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Danish Pharmaceutical Novo Nordisk to Pay \$25 Million to Resolve Allegations of Off-label Promotion of NovoSeven

WASHINGTON – Danish pharmaceutical manufacturer, Novo Nordisk Inc. has agreed to pay \$25 million to resolve its civil liability arising from the illegal promotion of its hemostasis management drug NovoSeven, the Justice Department announced today. NovoSeven was approved by the Food and Drug Administration (FDA) to treat certain bleeding disorders in hemophiliacs. Once approved by the FDA, a manufacturer may not market or promote a drug for any use not specified in its new drug application and approved by the FDA. Such unapproved uses are also known as “off-label” uses.

The U.S. subsidiary, Novo Nordisk Inc., which is located in Princeton, N.J., promoted NovoSeven to health care professionals for off-label uses, including as a coagulatory agent for trauma patients, general surgery, cardiac surgery, liver surgery, liver transplants and intra-cerebral hemorrhage. As a result of this unlawful promotion, Novo Nordisk caused false claims to be submitted to government healthcare programs that were not reimbursable by those programs. Medicare and Medicaid paid for off-label prescriptions throughout the United States as a result of Novo’s focused campaign to influence doctors and hospitals. Further, the Department of Defense was influenced by Novo’s unlawful off-label promotion and purchased NovoSeven to treat service members wounded in Iraq and Afghanistan. The federal share of the civil settlement is \$21,425,790.59, and the state Medicaid share of the civil settlement is \$3,574,209.41.

“Pharmaceuticals should be marketed only for uses that the FDA has approved as safe and effective,” said Tony West, Assistant Attorney General for the Civil Division of the Department of Justice. “The off-label promotion alleged here not only wasted taxpayer dollars, but also undermined the FDA’s important role in ensuring that drugs are properly marketed to government agencies and members of the public.”

The settlement resolves a whistleblower lawsuit filed under the *qui tam* whistleblower provisions of the False Claims Act that is pending in the District of Maryland: *U.S. ex rel. Black and Montiel v. Novo Nordisk, Inc.* As part of today’s resolution, the whistleblowers will receive payments totaling more than \$3.5 million from the federal share of the civil recovery.

“Federal law prohibits pharmaceutical manufacturers from marketing drugs for unapproved uses, and restricts them from creating a financial incentive for doctors that may conflict with the interests of their patients,” added United States Attorney for the District of Maryland Rod J. Rosenstein. “Drugs should be marketed only for purposes for which they have been deemed safe and effective and prescribed only because they are expected to benefit the patient.”

Also as part of the settlement, Novo Nordisk has agreed to enter into an expansive corporate integrity agreement with the Office of Inspector General of the Department of Health and Human Services. That agreement provides for procedures and reviews to be put in place to avoid and promptly detect conduct similar to that which gave rise to this matter.

“Our separate Novo Nordisk corporate integrity agreement requires company board members to assure their compliance program is effective,” said Daniel R. Levinson, Inspector General of the Department of Health & Human Services. “This should focus high-level attention on preventing future off-label drug promotion. As an added measure, an independent review organization will provide extensive monitoring.”

The civil settlement was reached by the U.S. Attorney’s Office for the District of Maryland and the Justice Department’s Civil Division. The Corporate Integrity Agreement was negotiated by the Office of Inspector General of the Department of Health and Human Services. Investigative support was provided by Department of Defense Criminal Investigative Services, U.S. Army Criminal Investigation Command, Major Procurement Fraud Unit and the Office of Inspector General of the Department of Health and Human Services. Assistance also was provided by the National Association of Medicaid Fraud Control Units and offices of various state Attorney’s General.

This resolution is part of the government’s emphasis on combating health care fraud and another step for the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative, which was announced by Attorney General Eric Holder and Kathleen Sebelius, Secretary of the Department of Health and Human Services in May 2009. The partnership between the two departments has focused efforts to reduce and prevent Medicare and Medicaid financial fraud through enhanced cooperation. One of the most powerful tools in that effort is the False Claims Act, which the Justice Department has used to recover more than \$5.7 billion since January 2009 in cases involving fraud against federal health care programs. The Justice Department’s total recoveries in False Claims Act cases since January 2009 are over \$7.3 billion.