pulling their products out of [a state market]," Philip Morris, 312 F.3d at 39 n.11, and Justice Selya's more emphatic statement in concurrence that "companies are left with a Hobson's choice: either comply with the Disclosure Act and forfeit your valuable trade secrets or withdraw from the . . . market. This constitutes an unconstitutional condition on [a] compan[y's] right to sell [its] products Id. at 50. I agree with PCMA that the Philip Morris opinion appears to assert that there is a constitutional right under the Takings Clause to access a state's markets without having first to satisfy a taking condition, and that a federal court has jurisdiction, at the very

least, to declare a statute imposing such a condition unconstitutional.⁹ Thus, PCMA's facial takings claim is ripe for adjudication.

B. Associational standing

The Attorney General argues that, even if the court has jurisdiction to evaluate a facial challenge to the constitutionality of the UPDPA under the Takings Clause, PCMA does not have associational standing to litigate the claim because "the nature of the takings claim is extraordinarily individualized, there is no commonality of relief because just compensation . . . is the appropriate remedy, and . . . the associational standing vehicle was not intended . . . to make it more difficult for defendants, and particularly sovereign states, to defend themselves." (Docket No. 88 at 26.) In support of this position, the Attorney General points to evidence obtained during discovery that tends to demonstrate voluntary divulgence of some trade secret information by certain PBMs to some of their customers, most commonly in the context of annual audits. (*Id.* at 27-28.) Because some of PCMA's members would likely have extra difficulty proving that the terms they have negotiated with drug manufacturers are "classic trade secrets," and therefore that the UPDPA subjects them to a taking, the Attorney General argues that PCMA cannot stand in for the PBMs in this litigation. (*Id.* at 28-30, arguing at page 30 that "[a]s long as there is one hypothetical contract between a PBM and the thousands of customers out there allowing access, there is no standing.") PCMA sees things quite differently. In PCMA's view, "[i]t would be sufficient for associational standing purposes if every PCMA member but one had abandoned their trade secrets." (Docket No. 103 at 23.)

⁹ Justice Torruella made it clear in his opinion that the Court only affirmed the district court's award of equitable relief because the State of Massachusetts failed to challenge the award of such relief on appeal. *Philip Morris*, 312 F.3d at 47 n.22. Justice Torruella also made it clear that his opinion did not rely on the Due Process Clause, although he did not rule out the possibility of a due process violation. *Id.* at 47.

In Warth v. Seldin, the Supreme Court first recognized associational standing, holding that:

The association must allege that its members, or any one of them, are suffering immediate or threatened injury as a result of the challenged action of the sort that would make out a justiciable case had the members themselves brought suit. So long as the nature of the claim and of the relief sought does not make the individual participation of each injured party indispensable to proper resolution of the cause, the association may be an appropriate representative of its members, entitled to invoke the court's jurisdiction.

422 U.S. 490, 511 (1975). Thus, the Attorney General focuses on the need for individual participation to prove the existence of a trade secret and individualized damages, whereas PCMA focuses on the fact that only one of its members need suffer a threatened injury that would generate a justiciable case if it brought suit in its own name. It seems to me that both parties are correct, but each of their statements focuses on a different aspect of the associational standing test. PCMA is correct that the mere fact one or more of its members might not be able to independently sustain a takings claim does not preclude PCMA from meeting the associational standing test, so long as one of its members does suffer injury to a cognizable interest. That fact goes to the first prong of the test (whether at least one of the association's members would have standing to sue on its own), but not the third, prudential, prong that the Attorney General's argument focuses on (whether the nature of the litigation requires the participation of individual members). See United Food & Commer. Workers Union Local 751 v. Brown Group, Inc., 517 U.S. 544, 554-557 (1996). Thus, although I credit PCMA's point, in my view it does not carry the day because it remains a basic fact of this litigation that at least one of PCMA's members must participate in this litigation in order for PCMA to prove that compliance with the UPDPA's disclosure provision will effectively "take" a trade secret and that the resultant injury to that member is sufficiently weighty to override the State's legislative prerogative. Whether or not the

information PBMs would have to divulge under the UPDPA deserves constitutional protection under the Takings Clause, i.e., whether or not justice and fairness require the payment of compensation for the disclosure of such information, Penn Central Transp. Co. v. New York City, 438 U.S. 104, 124 (1978), depends on a host of factors and PCMA cannot prove that the interest of trade secret protection is sufficiently compelling to require compensation for the UPDPA's disclosure provisions except by introducing 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. Thus, in my view, PCMA fails to meet the third, prudential,¹⁰ prong of the Supreme Court's standing test because its claim "requires the participation of [at least one] individual member[] in the lawsuit," Hunt v. Wash. State Apple Adver. Comm'n, 432 U.S. 333, 343 (1977), and cannot be determined without individualized evidence.

I recognize, of course, that an association can pursue a claim even though it must submit some evidence drawn from its members, as is demonstrated by Hunt, in which the trial court entered findings about the effects a North Carolina statute had upon some Washington apple growers, id. at 343-44. But here, unlike Hunt, the viability of PCMA's takings claim varies member-by-member, not based on the threshold question of whether a given member does business in Maine and complies with the statute, but based on the highly individualized, underlying factual questions of whether and how a given member protects the information at issue and whether the confidential disclosure of the information to specific benefits providers or "covered entities" strips the information of all value as a trade secret or causes economic injury

¹⁰ The Supreme Court has concluded that "the associational standing test's third prong is a prudential one," rather than a jurisdictional one. United Food, 517 U.S. at 555. "Hence the third prong of the associational standing test is best seen as focusing on these matters of administrative convenience and efficiency, not on elements of a case or controversy within the meaning of the Constitution." Id. at 557.

of constitutional proportion. By comparison, to dispose of the Commerce Clause claim in Hunt, it appears that the only evidence the association plaintiff had to put forward from its members was that the North Carolina statute had the "consequence of *raising the costs* of doing business in North Carolina for Washington apple growers and dealers," a generic condition imposed on every member participating in the North Carolina market.¹¹ In the instant case, however, there is a genuine issue of material fact whether the mere fact of a PBM's compliance with the UPDPA by disclosure of information, subject to confidentiality, at the request of a given provider customer, will cause appreciable economic injury, let alone effectuate a taking. In my view, prudence cautions against further entertaining PCMA's Takings Clause challenge to the UPDPA because the determination of this aspect of the litigation requires the court to evaluate highly-individualized evidence and circumstances, so much so that it is strange to even conceptualize this aspect of the litigation as presenting only a "facial" challenge. For this reason, I recommend that the court grant summary judgment in favor of the Attorney General with respect to count III.

C. Merits

Despite my recommendation concerning the Attorney General's challenge to PCMA's standing to sue in a representative capacity, I address the merits of PCMA's presentation of its facial takings claim because PCMA has separately moved for summary judgment in its favor and that motion has been referred for recommended decision. Should the courts choose to grant the Attorney General's motion for summary judgment against this claim, then this discussion will be largely academic.

¹¹ That evidence may well have come from institutional records or knowledge or other evidence available to the Washington State Apple Advertising Commission as a state agency. In this case, by comparison, PCMA asserts (as it must) that it does not have any first hand information about its members' alleged trade secrets. (See Docket No. 89, ¶ 172; Docket No. 104, ¶ 172: "No employees, officers, or directors of PCMA have had access to its members' contracts and trade secrets in the last three years.")

PCMA argues that it is entitled to summary judgment in its favor on its takings claim and its 42 U.S.C. § 1983 claim based on an analysis of the three takings factors set forth in Penn Central Transportation Company v. New York City, 438 U.S. 104 (1978), as applied to concerns over trade secret protection in Ruckelshaus v. Monsanto Company, 467 U.S. 986 (1984), and Philip Morris, Inc. v. Reilly, 312 F.3d 24 (1st Cir. 2002). According to PCMA, "if PBMs must reveal the information [required by the UPDPA] to their customers, even if to no one else, all value as property is destroyed, resulting in an unconstitutional taking." (Docket No. 85 at 24.) The Attorney General argues that summary judgment should enter against PCMA's takings claim because PCMA cannot meet the heightened burden that applies to a facial challenge. (Docket No. 88 at 32.) According to the Attorney General:

[I]f a single PBM had a single contract with a covered entity that afforded that covered entity access to the type of information to be disclosed under sections 2(D) and 2(G), with the same or fewer confidentiality protections than those in the statute, the facial challenge fails because . . . there is no "trade secret," no adverse economic impact, and no interference with investment backed expectations.

(Id.) Alternatively, the Attorney General argues that even if the court concludes that the information at issue in this case is entitled to trade secret protection, the UPDPA's confidentiality provisions "'inoculate' the disclosure provisions from constitutional infirmity." (Id. at 33.) Like PCMA, the Attorney General discusses all three of the Penn Central factors in his memorandum. (Id. at 35-42.) Those three factors are the following:

- (1) "the extent to which the regulation [would] interfere[] with distinct investment-backed expectations";
- (2) "the economic impact of the regulation on the claimant"; and
- (3) "the character of the governmental action."

Penn Central, 438 U.S. at 124.¹²

Because PCMA brings only a facial challenge, "the narrow inquiry" before this court is "whether the mere enactment of the [UPDPA] constituted a taking." Tahoe-Sierra Pres. Council, Inc. v. Tahoe Reg'l Planning Agency, 535 U.S. 302, 318 (2002). Typically, in the context of a physical taking of property, a facial challenge invites a categorical rule. See id. at 320-21. Although PCMA maintains that a *per se* taking results from the enactment of the UPDPA because it requires the disclosure of trade secrets as a condition of doing business in Maine (Docket No. 85 at 15), I am not persuaded that application of a *per se* rule makes sense in this case because of the need for searching and individualized fact finding in order to evaluate the Penn Central factors. See Tahoe-Sierra, 535 U.S. at 322-23 (describing the distinction between physical takings, which permit a categorical approach, and regulatory takings, which "entail[] complex factual assessments of the purposes and economic effects of government actions"). Indeed, I have concerns that PCMA is not really pressing a facial challenge here. For each of the three Penn Central factors, PCMA presents arguments that are dependent not only upon evidence of its members' internal practices, the economic value of the information at issue, and the impact the UPDPA would have on its members' use of information, but also upon entirely hypothetical projections about what some of its customers might do with the information once it is disclosed to them. (Docket No. 85 at 18-23.) In contrast, in Yee the Supreme Court held that a regulatory takings claim was ripe because the plaintiff argued only that the regulation in question did not "substantially advance" a 'legitimate state interest,' no matter how it is applied," and did not base the claim on the "extent to which [they were] deprived of the economic use of their [property]." 503 U.S. at 534. My impression is that PCMA's taking claim is really an unripe as-applied claim masquerading as a facial claim.

¹² I have listed these factors in the order they were addressed by Judge Torruella in Philip Morris.

PCMA contends that the constitutional finding it seeks is plainly required by Ruckelshaus v. Monsanto and Philip Morris and that the court only needs to determine that PCMA's members have at least some reasonable investment-backed expectation that their trade secrets will remain secret, to conclude, categorically, that disclosure to PBM's provider customers works a taking. (Docket No. 88 at 17-18.) I disagree because the record does not compel a finding that confidential disclosure to these customers will destroy or extinguish the PBMs' alleged trade secrets. The point is that viewing the record in the light most favorable to the Attorney General, and drawing all reasonable inference in his favor, the court cannot conclude that the confidential disclosures the UPDPA requires will destroy the PBMs' trade secrets or their reasonable investment-backed expectations.

In Ruckelshaus v. Monsanto, the Supreme Court considered whether trade secret data Monsanto submitted to the Environmental Protection Agency under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), could be disclosed publicly by the EPA without effecting a regulatory taking. The Court's answer was that it depended upon which of three evolving statutory schemes applied at the time the data were submitted. Ruckelshaus v. Monsanto, 467 U.S. at 990-97 (describing FIFRA's original purpose and its evolution through two amendments), 998-99 (describing the nature of Monsanto's claims), & 1004-14 (discussing the merits based on which statutory scheme the data were submitted under). The question of whether the data deserved trade secret protection was not before the Court. The EPA stipulated that Monsanto had property rights in the data, and the Court merely paused to consider whether "the intangible nature of a trade secret" deserved protection under the Fifth Amendment. Id. at 1001-1004. The Court concluded that trade secrets are protected by the Takings Clause. Id. at 1003-1004. Turning to the ultimate takings question, the Court observed that the ad hoc,

regulatory takings analysis set the appropriate standard. Id. at 1004-1005. The Court concluded that of the three *ad hoc* factors (the character of the government action, its economic impact, and its interference with reasonable investment-backed expectations), the case could be resolved solely by reference to Monsanto's investment-backed expectations. Id. at 1005. Based on that factor, the Court rejected most of Monsanto's case, holding that public disclosure of data submitted under the latest (post-1978) and the earliest (pre-1972) versions of FIFRA could not effect takings. As for post-1978, a taking could not be found because "Monsanto knew that, for a period of 10 years from the date of submission, EPA would not [disclose] data . . . without Monsanto's permission," because "Monsanto was further aware that it was entitled to an offer of compensation [from the party receiving a disclosure] . . . until the end of the 15th year from the date of submission," and because Monsanto knew that "much of the . . . data . . . could be disclosed to the general public at any time." Id. at 1006. Because Monsanto was aware of all these different avenues for public disclosure and nevertheless submitted its data to the FDA "in exchange for the ability to market pesticides," id. at 1007, the Court reasoned that it could not find that Monsanto had a reasonable, investment-backed expectation that could be "disturbed" by a disclosure made in compliance with the act. Id. at 1006-1007. As for pre-1972, the Court reasoned that a taking could not be found because there was no federal law in effect at that time that could have justified Monsanto in thinking that its data would remain confidential or that the EPA would not conclude that public disclosure was needed. Id. at 1008-1009. In other words, the Court appeared to reason that submission of trade secret data to a federal agency, without an "express promise" of confidentiality, precludes a finding of a reasonable investment-backed expectation that the trade secret would not be publicly divulged. Id. at 1008-1009. Another way of looking at this aspect of the holding is that government disclosure, for public benefit, of trade

secret data submitted to it in exchange for the right to market a regulated product does not amount to a taking unless the government has made an express promise to protect the data's confidentiality. This reading is born out by the Court's analysis of data submitted by Monsanto between 1972 and 1978. During this timeframe, FIFRA afforded a submitter of data the "opportunity to protect its trade secrets from disclosure by designating them as trade secrets at the time of submission." Id. at 1010-11. Thus, because "the Federal Government had explicitly guaranteed to Monsanto and other registration applicants an extensive measure of confidentiality and exclusive use[.]" the Court held that Monsanto had a "reasonable investment-backed expectation with respect to its control over the use and dissemination of the data it submitted." Id. at 1011.

In all three situations described above, the Court's holding turned entirely on the *past* submission of trade secret data with or without statutory assurances that the data would be protected. Reviewing a historical record of this kind, the task faced by the Court in Ruckelshaus v. Monsanto was much "cleaner" than what is presented in this case. Here, PCMA wants a prospective ruling that any requirement of disclosure, even if subject to confidentiality, works a taking, something that has very little resemblance to what the Supreme Court did in Ruckelshaus v. Monsanto. Also distinct from Ruckelshaus v. Monsanto is PCMA's demand for injunctive relief. With respect to remedy for disclosure of data submitted between 1972 and 1978, the Supreme Court in Ruckelshaus v. Monsanto entered an order that the time had not yet come for imposing any relief because there remained an opportunity for Monsanto to obtain just compensation:

EPA consideration or disclosure of health, safety, and environmental data will constitute a taking *if* Monsanto submitted the data to EPA between October 22, 1972, and September 30, 1978; the data constituted trade secrets under Missouri law; Monsanto had designated the data as trade secrets at the time of its

submission; the use or disclosure conflicts with the explicit assurance of confidentiality or exclusive use contained in the statute during that period; *and the operation of the arbitration provision does not adequately compensate* for the loss in market value of the data that Monsanto suffers because of EPA's use or disclosure of the trade secrets.

Id. at 1013-14 (footnote omitted). See also id. at 1016 ("Equitable relief is not available to enjoin an alleged taking of private property for a public use, duly authorized by law, when a suit for compensation can be brought against the sovereign subsequent to the taking. The Fifth Amendment does not require that compensation precede the taking.") (footnote and citation omitted), 1019 ("The District Court erred in enjoining the taking.") & 1020 (noting, in conclusion, that a Tucker Act remedy is available to provide Monsanto with just compensation," and that "[o]nce a taking has occurred, the proper forum . . . is the Claims Court"). In my view, Ruckelshaus v. Monsanto does not provide a good format for analyzing whether PCMA's prospective submission of information under the UPDPA works a taking because we are not concerned here with past submissions of data or information. If Ruckelshaus v. Monsanto dictates anything with respect to the disposition of this suit, it is that declaratory relief might be in order, but injunctive relief is not.

The First Circuit's *en banc* opinion in Philip Morris comes closer to the mark, but is still no cigar. In Philip Morris, the First Circuit reviewed a facial challenge to a Massachusetts tobacco ingredients disclosure act. 312 F.3d at 26. The act required disclosure of all ingredients used in tobacco products, "by relative amount," other than tobacco, water and reconstituted tobacco sheet. Id. The act further provided that the information would be disclosed to the public. Id. at 28. A number of tobacco companies (not an association)¹³ brought a facial challenge to the act, before it could be implemented, contending that the act "create[d] an

¹³ The panel opinion reveals that a number of separate suits were commenced and subsequently joined by the trial court. Philip Morris, Inc. v. Reilly, 267 F.3d 45, *3, 2001 U.S. App. LEXIS 22348, *11 (1st Cir. 2001) (withdrawn from bound volume).

unconstitutional taking." Id. at 26. The district court agreed, enjoining enforcement of the act; a divided First Circuit panel reversed, concluding that public disclosure . . . is a valid exercise of the police power and, in the absence of explicit guarantees of confidentiality . . . , does not effect an unconstitutional taking"; and after an "en banc" review of the takings issue by three judges, the panel decision was replaced with an opinion affirming the district court. Id. at 26. Like Ruckelshaus v. Monsanto and unlike this case, the key factual findings that the Philip Morris opinion turned on were not disputed. Thus, it was not disputed by the Massachusetts Attorney General "that the tobacco companies' ingredient lists are trade secrets," Philip Morris, 312 F.3d at 31, or that "publication of [the tobacco companies'] ingredient lists, organized by relative amount, on a brand-by-brand basis would likely destroy the secrecy of their formulas," id. at 27. Moreover, unlike the UPDPA, the Massachusetts act allowed for unrestricted public disclosure of the tobacco companies' ingredient lists. The Court found as a fact that Massachusetts "hope[d] to publicize the ingredient list of various brands" in order to "help consumers make more informed choices." Id. at 28. Based on those undisputed facts, the majority of the *en banc* Court concluded that it could dispose of the facial challenge on the merits, having a record that plainly established that the companies had, at least until passage of the act, reasonable expectations in the safety of their trade secrets by virtue of Massachusetts common law, and that public disclosure (and, thus, disclosure to competing manufacturers), would "extinguish," id. at 41, "essentially destroy," id. at 42, or "completely destroy," id. at 43, the companies' trade secrets. See also id. at 41 (finding it "*paradigmatic*" that the tobacco companies' assertion that their trade secrets would lose "all value" was true.) (emphasis added). Finally, the court concluded that the act also imposed an unconstitutional condition because Massachusetts was not offering tobacco companies a "benefit" of corresponding value to offset the taking. Id. at 47. As

for remedy, the Court affirmed the district court's entry of injunctive relief, but only on a technicality: the legality of imposing injunctive relief was not challenged on appeal. Id. at 47 n.22.

The takings claim presented in the instant case is like the takings claim presented in Philip Morris to the extent that PCMA seeks prospective relief and no PBM has yet divulged any of its alleged trade secrets in compliance with the UPDPA. According to Judge Torruella, author of the lead opinion in Phillip Morris, when a trade secret taking claim is raised before disclosure, it is more likely that a taking will be found, because unless a promise of confidentiality is extended or extracted from the government, there is no reasonable basis to expect that the trade secret will not be divulged by the State. Id. at 38. However, this case is also different from Philip Morris in significant ways. The UPDPA does not subject information to unfettered public disclosure, but affords a measure of confidentiality. Furthermore, it is not clear that the information that would be disclosed under the UPDPA deserves trade secret protection and it is established that disclosures of at least some information to at least some PBM customers will not undermine trade secrets protection because those customers have already been granted access to the information. In addition, PCMA's evidence about the likelihood of harm, given the confidentiality provisions now engrafted to the UPDPA, is entirely conjectural and will likely vary according to which PBM is under consideration. On this record, I am not persuaded that PCMA can carry its burden to prove that every disclosure under the UPDPA, if uncompensated, will result in an unconstitutional taking, and I believe that the question ought to be presented in the context of an as-applied challenge. Nevertheless, I follow Judge Torruella's lead and address the Penn Central factors in turn, mindful that PCMA faces "an uphill battle" and "must establish that no set of circumstances exists under which the Act would be valid." Philip

Morris, 312 F.3d at 52 (Lipez, J., dissenting) (quoting Tahoe-Sierra Pres. Council, 535 U.S. at 1477, and Pharm. Research & Mfrs. of Am. v. Concannon, 249 F.3d 66, 77 (1st Cir. 2001)).

According to PCMA, the UPDPA places PBMs' reasonable investment-backed expectations in jeopardy of destruction because the disclosures the UPDPA calls for will divulge trade secrets to customers who, as commercial entities, could derive economic value from the information by entering the PBM industry and eliminating PBMs as middlemen. (Docket No. 85 at 23-24.) Contrary to PCMA's assertions, the record does not clearly establish that any given disclosure under the UPDPA will divulge trade secrets, destroy or extinguish the economic value of the alleged trade secret information, or cause provider customers to enter the PBM market.

1. Reasonable investment backed expectations

From PCMA's perspective, if it can show that any one of its members would have to disclose information under the UPDPA that is otherwise subject to trade secret protection, then not only will the first *and* second prongs of the Penn Central test be established, but also a *per se* taking will be conclusively established. (Id.) PCMA thus fully briefs why the terms of the contracts that PBMs negotiate with drug manufacturers and pharmacies deserve trade secret protection. (Id. at 18-23.) I do not reproduce PCMA's arguments here because, although I agree with PCMA that the terms and conditions set forth in confidential contracts could¹⁴ amount to

¹⁴ I do not mean to suggest that proof of trade secret status is a foregone conclusion. Among the factors generally considered by Maine courts is the relative "ease or difficulty with which others could properly acquire . . . the information." Bernier v. Merrill Air Eng'rs, 2001 ME 17, ¶ 26, 770 A.2d 97, 106 n.6. Although PCMA asserts that every PBM forms a unique contract with any given drug manufacturer, it seems highly likely to me that any two comparably situated PBMs (as far as bargaining power is concerned) could, in any given year, extract the same or comparable rebate terms from a drug manufacturer as any other PBM. In other words, the likelihood that one PBM will negotiate functionally equivalent or even identical rebate terms as another PBM does from a given manufacturer in any one year (all of the contracts supplied by PCMA in the record are annual contracts) seems, to me, likely to occur. Also, I am not entirely sure that the court should simply assume that PCMA's factual assertions about the costs to PBMs of developing "relationships with manufacturers and pharmacy networks" (Docket No. 94, ¶ 8), is an appropriate substitute for the amount invested in, for example, each new year's rebate terms, which appear to be set forth in appendixes to the contracts. These and other concerns, such as those highlighted by the court in its order granting the preliminary injunction, do pose significant conceptual problems for treating the information at issue herein as deserving trade secret status. On another note, I also observe that the Maine Trade Secrets Act expressly

"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," 10 M.R.S.A. § 1542(4), I also agree with the Attorney General that the question under the first prong of the facial test is not whether such information *could* be a trade secret, but whether the record *proves* that it is reasonable for PBMs to expect that the information at issue could never be subject to a disclosure regulation, including a disclosure regulation with a confidentiality provision restricting further disclosure. On that question, I agree that PCMA cannot establish a facial taking on the existing record. The record clearly establishes that in at least some instances, confidential disclosure under the UPDPA would be in keeping with preexisting PBM practice between some PBMs and some of their customers.¹⁵ I therefore conclude that PCMA fails to carry its burden of demonstrating that the UPDPA could not be valid under any set of circumstances. Tahoe-Sierra Pres. Council, 535 U.S. at 1477; Pharm. Research & Mfrs. of Am., 249 F.3d at 77. Furthermore, it seems striking to me that, although the Attorney General has strived to present evidence of actual situations in which no taking would occur, PCMA has not even attempted to present one concrete situation where the disclosure of information by one of its representative PBMs to an actual, identified, Maine-based benefits provider customer or "covered entity" would compromise trade secret information. Instead it has put forth highly-generalized statements of fact that depend upon the

cautions that the Act "does not affect . . . [t]he duty of any person to disclose information where expressly required by law." See also 10 M.R.S.A. § 1548(1)(D). This express limitation in Maine's Trade Secrets Act may have more significance for the "reasonable investment-backed expectation" factor than did the ancillary common law principles and statutes raised by the Massachusetts Attorney General in Philip Morris. See 312 F.3d at 31-32. Given this express limitation in Maine's Trade Secrets Act, what basis is there for a PBM to expect that contracts and terms negotiated after the UPDPA's effective date will be afforded trade secret protection in Maine?

¹⁵ The Attorney General also asserts in his statement of material facts (Docket No. 88) that PBMs are already subject to extensive regulation, including regulation designed to prevent violation of state and federal anti-kickback legislation. (Docket No. 89, ¶¶ 182-184, citing position paper prepared by AdvancePCS, Caremark Rx and Express Scripts and a report produced by the U.S. Department of Health and Human Services, Office of the Inspector General).

court drawing rather liberal inferences in its favor as the summary judgment movant. Finally, I agree with the Attorney General that the year-to-year nature of these contracts significantly erodes PCMA's position that any diminution in the value of the information contained in the contracts works a taking. (Docket No. 88 at 40.) Unlike classic trade secrets, like the formulas used to produce pesticides or cigarettes, which have an abiding market value, the terms of an annual contract expire annually. The Legislature amended the UPDPA to provide that its terms were only applicable to contracts entered into or renewed after the UPDPA's effective date. 22 M.R.S.A. § 2699(5). Because expectations must be evaluated at the date of disclosure, Ruckelshaus v. Monsanto, 467 U.S. at 1014 n.17, and because the contracts found in the record reflect that drug rebates and other terms are renegotiated annually, the contractual information at issue does not deserve to be treated as categorically untouchable trade secrets but as new data that is subject to health and safety regulations requiring transparency. Stated another way, the PBMs' market "relationships" with drug manufacturers and pharmacy networks are not something that the Takings Clause requires governments to treat as sacrosanct or opaque in perpetuity and expectations in as-yet unexecuted or yet-to-be negotiated contracts are not reasonable if they fail to take into consideration newly enacted regulations.

2. *Economic impact*

PCMA's economic impact argument is the same argument it presents in support of its members' investment-backed expectations. The primary factual assertion that PCMA advances in support of its economic impact argument is the projection that disclosure will undermine the PBMs' negotiating position with their benefits provider customers, thereby costing them money, and that the PBMs' provider customers will potentially enter the PBM market and cut PBMs out of the loop if PBMs have to make the disclosures called for by the UPDPA. (Docket No. 94, ¶

19.) In support of this assertion, PCMA offers passages from the deposition testimony of numerous individuals currently or formerly retained by PCMA or otherwise within the PBMs' employ. (Id.) Even if the court were to credit these predictions, I conclude that the lack of reasonable investment-backed expectations in new and future contract terms overrides this factor and that the injuries alleged are but part and parcel of the regulatory environment. Philip Morris, 312 F.3d at 36 ("Courts protect only reasonable expectations. Ideally, the relevant inquiry should recognize that not every investment deserves protection and that some investors inevitably will be disappointed."); see also id. at 48 (arguing that the investment-backed expectation factor should have primacy when trade secrets are at issue); Penn Cent., 438 U.S. at 124 ("The economic impact of the regulation on the claimant and, *particularly*, the extent to which the regulation has interfered with distinct investment-backed expectations are, of course, relevant considerations) (emphasis added). In this case there is undisputed confidential evidence in the record demonstrating that with respect to at least one PBM's relationship with one of its provider customers, compliance with the UPDPA's disclosure provisions would have absolutely no economic impact. (Docket No. 89, ¶¶ 140-41.) Thus, PCMA cannot succeed with its facial challenge because it cannot establish that there is no circumstance under which the UPDPA will not effect a taking. Finally, PCMA's allegations that the UPDPA will undermine competition in the market is diluted by the fact that the disclosures called for by the UPDPA are to be made to benefits providers, not to PBMs and, except with respect to drug substitution information, the PBM may impose confidentiality obligations on the recipients of the information.

3. *Character of the governmental action*

PCMA argues that the character of the governmental action at work in the UPDPA is "a naked transfer of wealth by appropriation of property[,] a classic taking." (Docket No. 85 at 26;

Docket No. 103 at 31.) Thus, PCMA argues that the court must find the UPDPA to be an illegitimate exercise of the police power because the state has not offered any benefit to offset the burden imposed on PBMs (Docket No. 85 at 25-26) and because the stated goal of lowering drug costs will not result (Id. at 27). The problem with the first argument is that it conflates the inquiry of whether the State is pursuing a proper objective with the separate inquiry of whether the UPDPA imposes an unconstitutional condition. (Docket No. 85 at 24-26.) If the court cannot determine in the context of this facial challenge that the UPDPA would necessarily effect a taking, how can it make the finding that preconditioning market access on compliance with the UPDPA would impose an unconstitutional condition? The problem with the second argument is that it assumes that it is the province of this court to judge policy issues already addressed, and more appropriately addressed in our system of government, by the Legislature.

The standards assigned by the Supreme Court teach that violations of the Takings Clause are not so readily to be found when interference with property "arises from some public program adjusting the benefits and burdens of economic life to promote the common good." Penn Cent., 438 U.S. at 124. "Government hardly could go on if to some extent values incident to property could not be diminished without paying for every such change in the general law," Pa. Coal Co. v. Mahon, 260 U.S. 393, 413 (1922), and "recognized economic values" could not be adversely affected through the enactment of new laws or government programs, Penn Cent., 438 U.S. at 124. And where personal property is concerned, "regulation can severely undermine [its] economic value . . . and not rise to the level of a taking." Philip Morris, 312 F.3d at 43 (citing Andrus v. Allard, 444 U.S. 51, 66 (1979)). The purpose of the UPDPA is clearly to serve and protect the public health and welfare, whether its execution was ill-conceived or not. Adjusting the benefits and burdens of the prescription drug trade that transpires in this State to ensure

transparency in the sale and purchase of drugs is an appropriate governmental endeavor.¹⁶ The fact that, going forward, PBMs must abide by certain restrictions within that market in connection with the provision of PBM services to Maine "covered entities" simply influences or informs the PBMs' future (*i.e.*, post enactment) contract negotiations with drug manufacturers, pharmacy networks and their benefits provider customers, for future trades in prescription drugs. It does not serve to take the value of present or past contracts for PBM services. Setting these parameters on the provision of PBM services may or may not best serve the interest of the Maine public, but it is not an illegitimate exercise of the police power to regulate with respect to the public health.

D. Unconstitutional condition

In Philip Morris, Judge Torruella concluded that the tobacco disclosure act was invalid as an unconstitutional condition because Massachusetts sought to impose the burden of unrestricted public disclosure of trade secret information on tobacco companies as a precondition to marketing products in the Commonwealth. 312 F.3d at 47. This finding turned entirely on

¹⁶ In the 96th footnote of its memorandum (Docket No. 85 at 27), PCMA makes reference to the UPDPA's statutory requirement that PBMs pass through to their benefits provider customers (covered entities) all benefit or payment received from drug substitution practices or that are based on volume discounts. See 22 M.R.S.A. § 2699(2)(E)(3) & (2)(F). Although PCMA raises these provisions in this fashion, its briefing of the takings claim has focused entirely on the disclosure provisions rather than on the requirement that any benefits or payments from manufacturers be passed through to the PBMs' customers. I do not separately evaluate the constitutionality of these provisions because I conclude that PCMA has waived its challenge to them by its failure to separately brief them. Furthermore, even if these benefit and payment transfer provisions were independently objectionable under the Takings Clause, it would appear that the court could readily sever them from the remainder of the statute. See R.I. Med. Soc'y v. Whitehouse, 239 F.3d 104, 106 (1st Cir. 2001) ("Severability is a matter of state law."); 1 M.R.S.A. § 71(8) ("If any provision of the statutes or of a session law is invalid, or if the application of either to any person or circumstance is invalid, such invalidity does not affect other provisions or applications which can be given effect without the invalid provision or application."); Kittery Retail Ventures, LLC v. Town of Kittery, 2004 ME 65, ¶ 18, 856 A.2d 1183, 1190 ("An invalid portion of a statute or an ordinance will result in the entire statute or ordinance being void only when it is such an integral portion of the entire statute or ordinance that the enacting body would have only enacted the legislation as a whole."). The severability issue has been joined previously, see Pharm. Care Mgmt. Ass'n v. Rowe, 324 F. Supp. 2d 71 (D. Me. 2004) (Order on Defendant's Motion to Amend the Order of Preliminary Injunction), and left unresolved. At least with respect to the UPDPA's two benefit and payment transfer provisions, I conclude that the Attorney General has taken sufficient steps to preserve the matter (Docket No. 100 at 16), particularly when measured against PCMA's failure to directly challenge in its memoranda the constitutionality of these two provisions.

Judge Torruella's prior finding that the disclosure act effected a taking. Id. In this case PCMA has failed to carry the burden of demonstrating a facial taking and, therefore, I recommend that the court reject PCMA's assertion that the UPDPA imposes unconstitutional conditions on PBMs' access to the Maine market for PBM services.

IV. Due Process

PCMA maintains that the UPDPA violates the Due Process Clause because it deprives PBMs of property rights without providing any notice or opportunity to be heard. (Complaint, Docket No. 1, "Count Four," ¶ 68.) PCMA's memorandum of law makes it apparent that this claim is meant to tag along with its takings claim. (Docket No. 103 at 32-33.) Essentially, PCMA's position is that there must be a "predeprivation hearing" before a PBM can be expected to comply with the UPDPA's disclosure provisions. (Id.) See Zinermon v. Burch, 494 U.S. 113, 132 (1990) ("In 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."). I recommend that the court grant summary judgment in favor of the Attorney General on this claim. Because PCMA fails to demonstrate that the UPDPA facially works a taking of PBM property, I conclude that it likewise fails to demonstrate that the UPDPA is facially deficient for want of a predeprivation hearing provision.

V. Commerce Clause

Article I, Section 8, Clause 3 of the Constitution cedes to Congress the power "to regulate Commerce . . . among the several States." The Supreme Court has recognized as implicit within this affirmative grant of power a "negative" or "dormant" aspect that restricts the ability of state and local governments to burden interstate commerce by impeding private trade in the national marketplace through local regulation or taxation. GMC v. Tracy, 519 U.S. 278, 287 (1997).

According to PCMA, the UPDPA violates the Commerce Clause "because the burden it imposes on interstate commerce 'is clearly excessive in relation to the putative local benefits'" (Docket No. 103 at 33, quoting Pike v. Bruce Church, Inc., 397 U.S. 137, 142 (1970)), and because it has an impermissible extraterritorial effect (Id. at 38, relying on Edgar v. MITE Corp., 457 U.S. 624 (1982)). I address the extraterritoriality claim first.

A. Extraterritoriality

Among the various ways that state regulation may run afoul of the Commerce Clause is by having the effect of regulating commercial activity occurring wholly outside of the regulating state. Thus, in MITE, the Supreme Court held that an Illinois securities law that sought to regulate tender offers for the stock of Illinois corporations violated the Commerce Clause because of its "nationwide reach which purports to give Illinois the power to determine whether a tender offer may proceed anywhere." 457 U.S. at 643. Similarly, in Brown-Forman Distillers Corporation v. New York State Liquor Authority, the Supreme Court invalidated a New York wholesale liquor price control regulation because it "[f]orc[ed] a merchant to seek regulatory approval in [New York] before undertaking a transaction in another [state]." 476 U.S. 573, 582 (1986). According to PCMA, the UPDPA has an unconstitutional extraterritorial reach because it "could be applied to [PBM-manufacturer contracts] which would not affect a single [Maine resident]." (Docket No. 103 at 39, paraphrasing MITE, 457 U.S. at 642.) I disagree with this characterization. The UPDPA clearly provides: "Compliance with the requirements of this section is required in all contracts for pharmacy benefits management entered into in this State or by a covered entity in this State." 22 M.R.S.A. § 2699(3). Furthermore, the UPDPA defines "pharmacy benefits management" as "the procurement of prescription drugs . . . for dispensation within this State to covered individual." Id., § 2699(1)(E). Only someone engaged in a highly-

abstract theoretical exercise could seriously maintain that the UPDPA is designed to regulate contracts for pharmacy benefits management services that would not affect a single Maine resident. The obvious import of the provisions just quoted is that the UPDPA applies when a PBM enters into a pharmacy benefits management contract with a Maine covered entity for provision of pharmacy benefits management services that benefit Maine covered individuals.

B. Pike balancing test

Non-discriminatory and non-protectionist regulations that have indirect or incidental effects on interstate commerce are valid unless the party challenging the regulations can demonstrate that “the burden imposed on such commerce is clearly excessive in relation to the putative local benefits.” Bruce Church, 397 U.S. at 142. According to PCMA, the UPDPA imposes burdens that are excessive because “the costs of disclosure . . . could lead to the total curtailment of any PBM cross-border commerce.” (Docket No. 103 at 33.) Other than this threat, PCMA's argument for excessiveness turns entirely on the presupposition that the UPDPA will effect takings of information that would otherwise be given trade secret protection in every other state. (Id. at 33-34.) Because PCMA has failed to support its facial challenge under the Takings Clause, it has likewise failed to provide the court with any great weight to place on the excessive burden side of the scale. This is a failure of proof that warrants an entry of summary judgment against PCMA on this claim. N.H. Motor Transp. Ass’n v. Flynn, 751 F.2d 43, 48 (1st Cir. 1984) (“[T]he burden of proving ‘excessiveness’ falls upon the [plaintiff], not the state.”). As for the “putative local benefits” side of the scale, PCMA argues that the UPDPA will not achieve its purpose of reducing the costs of, and increasing the public's access to, prescription drugs. (Id. at 36.) Even assuming that the likelihood of the UPDPA achieving the State's objectives could be proven in this or any litigation, which I doubt, I do not believe that the

evidence PCMA offers of this likelihood is probative enough, even if all inferences are drawn against the Attorney General as the movant, for the court to presume that it might pass on the wisdom of the healthcare policies adopted by the Legislature in the context of a trial. In any event, the salient point is that the UPDPA is clearly designed to improve public health by increasing access to prescription drugs and, therefore, the *putative* benefit is substantial, quite distinct from the situation in Bruce Church, where the legislation under review involved the "tenuous interest in having . . . cantaloupes identified as originating in Arizona." 397 U.S. at 145. See also Pharm. Research & Mfrs. of Am., 249 F.3d at 84 (finding it a substantial benefit that Maine's Rx Program "will potentially provide prescription drugs to Maine citizens who could not otherwise afford them."). The substantiality of the putative benefit at issue here will support the imposition of some appreciable incidental burdens on interstate commerce. Without the benefit of an established taking on the record, I conclude that the burden of disclosing information to a customer, subject to confidentiality, is not "clearly excessive" in relation to the putative local benefit of "a novel legislative approach to one of the serious problems of our time." Pharm. Research & Mfrs. of Am., 249 F.3d at 80.¹⁷

VI. Free Speech

The seventh count of PCMA's complaint concerns the First Amendment. According to PCMA, the UPDPA violates the First Amendment because it compels PBMs to engage in commercial speech by mandating disclosure of their confidential business information to those they would not voluntarily communicate the information to. (Docket No. 103 at 41.) The Attorney General argues that the First Amendment has nothing to do with a mandatory

¹⁷ I am also not persuaded that the economic impact faced by PBMs necessarily presents anything more than "possible effects on the profits of the individual [PBMs]," Pharm. Research & Mfrs. of Am., 249 F.3d at 84, something that is distinct from a burden on interstate commerce. See id.

disclosure law and, alternatively, that the disclosures called for in the UPDPA serve an appropriate government interest. (Docket No. 88 at 47.)

""[C]ommercial speech [enjoys] a limited measure of protection, commensurate with its subordinate position in the scale of First Amendment values,' and is subject to 'modes of regulation that might be impermissible in the realm of noncommercial expression.'" Bd. of Trs. v. Fox, 492 U.S. 469, 477 (1989) (quoting Ohralik v. Ohio State Bar Ass'n, 436 U.S. 447, 456 (1978)). Broadly stated, "commercial speech compelled by government is governed by a . . . set of principles which require a court to balance a number of factors according to its judgment concerning the welfare of buyers and sellers in the market place." United Foods, Inc. v. United States, 197 F.3d 221 (6th Cir. 1999). First Amendment protections are implicated not only by regulations designed to restrict a person's right to speak freely, but also by regulations that would compel speech and thus override a person's "right to refrain from speaking at all." Wooley v. Maynard, 430 U.S. 705, 714 (1977). Because the UPDPA undeniably compels commercial speech, I disagree with the Attorney General's suggestion that the UPDPA is not subject to First Amendment scrutiny. However, there does not appear to be any clear precedent for the situation presented herein; those in the business of selling goods and services do not appear to have often raised First Amendment challenges to statutes forcing disclosures pertaining to the services being sold.

Loosely analogous to this case are those Supreme Court precedents in which the Court has reviewed state and federal regulations that exact monetary contributions from businesses in order to fund government advertising campaigns that are, ostensibly, supposed to benefit the entire industry that is subject to the regulation. See, e.g., United States v. United Foods, Inc., 533 U.S. 405 (2001) (holding unconstitutional a state regulatory scheme that mandated that fresh

mushroom handlers pay assessments to a state "Mushroom Council" to fund generic advertisements promoting mushroom consumption). For such cases, the Supreme Court has developed the rule that compelled contributions are generally constitutional when the industry at issue is characterized by a cooperative or collectivist market (such as the professional bar or a cooperative agricultural market subject to regulation that displaces competition) in which group action is deemed necessary to maintain a stable market, but unconstitutional where the only impetus behind the regulation is to ensure an adequate subsidy for the government's advertising campaign. Id. at 414-15. This line of demarcation appears to reflect the position that the government may not compel commercial speech or subsidization of commercial speech simply because it believes the commercial speech will serve the interest of those supplying the subsidy. In my view, because the UPDPA compels speech in order to advance the public good, those cases involving regulatory restrictions on commercial speech for public purposes are more analogous to the current situation than are the compelled advertising cases such as United Foods.

In Zauderer v. Office of Disciplinary Counsel, the Supreme Court reviewed the constitutionality of reprimands imposed on an attorney for certain newspaper advertisements he ran to attract clients. 471 U.S. 626 (1985). Zauderer illustrates how the constitutionality of restrictions on advertising generally turn on the government's ability to tie the restriction to concern over preventing "the dissemination of commercial speech that is false, deceptive, or misleading." Id. at 638. However, also recognized by the Court is the ability of the states to restrict commercial speech that is not false, deceptive or misleading so long as the restriction is imposed "in the service of a substantial governmental interest" and the means chosen "directly advance that interest." Id. The logical corollary to these rules is that states may also compel the dissemination of commercial speech in order to ensure that other commercial speech is not false,

deceptive or misleading, or in order to serve a substantial government interest, regardless of concerns over deception. Thus, states have broad authority to regulate the content of speech that is designed "to solicit or obtain legal business" in order to advance a substantial governmental interest. Id. at 641. Moreover, where a mere "disclosure requirement" is imposed, rather than a restriction on speech, the Supreme Court has held that the standard is lowered somewhat because a business's "interest in *not* providing any particular factual information in . . . advertising is minimal." Id. at 651. Thus, the Court has emphasized that "disclosure requirements trench much more narrowly on an advertiser's interest than do flat prohibitions on speech" and that disclosure requirements need only be "reasonably related" to advancing the governmental interest at issue. Id.

The Attorney General argues that the UPDPA's disclosure provisions are designed to overcome the potential conflict of interest that PBMs have to collude with drug manufacturers to increase the prescription drug costs imposed on benefits providers and their sponsors and subscribers ("covered entities" and "covered individuals" under the UPDPA), insofar as manufacturers afford monetary incentives for PBMs to manipulate their formularies or use drug switching programs and other practices to ensure a certain volume of purchases for a specific manufacturer's drugs, regardless of the cost effectiveness of such practices for the ultimate consumers. (Docket No. 88 at 47-48.) The Attorney General maintains that there is no doubt as to "the potential for conflicts and deceptive practices by PBMs," citing a handful of cases decided by this court and others and a consent order entered into by Medco and the Attorney General's Office.¹⁸ (See id. at 48.) In the Attorney General's words:

¹⁸ The Attorney General also points to a proclamation issued by Medco that its goal is "to position Medco as the most transparent company in [the] industry." (Docket No. 88 at 49, citing Docket No. 89, ¶¶ 187-188.)

Maine has chosen to [control costs and increase access] by providing information to the entity that is responsible for paying the cost of those drugs and is in the best position to protect the interests of Maine citizens; with that information, obtained from the PBM with which it contracts, the covered entity will be able to enter negotiations with a full picture of the PBM's arrangements.

(Id.) There is no question in this case but that the UPDPA is designed to serve a substantial governmental interest: increasing public access to prescription drugs. Thus, the only question is whether compelling PBMs to disclose confidential information to their provider customers, subject to confidentiality restrictions on further dissemination, is reasonably related to advancing the governmental interest the UPDPA is designed to achieve. I conclude that requiring PBMs to confidentially disclose to their provider customers: "financial and utilization information" regarding the services they provide, subject to confidentiality, 22 M.R.S.A. § 2699(2)(D); the costs of drugs involved in a drug substitution where the substituted drug is more expensive than the originally prescribed drug, id., § 2699(2)(E)(2); the financial incentive offered by the manufacturer for substituting its drug for another manufacturer's drug, if any, id.; and the "financial terms and arrangements for remuneration" that PBMs negotiate with manufacturers and pharmacies, subject to confidentiality, is reasonably related to controlling the cost of prescription drugs in Maine because it is 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. As argued by the Attorney General, the UPDPA essentially has the effect of imposing on entities seeking to sell pharmacy benefits management services within the State of Maine, the fiduciary duties of full disclosure and, with respect to drug substitution practices, non-self-dealing. Because the imposition of the duties to disclose financial information, subject to confidentiality, is reasonably related to the

substantial governmental interests that invigorate the UPDPA,¹⁹ I conclude that PCMA cannot sustain its facial free speech challenge and summary judgment should enter in favor of the Attorney General on this claim.

VII. 42 U.S.C. § 1983

Because I have concluded that the UPDPA does not violate any of the federal rights raised by PCMA, I recommend that summary judgment enter in favor of the Attorney General on the 42 U.S.C. § 1983 claim as well. PCMA argues that summary judgment cannot be entered on this claim, even if summary judgment is entered against all of the substantive claims, because there remains the question whether post-injunction amendments to the UPDPA²⁰ confer "prevailing party" status on PCMA for purposes of its pending motion for attorney's fees under 42 U.S.C. § 1988. (Docket No. 103 at 46.) I fail to see why the motion for fees requires the court to withhold the entry of judgment on this substantive claim and PCMA's memorandum fails to provide me with any rationale why the court should manage its docket in that fashion.

CONCLUSION

For the reasons stated herein, I **RECOMMEND** that the court **GRANT** the Attorney General's motion for summary judgment and **DENY** PCMA's motion for summary judgment.

¹⁹ To the extent that the applicable standard is in question, I also conclude that, for the same reasons, the means put in place by the UPDPA "directly advance" the substantial governmental interest of reducing the cost of, and increasing access to, prescription drugs. In other words, regardless of whether the UPDPA presents the "best" approach that might ever be conceived, there is:

a "fit" between the legislature's ends and the means chosen to accomplish those ends – a fit that is not necessarily perfect, but reasonable; that represents not necessarily the single best disposition but one whose scope is in proportion to the interest served; that employs not necessarily the least restrictive means but . . . a means narrowly tailored to achieve the desired objective.

Bd. of Trs v. Fox, 492 U.S. at 480 (internal quotation marks and citation omitted).

²⁰ The State amended the UPDPA in certain respects after the court granted PCMA's motion for preliminary injunction. The parties' cross-motions for summary judgment both address the constitutionality of the statute as amended.

NOTICE

A party may file objections to those specified portions of a magistrate judge's report or proposed findings or recommended decisions entered pursuant to 28 U.S.C. § 636(b)(1)(B) for which *de novo* review by the district court is sought, together with a supporting memorandum, and request for oral argument before the district judge, if any is sought, within ten (10) days of being served with a copy thereof. A responsive memorandum and any request for oral argument before the district judge shall be filed within ten (10) days after the filing of the objection.

Failure to file a timely objection shall constitute a waiver of the right to *de novo* review by the district court and to appeal the district court's order.

/s/ Margaret J. Kravchuk
U.S. Magistrate Judge

Dated February 2, 2005

PHARMACEUTICAL CARE MANAGEMENT
ASSOCIATION v. ATTORNEY GENERAL, ME
Assigned to: JUDGE D. BROCK HORNBY
Cause: 28:2201 Declaratory Judgement (Insurance)

Date Filed: 09/03/2003
Jury Demand: None
Nature of Suit: 950 Constitutional -
State Statute
Jurisdiction: Federal Question

Plaintiff

**PHARMACEUTICAL CARE
MANAGEMENT ASSOCIATION**

represented by **JOHN J. AROMANDO**
PIERCE, ATWOOD LLP
ONE MONUMENT SQUARE
PORTLAND, ME 04101-1110
791-1100
Email:
jaromando@pierceatwood.com
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

PAUL J. ONDRASIK, JR.
STEPTOE & JOHNSON
1330 CONNECTICUT AVENUE,
N.W.
WASHINGTON, DC 20036-1795
202-429-8088
Email: pondrasik@steptoe.com
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

CATHERINE R. CONNORS
PIERCE, ATWOOD LLP
ONE MONUMENT SQUARE
PORTLAND, ME 04101-1110
791-1100
Email: cconnors@pierceatwood.com
ATTORNEY TO BE NOTICED

MARTIN D. SCHNEIDERMAN
STEP TOE & JOHNSON
1330 CONNECTICUT AVENUE,
N.W.
WASHINGTON, DC 20036-1795
202-429-6282
Email: mschneiderman@step toe.com
ATTORNEY TO BE NOTICED

V.

Defendant

ATTORNEY GENERAL, ME

represented by **RONALD W. LUPTON**
MAINE ATTORNEY GENERAL'S
OFFICE
STATE HOUSE STATION 6
AUGUSTA, ME 04333
207-626-8800
Email: ronald.lupton@maine.gov
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

ANDREW L. BLACK
MAINE ATTORNEY GENERAL'S
OFFICE
STATE HOUSE STATION 6
AUGUSTA, ME 04333
206-626-8835
Email: andrew.black@maine.gov
ATTORNEY TO BE NOTICED

PAUL STERN
ASSISTANT ATTORNEY
GENERAL
STATE HOUSE STATION 6
AUGUSTA, ME 04333-0006

626-8800
Email: paul.d.stern@maine.gov
ATTORNEY TO BE NOTICED