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Ranbaxy Settlement Signals Expansion of FCA Actions against Generic Drug Manufacturers

May 15, 2013

On May 13, 2013, the U.S. Department of Justice (DOJ) announced a landmark settlement of claims under the civil False Claims Act (FCA) and related state laws against Indian generic drug manufacturer Ranbaxy Laboratories Limited and its subsidiaries. The case, *U.S. ex rel. Thakur v. Ranbaxy Laboratories Limited*, Case No. JFM-07-962 (D. Md.), continues DOJ's trend of aggressively prosecuting pharmaceutical companies under a host of federal laws and marks an extension of FCA actions against generic drug manufacturers.

The Ranbaxy case arose from a whistleblower suit filed by Dinesh Thakur, a former Ranbaxy executive and the company's Director of Research Information & Project Management. In his position at Ranbaxy, Thakur was responsible for compiling data used in filing Abbreviated New Drug Applications (ANDA) with the U.S. Food and Drug Administration (FDA). From August through November 2004, Thakur investigated Ranbaxy's drug portfolio and allegedly found rampant falsification of data concerning the formulation, bioequivalence and stability of generic drugs manufactured at two Ranbaxy facilities in India.

In April 2007, Thakur filed a complaint in the U.S. District Court for the District of Maryland alleging violations of the FCA and state analogs. The complaint, in which the government and plaintiff-states later intervened, alleged that Ranbaxy regularly falsified data and manufactured and sold drugs whose strength, purity, or quality differed from the drug's specifications or that were not manufactured according to the FDA-approved formulation. Ranbaxy thereby caused false claims for reimbursement to state and federal benefits programs, including Medicare and Medicaid. Ranbaxy settled the case in an agreement filed on May 10, 2013, agreeing to pay $350

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million to the United States and the plaintiff-states in what DOJ has billed "the largest drug safety settlement to date with a generic drug manufacturer." As part of the settlement, Ranbaxy USA Inc., a Ranbaxy subsidiary, pleaded guilty to felony counts under the Food, Drug and Cosmetics Act for selling adulterated drugs, and for knowingly making false statements to the FDA.

The Ranbaxy case signals an expansion of FCA claims against generic drug manufacturers for irregularities in manufacturing practices. Historically, FCA claims against drug manufacturers have arisen primarily from companies' off-label marketing of drugs for non-FDA approved uses. The Ranbaxy case highlights the potential for massive FCA liability for violations of drug manufacturing regulations.

The case also illustrates DOJ's recent trend toward aggressively prosecuting drug manufacturers as part of its effort to combat healthcare fraud. In May 2009, the government announced its Health Care Fraud Prevention and Enforcement Action Team initiative, a partnership between DOJ and the U.S. Department of Health and Human Services (HHS) aimed at combatting Medicare and Medicaid financial fraud. DOJ has made frequent use of the FCA in bringing claims for fraud against federal healthcare programs, recovering more than $10.2 billion since January 2009 from those claims. In 2010, SB Pharmco Puerto Rico Inc., a subsidiary of GlaxoSmithKline, PLC, paid $600 million to settle claims under the FCA and state analogs arising from its manufacture and distribution of adulterated drugs. In March of this year, Par Pharmaceuticals Inc. agreed to pay $45 million to settle criminal and civil claims under the FCA arising from off-label drug marketing.

In announcing the settlement with Ranbaxy, Stuart F. Delery, Acting Assistant Attorney General for DOJ's Civil Division, stated, "When companies sell adulterated drugs, they undermine the integrity of the FDA's approval process and may cause patients to take drugs that are substandard, ineffective, or unsafe. We will continue to work with our law enforcement partners to ensure that all manufacturers of drugs approved by the FDA for sale in the United States, both domestic and foreign, follow the FDA guidelines that protect all of us." As the Ranbaxy case and other recent settlements show, the FCA provides DOJ a powerful tool in this effort, and DOJ is certain to aim the law more frequently at generic drug manufacturers.

Wiley Rein's White Collar Defense and Government Investigations Practice has extensive experience defending against government actions and private whistleblower suits under the FCA. The Practice has worked extensively with the Fraud Section of DOJ's Civil Division Commercial Litigation Branch, and frequently responds to government subpoenas, develops detailed legal and factual responses to the government's inquiries and prepares witnesses for interviews by investigators.

Wiley Rein's Food, Drug, and Medical Device Law Practice is also deeply involved in assisting the pharmaceutical industry in connection with recent developments under the FCA. The Practice includes seasoned attorneys with FDA experience in counseling clients on complex regulatory strategies and compliance matters and representing clients in administrative and judicial enforcement actions and other proceedings involving the FDA and other federal and state agencies.