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Health Headlines

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Recent Prosecutions Reflect Heightened Focus by Regulators on Individual Liability of Healthcare Executives – Pronouncements in recent months by the Department of Justice and Department of Health and Human Services Office of Inspector General predict an increased focus on the individual liability of healthcare executives. Recent plea agreements of executives in the pharmaceutical and medical device industries confirm that regulators are carrying out this focus on individual liability. On March 14, 2011, Douglas Donofrio, a former sales director of an orthopedic device manufacturer, pled guilty to conspiracy to violate the Anti-Kickback Statute. Additionally, in a different matter, on March 10, 2011, Marc Hermelin, the former CEO of a pharmaceutical manufacturer, pled guilty to two misdemeanor violations of misbranding under the Food, Drug, and Cosmetic Act under a responsible corporate officer theory of liability.

Donofrio received a sentence of five years probation, restitution of $50,000—the amount of a bonus he received as a result of his illegal conduct—and a $6,000 fine. Hermelin agreed to a total repayment of $1.9 million, including administrative forfeiture of $900,000 and a fine of $1,000,000. He was also sentenced to 19 days in jail and one year of unsupervised release.

Donofiro's case is captioned *United States v. Donofrio*, 3:10-cr-836-GEB (D.N.J. Mar. 14, 2011), and his Plea Agreement and Judgment are available by clicking here and here.

Hermelin's case is captioned *United States v. Hermelin*, 4:11-cr-85 (E.D. Mo. Mar. 10, 2011), and his Plea Agreement and Judgment are available by clicking here and here.

Reporter, *Mike Paulhus*, Atlanta, +1 404 572 2860, mpaulhus@kslaw.com.

HHS Proposes to Allow State Data Mining for Medicaid Fraud – On March 17, 2011, the OIG published a proposed rule that would allow State Medicaid Fraud Control Units (MFCUs) to use federal matching funds to identify fraud through screening and analyzing State Medicaid claims data, a technique known as data mining. The OIG defines "data mining" as "the practice of electronically sorting Medicaid claims through statistical models and intelligent technologies to uncover patterns and relationships contained within the Medicaid claims activity and history to identify aberrant utilization and billing practices that are potentially fraudulent." Currently, HHS regulations prohibit State MFCUs from claiming Federal Financial Participation (FFP) for data mining activities that attempt to detect potential Medicaid fraud, and the MFCUs instead rely on referrals from State Medicaid agencies and their analysis methods. The OIG believes that amending current HHS regulations to permit State MFCUs to claim FFP for data mining activities could permit the MFCUs to identify early fraud indicators and would be an efficient use of resources. The OIG has proposed certain conditions that MFCUs must meet in order to claim FFP for costs related to data mining, including: (1) the MFCU must describe the duration of the data mining activity and the amount of staff time to be expended; (2) the MFCU must identify the methods of cooperation between the MFCU and Medicaid agency, and between the MFCU and review contractors selected by the CMS Medicaid Integrity Group; and (3) the MFCU must specially train employees engaged in data

mining. In addition, the proposed rule requires that an annual report be made that would, among other indicators, capture costs related to data mining activities and the number of cases generated from those data mining activities. The OIG is seeking public comments to the proposed rule, and such comments must be delivered no later than 5 p.m. on May 16, 2011. The proposed rule may be read here in its entirety.

Reporter, *Christina Gonzalez*, Houston, 1 + 713 276 7340, cagonzalez@kslaw.com.

Eleventh Circuit Rejects Insurers' RICO Class Action Against AstraZeneca Seeking Damages from Off-Label Promotion – On March 11, 2011, the United States Court of Appeals for the Eleventh Circuit ruled that a class action lawsuit filed by welfare benefit plans failed to state federal Racketeer Influenced and Corrupt Organizations Act (RICO) claims against AstraZeneca stemming from the pharmaceutical company's off-label promotion of the antipsychotic drug Seroquel.

The class action complaint—filed by labor unions and welfare benefit plans (referred to by the court as "insurers")—sought to recover damages allegedly sustained as the result of AstraZeneca's unlawful promotion of Seroquel. According to the complaint, physicians prescribed Seroquel for off-label uses because AstraZeneca falsely marketed the drug as safer and more effective in treating certain off-label conditions than other less expensive drugs.

The central allegation was that AstraZeneca's off-label promotion of the drug resulted in the insurers incurring increased drug reimbursement costs they would not have incurred absent such illegal marketing activities. Without the fraudulent activity, claimed the insurers, they would have paid less for their health plan enrollees' prescription drug costs. As such, the insurers sought "to recover the difference between the amount that was paid for the off-label Seroquel prescriptions and the amount that would have been paid for the less expensive substitutes."

Affirming the lower court's dismissal, the Eleventh Circuit's majority opinion held that the insurers failed to establish any economic injury arising from AstraZeneca's actions, as required to state a RICO claim. The Court found that insurers charge members premiums in exchange for healthcare coverage and that insurers use complex actuarial calculations in order to adjust premiums as necessary to account for and protect against known risks associated with such coverage.

In this instance, the Court held that the "insurers assumed the risk of paying for all prescriptions of drugs covered by their policies, including medically unnecessary or inappropriate prescriptions - even those caused by fraudulent marketing." These insurers elected to list Seroquel on their drug formularies and consequently provided coverage for all prescriptions for Seroquel, both on-label and off-label. Placing Seroquel on the formulary "contractually obligated the insurer to pay the drug's price anytime it was prescribed. Therefore, the insurers had to pay regardless of the facts surrounding the prescription."

The Court further reasoned that the insurers could have protected themselves by excluding coverage for medically unnecessary prescriptions of Seroquel or any formulary-listed drugs by requiring preauthorization: "[h]ere, however, the insurers made the conscious business decision not to require preauthorization review in their policies," and consequently "assumed the risk" of paying for medically unnecessary or inappropriate off-label Seroquel prescriptions. The Court concluded that "the risk that fraud—including fraudulent marketing by drug manufacturers—might result in insurers paying for medically unnecessary or inappropriate prescriptions is just another cost to be factored into premiums."

Concurring only in the judgment, Judge Beverly Martin stated that the "much simpler reason why [Astra Zeneca] should prevail" is because "the independent decisions of the physicians and other intermediaries . . . eviscerates the chain of causation necessary to demonstrate a RICO violation." The opinion is available by clicking here.

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HHS Issues Report on Early Results of the Affordable Care Act's Prevention Benefits – On March 16, 2011, HHS released a report (the "Report") finding that 151,764 Medicare beneficiaries have received an "annual wellness visit" between January 1 and February 23 of this year—an average of 2,800 seniors and disabled persons per day. Starting this year, annual wellness visits are considered preventive benefits, now covered by Medicare free of charge to the patient (no

deductible or cost-sharing) when obtained from qualified and participating practitioners. The Report notes that the Affordable Care Act waives cost-sharing for many preventive services as recommended by the United States Preventative Services Task Force and predicts that health care costs will be reduced due to early identification, treatment and management of disease. For example, the Report cites one study which found the rate of women getting mammograms increased by nine percent when cost-sharing was removed (only 43 percent of women with Medicare received mammograms in 2008). The Report further predicts that expanded coverage for prevention services will lead to lower premiums for employers who sponsor retiree coverage, for States that fill in Medicare's coverage gaps, and for seniors that purchase Medigap coverage. The Report is available by clicking here. HHS's news release is available by clicking here.

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