UNITED STATES DISTRICT COURT
DISTRICT OF MAINE

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION,	)	
Plaintiff	)	
v.	)	**Civ. No. 03-153-B-W**
G. STEVEN ROWE, IN HIS OFFICIAL CAPACITY AS ATTORNEY GENERAL OF THE STATE OF MAINE,	)	
Defendant	)	

ORDER GRANTING MOTION FOR PRELIMINARY INJUNCTION

On September 3, 2003, the Plaintiff, Pharmaceutical Care Management Association ("PCMA"), filed a Complaint in this Court against the Defendant, G. Steven Rowe, in his official capacity as Attorney General of the State of Maine ("State"), seeking declaratory and injunctive relief from "An Act To Protect Against Unfair Prescriptive Drug Practices" ("UPDPA"), 22 M.R.S.A. § 2699. With the filing of the Complaint, PCMA filed a Motion for Preliminary Injunction. This Court GRANTS the Motion for Preliminary Injunction.

I. Facts and Procedural History

a. Background

The pharmaceutical industry in the United States lies at the center of a complex public policy controversy about the delivery and cost of health care. This lawsuit is a symptom of a larger debate about access, affordability, and efficacy within the American health care system and tests the limits of state attempts to legislate a response. Located in Washington, D.C., PCMA is a

trade association of pharmaceutical benefits management companies ("PBMs"). PBMs administer prescriptive drug benefit plans for the more than 200 million Americans covered by the Employee Retirement Income Security Act of 1974 ("ERISA"), 29 U.S.C. §§ 1001-1461, and non-ERISA health care plans, self-insured employers, union-sponsored plans, and federal, state, and local government purchasers. They have become a central force in the $175 billion national market for prescription drugs.[1]

PCMA and the State draw strikingly different portraits of the PBM industry. PCMA sees its members as engaging in extraordinarily fierce, industry-wide competition and playing a vital role in the delivery of cost-effective, quality care. PCMA cites studies that indicate its members have saved billions of dollars for their customers and, ultimately, for consumers. PCMA also emphasizes its members' central role in the provision of quality health care: by organizing and rationalizing vast amounts of nationally-based data, the PBMs have been in a unique position to perform drug utilization reviews; avoid dangerous drug combinations, questionable doses, and excessive addictive medications; and engage in medical and pharmacy education.

[1] To describe, even briefly, the role of PBMs in the American health care system takes a moment. After a physician prescribes a drug and the patient presents the prescription to a pharmacy, the insured portion of the bill (after any co-pays or deductibles) is forwarded to a health maintenance organization ("HMO"), an employer, or an insurer for payment. These third-party payors have commonly entered into contracts with PBMs to process prescription drug payments. When PBMs first appeared on the national scene more than thirty years ago, they offered a niche service to third-party payors: computerized processing of prescriptive drug bills. The PBMs, in essence, became efficient financial intermediaries among third-party payors, pharmacies, and drug companies.

This has become no small service. As prescriptive medicine has become more vital to the provision of quality health care, it has assumed an ever-increasing percentage of the overall health care dollar. At the same time, third-party reimbursement mechanisms have become bewilderingly complex. The PBMs' niche has evolved as a consequence of enormous market forces, thaumaturgic scientific breakthroughs, spiraling health care costs, and Byzantine reimbursement formulas.

As time passed, however, PBMs have begun to offer more to their clients than efficient claims handling. By amalgamating the economic weight of their clients, the PBMs began to approach drug companies and pharmacies and negotiate significant volume discounts or rebates. The PBMs now offer a wide range of services, including rebate programs, pharmacy networks, and drug utilization reviews. Instead of remaining on the sidelines as quiet claims processors, the PBMs have themselves emerged as major players in the health care system with their own undeniable economic clout.

By contrast, the State sees the PBMs as a highly-concentrated industry, insulated from competitive pressures and garnering enormous profits in an unregulated and secretive niche. The State minimizes the PBMs' role in assuring quality care. It notes that the PBMs (with the exception of mail order services) do not handle drugs, do not purchase or sell drugs, do not prescribe drugs, do not act as insurers, and do not assume risk. In response to PCMA's point about drug utilization reviews, the State raises concerns about the use of "switching" or "intervention" strategies.[2]

The State contends that unlike virtually every other area of the health care system, PBMs have largely escaped governmental scrutiny. They are not regulated as financial institutions, health care providers, or insurance companies, and have in the past consistently maintained they are not subject to ERISA. This asserted regulatory gap has begun to attract the attention of federal and state government and the State contends the recent Maine legislation is only a harbinger of things to come. The PBMs vigorously deny what they contend are the "scattershot," "inflammatory," and "egregious mischaracterizations" set forth in the State position. *Pl.'s Reply Mem.* at 1-2.

[2] Again, to understand this allegation takes a moment. The State alleges the PBMs and the drug companies have made what amounts to a devil's bargain: in exchange for volume discounts and rebates relinquished by drug manufacturers, the PBMs agree to promote that manufacturer's drugs and, by doing so, receive a financial reward. Thus, when a physician prescribes one drug brand and the pharmacy begins to fill it, the PBM may seek to influence the choice by steering toward the favored drug manufacturer. Although this practice may inure to the benefit of the client and customer, there are instances when the PBMs engage in "low-to-high" switching, whereby the drug manufacturer pays the PBM to switch patients from less expensive to more expensive drugs. The State claims the PBMs employ scores of pharmacists whose sole function is to review computerized records and contact prescribers to persuade them to switch drugs for individual patients.

The State portrays these arrangements between the PBMs and drug companies as an undisclosed conflict of interest. The State claims the size and terms of these undisclosed paybacks are uniformly concealed from the PBMs clients and the lion's share of PBM profits come not from the covered entities, but from drug company payments deliberately concealed from their clients. A report by the Maine Legislature's Health and Human Services Committee estimated the PBMs receive $12.2 billion in undisclosed payments from drug manufacturers each year. Although acknowledging there are many PBMs, the State asserts that the industry as a whole is highly concentrated with four, soon to be three, companies controlling the national market and enjoying unusual levels of profitability.

b. Maine Legislation.

The UPDPA was enacted by the Maine Legislature in 2003 and signed into law by Governor Baldacci on June 13, 2003. The UPDPA itself is succinct, containing only one new statutory section: 22 M.R.S.A. § 2699. The UPDPA consists of a series of definitions and a list of "required practices." A violation of the UPDPA constitutes a violation of the Maine Unfair Trade Practices Act ("UTPA") and subjects the violator to a fine of not more than $10,000. 22 M.R.S.A. § 2699(4).

The UPDPA's dramatic impact on the PBM industry is immediately apparent. It statutorily defines the relationship between a PBM and its clients as a fiduciary relationship, imposing a "fiduciary duty" running from the PBM to each "covered entity." 22 M.R.S.A. §§ 2699(2)(A), (B). The UPDPA imposes extensive duties of disclosure from the PBM to the client, including the duty to disclose: (1) any "conflict of interest"; (2) "all financial and utilization information requested by the covered entity relating to the provision of benefits"; and, (3) "all financial terms and arrangements for remuneration of any kind that apply between the [PBM] and any prescription drug manufacturer or labeler, including, without limitation, formulary management and drug-switch programs, educational support, claims processing and pharmacy network fees. . . ." 22 M.R.S.A. §§ 2699(2)(D)-(E), (G).

While the UPDPA allows a PBM to substitute a lower-priced generic drug for a therapeutically equivalent higher-priced prescriptive drug, 22 M.R.S.A. § 2699(2)(E)(1), it prohibits the PBM from substituting a higher-priced drug for a lower-priced drug unless the substitution is made "for medical reasons that benefit the covered individual" and the "covered entity," 22 M.R.S.A. § 2699(2)(E)(2). The UPDPA also imposes disclosure and approval obligations on the PBM before doing so. *Id.* Finally, the UPDPA mandates that any benefit the

PBM receives from switching to higher-priced drugs or from volume discounting must be passed "in full" to the covered entity. 22 M.R.S.A. §§ 2699(2)(E)(3), (F). The UPDPA contains a limited confidentiality provision, as well: if a covered entity requests financial and utilization information, the PMB may designate the information as confidential and the covered entity is required not to disclose the information except as required by law. 22 M.R.S.A. § 2699(2)(D).

c. Preliminary Injunction Standard.

PCMA's Motion for Preliminary Injunction rests on three theories: (1) preemption under ERISA; (2) unlawful taking of trade secrets in violation of the Takings Clause of the United States Constitution; and (3) a violation of the Commerce Clause of the United States Constitution.

As a plaintiff in a motion for preliminary injunction, PCMA bears the burden of satisfying each element of a familiar four-part test: (1) it must be likely to succeed on the merits; (2) it must suffer from immediate irreparable injury without injunctive relief; (3) the harm to the plaintiff in the absence of an injunction must exceed the harm to the defendant if the injunction is not granted; and, (4) the public interest must be better served by granting the injunction than by denying it. *Pharmaceutical Research & Mfrs. of Am. v. Concannon*, 249 F.3d 66 (1st Cir. 2001) ("*PhRMA I*"), *aff'd*, *Pharmaceutical Research & Mfrs. of Am. v. Walsh*, 123 S. Ct. 1855 (2003) ("*PhRMA II*"); *New Comm. Wireless Serv., Inc. v. Spintcom, Inc.*, 287 F.3d 1, 8-9 (1st Cir. 2002).

In evaluating a motion for preliminary injunction in which the plaintiff is claiming constitutional infirmity and federal preemption, the court must apply some bedrock interpretive principles. First, this Court is required not only to presume the state legislative act is constitutional, but also to apply this presumption with special force, since the UPDPA seeks to

regulate an area of public health. *See PhRMA II*, 123 S.Ct. at 1867; *Hillsborough County v. Automated Med. Lab., Inc.*, 471 U.S. 707 (1985). Second, this Court is charged with avoiding a declaration of unconstitutionality if there is an alternative interpretation that would render the UPDPA lawful. These general principles apply more particularly to a motion for preliminary injunction. Finally, when addressing federal preemption, if the field Congress is said to have preempted has traditionally been occupied by the States, this Court must start with the assumption that the historic powers of the States are not to be superseded by the federal act unless that was the "clear and manifest purpose of Congress." *Hillsborough*, 421 U.S. at 715; *PhRMA I*, 249 F.3d at 75.

II. Likelihood of Success on Merits.[3]

a. Standing.

As a preliminary matter, this Court must address PCMA's associational standing to pursue this action on behalf of its member.[4] Under certain circumstances, injury to an organization's members will satisfy the Article III requirement of a case or controversy and the organization will be allowed to litigate in federal court on their behalf. *E.g., United Food & Com. Workers Union Local 751 v. Brown Group*, 517 U.S. 544, 551 (1996); *International Union, United Auto, Aerospace and Agric. Implement Workers of Am. v. Brock*, 477 U.S. 274, 281 (1986); *NAACP v. Alabama ex rel. Patterson*, 357 U.S. 449, 459 (1958). There are three

[3] This Court will not consider language not used in the final version of the UPDPA as indicative of legislative intent. *See, e.g., Availl Serv. Inc. v. Cooper Ind., Inc.*, 263 F.3d 134 (5th Cir. 2001) (stating court should limit reliance on legislative history to that part of history that Congress adopts into law); *United States v. Fox*, 845 F.2d 152 (7th Cir. 1988) (holding that deletion of language moots weight otherwise given to legislative history regarding that language); *Cairns v. Franklin Mint Co.*, 120 F.Supp. 2d 880 (C.D. Cal. 2000) (noting state court readings of deleted language as persuasive that such provisions should not be read into law).

[4] In its response, the State has questioned whether PCMA has standing to raise a takings issue for its members. As the absence of associational standing would bar PCMA from bringing any of its claims on behalf of its members, not just the takings clause claim, the Court will address the issue of standing before considering the claims themselves.

elements of associational standing: (1) association members must have standing to sue in their own right; (2) the interests sought to be protected must be germane to the purposes of the association; and (3) neither the relief requested nor the claim asserted requires the individual members' participation. *Hunt v. Washington State Apple Adver. Comm'n,* 432 U.S. 333, 343 (1977) (quoting *Warth v. Seldin*, 422 U.S. 490, 511 (1975)). The parties agree that the first two criteria are present; the State challenges whether the third is.

If the plaintiff claiming associational standing can ensure that "the remedy, if granted, will inure to the benefit of those members of the association actually injured," the association will be allowed to invoke the remedial powers of the court on behalf of its members. *Brock,* 477 U.S. at 288 (1986) (quoting *Warth,* 422 U.S. at 515 (1975)). Whether an association has standing for its members "depends in substantial measure on the nature of the relief sought." *Hunt,* 432 U.S. at 343. In this case, PCMA is seeing declaratory and injunctive relief and it "can be reasonably supposed that the remedy, if granted, will inure to the benefit of those members of the association actually injured." *Id.*

The First Circuit considered associational standing in the context of a motion for preliminary injunction in *Camel Hair & Cashmere Institute, Inc. v. Associated Dry Goods Corp.*, 799 F.2d 6, 12 (1st Cir. 1986). In *Camel Hair*, the First Circuit noted that "actions for declaratory, injunctive and other forms of prospective relief have generally been held particularly suited to group representation." *Id.* In addition, the *Camel Hair* Court distinguished "between the showing required to establish a right to injunctive relief and that required to establish a right to damages." *Id.* Generally, where, as in this case, the court is addressing only the question of preliminary injunctive relief, the participation of individual members is not necessary.[5] *Id.*

[5] The State contends not all PCMA members have taken the same position on the secrecy of the information the UPDPA mandates they disclose. It cites the "client principles" from PCMA member AdvancePCS, which state it

This Court concludes that PCMA has fulfilled the criteria set forth in *Hunt* and has associational standing to press its members' claims for declaratory and injunctive relief. Although there may be some differences among the PBMs as to their treatment of the financial and rebate information, the Court is persuaded that all PBMs view this information as a highly confidential trade secret. For associational standing purposes, the key is whether there is a nexus between the members' commonality and the remedy their association seeks. *Camel Hair*, 799 F.3d at 12 (finding "no conflict between the needs and interests of the members."). In this case, it is clear there is such a nexus. The members share the view that the information the UPDPA would disclose goes to the heart of their mutual competition and PCMA seeks an injunction against its revelation. Put another way, if there were evidence that the members were sufficiently disparate in their approach to trade secrets to conclude that some would gain a competitive edge by disclosure, then this would undercut PCMA's claim for associational standing. However, the evidence before the Court is exactly to the contrary: all PCMA members support its demand for relief. [6]

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views all rebates as the property of its clients and allows the client to audit the rebate amounts down to the transaction level. Similarly, the State points out that PCMA member Express Scripts, Inc., allows full audits by its clients. These differences, the State contends, negate PCMA's claim of associational standing, since enforcement of the UPDPA would affect its members differently. PCMA responded with supplemental declarations from Susan de Mars of AdvancePCS and Edward Ignaczak of Express Script, explaining that their companies require the auditors performing the rebate audits to sign confidentiality agreements and complete the review at their company offices. These auditing procedures are insufficient to convince this Court that the UPDPA disclosures would affect PCMA members differently.

[6] In *Rent Stabilization Association v. Dinkins*, 5 F.3d 591 (2d Cir. 1993), the Second Circuit discussed the *Hunt* criteria in the context of a takings claim. Noting that *Hunt* mandates "*neither the claim asserted* nor the relief requested" require the participation of the individual members (emphasis in *Rent Stabilization*), the Second Circuit concluded that because a takings claim commonly mandates an essentially *ad hoc*, factual inquiry, associational standing could not be granted to an association of 25,000 building owners because the law would necessarily affect each owner differently. *Rent Stabilization*, 5 F.3d at 597 (citing *Kaiser Aetna v. United States*, 444 U.S. 164, 175 (1979)). The *Rent Stabilization* holding does not prohibit the grant of associational standing in this case. Here, PCMA's members are readily identifiable. Further, even though there may be some differences in the exact way the UPDPA's mandated disclosures could affect individual members, this Court concludes that the UPDPA's disclosures would not only injure each member, but that the requested remedy would "inure to the benefit of those members of the association actually injured." *Warth*, 422 U.S. at 515; *see infra* note 17 (discussing facial and as-applied claims).

b. Commerce Clause.

PCMA claims the UPDPA violates the Commerce Clause, by having extraterritorial effect and discriminating against out-of-state companies in favor of in-state companies. This Court disagrees. Under the Commerce Clause, Congress has the power "to regulate commerce with foreign nations, and among the several states, and with the Indian tribes." U.S. Const. art I, § 8. In matters not governed by federal legislation, the Commerce Clause has long been understood to have a "negative" aspect that denies the States the power unjustifiably to discriminate against or burden the interstate flow of articles of commerce. *See Oregon Waste Sys., Inc. v. Dep't of Envtl. Quality*, 511 U.S. 93, 98 (1994); *Wyoming v. Oklahoma*, 502 U.S. 437, 454 (1992); *Welton v. Missouri*, 91 U.S. 275 (1876). This negative command, known as the dormant Commerce Clause, prohibits states from acting in a manner that burdens the flow of interstate commerce. *Id.*; *PhRMA I*, 249 F.3d at 79.

i. *Per Se* Violation: Extraterritorial Reach.

PCMA asserts that § 2699(1)(E) of the UPDPA impermissibly affects commerce outside Maine by requiring the disclosure of trade secrets contained in PCMA members' contracts, even if those contracts do not relate to Maine's "covered entities." As such, PCMA argues the UPDPA projects Maine legislation into other states by mandating disclosure of PBMs' confidential contracts in those states. *Pl.'s Mem.* at 23 (citing *Healy v. Beer Inst.*, 491 U.S. 324, 334 (1989)).

A state statute is a *per se* violation of the Commerce Clause when it has an "extraterritorial reach;" that is, necessarily requiring out-of-state commerce to be conducted according to in-state terms. *PhRMA I*, 249 F.3d at 79; *Healy*, 491 U.S. at 336. PCMA does not appear to argue that the UPDPA constitutes a *per se* violation of the Commerce Clause and, to

the extent the argument is being made, there has been no showing that the UPDPA regulates commerce wholly outside Maine's borders. *See id.*

PCMA argues the UPDPA would impermissibly regulate PBM services outside of Maine, since it requires disclosure of PBM contracts with drug manufacturers even if the contracts do not relate to Maine "covered entities." In this Court's view, the UPDPA clearly ties its reach to Maine. The statute limits PBM obligations to a "covered entity" as:

> . . . [A] nonprofit hospital or medical service organization, insurer, health coverage plan or heath maintenance organization *licensed pursuant to Title 24 or 24-A*; a health program *administered by the department or the State* in the capacity of provider of health coverage; or an employer, labor union or other group of persons *organized in the State* that provides health coverage to covered individuals *who are employed or reside in the State*.

22 M.R.S.A. § 2699(1)(A) (emphasis added).

The disclosure provisions of the UPDPA rely on the statute's definition of "covered entity" and, accordingly, are tied to Maine. For instance, § 2699(2)(D)[7] requires the PBM to provide to the covered entity, upon request, "all financial and utilization information requested by the *covered entity* relating to the provision of benefits to covered individuals through that

[7] 22 M.R.S.A. § 2699(2)(D) provides:

> A pharmacy benefits manager owes a fiduciary duty to a covered entity and shall discharge that duty in accordance with the provisions of state and federal law.
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> .....
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> D. A pharmacy benefits manager shall provide to a covered entity all 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. A pharmacy benefits manager providing information under this paragraph may designate that material as confidential. Information designated as confidential by a pharmacy benefits manager and provided to a covered entity under this paragraph may not be disclosed by the covered entity to any person without the consent of the pharmacy benefits manager, except that disclosure may be made in a court filing under the Maine Unfair Trade Practices UPDPA or when authorized by that UPDPA or ordered by a court of this State for good cause shown.

covered entity and all financial and utilization information relating to services to that *covered entity*." (emphasis added). Likewise, § 2699(2)(G)[8] mandates disclosure to the covered entity of "all financial terms and arrangements for remuneration of any kind that apply between the pharmacy benefits manager and any prescription drug manufacturer or labeler. . . ." Though § 2269(2)(G) is not by its express terms limited to disclosure of contracts between PBMs and manufacturers that directly relate to covered entities, the disclosure requirements are set forth as part of the fiduciary duties a PBM owes a "covered entity."

The UPDPA also establishes that compliance 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). If the PBM does not contract with Maine covered entities, the law has no application. The Maine UPDPA is not seeking to "project its legislation" into other States.[9] *See Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511, 521 (1935); *PhRMA*, 123 S.Ct. at 1870-71.

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[8] 22 M.R.S.A. § 2699(2)(G) provides:

> A pharmacy benefits manager owes a fiduciary duty to a covered entity and shall discharge that duty in accordance with the provisions of state and federal law.
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> .....
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> G. A pharmacy benefits manager shall disclose to the covered entity all 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.

[9] PCMA argues that disclosure of trade secrets for "covered entities" in Maine could "expose trade secret information relevant to the PBM's commercial relationships in other States–depriving PBMs of the competitive advantages they have in those jurisdictions that derive from their trade secrets." *Pl.'s Reply Mem.* at 23. But, as the First Circuit said in *PhRMA I*, "simply because the manufacturers' profits might be negatively affected by the Maine UPDPA . . . does not necessarily mean that the Maine UPDPA is regulating those profits." 249 F.3d at 82. The fact a law may have a potentially devastating effect on a particular interstate firm is not sufficient to rise to a Commerce Clause burden. *Id.* (citing *Instructional Sys., Inc. v. Computer Curriculum Corp.*, 35 F.3d 813, 827 (3rd Cir. 1994)). Where the burden on out-of-state interests rises no higher than that placed on competing in-state interests, it is a burden on *commerce* rather than a burden on *interstate* commerce. *Id.* The fact the State regulated indiscriminately supports the conclusion that the Commerce Clause has not been violated. *Id.*

ii. Virtually *Per Se* Rule: Discriminatory Against Out-Of-State Commerce.

If a state statute discriminates against interstate commerce, the Court will apply strict scrutiny under what the Supreme Court has termed the "virtually *per se* rule of invalidity." *Oregon Waste*, 511 U.S. at 100; *Brown-Forman Distillers Corp. v. N.Y. State Liquor Authority*, 476 U.S. 573, 579 (1986); *PhRMA I*, 249 F.3d at 80. This level of scrutiny will be applied "if the state statue discriminates against interstate commerce on its face or in practical effect." *PhRMA I*, 249 F.3d at 80. On its face, the UPDPA does not favor in-state economic interests over out-of-state interests; therefore, the line of case law that addresses facially discriminatory state statutes is inapposite.[10]

PCMA argues, however, the UPDPA favors an in-state Maine pharmacy over an out-of-state mail order pharmacy, since it expressly addresses the "mail service pharmacy," § 2699(2)(E)(1), but not the retail pharmacy. Yet, none of the mail order pharmacies affiliated with PCMA members are physically located in Maine and PCMA does not state or imply that no mail order pharmacies are located in Maine.[11] At the very least, PCMA has failed to sustain its burden on this issue. The UPDPA "regulates evenhandedly with only 'incidental' effects on interstate commerce" and does not "discriminate against interstate commerce either on its face or

[10] *See, e.g., Oregon Waste*, 511 U.S. at 93 (Oregon statute imposed higher disposal fee on out-of-state waste); *Wyoming*, 502 U.S. at 437 (Oklahoma statute required Oklahoma electric plants to burn a mixture of coal containing at least 10 percent Oklahoma-mined coal); *New Energy Co. v. Limbach*, 486 U.S. 269 (1988) (Ohio statute awarded tax credit against Ohio fuel sales tax for ethanol produced in Ohio or to out-of-state producers only if the other State granted similar credits); *Lewis v. BT Inv. Managers, Inc.*, 447 U.S. 27 (1980) (Florida statute favored in-state businesses over businesses with principal operations outside Florida).

[11] The State points out in its memorandum that PCMA could not demonstrate there are no mail order pharmacies located in Maine. *Def.'s Mem.* at 39.

in practical effect."[12] *See Oregon Waste*, 511 U.S. at 99; *Hughes v. Oklahoma*, 441 U.S. 322, 336 (1979).

iii. *Pike v. Bruce Church* Analysis.

Although PCMA did not make a *Pike v. Bruce Church* argument in its initial memorandum, it did so in rebuttal. *Pike* explained that where a state statute regulates evenhandedly and has only incidental effects on interstate commerce, the court balances the burden on interstate commerce against the putative local benefit. 397 U.S. 137, 142 (1970); *PhRMA I*, 249 F.3d at 80. In this Court's view, the potential benefit to Maine consumers in reducing the enormous burden of prescriptive medication substantially outweighs the incidental impact the UPDPA may have upon interstate commerce.

c. Takings Clause.

PCMA contends that by requiring revelation of its members' trade secrets, the UPDPA constitutes a "taking" of property for which just compensation is due under the Fifth and Fourteenth Amendments of the United States Constitution. Specifically, PCMA challenges the two provisions of the UPDPA that mandate disclosure of information: § 2699(2)(D) and § 2699(2)(G).[13] The Takings Clause claim requires an analysis of several separate issues.

i. Trade Secret.

First, this Court must determine whether the information required to be disclosed under the UPDPA constitutes a trade secret. The PBMs' trade secrets include the confidential terms of contracts with customers, drug manufacturers, and pharmacies as well as financial and utilization

[12] *See supra* note 9.

[13] *See supra* notes 7, 8.

information. The State contends that the information is simply not a trade secret,[14] arguing that a trade secret is not information "as to a single or ephemeral events in the conduct of the business, as, for example, the amount or other terms of a secret bid for a contract." *Def.'s Mem.* at 27 (citing *Restatement of Torts: Liability For Disclosure or Use of Another's Trade Secret*, § 757 cmt. b (1939)). However, intangible property can constitute a trade secret and a property right protected by the Takings Clause, *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1003-04 (1984), the first question is whether under Maine law, the contract terms disclosed under the UPDPA are trade secrets. *See also Reilly*, 312 F.3d at 33.

Maine has adopted the Uniform Trade Secrets Act ("UTSA"), 10 M.R.S.A. §§ 1541-1548, which defines "trade secret" as:

> [I]nformation, including, but not limited to, a formula, pattern, compilation, program, device, method, technique or process, that:
> a. Derives independent economic value, actual or potential, from not being generally known to and not being readily ascertainable by proper means by other persons who can obtain economic value from its disclosure or use; and
> b. Is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.

10 M.R.S.A. § 1542(4). In *Spottiswoode v. Levine*, the Maine Supreme Judicial Court listed five factors a court may examine to determine whether the information derives independent economic value from not being generally known or readily ascertainable: (1) the value of the information to the plaintiff and to its competitors; (2) the amount of effort or money the plaintiff expended in developing the information; (3) the extent of measures the plaintiff took to guard the secrecy of

[14] The State contends PCMA's motion should fail because PCMA did not comply with the best evidence rule since it did not introduce the original contracts that form the bases of PCMA's claims. *See* F.R.E. 1002. The State's argument, however, misperceives the issue. For purposes of ruling on this motion, whether the information set forth in a contract constitutes a trade secret does not depend upon the detailed contents of the document itself, but the context and significance of the contract. A description of what was negotiated in the contracts and why the PBMs consider the contents a trade secret is more significant than the specific contract terms. For this purpose, the declarations of the company officials are sufficiently probative. *See R & R Associates, Inc. v. Visual Scene, Inc.* 726 F.2d 36, 38 (1st Cir. 1984). However, this is not to say the actual contents of the contracts may not become fair game later.

the information; (4) the ease or difficulty with which others could properly acquire or duplicate the information; and, (5) the degree to which third parties have placed the information in the public domain or rendered the information "readily ascertainable" through patent applications or unrestricted product marketing. 730 A.2d 166 (Me. 1999).

Applying 10 M.R.S.A. § 1542(4)'s statutory definition, PCMA contends that the PBMs derive "independent economic value" from the specific contract terms each PBM has been able to negotiate with its drug suppliers and pharmacies. Precise information about rebates, if made generally known, would cripple the PBMs' ability to negotiate rebates with drug manufacturers and pharmacies and "destroy the value of this trade secret information."

The Maine statutory definition conveys the same underlying concept as the Restatement's definition of "trade secret": information is a trade secret if it generates "independent economic value" from not being "generally known" nor "readily ascertainable" and the holder of the secret makes an effort to maintain its secrecy. 10 M.R.S.A. § 1542(4). The record indicates that the PBMs consider this information highly-confidential and strive to maintain its secrecy. *See, e.g., supra* note 6. Comparing the *Spottiswoode* criteria to the facts in the record, the Court concludes that PCMA has sustained its burden for purposes of the motion for preliminary injunction to demonstrate that the information the UPDPA mandates disclosed constitutes a trade secret.[15]

ii. **Regulatory Taking.**

1. *Per Se* Taking.

[15] This should not be interpreted as the last word on this issue. The Court is disquieted by the notion that the rebate and secret contractual arrangements in this case can constitute a protected trade secret. Unlike the trade secrets in *Ruckelshaus* (data on pesticide ingredients) and *Reilly* (ingredient lists for tobacco products), information about negotiated contractual terms has no intrinsic economic value. Its true value is derived from the non-competitive impact of its confidentiality. The affidavits and argument submitted by the parties for purposes of a motion for preliminary injunction are insufficient to draw final conclusions on this issue and the consequences of denial of the motion on this ground would be that the information that the Court could ultimately conclude should be protected will be forever released. As Judge Selya stated in *Reilly*, 312 F.3d at 50, "a secret remains secret when not divulged."

In general, the law distinguishes between two types of takings: physical takings and regulatory takings. *Tahoe-Sierra Pres. Council, Inc. v. Tahoe Reg'l Planning Agency,* 535 U.S. 302, 323-24 (2002); *Reilly,* 312 F.3d at 33. In the context of tangible property, if the government physically takes possession of the property or a part of the property, then it has "a categorical duty to compensate the former owner." *Tahoe-Sierra,* 535 U.S. at 322. As Justice Stevens stated in *Tahoe-Sierra,* jurisprudence involving condemnations and physical takings is "as old as the Republic itself and, for the most part, involves the straightforward application of *per se* rules." *Id.*

By contrast, regulatory takings jurisprudence is "of more recent vintage and is characterized by "essentially ad hoc, factual inquires." *Id.* (quoting *Penn. Cent. Transp. Co. v. New York City,* 438 U.S. 104, 124 (1978)). To determine how far is too far requires a fact-based inquiry. Yet, the Supreme Court has also applied a *per se* analysis to some regulatory takings. *E.g., Tahoe-Sierra,* 535 U.S. at 325; *Lucas v. South Carolina Coastal Council,* 505 U.S. 1003, 1015 (1992) ("[W]e have found categorical treatment appropriate . . . where regulation denies all economically beneficial or productive use of land").

These distinctions, difficult enough in physical takings, become murky indeed when applied to intellectual property. Although acknowledging PCMA's contention that the disclosure of its members' trade secrets can be construed no other way than a *per se* taking of the secret, this Court has concluded the wiser course is to apply the *Penn Central* analysis.

2. The *Penn Central* Analysis.

Courts have generally applied a three-part *ad hoc,* factual inquiry to evaluate whether a regulatory taking has occurred: (1) the economic impact of the regulation; (2) whether the government action interferes with reasonable investment-backed expectations; and (3) the

character of the government action. *E.g., Reilly,* 312 F.3d at 33; *Penn Central,* 438 U.S. at 124. Applying these factors to the UPDPA, it is apparent that the two disclosure sections are distinct and must be treated separately.

As the Court understands it, § 2269(2)(D) requires the PBM to provide information to an employer, for example, about drug utilization and prescriptive medication payments to or on behalf of its employees. Similarly, it requires the disclosure to the covered entity of "all financial and utilization information relating to services to that covered entity." 22 M.R.S.A. § 2269(2)(D). This language presumably refers to services the PBM provide that do not result in the payment of a benefit. For example, if the PBM performs a drug utilization review untied to a particular payment, then the employer could require the PBM to disclose the information to it. It is true that the breadth of the phrase, "all financial . . . information," may implicate the rebate and remuneration information contemplated by § 2699(2)(G), but if this were the case, § 2699(2)(G) would be redundant.

Assuming § 2699(2)(D) is limited to information about benefits the covered entity has paid for or services the PBM provided to it, this Court cannot conclude that it runs afoul of the *Penn Central* criteria. Moreover, § 2699(2)(D) contains a confidentiality provision that prohibits disclosure of information the PBM has designated as confidential. To the extent this information is in fact a trade secret, the statute's protection from further disclosure inoculates it from constitutional infirmity. [16] *See Reilly,* 312 F.3d at 53 ("[A] more limited disclosure likely would not suffer from the same constitutional infirmities") (Lipez, J., dissenting).

[16] This Court does not credit PCMA's fear that the disclosure protections of § 2699(2)(D) are illusory because the information could be revealed in a subsequent judicial proceeding. A court would have the authority to impose restrictions on dissemination of disclosed information and presumably would do so, unless the information did not warrant such protection.

However, § 2699(2)(G) presents a different problem. It not only mandates disclosure of information that goes to the heart of what the PBMs contend are trade secrets, but it also fails to protect that information from further disclosure. The covered entities would be free to share this information with drug companies or pharmacies and reveal with impunity its PBMs' trade secrets to competitor PBMs. Turning to the first *Penn Central* factor, the record establishes that disclosure of this information would destroy its value. *Reilly*, 312 F.3d at 39 ("[A] trade secret is lost if its holder gives the trade secret to another without extracting a guarantee of confidentiality"). To paraphrase Judge Torruella in *Reilly*, once the competitors obtain this information, they can use it in a fashion that will undermine its value. *Reilly*, 312 F.3d at 41.

Likewise, PCMA has met the second *Penn Central* criterion: reasonable investment-backed expectations that the information would not be disclosed. To determine whether the holder of a trade secret had reasonable investment-backed expectations is, to borrow Judge Toruella's wording again, to "proceed into [a] quagmire." *See Reilly*, 312 F.3d at 37. In this case, the parties agree that the UPDPA is Maine's first foray into PBM regulation. *Def.'s Mem.* at 6. On the other hand, as an unregulated island in a highly regulated sea, the PBMs might well have expected that government regulation was inevitable, since "such restrictions are the burdens we all must bear in exchange for 'the advantage of living and doing business in a civilized community.'" *Ruckelshaus*, 467 U.S. at 1007 (quoting *Andrus v. Allard*, 444 U.S. 51, 67 (1979)). But the PBMs can effectively argue that the prospect of some regulation does not absolve the State from just compensation, especially since the PBMs should not have anticipated untrammeled and unprotected disclosure of their trade secrets. These reasonable investor-backed expectations were further enhanced by Maine's enactment of the UTSA.

Similarly, the third *Penn Central* criterion has been met. In determining the character of the government action—how the UPDPA regulates and the UPDPA's effect on the PBMs' trade secrets, the Court must balance Maine's interest in regulation against the PBMs interest in protecting their trade secrets. *See Reilly,* 312 F.3d at 41. As in *Reilly,* the unprotected disclosure of the PBMs' trade secrets will result in their inability to exclude others, a right that is fundamental to a property interest, *Kaiser Aetna,* 444 U.S. at 179-80, and a destruction of the value of the trade secret. *Reilly,* 312, F.3d at 41. At the same time, the state has a "significant, even compelling" interest in regulation involving public health. *Id.* at 44; *Keystone Bituminous Coal Assoc. v. DeBenedictis,* 480 U.S. 470, 488 (1987).

Where the economic impact of the regulation and effect on reasonable investment-backed expectations is profound, the Court is required to examine whether the regulation bears a reasonable relation to its ends. Of course, the parties disagree on the impact of the regulation: PCMA argues the benefits of disclosure are "speculative" and raises the possibility of serious economic consequences to Maine citizens; the State contends the UPDPA requires only "full and fair disclosure" to enable covered entities to "ensure that their PBMs are not gouging them."

However, the timing of a motion for preliminary injunction places the arguments in a different context. PCMA essentially asks for the maintenance of the *status quo* while the case is litigated. In weighing the respective positions of the parties, this Court concludes that for purposes of the motion for preliminary injunction, the *Penn Central* criteria have been met and the UPDPA to violate the Takings Clause.[17]

[17] In its supplemental brief, the State raises what amounts to a ripeness argument, though characterizes it as one of standing. Citing case law that requires a litigant to exhaust state remedies before seeking relief from a taking, the State claims that the Plaintiff's members do not have standing to contest the UPDPA because they never challenged the law in Maine. Accordingly, the State asserts the claims are not ripe and the Plaintiff does not have associational standing to pursue the claims on their behalf.

While the State is correct that the Plaintiff does not have a claim unless its members have claims, the argument paints existing case law with too broad a brush. In the regulatory takings context, challenges to a law may be facial;

d. Preemption.

PCMA argues ERISA preemption on the following grounds: (1) the UPDPA has a "connection with" employee benefit plans covered by ERISA; (2) the UPDPA has a "reference to" employee benefit plans covered by ERISA; and (3) the UPDPA undermines the exclusivity of ERISA's civil enforcement scheme. The State disputes these grounds and responds that because PBMs are not ERISA fiduciaries and do not otherwise fall into an ERISA entity category, the State is free to regulate them.

i. Background.

Congress enacted ERISA with the express intent to "establish pension plan regulation as exclusively a federal concern." *Alessi v. Raybestos-Manhattan, Inc.*, 451 U.S. 504, 523 (1981). In *Shaw v. Delta Air Lines, Inc.*, the Supreme Court concluded that through ERISA, Congress intended not only to preempt the field, but that the preemptive scope was as broad as ERISA's language. 463 U.S. 85, 98 (1983). ERISA defines "employee welfare benefit plan" to mean:

> [A]ny plan . . . established or maintained by an employer . . . for the purpose of providing for its participants or their beneficiaries, through the purchase or insurance or otherwise, (A) medical, surgical, or hospital care or benefits, or benefits in the event of sickness, accident, disability. . . .

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that is, a claim that the law affects a taking by its very terms, and as-applied; that is, a claim that the law affects a taking when applied to the claimant or particular property. It is true an as-applied claim is not ripe until the government entity charged with implementing the law has denied the property owner just compensation, *Williamson Co. Reg'l Planning Comm'n v. Hamilton Bank of Johnson City*, 473 U.S. 172, 186 (1985), because the "taking" depends on the extent to which the entity deprives the claimant of the use of the property without adequate compensation. *Yee v. City of Escondido, Cal.*, 503 U.S. 519, 533 (1992).

In the instant case, the Plaintiff has mounted a facial challenge to the UPDPA, arguing by its terms, the law effects a taking of the Plaintiff's members' trade secrets. The offense is not the State's lack of adequate compensation for the taking, but rather the taking itself. As a facial challenge, the argument ripened when the State enacted the UPDPA. *See Yee*, 503 U.S. at 533.

Further, with facial challenges, where an adequate remedy is not available at law, equitable relief, such as a preliminary injunction, is appropriate. *E.g.*, *Euclid v. Ambler Realty Co.*, 272 U.S. 365, 386 (1926) (stating that equitable relief is clear in instances of facial challenges); *Reilly*, 312 F.3d at 50 (evaluating merits of request for preliminary injunction where claimant had no adequate remedy at law and faced Hobson's choice of forfeiting trade secrets or withdrawing from market). Thus, equitable relief, such as a preliminary injunction, is appropriate to the extent that the UPDPA actually offends the Plaintiff's members' property rights.

29 U.S.C. § 1002(1); *see Pilot Life Ins. Co. v. Dedeaux,* 481 U.S. 41, 44 (1987). Congress "capped off" ERISA with provisions relating to the preemptive effect of the federal legislation, including the following:

> Except as provided in [ERISA's savings clause], the provisions of this subchapter and subchapter III of this chapter shall supersede any and all State laws insofar as they may now or hereafter relate to any employee benefit plan. . . .

29 U.S.C. § 1144(a).

Recently, however, the Supreme Court has grown "more guarded" in interpreting the scope of ERISA, *Carpenters Local Union No. 26 v. United States Fiduciary & Guaranty, Co.,* 215 F.3d 136, 139 (2000), and emphasized the starting presumption that "Congress does not intend to supplant state law," *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Insurance Co.,* 514 U.S. 645, 654 (1995); *see California Div. of Lab. Stds. Enf. v. Dillingham Constr.,* 519 U.S. 316, 324 (1997). The Court has been especially careful to note the field of health care is distinctive and "nothing in the language of [ERISA] or the context of its passage indicates that Congress chose to displace general health care regulation, which historically has been a matter of local concern." *Travelers,* 514 U.S. at 661. Indeed, there is no ERISA preemption in health care without clear manifestation of congressional purpose. *E.g., Pegram v. Herdrich,* 530 U.S. 211, 237 (2000).

Within these parameters, this Court must evaluate whether the UPDPA "relates to" any employee benefit plan, for, if it does, it is preempted. *Carpenters Local*, 215 F.3d at 140. A state law "relates to" an employee benefit plan if it either (1) has a connection with or (2) makes reference to such a plan. *Id.*; *Dillingham*, 519 U.S. at 324.

ii. Connection.

In *Travelers* and *Dillingham*, the Supreme Court modified the analysis as to whether a state law has a "connection with" ERISA: the Court "abandoned strict textualism in favor of a more nuanced approach." *Carpenters Local*, 215 F.3d at 140. *Travelers* explained, "For the same reasons that infinite relations cannot be the measure of pre-emption, neither can infinite connections." 514 U.S. at 656. Thus, to determine whether a State law is subject to ERISA pre-emption under the "connection with" portion of the inquiry, courts must consider the objectives of ERISA as a guide to the scope of the state law Congress understood would survive. *Id.*

Cataloguing the objectives of ERISA is a "fairly straightforward exercise." *Carpenters Local*, 215 F.3d at 140. When Congress enacted ERISA, it made manifest its intention to "protect . . . the interests of participants in employee benefit plans and their beneficiaries . . . by establishing standards of conduct, responsibility, and obligation for fiduciaries of employee benefit plans, and by providing for appropriate remedies." *Id.*; 29 U.S.C. § 1001(b). Achieving this end requires the avoidance of "a multiplicity of regulation" and, concomitantly, the creation of a climate that "permits the nationally uniform administration of employee benefit plans." *Travelers*, 514 U.S. at 657; *Carpenters Local*, 215 F.3d at 140. The First Circuit summarized the inquiry as follows: whether the state laws have a "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)." *Carpenters Local*, 215 F.3d at 141.

Here, there is no dispute that the UPDPA imposes new and broad regulations upon PBMs. It defines them as fiduciaries, requires disclosures of their provision of benefits and utilization reviews, mandates notification of any conflicts of interest, and compels disclosure of

contractual terms with drug companies and pharmacies. The UPDPA also establishes restrictions on the way the PBMs may operate: PBMs are allowed to substitute generic drugs for higher-priced prescription drugs but are forbidden from doing the opposite without obtaining the approval of the "prescribing health professional" and disclosing both the substitution and the cost of both drugs and any benefit derived from the switch to the covered individual and the covered entity. The PBMs are also obligated to transfer in full to the covered entity any financial benefit garnered from either substituting drugs or volume discounts.

This Court concludes that the provisions of the UPDPA are virtually bound to collide with the ERISA goal of a "nationally uniform administration of employee benefit plans." *See Travelers*, 514 U.S. at 657. For example, consider the inherent conflict between the PBM's duties to the covered entity and covered individuals and the entity and individuals' ability to resort to state litigation under the UPDPA.[18] This conflict is codified in 22 M.R.S.A. § 2699(2)(B): "A [PBM] shall discharge its duties with respect to the covered entity for the primary purpose of providing benefits to covered individuals *and* defraying reasonable expenses of administering health plans." The UPDPA assumes the two duties are reconcilable; however, an analysis of § 2699(2)(E)(2)'s implications demonstrates they are not. Section 2699(2)(E)(2) governs the substitution of a more expensive drug for a less expensive generic medication. The law requires the substitution "be made for medical reasons that benefit the covered individual *and* must benefit the covered entity." 22 M.R.S.A. § 2699(2)(E)(2) (emphasis added). If the PBM, even after obtaining doctor approval, were to substitute a drastically more expensive prescriptive medication for a generic drug, the covered entity could well be extremely

[18] The State can well argue that the law only recognizes a conflict that the PBMs already have, regardless of whether it is codified. However, the point for ERISA preemption purposes is whether the UPDPA in its operation is likely to have a real bearing on the intricate web of relationships described in *Carpenters Local* and this example, in the Court's view, demonstrates that it will.

dissatisfied with the increased cost, but the individual could well be fully satisfied—indeed happy—with the switch. Under the UPDPA, though, the PBM does not owe a direct fiduciary duty to the patient; it owes this duty solely to the covered entity. 22 M.R.S.A. § 2699(2) ("A [PBM] owes a fiduciary duty *to a covered entity*. . . . .) (emphasis added). If the PBM acts in the best medical interest of the patient over the best financial interest of the covered entity, the UPDPA virtually invites litigation through its notice and enforcement provisions.

Under § 2699(2(E)(2), before making the switch to a more expensive drug, the PBM must first reveal to both the covered entity and the patient the cost of both drugs and any payments the PBM is receiving directly or indirectly as a result of the substitution. It must then obtain the approval of the person's physician. Armed with information about the cost differential and any rebate, the covered entity is authorized to file suit under the Maine UTPA.

Further, the terms of the UPDPA provide an avenue for legal redress: a violation of the law constitutes a violation of the UTPA. The UTPA contains provisions for action by the Maine Attorney General and the filing of private causes of actions, 5 M.R.S.A. § 213, grants jurisdiction to the Maine Superior Court, and provides the right to trial by jury, 5 M.R.S.A. § 213(1). If a PBM were to switch to a higher-cost drug with the approval of the covered individual and his physician, but over the objection of the covered entity, the UPDPA gives the covered entity a clear cause of action against the PBM for violating its fiduciary obligation. On the other hand, if the PBM refused to substitute the higher priced prescription despite physician approval, the covered individual could presumably initiate a private cause of action under the UTPA for violation of the UPDPA's conflict of interest provision, seeking to enjoin the PBM.

This example is only the first of a host of issues that this Court concludes will find their way to state court as an inevitable consequence of the duties and remedies the UPDPA creates.[19]

The inquiry, then, is twofold: first, whether these potential issues invade the province of ERISA; and second, whether they raise the spectre of an alternative state enforcement mechanism to ERISA's enforcement scheme, triggering preemption. *Rush Prudential*, 536 U.S. at 375; *Ingersoll-Rand*, 408 U.S. at 142-45; *Carpenters Local*, 215 F.3d at 141. The decision as to what drug to prescribe, the price of the drug, the comparative medical efficacy of the drug, and the disclosure requirements to the covered entity and covered individual all seem to fall squarely within the First Circuit's concern: state law interference with the administration of covered employee benefit plans, purporting to regulate plan benefits or impose additional reporting requirements. *Carpenters Local*, 215 F.3d at 141.

Similarly, the prospect of Maine state law suits initiated to enjoin, fine, or obtain monetary damages for the filling of a prescription appear to this Court to conflict with the *Rush Prudential* Court's observation that there is an "overpowering federal policy in the civil

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[19] The UPDPA raises the likelihood that the Maine Superior Court will become the forum of choice for the resolution of controversies that are essentially between the covered entity and the covered individual. If the covered entity or covered individual were to challenge a PBM decision under the UTCP, although the pretext of the complaint might be the PBM's role, the nub of the issue could very likely be whether the covered entity's financial interests should take precedence over the covered individual's medical interests. For those health plans covered by ERISA, the issue litigated in Maine State Superior Court under the UTPA should be resolved under 29 U.S.C. § 1132(a)(1). The Supreme Court has not retreated from its view that ERISA enacted a comprehensive enforcement scheme, which preempts state regulation on the same issues. *Rush Prudential HMO, Inc. v. Moran*, 536 U.S. 355 (2002); *Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. 41 (1987); *Massachusetts Mut. Life Ins. Co. v. Russell*, 473 U.S. 134 (1985).

The Court is also concerned that the UPDPA places the personal physician in the center of the dispute about the cost and effectiveness of medication. Before the physician is asked to render an opinion, the UPDPA requires the PBM first to disclose the cost information to the covered entity and the patient (plus any benefit payment to the PBM), thereby making it a virtual certainty (if the expense is sufficiently great) that the doctor will be lobbied at least by his patient and perhaps by the covered entity, on her decision as to which drug is best and most cost effective for the patient.

Finally, the UPDPA provides that the PBM "shall transfer in full" to the covered entity any benefit or payment it receives as a result of the substitution. 22 M.R.S.A. § 2699(2)(E)(3). The determination of what is "in full" is a potential source of litigation, the extent to which it includes PBM overhead, for example. This portion of the UPDPA can be enforced only if the covered entity has detailed knowledge of the PBM's books, a knowledge consistent with the disclosures contemplated under subsection (2)(D), but for which there is no enforcement mechanism other than state litigation. Similar issues appear with subsection (2)(F).

enforcement provisions" of ERISA. 536 U.S. at 375-76. If the Maine UTPA provides a remedy for covered individuals to the extent they have made a co-pay or deductible payment for a prescriptive medication, this remedy conflicts with the remedy provided in 29 U.S.C. § 1132(a)(1). The UPDPA provides without question the right of covered entities to sue for injunctive relief and monetary damages under the UTPA. The UPDPA's right to injunctive relief would be duplicative of the fiduciary's right to redress under § 1132(a)(3). But the UPDPA also provides for monetary relief not found in § 1132(a)(3). *Massachusetts Mutual Life*, 473 U.S. at 146 (quoting *Nachman Corp. v. Pension Benefit Guaranty Corp.*, 446 U.S. 359, 361 (1980) (noting ERISA is an "interlocking interrelated, and interdependent remedial scheme, which is in turn part of a 'comprehensive and reticulated statute") (internal citation omitted).

Accordingly, this Court concludes that the terms of the UPDPA and its enforcement mechanisms intrude too far into the ambit of federal regulation of health benefits by ERISA plans. Therefore, the UPDPA has an impermissible "connection with" ERISA.

iii. Reference.

The Supreme Court has provided that a State law has a "reference to" an ERISA covered program, if it "acts immediately and exclusively upon ERISA plans . . . or where the existence of ERISA plans is essential to the law's operation." *Dillingham*, 519 U.S. at 325. In *Carpenter's Local*, Judge Selya concluded that *Travelers* and *Dillingham* required a revised approach to the "reference to" analysis:

> The sockdolager is that emergent Supreme Court precedent, by disavowing a strictly textual approach to the interpretation of ERISA's preemption provision, encourages us for the first time to conduct the "reference to" inquiry in light of the actual operation of the challenged state statue.

215 F.3d at 144.

The relevant factors in such an analysis include: (1) whether the State law imposes requirements on ERISA plans; (2) whether the State law exempts such plans from otherwise applicable statutory provisions; (3) whether the State law in its operation, comports with ERISA's objectives; (4) whether the State law dictates the form that a covered plan would take; (5) whether the State law specifies the mode or manner of plan administration; (6) whether the State law otherwise jeopardizes the sort of uniformity Congress aspired to achieve. *Id.* Additionally, the Court is to consider whether the state law applies "to a wide range of situations, including an appreciable number that have no specific linkage to ERISA plans" or "to a sufficiently broad, sufficiently generalized universe of situations." *Id.* at 144-45.

If the State law is one of general application, does not single out ERISA plans for special treatment, does not depend on the ERISA plans' existence as an essential part of its operation, and is indifferent to ERISA coverage, the State law is considered valid and not preempted. Indeed, *Carpenter's Local* reasoned that if the State law is one of the "myriad state laws" of general applicability that impose some burdens on the administration of ERISA plans, but do not "relate to them" within the meaning of the governing statute, preemption will not be triggered. 215 F.3d at 145 (citing *DeBuono v. Medical and Clinical Serv. Fund,* 520 U.S. 806, 815 (1997)).

To apply the *Carpenters Local* analysis, this Court is required to balance the impact of the statute on ERISA plans. The UPDPA imposes no express requirements on ERISA plans, does not exempt ERISA plans from its operation, is one of general applicability, and makes no express reference to ERISA—factors which weigh strongly against preemption. *Carpenters Local*, 215 F.3d at 144-45. On the other hand, for the reasons set forth above, this Court has concluded that the UPDPA substantially interferes with the "mode and manner of plan

administration" and in operation jeopardizes the sort of uniformity that Congress aspired to achieve. *Id.* at 144.

ERISA itself has become such an all-encompassing part of our legal lexicon that it is virtually impossible to wade into health care regulatory waters without referring, intentionally or not, to ERISA terminology. This is particularly true when the State seeks to regulate the administration and provision of a significant slice of health care benefits, as Maine is seeking to do in this case. Even where the State consciously seeks to craft its terms so as to avoid ERISA definitions, the language ultimately ends up bumping into ERISA terminology. Thus, where the UPDPA defines "covered entity" as, "an employer . . . or other group of persons organized in the State that provides health coverage to covered individuals," even though the UPDPA does not use the phrase, "employee welfare benefit plan," it is defining the same concept. ERISA defines "employee welfare benefit plan" as, "any plan . . . maintained by an employer . . . for the purpose of providing . . . medical . . . benefits. . . ." 29 U.S.C. § 1002(1). At oral argument, the State did not disagree with PCMA's contention that the "vast amount" of the covered individuals the PBMs service in Maine are covered under ERISA plans.[20] At least a significant number of "covered individuals," § 2699(1)(B), under "covered entities," § 2699(1)(A), receive prescriptive drug benefits through PBMs pursuant to ERISA-regulated "employee welfare benefit plans" under ERISA.

[20] At oral argument, the Assistant Attorney General stated:

> And the point is—here is that PBMs, they said, the vast amount of plans that they service are ERISA plans. That may be, in fact, true in the sense that they—that they're working on providing pharmaceutical products that ultimately will end up in the hands of ERISA participants. But, the contracts that they have themselves are not necessarily with ERISA fiduciaries, and they could be with a whole host of different entities and certainly could—I dare to say that most of them are not with the particular plans themselves.

Similarly, the ERISA regulatory scheme is premised on defining critical players as fiduciaries, imposing fiduciary obligations on them, and penalizing them for their failure to comply. What Maine has done is mimic ERISA's regulatory scheme on an emerging and important player, one not currently regulated by ERISA. The UPDPA defines the PBMs as fiduciaries, requires disclosures, and then penalizes non-compliance. From this Court's perspective, the very size and significance of the PBM industry—its national scope, its crucial position in the center of the health care delivery system—make it less likely that a comprehensive state regulatory scheme can be enacted against such a major player without reference to the overriding federal law that so permeates the employee health benefit plan landscape. This is especially true since the route the State has chosen tracks the federal regulatory scheme, effectively filling in by state law an ever-expanding hole in federal oversight.

This is not to say the State cannot enact legislation generally to regulate health care. The *Travelers* Court has expressly said otherwise. However, this legislation presents a series of factors that make it problematic in light of ERISA preemption: (1) the national, as opposed to state or even regional, impact of the PBM industry; (2) the significant economic weight of the industry; (3) the centrality of the industry in the delivery and cost of health care benefits; (4) the vital nature of the health care benefits the PBM industry affects; (5) the breadth and detail of State regulation over the PBM industry; (6) the comprehensive scope of its enforcement provisions; and (7) the availability of private causes of actions on benefit issues. In this context, for the Court to ignore ERISA would be to ignore the proverbial elephant in the room.

The final analysis relies on the *Carpenters Local* sockdolager: conducting the "reference to" inquiry in light of the actual operation of the statute. Having concluded that the UPDPA has a "connection with" ERISA plans, this Court is led by a similar process to the conclusion that the

UPDPA has simply too profound an impact on ERISA plans—their administration and benefits—to avoid the reality that, in its operation, the UPDPA has a "reference to" ERISA.

iv. Preemption Conclusion.

This Court does not take lightly its obligation to presume that state statutes, particularly those imposing general health regulations, are not preempted by federal law. However, reviewing the UPDPA in the shadow of *Travelers* and *Dillingham*, this Court concludes that PCMA has demonstrated substantial likelihood of success on the issue of whether the UPDPA relates to ERISA so as to trigger preemption. As Judge Hornby recently wrote, even though *Travelers* represented "a retreat from the broadest reading once given to 'relate to,'" it did not overrule *Shaw*. *Catholic Charities*, 2004 WL 231778 at 1, *8 (D. Me. 2004).

VIII. Other Preliminary Injunction Considerations.

As noted earlier, before this Court can issue a preliminary injunction, PCMA has the burden of satisfying each element of a four-part test: (1) the probability of success on the merits; (2) the likelihood of irreparable harm; (3) a favorable balance of equities; and (4) the impact the injunction will have on the public interest. Based on the record before this Court, PCMA has met the first two requirements: a likelihood of success on the merits and a significant risk of irreparable harm. To balance the equities, this Court notes that PCMA is currently seeking maintenance of the status quo pending final resolution of the case and this Order does not decide the State's ultimate ability to enforce the law. Finally, although the State has argued that a delay in enforcement will affect the public interest, this Court concludes the delay in any public benefit pending final resolution of the litigation is offset by the three other preliminary injunction criteria.

IX. Conclusion.

Considering the factors applicable to the extraordinary relief of a preliminary injunction, this Court concludes that PCMA has made a compelling showing to warrant the grant of a short-term injunction in this case. Accordingly, in order to preserve the status quo during the pendency of this action, the State is PRELIMINARILY ENJOINED from seeking to enforce 22 M.R.S.A. § 2699.

SO ORDERED.

Dated: March 9, 2004

/s/ John A. Woodcock, Jr.
JOHN A. WOODCOCK, JR.
UNITED STATES DISTRICT JUDGE

Plaintiff

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION

represented by **JOHN J. AROMANDO**
PIERCE, ATWOOD
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

BERNSTEIN, SHUR, SAWYER, & NELSON
100 MIDDLE STREET
P.O. BOX 9729
PORTLAND, ME 4104-5029
791-1100
Email: cconnors@pierceatwood.com
ATTORNEY TO BE NOTICED

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

V.

Defendant

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