Serono Settles for $44.3 Million

On May 4, 2011, the U.S. Department of Justice (DOJ) announced a $44.3 million settlement with Serono Laboratories Inc., Serono Inc., EMD Serono Inc., Merck Serono SA, and Ares Trading SA, (collectively, Serono), to resolve alleged violations of the False Claims Act. DOJ reported that in United States ex rel. Amato v. Serono Laboratories, the relator claimed that Serono: (1) paid doctors kickbacks in the form of payments to providers for speaker training meetings and programs, payments for attending consultant, marketing, and advisory board meetings, expense reimbursements, and other items to induce them to prescribe or promote its multiple sclerosis drug Rebif; and (2) knowingly failed to include the inducements paid in its calculation and reporting to Centers for Medicare & Medicaid Services (CMS) of Rebif’s “best price”—and thus, submitted false claims to federal healthcare programs. In addition, some funds were allegedly funneled through a nonprofit multiple sclerosis corporation, which purportedly then remitted a substantial portion of those funds to physicians.

Specific Allegations
The settlement stemmed from a whistleblower action brought by Tim Amato (Relator), a former employee of Serono. In the complaint, the Relator detailed a series of events beginning shortly after he was hired in 2003 as regional business director for Serono. The Relator alleged that he received a series of “requests” from Dr. Alan Bowling, a leading prescriber of multiple sclerosis drugs. Bowling was also the medical director of a multiple sclerosis center and the author of a number of guidebooks on managing and treating multiple sclerosis. The complaint alleged that Bowling requested $25,000 in cash, as well as 200 copies of one of his guidebooks, which had a retail value of $19.95 per copy. Allegedly, Bowling had previously received $25,000 from Serono. The Relator purportedly told the doctor that Serono could not comply with his requests, and he was subsequently fired in June 2004.

The complaint further alleged that Serono had developed a money-laundering scheme to funnel money to at least three physicians and four related entities. The relator alleged that Serono funneled $30,000 to a nonprofit multiple sclerosis corporation, from which the nonprofit would retain $5,000 as a donation and funnel the remaining $25,000 to Bowling. The complaint further alleged that Serono presented the nonprofit with a series of checks from March 2002 to December 2004 totaling $447,337. One of those payments was allegedly used to pay the membership dues of Dr. Patricia Coyle, who worked at a multiple sclerosis treatment center. The relator also alleged that at a management meeting he attended, Serono management admitted to funneling money to another physician, Dr. Dan Mikol.
Settlement Agreement

Pursuant to the Settlement Agreement and without admitting liability, Serono agreed to pay $44,300,000, plus interest accruing annually at 3.125% commencing on March 30, 2010 (Settlement Amount). The settlement amount will be split between the United States ($34,600,000, of which $5,190,000 will go to the Relator) and certain Medicaid Participating States ($9,700,000). Serono will also pay the Relator’s attorneys fees in the amount of $118,713.

The United States agreed to release Serono from any civil or administrative monetary claims it has or may have for the Covered Conduct under the False Claims Act, Program Fraud Civil Remedies Act, Civil Monetary Penalties Law, other civil statutory authority, and common law. In consideration of the obligations of Serono set forth in the Settlement Agreement and a new Addendum to the corporate integrity agreement (CIA), and conditioned upon full payment of the Settlement Amount, the Office of Inspector General (OIG) agreed to release and refrain from instituting, directing, or maintaining any administrative action seeking permissive exclusion from federal healthcare programs against Serono for the Covered Conduct. OIG reserved all rights to comply with any mandatory statutory obligations to exclude Serono and its affiliates from federal healthcare programs for the Covered Conduct. The settlement release also contained exclusions that are customary in many other False Claims Act settlement agreements.

Serono agreed that all costs incurred by or on behalf of Serono in connection with the following were “unallowable costs” under government contracts: (1) matters covered by the Settlement Agreement; (2) the audit and investigation of matters covered by the Settlement Agreement, as well as actions taken by Serono in response thereto; (3) the negotiation and performance of the Settlement Agreement (and related Medicaid State Settlement Agreements); (4) payments made by Serono pursuant to the Settlement Agreement and in connection with carrying out its other obligations thereunder; and (5) the negotiation of and obligations undertaken pursuant to the CIA Addendum. Serono may not seek reimbursement for any unallowable cost in the future, and agreed to adjust any previously submitted cost report to exclude unallowable costs.

Finally, the settlement also extends Serono’s existing CIA for three years. The original CIA stemmed from Merck Serono’s $704 million settlement in 2005 to resolve civil and criminal charges in connection with the promotion of the AIDS drug Serostim. The extended CIA enhances the provisions of the original CIA, and requires the company’s directors and senior management to ensure and monitor compliance with federal law, and requires Serono to retain an independent organization to perform detailed reviews of its drug marketing practices.

*We would like to thank Gary Herschman, Esquire, and Jack Wenik, Esquire (Sills Cummis & Gross PC, Newark, NJ) for authoring this email alert. The authors would like to thank Diana Giampiccolo, a law clerk at the firm, for her assistance in drafting this alert.