



Client Alert



Contact Attorneys Regarding
This Matter:

Alan G. Minsk
404.873.8690 - direct
404.873.8691 - fax
alan.minsk@agg.com

Meredith Mlynar Burris
404.873.8164 - direct
404.873.8165 - fax
meredith.burris@agg.com

Aaron M. Danzig
404.873.8504 - direct
404.873.8505 - fax
aaron.danzig@agg.com

Arnall Golden Gregory LLP
Attorneys at Law
171 17th Street NW
Suite 2100
Atlanta, GA 30363-1031
404.873.8500
www.agg.com

Medical Device Company Settles Marketing-Related Kickback Charges With the U.S. Government

The United States Department of Justice continues to take enforcement action against medical device manufacturers that unlawfully provide kickbacks to healthcare professionals. In February 2009, the United States Attorney's Office for the District of Massachusetts, in connection with the U.S. Department of Health and Human Services' Office of the Inspector General (OIG), announced a Deferred Prosecution Agreement (DPA) with NeuroMetrix, Inc., after an investigation into the device company's sales and marketing practices of its NC-stat System. The U.S. government alleged that the company engaged in unlawful marketing referral programs and encouraged improper reimbursement code billings.

Some Background Facts

- The NC-stat System is a medical device used in physicians' offices to assist in the diagnosis of neuropathies in peripheral nerves and the spine that can be caused by, or associated with, carpal tunnel syndrome, leg pain, diabetes and other clinical disorders. Purchasers of the NC-stat System must also buy disposable biosensors for use in connection with the device.
- From August 2004 through October 2006, the company marketed the device through two referral programs where, according to the DOJ, it paid physicians in the form of free boxes of disposable biosensors "to induce them to recommend purchase of the NC-stat system to their colleagues for the purpose of conducting nerve conduction studies that were reimbursed by federal health care programs."
- In addition, the government alleged that, from January 2003 through April 2006, NeuroMetrix knowingly caused the submission of false or fraudulent claims for payment to Medicare by providing coding reports to physicians that led to excess payments from Medicare to which the physicians were not entitled, i.e., the billing led to inflated Medicare charges.

Settlement

- The DPA is for a term of 36 months. If NeuroMetrix complies with its obligations under the agreement for its full term, the United States government will not prosecute the company in connection with the illegal kickbacks paid to physicians through the marketing referral programs.

- The company also entered into a five-year Corporate Integrity Agreement (CIA) with the OIG where, among other conditions, NeuroMetrix must establish a compliance officer and committee, train employees on the Anti-Kickback Statute and federal reimbursement rules, create a database to track all sales and marketing arrangements (to be audited by an Independent Review Organization), and report annually to the OIG on its progress. The company may be fined for failure to comply with the CIA.
- NeuroMetrix agreed to pay approximately \$2.5 million in civil damages and penalties to the DOJ and the OIG and a \$1.2 million criminal penalty to DOJ as part of the DPA.

AGG Recommendations

- Medical device companies must continue to ensure that marketing and sales practices comply with applicable fraud and abuse laws. Internal Standard Operating Procedures must reflect such compliance.
- Companies must train and audit employees to reinforce corporate compliance and, if non-compliance is observed, take appropriate corrective action. It is not advisable for a company to look the other way if an employee or another source raises concern about a particular marketing program or a deviation from company policy. The company's Compliance Officer and/or Committee must take all such issues seriously and investigate and document thoroughly. The company may want to enlist the assistance of outside counsel if the investigation indicates a potential area of non-compliance. An effective and robust compliance program can help prevent and detect unlawful conduct, but only if the individuals responsible for its implementation recognize the need to act accordingly when a potential problem surfaces.
- Firms may choose to benchmark their compliance programs against recommendations in CIAs or adopt measures outlined in these documents. In addition, companies should review CIAs and DPAs to learn the types of activities about which the government may object and the corrective actions the government will expect a company to take to resolve an enforcement action.
- Companies must recognize that the government will prosecute those companies that it believes have engaged in unlawful conduct, regardless of the company's size or its revenues.

For more information, please contact Alan Minsk, Meredith Burris or Aaron Danzig. Mr. Minsk and Ms. Burris are members of AGG's Life Sciences Practice Group, and Mr. Danzig is a member of the Firm's Litigation and Government Investigations and Special Matters Practice Groups.

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