

**IN THE COURT OF APPEALS
STATE OF GEORGIA**

**ADVANCE PCS, PCS HEALTH)
SYSTEMS, INC., PCS MAIL SERVICES)
OF FORT WORTH, INC., and PCS)
MAIL SERVICES OF BIRMINGHAM,)
INC.)**

Appellants,

V.

Docket No. A05A0455

**DEBORAH R. BAUER and DIANE G.)
WRIGHT, on behalf of themselves and)
all others similarly situated,)**

Appellees,

BRIEF OF APPELLEES

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BRIEF OF APPELLEES

I. APPELLEES' ADDITIONAL STATEMENT OF FACTS

In their Second Amended Class Action Complaint (“SAC”) Appellees, Deborah R. Bauer and Diane G. Wright (“Bauer and Wright”) allege an unjust enrichment state cause of action under Georgia Statute § 9-11-23 and Georgia Common Law against Appellants, ADVANCE PCS, PCS Health Systems, Inc., PCS Mail Services of Fort Worth, Inc., and PCS Mail Services of Birmingham, Inc., (“PCS”).

PCS is a pharmaceutical benefits manager (“PBM”). PBMs manage

pharmaceutical claims for health insurance companies, HMOs, or other types of health care plans. Bauer and Wright's claims arise from PCS' systematic practice of mis-classifying the generic drug "tamoxifen" as a brand name drug when processing pharmaceutical claims for its health plan clients.

(SAC ¶ 1, R. 1080) As a direct result of this mis-classification, Bauer and Wright have been forced to pay higher "brand name" prescription drug co-payments than if PCS properly classified tamoxifen as a generic drug.

(SAC ¶1 R. 1080) Indeed, PCS admits it classifies tamoxifen as brand "across the board" and that this classification does not depend upon the language of any insurance policy or health care plan it services. (SAC ¶ 18, R. 1080) PCS further admits that the brand co-payment is always higher than the "generic" co-payment. (SAC ¶ 18 R. 1080)

The role of "PBMs" such as PCS.

PCS is not a health care plan. PCS does not determine health care benefits. PCS does not make coverage decisions under its customers' ERISA plans. PCS merely processes drug claims for the customers with whom it contracts. PCS' customers include employers, unions, insurance companies, health maintenance organizations ("HMOs"), Blue Cross/Blue Shield plans,

and similar organizations that pay for health care products and services:

ERISA ENTITIES. PCS is *not* an ERISA entity.

When a person becomes a member of a health care plan that PCS services, the individual receives a notice that PCS will process drug claims for that individual. (SAC ¶ 11, R. 1080) PCS' drug processing program consists of a nationwide network of pharmacies that are connected to PCS' computer system. Under this system, a patient presents a prescription along with his or her benefit card to a pharmacist. Before the pharmacist releases a prescription to the patient, the pharmacist accesses PCS' online computer system, through which all claims are processed, and enters the patient's identification and prescription information. PCS' database identifies the co-payment that corresponds to the patient's prescription and displays that amount on the pharmacy's computer terminal. If the PCS system indicates a co-payment is due, the pharmacist requires a patient to make the co-payment before receiving the prescription. PCS records the transaction for processing and payment, PCS is then paid by its customer health care plan for this service. (SAC ¶ 15, R. 1080) PCS' mail order program operates much the same way, except PCS actually supplies the drug directly to the patient. In

that respect it is a mail order pharmacy with its own inventory of drugs such as tamoxifen. Its supplier for tamoxifen is Barr Laboratories. (*infra*, p. 6) PCS bills the patient and that patient's ERISA healthcare for payment. PCS processes hundreds of millions of dollars of prescription claims for its customers. (SAC ¶ 13, R. 1080)

**The manner in which Bauer and Wright have been
damaged by PCS' conduct.**

BAUER and WRIGHT were recovering from breast cancer. (SAC ¶¶ 2 & 3, R. 1080) To prevent the recurrence of cancer, Bauer and Wright were prescribed tamoxifen by their doctors, which they were required to take for five years. Bauer and Wright were specifically prescribed generic tamoxifen by their oncologists, rather than the brand name, "Nolvadex." (SAC ¶ 20, R. 1080) Tamoxifen citrate is a drug that interferes with the effects of the body's estrogen on breast cancer cell growth by slowing or stopping the growth of cancer cells that are already present in the body. Tamoxifen citrate has also been shown to help prevent breast cancer from returning and to prevent the development of new cancers. (SAC ¶ 21, R. 1080) Tamoxifen citrate is sold under the brand name "Nolvadex" by Zeneca, Inc. (SAC ¶ 14, R. 1080) Tamoxifen citrate is sold as generic "tamoxifen" by

Barr Laboratories, Inc. Nolvadex and generic tamoxifen are functionally equivalent and require the same dosage to be effective. Although each has the same effect on the individual's physical well-being, the brand name drug carries a greater cost. To Bauer and Wright, the difference is not only the ultimate price differential between the two products, but the impact the classification of tamoxifen has on Bauer and Wrights' co-payments.

Saliently, Bauer and Wright's ERISA healthcare plans also face higher costs when having to pay PCS for non-generic tamoxifen. Thus, PCS has artificially created a tamoxifen "brand" classification with the resultant increased cost to its ERISA customers and the breast cancer beneficiaries of those ERISA health care plans. (Plaintiffs' Responsive Memorandum of Law In Opposition to Defendants' Motion for Reconsideration of This Court's Order of June 10, 2004, R. 2312, p. 10)

Bauer and Wright were beneficiaries of ERISA plans paid by their former employers, Kindred and Broniec. (SAC ¶¶ 2 & 3, R. 1080) Bauer and Wright's ERISA plans expressly provided for coverage of prescription drugs. Under their plans, a co-payment for brand name drugs is greater than a co-payment for a generic drug. (SAC ¶ 17, R. 1080)

Although tamoxifen is a generic drug, PCS, as stated, classified it as a brand name drug in its nationwide computer system. As a result, consumers such as Bauer and Wright are responsible for a correspondingly higher co-payment. (SAC ¶ 26, R. 1080) Using PCS' mail order procedure, Bauer mailed her prescription for tamoxifen to PCS for processing. Her tamoxifen prescription was processed as a "brand" name drug, requiring her to pay a higher co-payment for her prescription. PCS' processing of this drug as brand also required her ERISA plan to pay PCS more for "brand" tamoxifen. Similarly, when Wright purchased her tamoxifen, she also had to make a higher co-payment. (SAC ¶ 25, R. 1080)

Bauer and Wright, like many others, should not bear unnecessary expenses to receive life sustaining medication. They are only required to make generic co-payments for tamoxifen, but were being charged the higher co-payment for a preferred, brand name drug – not by their ERISA plans, but by PCS. This wrongful classification is the result of PCS' company policy. PCS' wrongful classification results in thousands of breast cancer victims nationwide bearing responsibility for a much larger percentage of the cost of their prescriptions. The ERISA plans PCS serves must also pay more for the

drug. (Plaintiffs' Responsive Memorandum of Law In Opposition to Defendants' Motion for Reconsideration of This Court's Order of June 10, 2004, R. 2312)

Bauer and Wright are *not* being denied benefits by their ERISA plans and they do *not* claim they are being denied benefits by their ERISA plans. They have no complaints against their ERISA plans. It is PCS which classifies tamoxifen as brand without regard to which ERISA plan it services or the terms of that particular ERISA plan. It is PCS against whom their claim lies. (SAC, R. 1080)

II. ARGUMENT

A. **The trial court was correct in denying PCS' Motion to Dismiss, which was based upon lack of jurisdiction.**

On July 7, 2003, PCS filed a Notice of Removal of this case to the United States District Court for the Northern District of Georgia, Atlanta Division from the Superior Court of Georgia. (PCS' brief at page 8) As a purported basis for removal, PCS claimed 28 U.S.C. § 1331 mandated that the GA Fed. Dist. Ct. had original jurisdiction. PCS argued Bauer's state law claim was *completely* preempted by ERISA: the same argument being made by PCS before this Court. On January 21, 2004, Judge Jack T. Camp of the

GA. Fed. Dist. Ct. disagreed with PCS. He ruled that Bauer's claim was not completely pre-empted. He remanded this case back to the Georgia State Court. A full copy of Judge Camp's opinion on remand is attached as Exhibit 1 to Plaintiffs' Responsive Memorandum of Law in Opposition to Defendants' Motion to Dismiss for Lack of Jurisdiction. (R. 1231) After remand, PCS asked Judge Goger to dismiss this case for lack of jurisdiction. This effort by PCS also failed. On June 10, 2004, Judge Goger agreed with Judge Camp. Judge Goger's Order stated:

“The controlling case in this matter unambiguously states that ‘when a state law claim brought against a non-ERISA entity does not affect relations among principal ERISA entities as such, then it is not preempted by ERISA.’ Morstein v. Nat’l Ins. Servs. Inc. 93 F.3d 715, 722 (11th Cir. 1996). The Defendants in the present case are non-ERISA entities. Further, Plaintiffs’ action will not affect ‘relations among’ their respective health plans. The Court agrees with the assertion that Plaintiffs’ healthcare plans are only incidentally relevant to this dispute.⁴ As recognized by the United States Supreme Court, ‘[s]ome state actions may affect employee benefit plans in too tenuous, remote, or peripheral a manner to warrant a finding that the [action] ‘relates to’ the plan...’ Shaw v. Delta Air Lines, Inc. 463 U.S. 85, 100, 103 S. Ct. 2890, 77 L. Ed.2d 490 (1983); see also New York Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co 514 U.S. 645, 655, 115 S. Ct. 1671, 131 L. Ed. 2d 695 (1995) (noting that ‘[i]f ‘relate to’ were taken to extend to the furthest stretch of its indeterminacy, then for all practical purposes pre-emption would never run its course, for ‘[r]eally, universally, relations stop nowhere.’) (citations omitted). The case before the Court presents a situation where any relation between the claim and the ERISA entity is simply

too remote. Recognizing a relationship between the Plaintiffs' claims and their health plans would render the 'relate to' standard virtually useless, and obviate the guidance that it currently provides.

Conclusion

Defendants' Motion to Dismiss is DENIED. The prevailing issue in this case is whether or not tamoxifen is a 'generic' drug. Accordingly, the parties are ORDERED to advise the Court within 30 days whether or not this issue can be resolved by a dispositive motion. The Court defers ruling on Plaintiffs' Motion for Class Certification until the parties have complied with this order.

⁴ The District Court ruling on the issue of super preemption recognized as much. Even though the issue of defensive preemption was not before that Court, Judge Camp, speaking in defensive preemption terms, recognized that 'the [Defendants' alleged] misrepresentation affects the [Plaintiffs' health] plan only because the plan will offer the measure of damages.'

A full copy of Judge Goger's Order of June 10, 2004 is attached to Plaintiffs' Responsive Memorandum of Law In Opposition to Defendants' Motion for Reconsideration as Exhibit 2. (R. 2312) Judge Goger recognized that PCS is a non-ERISA entity.

B. PCS cannot recharacterize Bauer and Wright's claims as claims for benefits under ERISA. Bauer and Wright make no claims under ERISA.

In order to establish that ERISA is applicable, PCS is required to

demonstrate not only that Bauer and Wright’s claims fall within the scope of ERISA’s civil enforcement scheme, but also that the claims “relate to” an ERISA plan under §1144(a). In Caterpillar Inc. v. Williams, 482 U.S. 386, 392, 107 S.Ct. 2425, 2429 (1987), the Supreme Court held that “the presence of a federal question . . . in a defensive argument does not overcome the paramount policies embodied in the well-pleaded complaint rule,” and a defendant “cannot, merely by injecting a federal question into an action that asserts what is plainly a state-law claim, transform the action into one arising under federal law.” Caterpillar, 482 U.S. at 398-399. PCS in this case is “merely...injecting a federal question” into an action that deals only with unjust enrichment - - there is no question of an ERISA plan’s coverage.

Bauer and Wright’s claims do not “relate to” any ERISA plan under § 1144. Bauer and Wright’s claims are clearly and simply predicated on PCS’ wrongful misclassification scheme. Bauer and Wright’s claims are not made to “escape ERISA’s preemption of alternative remedies either by characterizing their cause of action as one for ‘unjust enrichment’ or by seeking monetary relief from Advance PCS rather than reimbursement from the plans themselves...” (PCS’ brief at page 22.) Bauer and Wright do not

receive insurance coverage from PCS. PCS is not Bauer and Wright's ERISA health care plan from which they can seek reimbursement. In fact, PCS' 30(b)(6) witness, Lorraine Stevens, in a RICO case filed against PCS in the U.S. District Court for the Northern District of Illinois, *Evelyn Morse v. Bankers Life & Casualty and PCS, Inc.*, 2000 WL 246245 (N.D.Ill), has said ERISA healthcare plans have absolutely no involvement in the classification of tamoxifen or the effects of this classification on the price of tamoxifen.

Plaintiffs' SAC at ¶ 18 (R. 1080) states as follows:

PCS' classification of tamoxifen as brand is a unilateral, arbitrary, and self-serving classification as, on July 17, 1999, in Phoenix, Arizona, the deposition of PCS DEFENDANTS' Lorraine Stevens, their most knowledgeable person with regard to tamoxifen's brand classification, occurred in the case of *Morse v. PCS, INC., et al.* case no. 99 C 0193, U. S. District Court for the Northern District of Illinois. She provided sworn testimony that PCS classifies tamoxifen as a brand-name drug *across the board* - for *all* of its insurance clients - irrespective of any individual policy variations and that *all* of the PCS - administered policies require a greater co-pay for a brand name drug. Specifically, this PCS witness was asked the following questions and gave the following answers:

* * *

“Q. So it doesn't matter which insurance company, employer, third-party administrator that PCS is administering pharmaceutical claims for, as concerns the drug tamoxifen, PCS will also - - that will always designate it as a brand name drug, true?”

A. Correct.” (pp. 7-8)

* * *

“Q. You have told us that the data base of PCS designates tamoxifen as a brand name across the board, true?”

A. Correct.

Q. ...Because PCS identifies tamoxifen as a brand name drug, it does so for every one of its clients, true?”

A. True.

Q. And therefore, it doesn't matter, does it, what language of any policy of any one of its clients contains insofar as PCS' designation of tamoxifen as a brand name drug, true?”

A. I believe so, in the way you stated it.” (Pp. 8-9)

* * *

Q. Now the copay for all brand name drugs, whatever the formula is for all of PCS' clients, is greater than if the drug is generic, true?”

A. True.

Q. And that's true no matter who the client is, true?”

A. True.” (P. 10) (Ex. 1 to SAC, R. 1080) (emphasis added).

C. New Jersey U.S. District Court Judge Cavanugh and his observations that PBMs are not ERISA entities.

In addition to U.S. District Court Judge Jack T. Camp's opinion, cited at page 22 *infra*, New Jersey U.S. District Judge Cavanugh in

Ruth Ann Smith v. Merck Medco Managed Care LLC and Paid

Prescriptions LLC, Civil action # 02-3374 (DMC) (Exhibit 2 attached

to Plaintiffs' Responsive Memorandum of Law in Opposition to

Defendants' Motion to Dismiss for Lack of Jurisdiction, R. 1231) gives

us an additional inciteful explanation of why Bauer and Wright's

lawsuit is not preempted by ERISA. In part, his opinion says:

“Initially, the Supreme Court broadly interpreted section 1144(a)'s preemptive reach, see Pilot Life Ins. Co. v. Dedeaux, 481 U.S. 41, 45-46 (1987), by holding that ‘[a] law ‘relates to’ an employee benefit plan, in the normal sense of the phrase, if it has a connection with or reference to such plan.’ Shaw v. Delta Airlines, Inc., 463 U.S. 85, 96-97 (1983). In 1995, however, the Court reigned in its expansive interpretation of section 1144(a) because it noted that the Shaw interpretation ‘was of limited utility because ‘an uncritical literalism [of the phrase ‘connection with’] is no more help than in trying to construe ‘relate to’...for the same reasons that infinite relations cannot be the measure of preemption, neither can infinite connections.’ ‘Trustees of the AFTRA Health Fund v. Biondi, 303 F.3d 765, 773 (7th Cir. 2002) (quoting Travelers Ins. Co., 514 U.S. 645, 656 (1995)). The Court’s commentary in Travelers Ins. Co. evidences the problem with the dichotomous interpretations of ‘relate to:’

Our past cases have recognized that the Supremacy Clause, U.S. Const., art. VI, may entail pre-emption of state law either by express provision, by implication, or by a conflict between federal and state law. And yet, despite the variety of these opportunities for federal pre-emption, we have never assumed lightly that Congress

has derogated state regulation, but instead have addressed claims of pre-emption with the starting presumption that Congress does not intend to supplant state law. Indeed, in cases like this one, where federal law is said to bar state action in fields of traditional state regulation, we have worked on the ‘assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.’ [Travelers Ins. Co. 514 U.S. at 654-55]

Justice Souter’s revised and more stringent standard in Travelers Ins. Co., ultimately provides that a state law will be preempted if it effects the structure or administration of a plan. Although preemption will be found if, for example, the employee benefits plan’s ‘existence’ is ‘a critical factor in establishing liability’ under the state law, see Ingersoll-Rand Co., 498 U.S. at 140, section 1144(a) will not be held to preempt state laws that have merely a ‘tenuous, remote or peripheral connection’ to employee benefit plans. District of Columbia v. Greater Washington Board of Trade, 506 U.S. 125, 130 (1992).

...

Following the line of cases set forth above, it can be said that the Supreme Court’s analysis of ERISA preemption has become increasingly narrow. Furthermore, the court thought it was compelling enough to caution courts against an all-encompassing interpretation of section 1144(a) preemption. The Court specifically warned that if section 1144(a)’s ‘words of limitation’ - i.e., ‘relate to’ - ‘were taken to extend to the furthest stretch of its indeterminacy, then for all practical purposes pre-emption would never run its course, for really, universally, relations stop nowhere.’ ‘Biondi, 303 F.3d at 774 (quoting Travelers Ins. Co., 514 U.S. at 655).

...

this Court finds that the employee benefit plan of which

Plaintiff is a participant is not critical to the resolution of her claims. Contrary to Defendants' contentions, this Court would not be required to interpret the provisions of Plaintiff's benefit plan; the only issue is the five dollar difference between the price of generic and brand name tamoxifen, which is unlike, *for example, the analysis and interpretation of a plan to determine a person's eligibility for benefits.*

...

The issue in this case, however, is not eligibility or coverage and really has nothing to do with Plaintiff's ERISA plan.

Furthermore, Defendants argue 'that Plaintiff would not have the right she seeks to vindicate in this case- the right to obtain a tamoxifen prescription for a \$10 co-payment if her contention that it is a generic drug is correct - absent her participation in her plan.' (Defs.' Br. Opp'n Remand, at 1). This Court, however, is not persuaded by Defendants' argument. *This Court does not construe Plaintiff's claims as an effort to vindicate a violation of her employee benefit plan. Stated otherwise, this court finds that Defendants' alleged mis-classification of tamoxifen is not a violation of the provisions of the employee benefit plan such that ERISA would govern its resolution.*

...

Thus, the case cannot be construed to be for the recovery of benefits to which Plaintiff is entitled under the terms of the plan; we already know Plaintiff was eligible for, entitled to and received the benefit due. Plaintiff questions not her receipt of or eligibility to the tamoxifen, but rather Defendants' classification of it because it affects her co-payment under her plan, which the Court finds is only peripherally involved to the resolution of this case.

...

Plaintiff in this case sues not to enforce a provision of the employee benefit plan, but rather for the alleged mis-classification of tamoxifen.

. . .

Defendants argue that this Court will have to review and interpret the terms and provisions of the plan and that ‘Plaintiff would not have the right to vindicate absent her participation in her plan.’ (Def.’ Letter Br. At 1). Indeed, the Complaint refers to certain provisions of the plan. This Court finds, however, *that the plan itself and the interpretation of its provisions are not critical to the underlying issue - clarifying the classification of tamoxifen. Accordingly, this Court holds that Plaintiff’s claims are not completely preempted under Section 1132(a).*” (Emphasis added.)

Bauer and Wright’s claims do not “relate to” any ERISA plan under § 1144. As explained above, Bauer and Wright’s claims are clearly and simply predicated on PCS’ misclassification scheme. Bauer, Wright and PCS all concede that Bauer and Wright were “eligible for, [and] entitled to” receive the benefits due. The only dispute involves PCS’ misclassification of tamoxifen and its resultant profiteering.

Liability issues in this case are easily determined by the trier of fact when looking at PCS’ conduct. Exhibit 1 of the SAC (R. 1080), the deposition of PCS’ Lorraine Stevens, at pp. 7-8 and 11-12, demonstrates that PCS classifies tamoxifen as brand regardless of the terms of any of the healthcare plans it services. PCS never looks at the plans before making its wrongful classification. In the fortuitous, but rare situation, where a

healthcare plan defines “generic” in such away as to permit PCS’ tamoxifen brand classification scheme to stand, such policy language becomes an issue of damages relative to putative class members’ claims. *See* Judge Camp’s decision remanding this case to Georgia State court - the italicized portion, at page 22 *infra*. Neither BAUER’s nor WRIGHT’s plans permit a brand classification for tamoxifen.

**D. PCS cannot rely on the Trial Court’s findings in
Bauer v. Express Scripts.**

At page 21 of its brief, PCS refers to Judge Goger’s order of April 28, 2004. That Order denied Class Certification in the case of *Bauer v. Express Scripts*, 2002 CV 60672. Judge Goger found that the state health plan at issue defined “generic” in such a way as to prohibit Bauer from being a class representative in *that* case. A full copy of that Order is attached as Exhibit 3 to Plaintiffs’ Responsive Memorandum of Law in Opposition to Defendants’ Motion to Dismiss for Lack of Jurisdiction. (R.1231) In *this* case, however, no such health plan definition of “generic” exists. PCS does not have the luck as did Express Scripts in 2002 CV 60672. To be sure, the PBM defendants *never* look at their clients’ health care plan language for a definition of the word “generic” before classifying tamoxifen as brand. They

only look to their pocketbooks. (See Exhibit 4 attached to Plaintiffs' Responsive Memorandum of Law In Opposition to Defendants' Motion to Dismiss for Lack of Jurisdiction, R. 1231, PCS' internal e-mails provided in discovery and filed under seal, demonstrating that profit motive dictates the classification of tamoxifen as brand. Saliently, substantial portions of these e-mails have been "redacted" by PCS without explanation.)

Express Scripts lucked out in 2002 CV 60672 because, though it never looked at the health care plan before litigation, it argued, as an after thought, that Bauer's Georgia State Health Plan permitted Express Scripts to profit from classifying tamoxifen as brand. Judge Goger determined that he had to disqualify Debra Bauer as a class representative against Express Scripts because of her particular healthcare plan while employed by the State of Georgia. PCS does not enjoy the fortuitous luck of Express Scripts. PCS cannot rely on the BAUER and WRIGHT health care plan language in *this* case to defend its conduct.

E. PCS' reliance on the Department of Labor is misplaced.

PCS attempts to sidestep the obvious-- that Bauer and Wright's claims are not claims for denial of benefits or coverage claims under ERISA – and

selectively cites to a Department of Labor website at page 20 of its brief to support its position. The *full* text of the PCS reference is as follows:

“C-12: If a claimant submits medical bills to a plan for reimbursement or payment, and the plan, applying the plan’s limits on co-payment, deductibles, etc., pays less than 100% of the medical bills, must the plan treat its decision as an adverse benefit determination?”

Under the regulation, an adverse benefit determination generally includes any denial, reduction, or termination of, or a failure to provide or make payment (in whole or in part) for, a benefit. In any instance where the plan pays less than the total amount of expenses submitted with regard to a claim, while the plan is paying out the benefits to which the claimant is entitled under its terms, the claimant is nonetheless receiving less than full reimbursement of the submitted expenses. Therefore, in order to permit the claimant to challenge the plan’s calculation of how much it is required to pay, the decision is treated as an adverse benefit determination under the regulation. Providing the claimant with the required notification of adverse benefit determination will give the claimant the information necessary to understand why the plan has not paid the unpaid portion of the expenses and to decide whether to challenge the denial, e.g., the failure to pay in full. This approach permits claimants to challenge whether, for example, the plan applied the wrong co-payment requirement or deductible amount. The fact that the plan believes that a claimant’s appeal will prove to be without merit does not mean that the claimant is not entitled to the procedural protections of the rule. This approach to informing claimants of their benefit entitlements with respect to specific claims, further, is consistent with current practice, in which Explanation of

Benefits forms routinely describe both payable and non-payable portions of claim-related expenses. See § 2560.502-1(m)(4).”

A complete and accurate reading of this regulation further demonstrates that Bauer and Wright’s claims against PCS are not ERISA claims. This regulation is applicable *only* to conduct by ERISA plans. PCS is *not* an ERISA “plan” as set forth in this regulation. PCS is *not* an ERISA entity.

F. PCS’ reliance on *Aetna Health Inc. v. Davila*, 124 S.Ct. 2458 (June 21, 2004) is misplaced: this is not an ERISA case.

Aetna does not support PCS. PCS is just plain wrong when at page 9 of its brief it claims: “*Aetna* establishes beyond question that Bauer’s state unjust enrichment cause of action is completely pre-empted by ERISA’s cause of action for plan benefits, ERISA §502(a)(1)(B)...” In fact, *Aetna* supports the position of Bauer and Wright.

The U.S. Supreme Court in *Aetna* barred malpractice and negligence actions against ERISA healthcare entities, the effect of which is to prevent increased healthcare costs. *Aetna*’s facts form no basis for this Court to overturn the trial Court’s Order of June 10, 2004, but instead provide additional grounds for affirmance. PCS, itself, is guilty of increasing

healthcare costs for its ERISA entity customers and its customers' consumer beneficiaries. Reversing the trial court's ruling would blunt the effect of our Supreme Court in *Aetna*. Reversing the trial court would lead to increased health care costs to consumers and their health care plans.

Moreover, the Supreme Court's *Aetna* decision doesn't change PCS' status. It doesn't change Judge Goger's reasoning in his June 10, 2004 Order. It doesn't change U.S. District Judge Camp's Order reasoning that:

“Plaintiff does not contend that Humana denied her benefits under her health care plan. Instead, Plaintiff contends that Defendants. . . misrepresented the classification of tamoxifen, resulting in damages that are measured by the higher co-payment Plaintiff was required to pay. The mis-classification of tamoxifen was not perpetuated by any definition in Plaintiff's plan or by a decision of Humana's, but by Defendants. . . the misrepresentation affects the plan only because the plan will offer the measure of damages. These damages are sought from the Defendants, non-ERISA entities, not from the plan or Humana. Thus, the lawsuit does not affect the relationship between the principle ERISA entitles.” (Emphasis added, R. 1231, Plaintiffs' Responsive Memorandum of Law In Opposition to Defendants' Motion for Reconsideration of This court's Order of June 10, 2004, Exhibit 1.)

Contrary to the PCS spin, and as Judge Camp observed, Bauer and Wright's claims are not for benefits under the terms of their health plans. Bauer and Wright have not sued their health plans as

did the plaintiffs in *Aetna*. Bauer and Wright’s claims are not claims for denial of coverage, as were the claims of the plaintiffs in *Aetna*. Bauer and Wright may have pursued their health care plans if those plans had anything to do with misclassifying tamoxifen as brand. Bauer and Wright’s healthcare plans had nothing to do with this misclassification. The health care plans are not the culprits. PCS is.

To support its *conclusory* statement as to what *Aetna* purports to stand for, at page 16 of its brief, PCS argues as follows:

“Davila alleged that Aetna refused to pay for a drug prescribed by his treating physician. Davila did not appeal this decision, nor did he purchase the prescribed drug with his own funds and seek reimbursement. Instead, Davila began taking an alternative medication - covered by his plan- that allegedly caused a ‘severe reaction’ requiring ‘extensive treatment and hospitalization.’ *Id.* Calad alleged that, after undergoing surgery, a CIGNA discharge nurse determined that she was ineligible for an extended hospital stay even though an extended stay had been recommended by her treating physician. Calad experienced post-surgery complications as a result of her premature discharge and had to return to the hospital. *Id.* at 2492-2493.”

But in *Aetna*, Davila and Calad were complaining that their *ERISA plans denied them coverage* leading to consequential damages. Not true in the

facts before this Court. In this case, PCS is not Bauer and Wright's health care plan. PCS in this case is *not* Bauer and Wright's health care plan administrator. PCS has nothing to do with coverage issues under Bauer and Wright's health care plans. Bauer and Wright's claims are clearly predicated on PCS' scheme of misclassifying the generic drug tamoxifen for its own profit. The PCS scheme results in increased costs to Bauer and Wright's ERISA plans and to Bauer and Wright: all of which is contrary to what *Aetna* stands for.

PCS further argues that *Aetna* sets forth a "two prong" preemption test. According to PCS' reading of *Aetna*, preemption lies if the claim could have been brought under ERISA, and no other "independent legal duty" arises as a result of PCS' actions. But Bauer and Wright's claims are not for denial of coverage under their ERISA plans, are not against their ERISA plans, could never have been brought under ERISA, and, as explained in the preceding pages, do not "relate" to their ERISA plans.

As to PCS' "first prong" contention, PCS' reference to *Del Greco I* and *Del Greco II* at page 21 of its brief that Bauer and Wright "could have brought an action under ERISA" offers it no support. Anybody can bring any

type of a lawsuit anywhere. It doesn't make it right. Ironically, summary judgment was granted against Del Greco in her ERISA filed case. (*Del Greco v. CVS*, 2004 WL 2211600 S.D.N.Y) Preemption was never raised. Bauer and Wright have not made the mistake that Del Greco made. Bauer and Wright have placed blame on the true culprit PCS.

Furthermore, and as Judge Camp has ruled, PCS is not an ERISA entity and Bauer and Wright could not have sued an ERISA plan for the misclassification of tamoxifen:

“...and AdvancePCS admits it was not a plan fiduciary because it performed only ministerial functions. (Defs’ Resp. at 6 n.7)... Thus, the issue is whether the unjust enrichment claim against Defendants affects the relationship between Plaintiff, her plan, and Humana. Defendants contend that this lawsuit will affect the relationship between plaintiff and Humana because the Court must determine the meaning of ‘generic’ under the plan and whether Humana properly assessed the copayment for tamoxifen as a brand drug. The Court rejects this reasoning because AdvancePCS, not Humana, classified tamoxifen as a brand drug, and this classification was not based on the definition of ‘generic’ in Plaintiff’s plan. AdvancePCS managed several plans, and, irrespective of their terms or definitions, treated tamoxifen as a brand drug across the board...such indirect relation between a beneficiary and the plan is not enough for preemption...The mis-classification of tamoxifen was not perpetuated by any definition in Plaintiff’s plan or by a decision of Humana’s, but by Defendants.” (Exhibit 1 to Plaintiffs’ Responsive Memorandum of Law In Opposition to Defendants’ Motion for Reconsideration of this Court’s order of June 10, 2004, R. 1231). Emphasis added.

Bauer and Wright’s respective ERISA plans have no involvement in the classification of tamoxifen or the effects of this classification on its price. The fact that PCS has unilateral control over the classification and pricing of tamoxifen is underscored by the testimony of PCS employee Lorraine Stevens, *supra* at pp. 12-13. There is no denial of coverage in this case that would allow Bauer and Wright to sustain a claim against their ERISA plans. Therefore, the first prong of PCS’ *Aetna* test is not satisfied.

As to PCS’ “second prong” contention, PCS has an “independent legal duty” to a universe of breast cancer victims to refrain from unjustly stealing their money. PCS’ actions “implicate” its violation of this duty: a duty independent of any ERISA requirements. PCS disingenuously argues that it has no "independent legal duty" to Bauer and Wright, absent their ERISA plan when it states:

“Just as in *Aetna*, the only relationship Appellees had with AdvancedPCS was its partial administration of the prescription drug benefits provided by their employer's ERISA covered plans. Furthermore, as Judge Goger ruled in a related case involving a non-ERISA plan, Appellees have "no valid unjust enrichment claim" unless the *plan* at issue entitled them to a "lower' generic drug' co-payment" for Tamoxifen. (PCS’ brief at p. 21)

This argument makes no sense. First, the plaintiffs in *Aetna* were *denied*

coverage under the terms of their ERISA plans. PCS is not Bauer and Wright's health care plan and Bauer and Wright have not been denied coverage for tamoxifen by their health care plans. Second, by citing Judge Goger as authority, PCS admits that Bauer and Wright have valid unjust enrichment claims under *their* plans. Contrary to the circumstances in *Bauer v. Express Scripts*, Bauer and Wright's respective ERISA plans do entitle them to a lower generic drug payment. Reference to this plan for the sole purpose of determining damages warrants no preemption. As Judge Goger stated in his opinion related to *this* case:

"any relation between the claim and the ERISA entity is simply too remote...the [Defendants alleged] misrepresentation affects the [Plaintiffs' health plan] only because the plan will offer the measure of damages." (citations omitted). (Exhibit 2 attached to Plaintiffs' Responsive Memorandum of Law in Opposition to Defendants' Motion for Reconsideration, R. 2312).

Norton and *Porter*, cited at page 10 of PCS' brief, are also of no avail. Both cases involved claims for denial of disability benefits against those plaintiffs' employers. PCS is not Bauer and Wright's employer. PCS does not make coverage decisions. Accordingly, the "second prong" of PCS' *Aetna* test is not satisfied.

PCS prays that *Aetna* will carry the day for it. Its prayer must be rejected. It cannot “relate” *Aetna* to the facts of this case. It does not even make the attempt. PCS knows Bauer and Wright’s claims are far removed from the claims of the *Aetna* plaintiffs. Therefore, PCS manufactures an illusion that somehow the legal principle of *Aetna* permits its conduct of ripping off breast cancer victims and their ERISA plans. PCS fools nobody. PCS’ conduct with its resultant increase in health care costs to ERISA entities and their beneficiaries should not be rewarded with an improper application of *Aetna*.

G. The recent ruling of the Third Circuit Court of Appeals in *Pascack Valley Hospital, Inc., Community Medical Center (Lawrence Taylor, Debra Saverino) v. Local 464A UFCW Welfare Reimbursement Plan*, decided November 1, 2004, is inciteful as to why Bauer and Wright’s unjust enrichment claims do not fall under ERISA and why *Aetna* is of no avail to PCS.

Pascack involved a hospital’s suit against an ERISA plan for breach of contract claiming the plan improperly took a discount for services provided. The hospital claimed that this breach of contract was not pre-empted by ERISA and should not have been removed from the state court. The *Pascack* court agreed and referring to *Aetna*, at page 10 of its slip opinion, ruled as

follows:

“We further conclude that the Hospital’s state law claims are predicated on a legal duty that is independent of ERISA. *See Davila*, slip op. at 8. The Hospital’s claims, to be sure, are derived from an ERISA plan, and exist ‘only because’ of that plan. *Id.* at 11. The crux of the parties’ dispute is the meaning of Section 2.1 of the Subscriber Agreement, which governs payment for ‘Covered Services furnished to Eligible Persons.’ Were coverage and eligibility disputed in this case, interpretation of the Plan might form an ‘essential part’ of the Hospital’s claims. *Id.*

Coverage and eligibility, however, are not in dispute. Instead, the resolution of this lawsuit requires interpretation of the Subscriber Agreement, not the Plan. The Hospital’s right to recovery, if it exists, depends entirely on the operation of third-party contracts executed by the Plan that are independent of the Plan itself. *Cf. Caterpillar Inc. v. Williams*, 482 U.S. 386 (1987) (suit for breach of individual employment contract, even if defendant’s action also constituted a breach of an entirely separate collective bargaining agreement, not pre-empted by §301 of the Labor Management Relations Act).

We find instructive the Ninth Circuit’s opinion in *Blue Cross of California v. Anesthesia Care Associates Medical Group, Inc.*, 187 F.3d 1045 (9th Cir. 1999). In that case, the court held that claims asserted by health care providers against a health care plan for breach of their provider agreements were not completely pre-empted under ERISA. *Id.* at 1051-52. The court reached this conclusion notwithstanding ‘the fact that these medical providers obtained assignments of benefits from beneficiaries of ERISA-covered health care plans.’ *Id.* at 1047, 1052.

The litigation in *Anesthesia Care* arose from a fee dispute between four health care providers and Blue Cross. *Id.* 15 1048. Blue Cross had entered into ‘provider agreements’ with physicians in which Blue Cross agreed to identify the providers in the information it distributed to beneficiaries of the plan and to direct beneficiaries to those providers.

~~In return, the providers agreed to accept~~ payment for services rendered to beneficiaries according to specified fee schedules. When Blue Cross attempted to change the fee schedules, the providers filed a class action in state court alleging a breach of the provider agreements. *Id.* at 1049.

The Ninth Circuit held that ‘the Providers’ claims, which arise from the terms of their provider agreements and could not be asserted by their patient-assignors, are not claims for benefits under the terms of ERISA plans, and hence do not fall within §502(a)(1)(B).’ *Id.* at 1050. The court explained:

[T]he Providers are asserting contractual breaches...that their patient-assignors could not assert: the patients simply are not parties to the provider agreements between the Providers and Blue Cross. The dispute here is not over the right to payment, which might be said to depend on the patients’ assignments to the Providers, but the amount, or level, of payment, which depends on the terms of the provider agreements.”

Id. at 1051 (first emphasis added). Because the Providers asserted ‘state law claims arising out of separate agreements for the provision of goods and services,’ the court found ‘no basis to conclude that the mere fact of assignment converts the Providers’ claims into claims to recover benefits under the terms of an ERISA plan.’ *Id.* at 1052.²

The facts of this case are similar to *Anesthesia Care* in important respects: (1) the Hospital’s claims in this case arise from the terms of a contract-the Subscriber Agreement - that is allegedly independent of the Plan; (2) the participants and beneficiaries of the Plan do not appear to be parties to the Subscriber Agreement; and (3) ‘[t]he dispute here is not over the *right* to payment, which might be said to depend on the patients’ assignments to the [Hospital], but the *amount*, or level, of payment, which depends on the terms of the [Subscriber Agreement].’ *Id.* at 1051.

² The reasoning in *Anesthesia Care* was followed by *Orthopaedic Surgery Associates of San Antonio, P.A. v. Prudential Health Care Plan, Inc.* 147 F. Supp. 2d 595 (W.D. Tex. 2001). The facts in *Orthopaedic Surgery* are nearly identical to this case. In *Orthopaedic Surgery*, health care providers entered into contracts with a healthcare plan, Prudential. Under the contracts, Prudential agreed to pay the providers for services rendered to beneficiaries of the plan. When Prudential allegedly paid the providers less than the agreed upon amount, the providers sued for breach of the physician agreements. *Orthopaedic Surgery*, 147 F. Supp. 2d at 597. The District court in *Orthopaedic Surgery* remanded the case to state court, concluding that §502(a) didn't completely pre-empt the providers' claims. Citing *Anesthesia Care*, the court characterized the providers' claims as 'claim[s] for the amount or level of payment and not the right to payment.' *Id.*, at 601. The court rejected Prudential's argument that, since the medical services that were allegedly unpaid were provided to participants or beneficiaries of ERISA plans, the providers' claims sought benefits payable under the terms of those plans."

Just like in *Pascack*, the “dispute here is not over the *right* to payment, but the amount or level of [co]payment...” That co-payment is set by PCS, a PBM with which Bauer and Wright have no contract. PCS contracts with plans and insurance companies. Nothing in these “separate agreements” to which Bauer and Wright are not parties gives PCS the right to unjustly enrich itself at the expense of Bauer and Wright or their ERISA plans.

CONCLUSION

For all these reasons, the trial court should be affirmed and this matter should be sent back to the trial court for further proceedings.

Respectfully submitted,

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