

GOVERNMENT OF THE DISTRICT OF COLUMBIA
Office of the Inspector General



Inspector General
July 31, 2013

**ISTA PHARMACEUTICALS, INC. PAYS \$15 MILLION IN SETTLEMENT OF
OFF-LABEL MARKETING CLAIMS**

Inspector General Charles J. Willoughby announced today that the District of Columbia joined with other states and the federal government to reach an agreement with ISTA Pharmaceuticals, Inc. (ISTA) to settle allegations that ISTA marketed its ophthalmic drug Xibrom® for uses that were not approved by the United States Food and Drug Administration (FDA), and paid inducements to doctors to write Xibrom® prescriptions between January 2006 and March 2011. ISTA was acquired by Bausch + Lomb in June, 2012. Bausch + Lomb incorporated ISTA's products into its own and wound down ISTA's operations. The ISTA conduct alleged in this settlement predated the acquisition by Bausch + Lomb.

ISTA paid the states and federal government a total of \$15,000,000 in civil damages to compensate Medicaid, Medicare, and other federal health care programs for harm suffered as a result of its conduct. The state Medicaid programs received over \$740,000. The federal damages are significantly higher because the vast majority of Xibrom® prescriptions were for conditions primarily suffered by older Medicare patients, such as cataracts and glaucoma.

To resolve concurrent criminal charges, ISTA entered into a plea agreement with the federal government in which it pled guilty in federal court on May 24, 2013, to conspiracy to introduce a misbranded drug into interstate commerce and conspiracy to pay illegal remuneration in violation of the Federal Anti-Kickback Statute. ISTA paid criminal fines and forfeitures of approximately \$18.5 million in the criminal case in addition to the civil settlement.

Xibrom® had FDA approval only for use following cataract surgery, for up to 14 days. The government entities alleged that ISTA marketed the drug for a wider range of uses, including treatment and prevention of cystoid macular edema, treatment of glaucoma and inflammation other than postoperative inflammation, and treatment of pain and inflammation associated with non-cataract eye surgery. Pharmaceutical manufacturers are generally not allowed to market their drugs for uses that are not approved by the FDA, and federally-funded health care plans, including Medicare and Medicaid, generally do not pay for prescriptions for such uses.

Further, ISTA allegedly offered and paid illegal remuneration to certain ophthalmologists and optometrists to induce them to prescribe Xibrom®, in violation of the Federal Anti-Kickback Statute. This remuneration allegedly included monetary payment, paid consulting or speaker arrangements, and honoraria for participation in advisory meetings that were intended to be marketing opportunities.

This settlement is based on whistleblower actions filed in the United States District Court for the Western District of New York under state and federal false claims statutes.

A National Association of Medicaid Fraud Control Units team participated in the investigation and conducted the settlement negotiations with ISTA on behalf of the settling states. Team members included representatives from the Offices of the Attorneys General for the states of California, Colorado, Maryland, New York, and North Carolina, and the Office of the Inspector General for the District of Columbia. Inspector General Willoughby recognized Medicaid Fraud Control Unit attorney Elaine Block for her work on this matter.