BlueCross BlueShield Association

An Association of Independent Blue Cross and Blue Shield Plans

Legal Affairs

# Bulletin

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## II. In-Depth



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## I. Litigation

- **Antitrust**

FTC files complaint against chiropractic associations and attorney for engaging in an illegal boycott of benefits administrator.

***In re Connecticut Chiropractic Association***, File No. 071 0074, (FTC complaint filed March 5, 2008).

The Federal Trade Commission filed a complaint against the Connecticut Chiropractic Association (CCA), the Connecticut Chiropractic Council (CCC), and Robert L. Hirtle, Esq., alleging that respondents engaged in an illegal boycott of American Specialty Health (ASH) to prevent ASH from administering chiropractic services in Connecticut. ASH offers a chiropractic benefits administration program to payors nationwide. Under the program, payors delegate to ASH the management of chiropractic services, and ASH contracts with chiropractors to provide services to the payors' enrollees. The purpose and effect of the boycott was to prevent ASH from contracting with Anthem Blue Cross and Blue Shield of Connecticut, Empire Blue Cross Blue Shield, and CIGNA HealthCare.

According to the complaint, Anthem entered into an arrangement with ASH in 2006, under which ASH agreed to provide Anthem a chiropractic provider network and administer its chiropractic benefits. When they learned of the arrangement, CCA and CCC organized meetings of their member chiropractors, during which they discussed their dissatisfaction with ASH's price terms and utilization management requirements and agreed to opt out of ASH's program for Anthem. To implement the agreement, respondents distributed a model opt-out letter for chiropractors to notify ASH that they were not electing to participate in the Anthem program. As a result of the boycott, all but four chiropractors opted out of the ASH/Anthem network, forcing Anthem and ASH to cancel their arrangement. During this time, respondents encouraged and assisted chiropractors to refuse to participate in the ASH program for Empire and to end their participation in the ASH program for CIGNA. Their efforts succeeded. ASH was unable to contract with chiropractors for the Empire network, and CIGNA abandoned its program with ASH.

The FTC has filed a proposed consent order. It would prohibit respondents from entering into or facilitating any agreement among chiropractors (1) to negotiate with payors on any chiropractor's behalf; (2) to deal, not to deal, or threaten not to deal with payors; or (3) on what terms to deal with any payor.

- **Antitrust**
  North Carolina oncologist sues three Plans and BCBSA, alleging that defendants conspired to exclude him as a network provider to prevent paying for clinical cancer trials.

  ***Powderly v. Blue Cross and Blue Shield of North Carolina***, No. 08-CVS-3792, (N.C. Super. Ct, Mecklenburg County, filed Feb. 21, 2008).

  Dr. John Powderly II and Carolina BioOncology Institute sued Blue Cross and Blue Shield of North Carolina (BCBSNC), alleging that the Plan refused to renew his status as a participating provider to limit reimbursement for seriously ill cancer patients. From August 2002 until May 2005, Dr. Powderly participated in BCBSNC's provider network. In 2005, the doctor established the Carolina BioOncology Institute, which provided medical services, including clinical trials, to cancer patients. He subsequently sought from BCBSNC recredentialing and a renewed provider contract. BCBSNC approved his credentialing package but refused to renew his contract because he provided medical services for Phase I clinical trials, which were noncovered services.

  Dr. Powderly also alleges that Blue Cross and Blue Shield Association (BCBSA), Health Care Service Corporation (HCSC), and Blue Cross and Blue Shield of South Carolina (BCBSSC) are engaged in an unlawful combination with BCBSNC to restrain trade in violation of state and federal antirust laws. The unlawful combination, which is allegedly overseen and coordinated by BCBSA, has denied Dr. Powderly the ability to treat patients covered by other Licensees.

  In addition to antitrust violations, the complaint asserts against BCBSNC tortious interference and unfair trade practices. Plaintiffs seek against all defendants as to the antitrust claims compensatory damages in excess of $20 million, reimbursement of services provided, and treble damages under antitrust laws. They seek damages against BCBSNC as to the other claims for harm to plaintiffs' reputation and a judgment compelling BCBSNC to approve Dr. Powderly as an in-network provider.

- **Compliance**
  Seventh Circuit affirms the convictions of compliance officer and CEO of medical device company.

  ***United States v. Caputo***, No. 06-3612, 2008 WL 509177 (7th Cir. Feb. 27, 2008).

  [Editor's Note: This summary was written by Michael Z. Gurland, Esq., Neal, Gerber & Eisenberg LLP, as a follow-up to his article, "Compliance Officers at Risk: Personal Liability for Seeing Without Doing," 978 LAB 10 (July 2007). He can be contacted at 312-269-8440 or mgurland@ngelaw.com.]

  The criminal convictions of the Compliance Officer and Regulatory Advisor (Robert Riley) and the CEO (Ross Caputo) of AbTox Corporation, a medical device company, were affirmed by the Seventh Circuit Court of Appeals on February 27, 2008. Riley and Caputo had been convicted after a jury trial of criminal conspiracy to defraud the Food and Drug Administration (18 U.S.C. § 371), delivery of misbranded devices (21 U.S.C. §§ 331(a) and 333(a)(1)), lying to federal agents (18 U.S.C. § 1001), mail fraud (18 U.S.C. § 1341), and wire fraud (18 U.S.C. § 1343). *See United State v. Caputo*, 458 F. Supp. 2d 970 (N.D. Ill.

2006). Caputo was sentenced to 10 years imprisonment and Riley was sentenced to 6 years imprisonment.

In 1994 AbTox received FDA approval to sell a small gas-plasma sterilizer for flat stainless steel instruments. The small sterilizer used a 10% peracetic acid solution as the sterilant. In obtaining the FDA approval, AbTox withheld adverse test data and failed to disclose that, rather than sell the approved device, AbTox intended to sell a larger sterilizer that used a 5% peracetic acid solution as the sterilant and to promote the sterilizer for use metals and materials other than stainless steel.

AbTox aggressively marketed and promoted the larger device for sterilizing a wide range of materials, including off-label uses (that is, uses beyond those approved by the FDA). One promoted use was for instruments containing copper, notwithstanding that Compliance Officer Riley and CEO Caputo had learned that copper reacted with the peracetic acid to produce a blue-green residue (copper acetate), which remained on the instruments after they were sterilized. That residue led to a series of eye injuries, which hospitals reported to Compliance Officer Riley, but which Riley failed to report to the FDA.

On several occasions, the FDA told AbTox to cease marketing the larger sterilizer until it obtained separate approval. AbTox refused, disputing the FDA's interpretation of the regulations by arguing that the larger sterilizer was a modification of the approved small one and could therefore be marketed under the FDA's approval of the small sterilizer.

On appeal, Caputo and Riley argued that the regulations surrounding the marketing of a modified device were so vague as to violate the Due Process Clause of the Fifth Amendment. The Seventh Circuit did not need to reach the vagueness argument because, factually, the larger sterilizer was in existence *before* the small sterilizer received FDA approval. Consequently, the larger sterilizer was not a "modification" as addressed in the regulations, but as it existed prior to FDA approval of the small sterilizer, the larger sterilizer could have been submitted for FDA approval at that time.

Caputo and Riley also argued on appeal that the Food, Drug and Cosmetics Act violates the First Amendment by restricting commercial speech about the sterilizer to those uses that the FDA approved. Caputo and Riley asserted that off-label promotion of the sterilizer was constitutionally protected commercial speech, under such U.S. Supreme Court precedents as *Virginia Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976). The Seventh Circuit concluded that it did not need to resolve this argument because the larger sterilizer could not be lawfully sold in the first place. Consequently, any promotion of the larger sterilizer, whether for the use approved for the small sterilizer or off-label, was illegal.

- **Confidentiality**
  Court finds no evidence that former Aetna employee would disclose trade secrets to WellPoint.

  ***Aetna, Inc. v. Fluegel***, No. CV074033345S, 2008 WL 544504 (Conn. Super. Ct. Feb. 7, 2008) (unpublished).

  Bradley Fluegel began working at Aetna, Inc., in March 2005. He was hired as head of strategic planning and eventually became head of national accounts. When he began his

employment, he signed a confidentiality agreement. Aetna, however, denied his request for an employment contract and did not ask him to sign a noncompete agreement. In October 2007, Fluegel left Aetna and began working for WellPoint, Inc., as a member of its executive leadership team, performing functions in public affairs, corporate communications, and social responsibility.

Aetna sued Fluegel and WellPoint, alleging a threatened misappropriation of Aetna's trade secrets in violation of the Connecticut Uniform Trade Secrets Act (CUTSA) and a breach of his confidentiality agreement on the ground that Fluegel would inevitably disclose Aetna's trade secrets in performing his responsibilities at WellPoint. Aetna sought an ex parte injunction, an order to show cause, and a preliminary injunction against defendants. The court granted a preliminary injunction, allowing Fluegel to perform certain functions at WellPoint but limiting his strategic planning responsibilities to the review of historical documents and prohibiting him from attending strategic planning meetings.

After a closed hearing, allowing Aetna to provide testimony regarding its trade secrets, the court dissolved the preliminary injunction and denied Aetna's application for a permanent injunction. The court found that the evidence did not support Aetna's claim that Fluegel would inevitably disclose its trade secrets while working at WellPoint. The court reasoned:

> First, Aetna and WellPoint are not direct competitors. WellPoint is the largest of the four major competitors in the health insurance industry, whereas Aetna is the third largest and half the size of WellPoint. WellPoint, however, is not as strong as its competitors in the national accounts sector. Approximately ninety-five percent of WellPoint's business is in fourteen states operating as a licensee of the Blue Cross Blue Shield Association "Blue" brand. Aetna operates nationally under its own brand, with national accounts representing forty percent of its business and half of it revenues, whereas WellPoint's national accounts business only represents approximately three percent of its revenue.

2008 WL 544504, at *6.

The court then found that it was "unfair to create a noncompete agreement after the fact by enjoining Fluegel from performing his responsibilities at WellPoint when he has credibly stated, in no uncertain terms, that he will uphold the confidentiality of Aetna's trade secrets." The court further found that if Fluegel were to misappropriate Aetna's trade secrets, Aetna would become aware of that, based on WellPoint's actions, and could then bring an action under CUTSA for an injunction and damages.

- **Contract Interpretation—Investigational Exclusion**
  Court finds that Plan properly excluded coverage for MRI of the breast as investigational.

***Smith v. Blue Cross Blue Shield of Louisiana***, No. 07-033, 2008 WL 341381 (W.D. La. Feb. 5, 2008).

Linda Smith challenged Blue Cross and Blue Shield of Louisiana's denial of her claim for an MRI of the breast as being investigational. Under her plan, an MRI of the breast was considered investigational if used "as a screening technique for the detection of breast cancer when the sensitivity of mammography is limited (i.e., dense breasts, implants,

scarring after treatment for breast cancer)" regardless of medical necessity. Smith's doctor had ordered the MRI because the density of her breasts limited the sensitivity of a mammography.

The court held the Blue Cross and Blue Shield of Louisiana did not abuse its discretion in denying the claim. Based on the plan's specific exclusion, the court found that there was a rational connection between the known facts and the decision and that, therefore, the determination was reasonable.

- **Contract Interpretation—Out-of-Network Services**
  Ninth Circuit finds that insurer abused its discretion in denying benefits for out-of-network services.

  ***Jacobs v. Kaiser Foundation Health Plan Inc.***, No. 04-57131, 2008 WL 268077 (9th Cir. Jan. 30, 2008) (unpublished).

  Caryn Jacobs and her daughter Laura sued Kaiser Foundation Health Plan for denying an out-of-network referral to treat Laura's eating disorder. Laura sought treatment from Kaiser for bulimia under her mother's ERISA plan. At that time, Kaiser did not offer treatment for eating disorders. Under the plan, if a medically necessary service was not available from a network provider, Kaiser agreed to provide out-of-network coverage. Kaiser therefore recommended to Laura an acute phase outpatient group, but it was closed to her as a new patient for three months. Kaiser then recommended that in the meantime Laura attend a drop-in group, meet with a clinical social worker, and see her primary care physician for a physical. Laura found that the drop-in group was inadequate because it met infrequently and was poorly attended. When her condition worsened, Laura's mother admitted her to a hospital, where she was treated for four weeks.

  The district court entered summary judgment for Kaiser, finding that although Kaiser made it frustrating for Laura to obtain treatment, its decision to deny benefits for out-of-network services on the ground that appropriate treatment was available from a network provider was reasonable. Reversing, the Ninth Circuit held that Kaiser's denial was unreasonable, especially given its inherent conflict of interest. It found that contrary to its assertions, Kaiser did not have available any appropriate care to serve Laura's specific medical needs within it own facilities. It therefore instructed the district court to order Kaiser to reimburse the Jacobses for out-of-network services and award fees and costs.

- **Contract Interpretation—UCR Rates**
  Second Circuit affirms that UCR limit for bilateral breast surgery did not violate ERISA or the Woman's Health and Cancer Rights Act.

  ***Krauss v. Oxford Health Plans, Inc.***, No. 06-0343-cv, 2008 WL 495654 (2d Cir. Feb. 26, 2008). (*See* 960 LAB 4, 1/06.)

  Geri Krauss, an ERISA plan participant, was diagnosed with breast cancer. After receiving precertification from Oxford Health Plans, Inc., she underwent a bilateral mastectomy and breast reconstruction. During recovery, she had private-duty nursing care. Because the surgeon who performed the procedure did not participate in Oxford's network, the Krausses paid for the surgery, which cost $40,000, and then sought reimbursement from Oxford. Oxford's usual, customary, and reasonable (UCR) limit for bilateral surgeries was 150

percent of the single surgery rate, here $20,000. Oxford's UCR fee schedules were based on data from Health Insurance Association of America (HIAA) and Medicare's bilateral surgery policy. Based on its UCR calculations, it reimbursed the Krausses $30,000. It completely denied reimbursement for the private-duty nursing care, which cost $8,300, because the plan excluded such coverage.

After an unsuccessful internal appeal, the Krausses sued Oxford, seeking recovery of the unpaid portion of the breast reconstruction and the cost of private-duty nursing care. They alleged that Oxford's application of the UCR violated the Woman's Health and Cancer Rights Act (WHCRA), which requires insurers to cover post-mastectomy breast reconstruction. They also alleged various ERISA violations. The district court entered summary judgment for Oxford. The Krausses appealed.

Reviewing under an arbitrary and capricious standard, the Second Circuit held that Oxford did not violate the WHCRA or the plan when it partially paid for the surgery. In so doing, it rejected the Krausses' argument that the WHCRA's language allowing insurers to impose annual deductibles and coinsurance on coverage precluded the application of any other cost-sharing mechanism, such as UCR, that would make participants responsible for part of a procedure's costs. Analyzing the WHCRA's legislative history, the court said that it could not conclude that Congress, in failing to provide explicit permission for insurers to use other cost-sharing devices, intended to limit permissible cost-sharing mechanisms to annual deductibles and coinsurance. It therefore held that Oxford's application of UCR limits and, specifically, the bilateral surgery policy, to the surgery did not violate the WHCRA. Similarly, the court found nothing in the WHCRA that required an insurer to pay for private-duty nurses.

The court then held that Oxford's application of its Medicare-based bilateral surgery policy to the claim did not violate ERISA or the plan. It said, "Nothing in the Plan's terms forbids Oxford from adopting a UCR based not only on HIAA data, but on some other 'recognized' source." The court was unprepared to conclude that Medicare's policy was arbitrary and capricious and therefore held that Oxford's decision to apply the bilateral surgery policy to the claim was reasonable. Similarly, it found that the plan's explicit and unambiguous exclusion of private-duty nursing controlled.

- **Discounts**

  Court affirms dismissal of complaint alleging that providers' undisclosed discounting policy violated California law.

  ***Buller v. Sutter Health***, No. A118541, 2008 WL 588399 (Cal. Ct. App. Mar. 5, 2008).

  Plaintiff filed a proposed class action against Sutter Health, a not-for-profit provider network, and its affiliated medical center for alleged violations of California's Unfair Competition Law (UCL) and the Consumers Legal Remedies Act (CLRA). Plaintiff, who had Blue Cross insurance, paid within 30 days his noncovered portion of a hospital bill for a shoulder injury. He alleged that defendants failed to disclose the availability of discounts to consumers who had private health insurance and who timely paid their invoice for medical services. Specifically, he contended that defendants had an undisclosed policy of allowing a 10 to 44 percent discount if a patient's bill was paid within a specified time, typically 30 or 60 days. Defendants, however, allegedly did not disclose the discount, and consumers who paid the bill within the specified time did not automatically receive a refund.

Defendants moved to dismiss the complaint for failure to state a claim. The trial court dismissed the complaint without leave to amend, finding that defendants had no duty to disclose the existence of the discount policy. Plaintiff appealed.

Affirming, the appellate court held that plaintiff did not state a cause of action for unfair competition under the "fraudulent" prong of the UCL. It found that the complaint failed to allege that defendants had an affirmative duty to disclose the availability of a prompt-pay discount. Because the discount was not disclosed, the court concluded that patients were not likely to expect that they would be entitled to a discount. Therefore, the alleged failure to disclose was not conduct likely to deceive, the court said.

The court also held that plaintiff did not state a cause of action for unfair competition based on the "unfair" prong of the UCL. "Appellant makes no argument on appeal that his allegations are directly connected to any legislatively declared policy or threatened competition," the court said. It also found that defendants' practice was beneficial to consumers, because defendants were not required to offer discounts to privately insured patients.

- **ERISA—Fiduciary Duties**

  U.S. Supreme Court holds that participant in a defined contribution pension plan can sue for fiduciary breaches to his individual account.

  ***LaRue v. DeWolff, Boberg & Associates, Inc.***, 128 S. Ct. 1020 (U.S. 2008).

  The U.S. Supreme Court held that a participant in a defined contribution pension plan could sue the plan for breaches that impair the value of the assets in his account. Section 502(a)(2) of ERISA allows a participant to sue on behalf of the plan but does not provide a remedy for individual injuries. The Court, however, found that concerning defined contribution plans, an action alleging fiduciary misconduct to reduce benefits below the amount that participants would otherwise receive was allowed. It reasoned that the principal statutory duties imposed on fiduciaries by section 409(a) of ERISA related to the proper management, administration, and investments of fund assets and that "[t]he misconduct alleged by the petitioner in this case falls squarely within that category."

  Plaintiff filed this action against his former employer and its 401(k) plan, alleging that his employer failed to carry out changes he had requested to the investments in his account, thereby depleting his interest in the plan by $150,000. The district court granted defendants' motion for judgment on the pleadings, concluding that plaintiff was seeking damages rather than equitable relief under ERISA. The Fourth Circuit affirmed, holding that section 502(a)(2) provides for suits to "protect the entire plan, rather than the rights of an individual beneficiary."

- **ERISA—Fiduciary Duties**

  Court finds that processing enrollment forms is not a fiduciary duty.

  ***New Life Homecare, Inc. v. Blue Cross of Northeastern Pennsylvania***, No. 3:06-CV-2485, 2008 WL 423837 (M.D. Pa. Feb. 14, 2008).

  New Life Homecare Inc. (New Life) is a specialty pharmacy providing home care treatment for bleeding disorders. New Life had group health coverage from 2001 to 2007 through Blue Cross of Northeastern Pennsylvania and Highmark Blue Shield. In 2007, defendants

terminated New Life's group policy based on its noncompliance with underwriting requirements. New Life and plan participants sued defendants, alleging breach of contract, breach of fiduciary duty, equitable estoppel, failure to offer continuation coverage, violation of HIPAA's nondiscrimination provision and of ERISA's nondiscrimination and retaliation clause, and tortious interference with business and contractual relations. New Life also alleged that defendants directed its pharmacy benefit manager, Express Scripts, Inc., to terminate New Life as a participating provider in its specialty pharmacy network. Defendants moved to dismiss.

The court first addressed ERISA standing. Defendants argued that the individual plaintiffs lacked standing to obtain future insurance coverage because they were not participants at the time the complaint was filed. The court disagreed, saying, "The essence of this action is that the individual plaintiffs would still be participants in the 2007 Policy but for Defendants' alleged breach of the 2007 agreement . . . ." It therefore held that the individual plaintiffs had a colorable claim to relief under ERISA. The court found, however, that New Life, as the plan sponsor, lacked standing to bring an action under ERISA because it performed purely ministerial functions regarding the administration of the plan.

The court then dismissed, in part, plaintiffs' breach of fiduciary duty claim. Plaintiffs had argued that defendants had fiduciary duties under ERISA because of their authority regarding enrollment eligibility decisions and that they breached those duties by failing to (1) remove an out-of-state employee from the Plan in order to comply with service area requirements, (2) offer New Life an option to request a waiver for its out-of-state employee, or (3) enroll three additional employees. Examining the enrollment procedure of the 2006 policy, the court found that defendants' discretion "does not extend to the decision to terminate or not terminate the enrollment of an eligible employee, on New Life's request, simply because his enrollment jeopardized New Life's compliance with its requirements under the Policy. That discretion, further, does not extend to the ministerial task of processing, or not processing, a change of enrollment form." The court therefore dismissed the breach of fiduciary claim challenging the enrollment processing actions. But it allowed the claim alleging that defendants' failed to offer New Life an option for a waiver for an out-of-state employee, because that act involved some discretion.

The court also allowed the individual plaintiffs' claim alleging that defendants violated ERISA's nondiscrimination and anti-retaliation provisions when defendants allegedly took adverse actions, such as terminating the group policy and not providing participants with conversion policies. It further found that New Life stated a claim on which relief could be granted on the breach of contract claim and the tortious interference claim. It dismissed the remaining claims.

- **ERISA—Preemption**

Court holds that ERISA preempts parity claim for eating disorder treatment.

***DeVito v. Aetna, Inc.***, No. 07-0418 (FSH), 2008 WL 482847 (D.N.J. Feb. 25, 2008.)

Arguing that an eating disorder was a biologically based mental illness, plaintiffs DeVito and Meiskin sued Aetna, Inc., seeking treatment for their daughters' eating disorders under their respective ERISA plans. Aetna had denied DeVito's claim as not medically necessary. It provided coverage to Meiskin's daughter until the treatment exceeded the policy's limitations for coverage of a nonbiologically based mental illness. (Under the policies, a biologically based mental illness had the same coverage as a physical illness.) Alleging breach of

contract and breach of fiduciary duties, plaintiffs sought coverage under ERISA and New Jersey's parity law.

Aetna moved to dismiss, arguing that the court should abstain from ruling because a proposed bill was pending in the state legislature that would extend the parity law to cover eating disorders. Aetna also argued that the claims were preempted by ERISA, that the breach of fiduciary claim was duplicative of the claim for benefits, and that plaintiffs failed to exhaust administrative remedies.

The court first held that it would not abstain from ruling on plaintiffs' claims. It said that whether or not the parity law was changed did not affect the case because the policies remained in force regardless of future legislation.

The court next found that plaintiffs had no private cause of action under the parity law that they did not already have under the terms of their respective plans. It likewise found that Aetna's duties under the parity law were identical to its duties under the parity language in plaintiffs' policies. It therefore held that because plaintiffs could bring their claims under ERISA section 502(a)(1)(B), and because there was no other independent legal duty implicated by Aetna's actions, any individual cause of action under the parity law was completed preempted. It also held that parity claim was not saved from preemption, because it duplicated the claim for ERISA benefits. The court then refused to dismiss the breach of fiduciary duty claim, finding that there was no bright-line rule that a claim for equitable relief under section 1132(a)(3) should be dismissed when a plaintiff also brings a claim for benefits under section 502(a)(1)(B). Finally, the court found that plaintiffs properly pled futility in resorting to Aetna's internal appeals process.

- **Labor and Employment Law**
  Nurses sue Plan for unpaid overtime wages.

  ***Ruggles v. WellPoint, Inc.***, No.1:2008CV00201 (N.D.N.Y. filed Feb. 21, 2008).

  Three nurses employed by WellPoint, Inc., have sued the company under the Fair Labor Standards Act (FSLA) and New York states laws for allegedly failing to pay overtime wages. Plaintiffs bring the lawsuit on behalf of themselves and other similarly situated current and former employees who work or worked as a utilization review nurse, case management nurse, medical management nurse, or in a similar position. They seek nationwide class certification, a certification of a class in New York, a declaration that the WellPoint's practices violate the FLSA, an injunction, and damages.

- **Medicare—Immunity**
  Court holds that Plan does not have statutory immunity as Medicare carrier.

  ***United States ex rel. Conrad v. Blue Cross Blue Shield of Mississippi***, No. 2:99cv72-LG-JMR, 2008 WL 341650 (S.D. Miss. Feb. 5, 2008).

  Sherrie Conrad, a management consultant for Mid-South Rehab Companies, a Medicare provider, sued Blue Cross & Blue Shield of Mississippi, d/b/a Tri-Span Health Services, for allegedly submitting false Medicare claims to the government in violation of the False Claims Act. She alleged that the Plan's conduct was grossly negligent and knowing. The Plan moved for judgment on the pleadings based on a claim of complete immunity under 42

U.S.C. § 1395(u)(e)(3). Relying on *United States ex rel. Body v. Blue Cross & Blue Shield of Alabama*, 156 F.3d 1098 (11th Cir. 1998), the Plan argued that it was entitled to statutory immunity regardless of whether it acted with gross negligence or fraudulent intent. It also filed a supplemental motion, arguing that Conrad failed to state a claim under the False Claims Act.

Denying the motion for judgment on the pleadings, the court concluded that under 42 U.S.C. § 1395(u)(e)(3), a Medicare carrier was liable for payments made with gross negligence or intent to defraud the government and that, therefore, the Plan was not entitled to completed statutory immunity. In so doing, it followed the analysis in *United States ex rel. Sikkenga v. Regence BlueCross BlueShield of Utah*, 472 F.3d 702 (10th Cir. 2006), which held that § 1395(u)(e)(3) unambiguously conferred limited immunity on Medicare carriers, and that of *United States ex rel. Drescher v. Highmark, Inc.*, 305 F. Supp. 2d 451 (E.D. Pa. 2004), which found the statute ambiguous but nevertheless held that Congress did not intend Medicare contractors to have full statutory immunity. The court also denied the supplemental motion, finding that Conrad properly stated a claim for relief under the False Claims Act.

- **Policy Rescission**
  Los Angeles city attorney sues Health Net for improperly rescinding policies.

  ***California v. Health Net, Inc.***, No. BC385816 (Cal. Super. Ct. filed Feb. 20, 2008).

  The Los Angeles city attorney sued Health Net, Inc., and two of its subsidiaries for engaging in alleged postclaims underwriting in violation of California's unfair competition and false advertising laws. According to the complaint, defendants engage in numerous unlawful, unfair, and fraudulent acts, including (1) using an application for coverage that poses ambiguous and confusing questions; (2) marketing products through agents who lack meaningful training in taking a health history and who have an economic incentive to avoid the disclosure of an applicant's adverse medical information; (3) failing to investigate an applicant's information before issuing coverage; (4) promoting products using untrue and misleading statements; (5) suspending the claims processing during postclaims underwriting; (6) failing to ascertain whether the alleged error or omission was innocently made; (7) applying an incorrect legal standard when determining whether recession is warranted; (8) communicating to the consumer in a misleading form letter that falsely asserts that the rescission is unrelated to the claim; and (9) failing to refund all premiums when rescinding coverage. The complaint alleges that Health Net has an "investigation unit" specifically charged with rescinding coverage after a substantial claim is received. The insurer allegedly a sets quotas for policy rescissions and provides economic incentives to employees to rescind policies. Plaintiff seeks civil penalties, an injunction stopping defendants from engaging in the unlawful practices, reinstatement of the wrongfully rescinded policies, and disgorgement of ill-gotten gains.

- **Product Liability**
  U.S. Supreme Court holds that federal law preempts common law claims against medical device manufacturer.

  ***Riegel v. Medtronic, Inc.***, 128 S. Ct. 999 (U.S. 2008).

  In 1996, Charles Riegel underwent a coronary angioplasty. During the procedure, a Medtronic Evergreen Balloon Catheter burst. Riegel and his wife sued Medtronic, Inc., alleging that its catheter was designed, labeled, and manufactured in a manner that violated

New York law. The complaint asserted claims of strict liability, breach of implied warranty, and negligence in the design, testing, inspection, distribution, labeling, marketing, and sale of the catheter. The catheter had received preapproval from the Food and Drug Administration in 1994 under the Medical Device Amendments of 1976 (MDA).

The district court held that the MDA preempted the Riegels' common law claims and dismissed the complaint. Under the MDA, state requirements "different from, or in addition to, any requirement applicable . . . to the device" under federal law are preempted. The U.S. Court of Appeals for the Second Circuit affirmed, holding that the Riegels' claims were preempted because they "would, if successful, impose state requirements that differed from, or added to" the device-specific federal preapproval requirements.

In an 8-to-1 decision, the Supreme Court affirmed. It found that the FDA's premarket approval process was specific to individual devices and that, therefore, the federal government had established requirements specific to Medtronic's catheter. It then concluded that New York's tort duties were requirements "different from, or in addition to" the federal requirements. Consequently, it held that the Riegels' common law claims were preempted by the MDA.

# II. In-Depth

## STATUS AND SIGNIFICANCE OF THE SAN FRANCISCO HEALTH CARE ORDINANCE FOR EMPLOYERS

By

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*This article is intended for informational purposes only and is expressly not intended to create an attorney-client relationship. It sets forth the views of the author only and does not express the opinions of the Blue Cross and Blue Shield Association or of any of its member Plans.*

Beginning January 1, 2008, the San Francisco Health Care Security Ordinance requires medium and large businesses to make minimum "qualifying" health care expenditures or make payments to the city to be used on behalf of covered employees. Required expenditures range from $1.17 to $1.76 per employee per hour. The Golden Gate Restaurant Association filed suit arguing that the employer-spending requirement was preempted by ERISA. In December, the U.S. District Court for the Northern District of California agreed with the Association. However, the Ninth Circuit Court of Appeals granted an emergency stay pending a decision on appeal, which allows the city to begin implementing the ordinance. The stay decision was been appealed to the U.S. Supreme Court, but the Court did not grant certiorari. The appeal on the merits is still pending before the Ninth Circuit.

This case has important implications for all ERISA plans. The Ninth Circuit's decision is at odds with the Fourth Circuit's findings in the litigation that had involved similar legislation in Maryland. The Ninth Circuit will still pursue its full appellate proceedings on the merits (with a decision expected this summer); however, given the emergency stay it granted earlier, the court seems ready to rule in favor of the city. A conflict with the Fourth Circuit would likely send this issue to the U.S. Supreme Court. As almost half the states are currently considering some kind of health care reform, this is a major development indicating that, at least in the Ninth Circuit, ERISA plans might well have to comply with health expenditure mandates that state and local governments adopt.

The central feature of the ERISA preemption provision is that employers operating in more than one state can maintain uniform benefit plans because ERISA preempts states and local governments from regulating employer-sponsored benefit plans. Through ERISA, employers are able to provide benefits nationwide on a uniform basis. The ability to uniformly cover employees and retirees - who often live and work in different states throughout the country - is essential to employers' sponsorship of health and retirement benefits. Without uniformity,

the administrative complexity and burden would prevent many employers from offering benefits at all.

Because of the considerable impact on all employers if state and local governments are allowed to dictate benefit terms, employers across the country are keeping a close eye on the developments in this case. The best result would be for either the Ninth Circuit's three-judge panel or an en banc review by a fifteen-judge panel to decide that the San Francisco ordinance is preempted. Such a decision would likely resolve the matter in the near term and send a strong signal to future state and local governments to keep future health care reform within ERISA's current framework.

# COURTS DELVE INTO WHETHER A PHARMACY BENEFIT MANAGER IS A FIDUCIARY UNDER ERISA

By

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## Introduction

A number of lawsuits have recently been brought by health benefit plan participants against pharmacy benefit managers ("PBMs") that provide prescription drug services for their plans. In these cases, plaintiffs have alleged that the PBM breached a fiduciary obligation that it purportedly owed the plan pursuant to the Employee Retirement Income Security Act of 1974, as amended ("ERISA"). Plaintiffs have sought monetary relief for the alleged breach of fiduciary duty under Section 502(a)(2) of ERISA. That ERISA section authorizes a participant to sue a fiduciary for breach of its fiduciary duties and to make good on any monetary losses resulting from such fiduciary breach. Because a defendant can be liable for an ERISA breach of fiduciary duty only if it is, in fact, a fiduciary, the cases have turned on whether the PBM satisfies the definition of "fiduciary" under the statute. As we discuss below, courts that have addressed the question have uniformly answered "no," the PBM is not an ERISA fiduciary.

## Fiduciary Status Under ERISA

As noted above, a defendant can be liable for an ERISA breach of fiduciary duty only if it is a fiduciary. *Concha v. London*, 62 F.3d 1493, 1501 (9th Cir. 1995). The definition of "fiduciary" is set forth in Section 3(21)(A) of ERISA, which provides that a person is a "fiduciary" with respect to a plan "to the extent that" the person performs one of the following three functions:

> (i) exercises any discretionary authority or discretionary control respecting management of such plan or exercises any authority or control respecting management or disposition of its assets,
>
> (ii) renders investment advice for a fee or other compensation, direct or indirect, with respect to any moneys or other property of such plan, or has any authority or responsibility to do so, or

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(iii) has any discretionary authority or discretionary responsibility in the administration of such plan.

29 U.S.C. § 1002(21)(A). ERISA thus defines fiduciary "in *functional* terms of control and authority over the plan." *Mertens v. Hewitt Assocs.*, 508 U.S. 248, 262 (1993) (emphasis in original). Additionally, a fiduciary is not a fiduciary for all purposes. Rather, it is a fiduciary only for those matters for which it has responsibility as described in the statute. *Briscoe v. Fine*, 444 F.3d 478, 486 (6th Cir. 2006) ("Fiduciary status…is not an all or nothing concept"); *F.H. Krear & Co. v. Nineteen Named Trustees*, 810 F.2d 1250, 1259 (2d Cir. 1987) (Someone "may be an ERISA fiduciary with respect to certain matters but not to others, for he has the status only 'to the extent' that he has or exercises the [statutorily] described authority or responsibility").

Plaintiffs have argued that fiduciary status should be conferred on PBMs based on the PBMs' involvement in (among other things) negotiating the prices that participants pay for drugs at retail pharmacies and negotiating pharmacy rebates with drug companies. In seeking an answer to the fiduciary question, courts have started by reviewing the terms of the agreement between the health plan and the PBM.

## Leading Decisions

### 1. *Caremark*

The leading example is *Chicago Dist. Council of Carpenters Welfare Fund v. Caremark, Inc.*, 474 F.3d 463 (7th Cir. 2007). There, the Carpenters Welfare Fund ("Fund"), in an action against Caremark, Inc. ("Caremark") for breach of fiduciary duty, alleged that the PBM was an ERISA fiduciary because it had discretion and control over the Fund's drug benefit plan, including negotiations with drug retailers over drug prices, negotiations with drug manufacturers over rebates and other discounts, management of the formulary program, and management of the drug-switching program. *Id.* at 467. The Seventh Circuit held otherwise, finding Caremark was not a fiduciary for several reasons. First, with respect to drug pricing, in which the Fund argued that Caremark had discretionary authority to adjust prices the Fund paid for drugs that members obtained from retail pharmacies, the Court noted that the price paid by the Fund was fixed by contract and that Caremark was given no contractual discretion to make any price changes. *Id.* at 467-468.

Second, the *Caremark* Court determined that Caremark did not become a fiduciary simply because it may have received rebates or discounts from drug retailers. *Id.* The Court pointed out that nothing in the contract between Caremark and the Fund required Caremark to pass along any such rebates or discounts to the Fund. *Id.* Instead, the contract simply required Caremark to obtain the lowest prices it could from retailers. *Id.* Thus, it was obvious to the Court that Caremark made its profit from the spread between the drug prices it negotiated with retailers and the fixed prices paid by health participants. *Id.* Since there was no required "pass through" of savings to participants, Caremark was not acting on behalf of the Fund in negotiating with retailers and therefore was not acting as a fiduciary in those negotiations. *Id.*

The *Caremark* Court handled the question of drug manufacturer rebates in the same manner. As with drug retailer rebates, the Court concluded that Caremark was not negotiating those rebates on behalf of the Fund since there was no contractual requirement that any rebates "pass through" to the Fund. *Id.* at 475. As a consequence, the Court found

that Caremark was not acting as a fiduciary in negotiating those rebates with manufacturers. *Id.*

Finally, the *Caremark* Court held that Caremark was not a fiduciary in its management of the formulary and drug switching programs. *Id.* at 477. Again, looking to the contract between Caremark and the Fund, the Court found that the Fund had retained sole authority to determine the formulary for the plan to administer the drug-switching program. *Id.* at 476- 77. Accordingly, because Caremark lacked discretionary authority (or any authority) with respect to the Fund's formulary program, the Court found that Caremark could not be a fiduciary for those purposes. *Id.* at 477.

### 2. *Mulder*

The decision in *Mulder v. PCS Health Sys., Inc.*, 432 F. Supp. 2d 450 (D.N.J. 2006) is equally instructive. In that case, Scott Printing Co. ("Scott") delegated authority and control of health prescription benefit coverage to Oxford Health Plan, Inc. (“Oxford”). *Id.* at 452. Oxford then retained PCS Health Systems ("PCS") to serve as its PBM to provide formulary and preferred drug list services, rebate services, and drug use and therapeutic intervention services. *Id.* at 453. Subsequently, Mulder, an employee of Scott, sued PCS for breach of fiduciary duty for switching one of his drugs under the formulary program to receive rebates and kickbacks from drug manufacturers. *Id.* at 452-53. Mulder asserted that PCS was a fiduciary based on PCS's claims processing services, PCS's alleged control over the formulary program, including its final drug lists, and its design, implementation, and review of drug use and therapeutic intervention services.

The *Mulder* Court found that PCS did not act as an ERISA fiduciary. The Court first decided that PCS did not exercise any discretion in its claims processing services. According to the Court, PCS's role was merely ministerial, which did not elevate PCS to an ERISA fiduciary. The Court also determined that PCS's decision as to which drugs to include on the formulary did not give rise to fiduciary status. The Court noted that the contract between PCS and Oxford specified that PCS and Oxford "would work together to develop a formulary" and that Oxford had final authority over which drugs to include. *Id.* at 457-58. Similar to *Caremark*, the *Mulder* Court also found that PCS did not act on behalf of the health plan in negotiating discounts with drug manufacturers and thus was not functioning as an ERISA fiduciary. *Id.* Finally, the Court found PCS's mere design, implementation, and review of drug use and therapeutic intervention programs was not enough to show that PCS had discretionary authority to persuade physicians and pharmacists to switch drugs without Oxford’s approval. *Id.* at 461.

### 3. *Moeckel*

Caremark also was sued as a PBM in *Moeckel v. Caremark, Inc.*, 2007 WL 3377831 (M.D. Tenn. 2007). As with the action in the Seventh Circuit, in *Moeckel*, Caremark was charged with being an ERISA fiduciary based on the prescription drug services it provided to a health plan. The Court in *Moeckel* reasoned that although Caremark did negotiate prescription drug prices with retail pharmacies and drug manufacturers, the negotiations were separate and apart from Caremark's contractual relationship with the plan in which the plan simply adopted Caremark's negotiated prices. *Id.* at *13- 14. Like the situation in *Carpenters,* Caremark simply negotiated drug prices, including its own compensation, discounts, and rebates, with retail pharmacies and drug manufacturers as part of its own business operations. *Id.* at *14. Without a contractual obligation requiring Caremark to share its

compensation with the plan, the *Moeckel* Court rejected the proposition that Caremark's negotiations were on behalf of the health plan. From this, the Court determined that no fiduciary duty was imposed on Caremark in rendering PBM services to the plan. *Id* at *14, 20.

The Court also discounted the claim that Caremark was a fiduciary in its management of the plan's formulary and drug-switching programs. *Id.* at *21-22. Relying on *Mulder*, the *Moeckel* Court determined that Caremark "developed its formularies [and drug switching programs] for its own account" as part of its own business operations and that prospective clients could elect to adopt those formularies and drug switching programs. *Id.* at *21. Pointing to the Seventh Circuit's *Caremark* decision, the Court held that in this instance, the plan simply adopted the formulary programs and drug-switching programs independently established by Caremark. *Id.* at *22. Accordingly, the Court concluded that the subsequent agreement by the plan to adopt the programs did not retroactively make Caremark a fiduciary. *Id.*

#### 4. *Deluca*

Among the recent lawsuits in this area is an analogous case involving a third-party administrator to a health plan. In *Deluca v. Blue Cross Blue Shield of Michigan*, 2007 WL 3203131 (E.D. Mich. 2007), Flagstar Bank served as the named fiduciary and administrator of the Flagstar Plan, which provided health insurance coverage to its employees. *Id.* at *2. Flagstar Bank was contractually given "sole responsibility and authority" over the plan; but the Bank also had authority to delegate responsibilities to third parties. *Id.* Pursuant to that authority, Flagstar Bank delegated its responsibility for negotiating hospital rates on behalf of participants and beneficiaries of the Flagstar Plan to Blue Cross Blue Shield Michigan ("BCBSM"). *Id.* Deluca, a participant in the Flagstar Plan, filed suit against BCBSM, asserting that it violated its fiduciary duties in negotiating hospital rates. *Id.* at *4.

The Court in *Deluca* faced a similar factual situation as in *Mulder* and *Caremark* where a plan adopts rates independently negotiated by a third party. In *Deluca*, the issue was whether BCBSM became a fiduciary based on the plan's subsequent adoption of hospital rates negotiated by BCBSM. *Id.* at *6. The Court in *Deluca* reviewed the rate agreements between BCBSM and various hospitals and found that BCBSM entered into those agreements separate and apart from any subsequent agreement between BCBSM and the plan. *Id.* The Court found that plans were free to select the hospital rates previously negotiated by BCBSM or to select hospital rates negotiated by a different TPA. *Id.* at *7. Relying on *Mulder,* the *Deluca* Court reasoned that BCBSM was not rendered a fiduciary simply because Flagstar Bank decided subsequently to select the hospital rates negotiated by BCBSM. *Id.* Moreover, the Court found that nothing in the BCBSM contract with the Flagstar Plan authorized BCBSM *to* negotiate hospital rates on behalf of the Flagstar Plan. *Id.* at *8. As a result, the Court concluded that BCBSM was not an ERISA fiduciary.

## Concluding Thoughts

There is no doubt that pharmacy benefit managers will continue to face claims that they have breached fiduciary obligations to health benefit plans pursuant to ERISA. And, it is also clear that the courts adjudicating these claims will continue to address the contractual responsibilities of the PBM with respect to the health benefit plan. Where a PBM enters into its own contract with a retailer or drug manufacturer (or a hospital in the case of a TPA) to set rates or prices, courts have generally recognized that a plan's subsequent adoption of those negotiated prices does not elevate the PBM to a fiduciary. Likewise, where a PBM

negotiates independent discounts or rebates for itself that need not be passed through to a plan, the courts generally have held that such negotiations are not on behalf of the plan and therefore do not make the PBM into a fiduciary.

Thus, the lesson from these cases is that, as a starting point, courts will treat the question of whether a PBM is a fiduciary as a matter of contract interpretation. The courts will look askance at plaintiffs who argue that these entities are fiduciaries when the terms of the contract contemplate that they are not. Therefore, a PBM would be wise to pay careful attention to the functions it agrees to perform under the terms of a particular contract. Where the terms of the contract contemplate the exercise of discretion, or call for the performance of designated acts on behalf of the plan, as opposed to the PBM's own interests, the PBM may be vulnerable to a participant's claim that the PBM acts as a fiduciary to the plan.