

Medicaid Fraud Press Release

FOR IMMEDIATE RELEASE
Parke-Davis/Warner-Lambert (now Pfizer)
Neurontin Global Settlement
May 18, 2004

The National Association of Medicaid Fraud Control Units (NAMFCU) and the District of Columbia Office of Inspector General, Medicaid Fraud Control Unit, announced on May 13 that DC has reached an agreement-in-principal with Parke-Davis, a division of Warner-Lambert, (now Pfizer- the largest pharmaceutical manufacturer in the world). Warner-Lambert will pay \$152 million dollars in damages and penalties to the various states' Medicaid programs to resolve allegations of illegal off-label marketing of Neurontin. As part of that settlement, the District of Columbia will recover \$303,081.42 in Medicaid restitution and penalties.

This case marks the first time that representatives of state Attorneys General Consumer Protection Divisions and NAMFCU jointly negotiated a case. In addition, to the Medicaid fraud settlement, Warner-Lambert entered into an Assurance of Voluntary Compliance with the State Attorneys General, Consumer Protection Divisions, which include remediation efforts that will benefit all consumers, including the Medicaid programs. These state settlements were reached in conjunction with a federal settlement negotiated by the United States Attorney's Office (D.M.A.) in which Warner-Lambert pled guilty in the United States District Court in Boston of violating the Food, Drug and Cosmetics Act (FDCA) and paid a fine of \$240 million dollars. This is the first, of what may be many, off-label marketing cases being investigated by the government and sends a strong message to the pharmaceutical industry that off-label marketing of pharmaceuticals is not only unacceptable but criminal and will be prosecuted aggressively by the government.

The global federal and state settlement, totaling \$430 million dollars, is a result of a 1996 False Claims Act (FCA) qui tam action filed in Boston by a former Warner-Lambert employee, David Franklin, alleging that the company engaged in a massive off-label marketing scheme to promote the epilepsy drug, Neurontin.

At that time, Neurontin was FDA approved only as an adjunctive therapy epilepsy drug, a drug that should only be prescribed in combination with another drug to treat epilepsy.

Although it may be appropriate for physicians to prescribe drugs for off-label uses, it is illegal for pharmaceutical manufacturers to promote the off-label use of their drugs. Warner-Lambert subsidized the production and dissemination of anecdotal reports promoting Neurontin for off-label uses including to treat pain management, bipolar disorder, restless leg syndrome, alcohol/drug withdrawal and migraines. In addition, Warner-Lambert made payments to physicians for “research” that the government contended was in effect, a kickback for off-label prescribing and provided expensive perks to physicians who attended and/or spoke at the continuing medical education (CME) classes where Neurontin was promoted for off-label uses. This off-label marketing campaign, aimed at tainting the information stream to physicians and ultimately consumers, resulted in inappropriate, unnecessary and/or ineffective prescriptions for Neurontin which was paid for by the Medicaid program. Approximately 90% of Neurontin usage is for off-label purposes.

As a part of the settlement, Warner-Lambert entered into a Corporate Integrity Agreement (CIA) with the Department of Health & Human Services, Office of Inspector General requiring strict scrutiny of its future marketing and sales practices. The CIA will be available on the HHS/OIG website (www.oig.hhs.gov).

NAMFCU team members included the Directors of the Washington State and North Carolina MFCUs and Assistant Attorneys General from the Delaware, Florida and Oregon MFCUs. For further information, please contact Barbara Zelner, Counsel for NAMFCU (202) 326-6020 or Susan Kennedy at the District of Columbia, Medicaid Fraud Control Unit , (202) 727-2245.