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May 4, 2011
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SERONO TO PAY $44.3 MILLION TO RESOLVE FALSE CLAIMS ACT ALLEGATIONS IN CONNECTION WITH PROMOTION OF DRUG REBIF

Baltimore, Maryland - Pharmaceutical manufacturers Serono Laboratories, Inc., EMD Serono, Inc., Merck Serono S.A., and Ares Trading S.A., have agreed to pay $44.3 million to resolve False Claims Act allegations in connection with the marketing of the drug Rebif. The settlement resolves allegations that, between January 1, 2002 and December 31, 2009, Serono paid health care providers to induce them to promote or prescribe Rebif, a recombinant interferon injectable that is used to treat relapsing forms of multiple sclerosis, a chronic autoimmune disease that attacks the central nervous system.

The settlement was announced by United States Attorney for the District of Maryland Rod J. Rosenstein, Assistant Attorney General Tony West of the Civil Division of the Department of Justice; Daniel R. Levinson, Inspector General of the Department of Health & Human Services; Gordon S. Heddell, Inspector General of the Department of Defense; and Patrick E. McFarland, Inspector General of the U.S. Office of Personnel Management.

“Health care decisions must be based solely upon what is best for the individual patient and not on which pharmaceutical company is paying the doctor the biggest kickback,” said Rod J. Rosenstein, U.S. Attorney for the District of Maryland. “All consumers have the right to know that their health care provider’s judgment about medications they should take has not been undermined by kickbacks from pharmaceutical manufacturers.”

“The health care of our seniors and other vulnerable citizens under the Medicare and Medicaid programs should be based upon sound medical decisions, not upon decisions tainted by influence and corruption,” said Tony West, Assistant Attorney General for the Justice Department’s Civil Division.

“In settling this second case with Serono, OIG extended Serono's existing corporate integrity agreement by three years, and required enhanced provisions such as specifically requiring that company directors and senior executives take responsibility for ensuring and monitoring compliance with federal law,” said Daniel R. Levinson, Inspector General of the Department of Health & Human Services. “If we can alter the cost-benefit calculus of some directors and executives, OIG can influence corporate behavior without putting access to government health care benefits at risk.”

“Federal employees deserve health care providers and suppliers, including drug manufacturers, that meet the highest standards of ethical and professional behavior,” said Patrick E. McFarland, Inspector General of the U.S. Office of Personnel Management. “Today's settlement reminds the pharmaceutical industry that they must observe those standards and reflects the commitment of Federal law enforcement organizations to pursue improper and illegal conduct that places health care consumers at risk.”

The settlement resolves allegations that Serono submitted false claims to federal health care programs including Medicare and Medicaid for the payment of Rebif. The government contends the claims were tainted by payments to health care professionals in the form of promotional speaking engagements; speakers’ training, and advisory and consultant meetings; expense reimbursement; independent medical and educational grants; sponsorships and charitable contributions. Serono denies the allegations. There were no allegations of patient harm or of conduct by Serono that adversely affected patient care. EMD Serono (formerly Serono, Inc.) markets and sells Rebif. Serono Labs is a sister company of EMD Serono. Ares Trading supplies EMD Serono with its products. Merck Serono is parent corporation of all the entities.

Under the agreement announced today, the proceeds from the settlement will be split between the federal government and various states, with the United States receiving $34.6 million to resolve the federal claims and the states receiving $9.7 million to settle their respective claims under Medicaid.

The settlement resolves a lawsuit brought by a whistleblower, Tim Amato, in 2005 under the qui tam or whistleblower provisions of the False Claims Act, which permit private citizens with knowledge of fraud against the government to bring a lawsuit on behalf of the United States and to share in any recovery. Under the civil settlement announced today, Mr Amato will receive $5.19 million out of the federal share of the recovery.

The settlement is part of the government's emphasis on combating health care fraud. The False Claims Act is a powerful tools in that effort and allows the government to recover triple the amount of its actual damages, plus a civil penalty of $5,500 to $11,000 for each false claim.

The settlement announced today was the result of an investigation by the U.S. Attorney’s Office for the District of Maryland with assistance from the U.S. Department of Health and Human Services, Office of Inspector General; the Department of Defense, Defense Criminal Investigative Service; and the Office of Personnel Management, Office of Inspector General. The investigation was handled by Assistant United States Attorney Roann Nichols and Auditor Mary Hammond.

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