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# OIG NEWS

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## **OIG SETTLES CIVIL MONETARY PENALTIES LAW CASE AGAINST MEDICAL DEVICE MANUFACTURER**

*Advanced Neuromodulation Systems, Inc. Pays \$2.95 Million and  
Signs 3-Year CIA To Resolve Kickback Allegations*

**Washington, D.C.** – Inspector General Daniel R. Levinson today announces a settlement with Advanced Neuromodulation Systems, Inc. (ANS) resolving allegations that ANS, a medical device manufacturer specializing in spinal cord stimulation used for pain management, paid kickbacks to physicians in violation of the Civil Monetary Penalties Law (CMPL). Under the terms of the settlement, ANS has paid the Office of Inspector General (OIG) for the U.S. Department of Health and Human Services \$2.95 million and entered into a 3-year Corporate Integrity Agreement that includes reviews of the company’s arrangements with physicians.

The OIG alleged that ANS engaged in a marketing program in which a number of physicians were paid \$5,000 for every five new patients tested with an ANS product. The OIG alleged that this program did not have any significant clinical value but rather served as a marketing tool to increase ANS sales. In addition, the OIG alleged that ANS sales and marketing personnel provided physicians with sports tickets, free trips, free dinners, grants, and other gifts during the relevant time period.

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“This significant settlement is an important example of OIG’s continuing effort to eliminate illegal kickback practices and demonstrates our commitment to use our administrative enforcement tools to penalize medical device manufacturers that pay kickbacks to physicians,” said Inspector General Levinson. “In addition, the Corporate Integrity Agreement ensures OIG’s oversight on future practices that affect the Federal health care programs and their beneficiaries.”

Under the CMPL, OIG may seek civil monetary penalties, assessments, and exclusion for a wide variety of conduct, including violations of the Anti-Kickback Statute. The Anti-Kickback Statute is designed to protect Federal health care programs and their beneficiaries from kickbacks, which often result in the inappropriate steering of patients, unfair competition, and overutilization of items or services furnished to program beneficiaries.

ANS, which is based in Plano, Texas, cooperated with OIG’s investigation that resulted in the settlement. During the OIG’s investigation, ANS was purchased by St. Jude Medical, Inc., a publicly-traded company headquartered in St. Paul, Minnesota.

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