Pharmaceutical Compliance Congress
November 11-13, 2009
Washington, DC

Managed Care and Reimbursement:

Risks and Compliance Strategies

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Topics for Discussion

- Industry Trends Creating New Compliance Risks
- Recent Enforcement Actions
- Key Risk Areas
- Compliance Strategies

Industry Trends → Emerging Risks

Industry Trend	Evolving Risks
Growing role of formulary/P&T committees	▪FDCA compliance ▪Financial/other relationships with Formulary sponsors, committee members
Increasing burdens on physicians due to prior authorization, tiered co-payments, coverage exclusion	▪Value of reimbursement support services (particularly beyond product-specific services) ▪FDCA compliance
Continuing importance of compendia to patient access/reimbursement	▪Same as for formulary interactions
Push for patients to shoulder some payment responsibility	▪Financial assistance to patients
Industry focus on biologics, where providers are at financial risk for reimbursement	▪Sampling ▪Value of support services ▪FDCA compliance
Healthcare reform	▪Potentially accelerates all of the above

Recent Enforcement Actions

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

UNITED STATES OF AMERICA, *ex rel.* JAMES MARCHESE, Plaintiff, v. CELL THERAPEUTICS, INC. MEDCOMM SOLUTIONS, ENVISION PHARMA, INC., and AMERISOURCEBERGEN CORP., Defendants.	NO. O6-0168-MJP **FILED IN CAMERA and UNDER SEAL**

SETTLEMENT AGREEMENT

I. PARTIES

This Settlement Agreement ("Agreement") is entered into between the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General ("OIG-HHS") of the Department of Health and Human Services ("HHS") (collectively the "United States"); James Marchese ("Relator"); and Cell Therapeutics, Inc. ("CTI") (hereafter referred to as "the Parties"), through their authorized representatives.

Recent Enforcement Actions

2. The United States contends that CTI made false and misleading statements to treating doctors to the effect that Trisenox was medically accepted for its off-label indications, and therefore eligible for Medicare reimbursement; thereby causing treating physicians to mistakenly administer Trisenox off-label to their patients, and causing them to present false or fraudulent claims for payment to Medicare.

3. The United States contends that CTI caused a series of false statements to be made to medical directors of Medicare program intermediaries and carriers, to the effect that Trisenox's off-label indications were medically accepted and therefore eligible for Medicare reimbursement, when CTI knew that Trisenox's off-label indications were not medically accepted, thereby causing Medicare medical directors to mistakenly approve Medicare reimbursement for off-label indications of Trisenox.

Recent Enforcement Actions

H. WHEREAS, CTI denies each and every one of these allegations and all allegations described in any pleading filed in the Civil Action.

I. WHEREAS, CTI contends that to the extent that any false or misleading statements were made by CTI or its agents pertaining to the availability of Medicare reimbursement for Trisenox, such statements were a consequence of negligent advice provided to CTI by a third party, which advice is the subject of Cell Therapeutics, Inc. V. The Lash Group et al., U.S. District Court for the Western District of Washington, No. 07-310-JLR.

J. WHEREAS, to avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, the Parties reach a full and final settlement pursuant to the Terms and Conditions below.

Recent Enforcement Actions

Department of Justice

United States Attorney Michael J. Sullivan
District of Massachusetts

FOR IMMEDIATE RELEASE
MONDAY, APRIL 2, 2007
WWW.USDOJ.GOV/USAO/MA

CONTACT: SAMANTHA MARTIN
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PFIZER SUBSIDIARY AGREES TO PLEAD GUILTY FOR OFFERING KICKBACK AND PAY $19.68 MILLION CRIMINAL FINE; SECOND SUBSIDIARY AGREES TO PAY ADDITIONAL $15 MILLION PENALTY TO RESOLVE ALLEGATIONS OF ILLEGAL PROMOTION OF HUMAN GROWTH HORMONE

BOSTON, MA- **PHARMACIA & UPJOHN COMPANY, INC.**, a subsidiary of Pfizer, Inc., was charged today in federal court with offering a kickback in connection with its outsourcing contract for the administration and distribution of its human growth hormone product, Genotropin. The company has agreed to plead guilty to the charge and pay a criminal fine. Additionally, another Pfizer subsidiary, **PHARMACIA & UPJOHN COMPANY LLC**, has entered into a Deferred Prosecution Agreement with the Government for its illegal promotion of Genotropin for such "off-label" uses as anti-aging, cosmetic use and athletic performance enhancement. As a result of the criminal plea and Deferred Prosecution Agreement, the companies will pay a total of $34.7 million.

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The Information alleges that **PHARMACIA** violated the Anti-Kickback Act by offering to make excess payments on a distribution contract, in the amount of $12.3 million, to a subsidiary of a pharmacy benefit manager, in the expectation of obtaining improved formulary positioning and improved formulary ancillary benefits from that pharmacy benefit manager for **PHARMACIA**'s drug products.

A pharmacy benefit manager, commonly referred to in the pharmaceutical industry as a "PBM," often acts as a middleman between pharmaceutical companies and health insurers. PBMs often recommend pharmaceutical products to health plans. The list of pharmaceutical product recommendations is called a formulary. In this case, **PHARMACIA** offered to overpay a subsidiary of a PBM for work on a drug distribution contract in the expectation that the PBM would in turn recommend **PHARMACIA**'s drug products, including by means of formulary recommendations, to certain of the PBM's clients.

Recent Enforcement Actions

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

UNITED STATES *ex rel.* STROM, Plaintiffs, v. SCIOS, INC. and JOHNSON & JOHNSON, Defendants.	No. C 05-3004 CRB **UNITED STATES' COMPLAINT** **JURY TRIAL DEMANDED**

1. The United States brings this action to recover losses from false claims submitted to federal health care programs as a result of the sustained fraudulent course of conduct of Defendants, Scios, Inc. ("Scios") and Johnson & Johnson ("J&J"). Scios and J&J illegally marketed and promoted the cardiac drug Natrecor for serial, scheduled outpatient infusions — a use not approved by the Food and Drug Administration ("FDA") and not covered by the federal health care programs — causing false claims to be submitted.

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(7) Reimbursement

91. Defendants knew that Medicare paid for the vast bulk of Natrecor used in the United States, including scheduled outpatient infusions. A presentation at the August 2001 Natrecor launch National Sales Meeting by Scios Vice President of Sales and Marketing Tom Feldman noted that "[o]ver 80% of the CHF patient population is over 65 years old." That same presentation noted that Medicare paid for 72.98% of the claims for CHF diagnosis code (ICD-9) 428.0, and stated that CHF is the "[s]ingle largest expense for Medicare." A presentation at Scios's July 19, 2002 Natrecor Outpatient Infusion Advisory Board meeting noted that reimbursement for outpatient infusions was from Medicare Part B. In a November 19, 2003 presentation to J&J officials, Scios officials stated that "CHF is [the] most significant Medicare healthcare cost burden." Defendants' January 31 to February 4, 2005 training for the Natrecor sales force stated that "Medicare is the primary payer for NATRECOR. Based on various claims analyses, we estimate that Medicare is the payer for 75% - 80% of NATRECOR used in the inpatient and outpatient settings."

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92. Scios knew, even prior to the FDA's August 2001 approval of Natrecor, that Medicare reimbursement was key to physicians' decisions to use Natrecor in the outpatient setting.

93. Outpatient Reimbursement was listed under "Outpatient Marketing Overview" in a presentation at Scios's July 19, 2002 Natrecor Outpatient Infusion Advisory Board meeting. Defendants' March 2004 ADHERE Investigator Meeting likewise included a presentation on "Reimbursement Challenges and Opportunities in the Outpatient Management of Heart Failure."

94. Defendants established a reimbursement team, headed by Christopher Panarites, to handle reimbursement issues and the Medicare Contractors' local coverage determinations ("LCDs") regarding Natrecor. The main objective of Mr. Panarites's job was to maintain

Recent Enforcement Actions

unrestricted access to Natrecor in the outpatient setting.

95. Defendants contracted with a consultant, the Lash Group, to develop reimbursement guides that instructed health care professionals, in great detail, how to bill Medicare for outpatient infusions of Natrecor. While the guide provided limited information on billing for inpatient infusions, the vast majority of the guide, which was updated annually, covered billing in the hospital outpatient and physician office settings. The guide included, for example, detailed billing codes for the outpatient settings; instructions on how to complete claim forms and appeal denied claims; sample letters of medical necessity and appeals; and sample claim forms. The Defendants provided their Natrecor sales representatives with these reimbursement guides to distribute to Natrecor providers in the outpatient setting. The sales force also had laminated "Natrecor (nesiritide) Hospital Outpatient Reimbursement Quick Reference" and "Natrecor (nesiritide) Physician Office Reimbursement Quick Reference" handouts that showed health care professionals how to fill out a Medicare claim form for outpatient Natrecor infusions.

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96. Defendants also provided a hotline number (staffed by the Lash Group) for health care professionals to call with Natrecor reimbursement questions. One of Scios's written sales aids from February 2002 instructed sales representatives to refer physicians to the reimbursement hotline if they needed assistance with outpatient reimbursement, noting that "[t]o imply or recommend reimbursement for off-label product uses (home health, intermittent usage) is considered Medicare Fraud and is punished severely."

97. At Scios's expense, the Lash Group also assisted providers through the Medicare appeal process for denied claims for payment.

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14. All documentation of communications made by any representative or agent of the Company with any Medicare contractor regarding coverage and/or reimbursement for any Off-Label use of the Covered Drug.

15. All documentation of communications with the American Hospital Formulary Service Drug Information, United States Pharmacopeia-Drug Information, or the DRUGDEX Information System regarding the Covered Drug.

FDA Action & Guidance

TRANSMITTED BY FACSIMILE

Frank Baldino, Jr., Ph.D.
Chairman and Chief Executive Officer
Cephalon, Inc.
41 Moores Road
P.O. Box 4011
Frazer, PA 19355 USA

RE: NDA # 20-717
Provigil® (modafinil) Tablets [C-IV]
MACMIS # 14707

WARNING LETTER

Dear Dr. Baldino:

The Division of Drug Marketing, Advertising, and Communications (DDMAC) of the U.S. Food and Drug Administration (FDA) has reviewed a promotional piece distributed on behalf of your company to the Maryland Department of Health and Mental Hygiene's Pharmacy and Therapeutics Committee (Committee) on August 17, 2006. This piece recommends or suggests uses for Provigil (modafinil) Tablets [C-IV] (Provigil) that have not been approved by FDA, and thus creates new "intended uses" for Provigil for which the product lacks adequate directions, broadens the indication for Provigil, and fails to communicate any risks associated with its use. Therefore, the piece misbrands the drug in violation of the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. §§ 352(a) & (f)(1); 321(n), and FDA implementing regulations. 21 C.F.R. §§ 201.5(a); 201.128; *cf.* 21 C.F.R. § 202.1(e)(6)(i). Furthermore, the FDA-approved product labeling (PI) for Provigil did not accompany the promotional piece, in violation of 21 C.F.R. § 201.100(d). Finally, Cephalon failed to submit the piece to FDA under cover of Form FDA-2253, as required by 21 C.F.R. § 314.81(b)(3)(i). These violations present serious public health and safety concerns.

Regulatory Guidance

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

APR 1994

Dear Sir or Madam:

This letter provides guidance and information from the Division of Drug Marketing, Advertising, and Communications (DDMAC) to all New Drug Application, New Antibiotic Drug Application, Abbreviated New Drug Application, and Abbreviated Antibiotic Drug Application holders. Enclosed are the following items:

VI. Formulary Kits as Promotional Labeling

Formulary "kits" or other similar materials (e.g., materials prepared for review by pharmaceutics and therapeutics committees, formulary committees, etc.), that discuss a regulated product and that are prepared for and disseminated to hospitals, managed health care organizations, buying groups, and other institutions are promotional labeling. Pursuant to 21 CFR 314.81(b)(3), formulary kits should be submitted to DDMAC with FDA Form 2253. DDMAC has provided an exception to this requirement for materials that are individually prepared in response to unsolicited requests for information. (See paragraph VIII.)

Regulatory Guidance

Product Support Services. Pharmaceutical manufacturers sometimes offer purchasers certain support services in connection with the sale of their products. These services may include billing assistance tailored to the purchased products, reimbursement consultation, and other programs specifically tied to support of the purchased product. Standing alone, services that have no substantial independent value to the purchaser may not implicate the anti-kickback statute. However, if a manufacturer provides a service having no independent value (such as limited reimbursement support services in connection with its own products) in tandem with another service or program that confers a benefit on a referring provider (such as a reimbursement guarantee that eliminates normal financial risks), the arrangement would raise kickback concerns. For example, the anti-kickback statute would be implicated if a manufacturer were to couple a reimbursement support service with a promise that a purchaser will pay for ordered products only if the purchaser is reimbursed by a federal health care program.

Key Risks and Considerations

- Managed care and/or reimbursement support activities to raise the major risks familiar to pharma companies:
  - Anti-kickback issues in financial relationships
  - Contracting and discounting
  - Fee-for-service arrangements with “customers” (broadly defined)
  - Financial relationships with individuals
  - FDCA (in interactions with HCPs, formulary sponsors, etc.)
  - Government price calculation
  - Privacy
  - Disclosure/transparency
- Common use of vendors/third parties does not outsource risk – and, in fact, creates some new risk
- While activities are different from traditional commercial efforts, the basic regulatory framework remains relevant

Assessment of Control Environment

(Partial List)

Activity	Clear Lines of Responsibility & Accountability	Policies & Procedures	Expertise/Training	Monitoring & Auditing
Contractual relation-ships with MCOs, PBMs				
Fee-for-service agreements with MCOs				
Financial relationships with individuals at MCOs				
Communication with Formularies				
Communication with Compendia				
Reimbursement support activities				
Coverage and coding advice				

Control Environment -- Thoughts

Accountability:

- Within business unit, is there reasonably clear responsibility and accountability?
- Is there accountability for specific programs/projects?
- Are there designated personnel within Legal, Compliance, MA, RA
- Have you considered “drivers” of behavior? Incentive comp, client targets, etc.

Policies and SOPs:

- Are there reasonably clear compliance policies/SOPs in place that address full range of regulatory requirements
- Are policies/SOPs readily available?
- Are they reviewed and updated periodically?

Expertise and Training:

- Do relevant personnel have current knowledge/expertise? How is that knowledge re-freshed to reflect new developments?
- Do oversight personnel (Compliance, Legal, etc.) have expertise?

Monitoring and Auditing:

- Do oversight functions have good visibility into the activity? (E.g., databases)
- Do you periodically monitor and/or audit the activity?