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Ranbaxy Resolves Criminal and Civil Charges Through Record Settlement

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Executive Summary

On May 13, 2013, generic drug manufacturer Ranbaxy USA Inc. (Ranbaxy), a subsidiary of Indian generic drug manufacturer Ranbaxy Laboratories Limited, pled guilty to seven felony charges as part of a global settlement pursuant to which Ranbaxy will pay a total of $500 million to resolve criminal and civil False Claims Act (FCA) liability.[1] In pleading guilty, Ranbaxy admitted to manufacturing and distributing adulterated drugs made at two of Ranbaxy's facilities in Ponta Sahib and Dewas, India, failing to file required reports with the U.S. Food and Drug Administration (FDA), and making material false statements to FDA. Ranbaxy Laboratories Limited's press release following the settlement noted that the conduct at issue occurred several years ago and that Ranbaxy's current management cooperated fully in the Department of Justice's (DOJ) investigation. The settlement follows upon Ranbaxy's 2012 Consent Decree of Permanent Injunction and represents the largest drug safety settlement to date with a generic drug manufacturer. The settlement also makes good on government threats to use criminal and civil enforcement tools, including the FCA, to address serious manufacturing violations.

Settling Entities	Ranbaxy USA Inc. (US subsidiary); Ranbaxy Laboratories Limited (Indian parent company); Ranbaxy, Inc.; Ranbaxy Pharmaceuticals, Inc.; Ranbaxy Laboratories, Inc.; and Ohm Laboratories, Inc. (all subsidiaries of Ranbaxy Laboratories Limited named in the *qui tam* FCA complaint).
Government Entities Involved	U.S. Attorney's Office for the District of Maryland; DOJ Civil Division Consumer Protection and Commercial Litigation Branches; certain states and the District of Columbia (which will enter Medicaid State Settlement Agreements with Ranbaxy).
Criminal Charges Resolved	One felony count of violating the Federal Food, Drug, and Cosmetic Act (FDCA) by introducing adulterated drugs into interstate commerce with the intent to defraud and mislead; two felony counts of violating the FDCA by failing to file required reports with the intent to defraud and mislead; and four felony counts of violating 18 U.S.C. § 1001 by knowingly making material false statements to FDA.

1 The information set forth herein is derived from publicly available sources.

Products Involved	Felony FDCA counts: Sotret (branded generic isotretinoin, used to treat severe recalcitrant nodular acne), gabapentin (used to treat epilepsy and nerve pain), and ciprofloxacin (broad-spectrum antibiotic); Felony false statements counts: Cefaclor; Cefadroxil; Amoxicillin; and Amoxicillin and Clavulanate Potassium (all antibiotics).
Monetary Settlement Breakdown	Total criminal penalties — $150 million, consisting of a criminal fine of $130 million and forfeiture of $20 million; total civil penalties — $350 million, of which the federal government share is $231.8 million and $118.2 million will go to the states participating in the settlement.
Relevant Time Period	Felony adulteration charge relates to conduct between January 1, 2005, and December 31, 2006; failure to file reports charges relate to conduct in 2003, 2004 and 2007; civil FCA claims relate to conduct between April 1, 2003, and September 16, 2010.
Relator	Dinesh Thakur, director of Project & Information Management with Ranbaxy Laboratories Limited in Gurgaon, Haryana, India, from June 2003 until April 2005. According to his *qui tam* complaint, Thakur had responsibility for portfolio and product management and established a program management office that oversaw internal data created during the formulation and manufacturing of Ranbaxy's drugs. Thakur filed his *qui tam* action in April 2007. Pursuant to the settlement agreement, Thakur will receive approximately $48.6 million from the federal share of the civil settlement.
Related Matters	In January 2012, Ranbaxy Laboratories Limited, its senior vice president, head global quality, and its managing director, as well as Ranbaxy USA Inc. and its regional director for the Americas, entered a consent decree of permanent injunction with FDA, acting through the U.S. Attorney's Office for the District of Maryland. Pursuant to the consent decree, Ranbaxy is enjoined from manufacturing drugs at the Ponta Sahib and Dewas facilities until the facilities have been brought into full compliance with Good Manufacturing Practices (GMP). The consent decree also comprises notable data integrity requirements, including an audit of pending applications, the implementation of new procedures and controls to ensure data integrity, and the withdrawal of applications found to reflect untrue statements of material fact or a pattern or practice of data irregularities. Ranbaxy also agreed to relinquish 180-day marketing exclusivity rights for three pending generic drug applications, and additional applications are at risk if the consent decree's deadlines are not met.
Exclusion/Debarment Implications	Ranbaxy's felony pleas under the FDCA subject it to mandatory FDA debarment pursuant to 21 U.S.C. § 335(a)(1). Ranbaxy's felony false statements pleas under 18 U.S.C. § 1001 subject it to mandatory exclusion from participation in federal health care programs, pursuant to 42 U.S.C. § 1320a-7(a)(3) (felony conviction relating to health care fraud). The import of this debarment and exclusion is unclear, as Ranbaxy was purchased by Daiichi Sankyo Company, Limited in June 2008.

Allegations and Resolution

The Ranbaxy settlement resolves allegations that fall into three general categories, and are detailed in an Agreed Statement of Facts: (1) violating the FDCA by manufacturing and distributing drugs deemed adulterated because they were not manufactured in compliance with GMP; (2) violating the FDCA by failing to file required reports with FDA; and (3) making material false statements to FDA in annual reports. The felony adulteration count is based on FDA's documentation of GMP violations during inspections of the Ponta Sahib facility in February 2006 and the Dewas facility in February to March 2006 and January to February 2008.

Ranbaxy has further admitted significant discrepancies in stability testing at both facilities. In particular, Ranbaxy admitted that it conducted stability testing several weeks or months later than the dates that were reported to FDA in annual reports and also conducted stability tests that were required to be conducted at specified intervals (*e.g.*, three, six and nine months) on the same day. Ranbaxy also admitted to storing stability samples pending testing in a four-degree Celsius refrigerator rather than a stability chamber. This practice was not disclosed to FDA; instead, Ranbaxy represented to FDA that its stability testing program was being conducted in compliance with protocols submitted to FDA. Significantly, Ranbaxy admitted that its GMP and stability testing deviations were identified in 2003 and 2005 by outside consultants hired to audit its manufacturing operations.

These stability testing deviations form the basis for Ranbaxy's felony pleas to failing to timely file required reports and making material false statements to FDA. In particular, Ranbaxy admitted that it failed, as required under 21 U.S.C. § 314.81(b)(1), to submit a "field alert report" within three working days after receiving information concerning any bacteriological contamination, significant chemical, physical, or other change or deterioration, or failure to meet a specification established in an Abbreviated New Drug Application, of a distributed drug product. Ranbaxy further admitted that it made materially false statements to FDA regarding its stability testing program in annual reports filed in 2006 and 2007.

The settlement also resolves the allegations levied in the *qui tam* civil FCA action, *United States ex rel. Thakur v. Ranbaxy Laboratories Limited*, Civ. No. 1:07-cv-00962-JFM (D.Md.). In addition to alleging widespread GMP violations, the February 2010 amended complaint in that matter alleges that, with the knowledge and approval of senior management in India and the United States, Ranbaxy filed marketing applications for its generic antiretroviral drugs that were not supported by formulation, bioequivalence and/or stability data, or were supported by falsified data. The civil settlement agreement ultimately resolves allegations that Ranbaxy knowingly caused the submission of false claims by manufacturing, distributing and selling drugs whose strength, purity or quality differed from their specifications or were not manufactured according to the FDA-approved formulations.

Conclusion

The Ranbaxy settlement is significant in a number of respects. First, the $500 million total financial settlement represents the largest drug safety-related settlement with a generic manufacturer to date, and the seven felony guilty pleas are indicative of the severity of the allegations resolved. Second, the settlement has broader implications for DOJ and FDA enforcement trends: It makes good on repeated threats that the government intends to focus on manufacturing issues in addition to the advertising and promotion claims that have historically dominated drug and device manufacturer government investigations and settlements. Third, while there are strong legal arguments to the contrary, the settlement reflects DOJ's belief that manufacturing and safety violations may be actionable under the civil False Claims Act.

However, the terms of the settlement provide only limited guidance for practitioners. Ranbaxy and the government agreed that Ranbaxy's pecuniary gain from the criminal conduct was $100 million and that its gross gains were in excess of $100 million. Accordingly, the agreed upon criminal fine of $130 million is at the low end of the range determined by application of federal sentencing rules. However, Ranbaxy and the government did not stipulate as to the amount of the false claims that had been paid by the government for purchases of adulterated generic drugs. It is impossible, therefore, to determine the multiplier (from losses) that the government and Ranbaxy agreed to use to calculate the civil settlement of $350 million.