***United States of America ex rel. Dinesh S. Thakur v. Ranbaxy et al.* – Key Facts**

1. On May 13, 2013, Ranbaxy, India's largest generic drug manufacturer, agreed to pay $500 million to the United States and thirty-two States ("States") to resolve criminal and civil allegations by the United States and Dinesh S. Thakur that Ranbaxy falsified drug data and systemically violated current Good Manufacturing Practices (cGMP) and current Good Laboratory Practices (cGLP) resulting in substandard and unapproved drugs. The groundbreaking settlement is the largest of its kind against a generic drug manufacturer under the *qui tam* provisions of the False Claims Act ("FCA").

2. With the assistance of his counsel Andrew M. Beato and Bob Muse of Stein Mitchell Muse & Cipollone in Washington, DC, Mr. Thakur filed a lawsuit in 2007 under the FCA detailing Ranbaxy's violations. The lawsuit was filed in the United States District Court for the District of Maryland (Civ. No. 1:07-cv-00962-JFM), and alleges that Ranbaxy caused false claims for payment to be submitted to government healthcare programs for numerous adulterated drugs. The FCA's *qui tam* provisions allow whistleblowers to report fraud on a government program with the protection of a court-ordered seal and confidentiality, and receive a percentage of the amount recovered in a successful case.

3. Mr. Thakur is a United States citizen and a former Director of Research Information & Project Management of Ranbaxy (2003-2005). His senior executive position gave him access company data generated during product development and commercialization processes (formulation development, process chemistry, analytical characterization, bio-equivalence, and product stability). His job provided him with a comprehensive understanding of Ranbaxy's global operations.

4. Beginning in 2004, Mr. Thakur conducted an audit of Ranbaxy data used to gain approvals for various drugs across multiple markets, including the United States. He discovered and documented that Ranbaxy had falsified data to secure FDA approvals and systematically violated the FDA's cGMPs. These actions resulted in sub-standard or unapproved drugs sold in the United States.

5. Mr. Thakur and his manager alerted Ranbaxy's senior leadership to the problem. The company refused to stop these practices and acted to cover up the fraud. He resigned in 2005, and alerted United States authorities of the fraud.

6. For two years, Mr. Thakur worked as a confidential informant for government authorities to understand the magnitude and technical aspects of Ranbaxy's complex fraud.

7. Beginning in 2007, Mr. Thakur teamed up with Stein Mitchell Muse & Cipollone LLP to prove Ranbaxy's fraud by (1) analyzing millions of pages of complex drug development and commercial manufacturing data, (2) preparing detailed memoranda summarizing

evidence of Ranbaxy's fraud for more than 20 generic drugs, (3) analyzing more than 20 internal and external audits, and (4) preparing memoranda and evidence notebooks for Ranbaxy witness interviews.

8. In addition to the criminal and civil resolution announced on May 13, 2013, Mr. Thakur and Stein Mitchell Muse & Cipollone's support of the government's investigation contributed to the following:

    - Numerous FDA-issued warning letters against Ranbaxy for violations similar or identical to those reported by Mr. Thakur;
    - Invocation of FDA's Application Integrity Policy on several Ranbaxy plants in India due to pervasive data falsification;
    - FDA's imposition of an Import Alert on more than 30 Ranbaxy drugs, banning them from the United States;
    - Widespread turnover in Ranbaxy senior management positions and key functional departments previously responsible for Ranbaxy's illegal conduct;
    - Reconstitution of Ranbaxy's Board of Directors;
    - Closure of a Ranbaxy manufacturing plant in the United States following FDA's issuance of a warning letter for violations; and
    - Entry of an unprecedented FDA Consent Decree, requiring corrective measures such as:
        - Prohibiting Ranbaxy from introducing into interstate commerce all drugs manufactured at three facilities in India (Paonta Sahib, Batamandi, and Dewas) and one in the United States (Gloversville) until Ranbaxy establishes that the facilities comply with cGMP;
        - Hiring an outside expert to conduct an internal review and audit Abbreviated New Drug Applications (ANDAs) from the facilities to identify falsified data;
        - Withdrawing ANDAs with falsified data;
        - Instituting a new Office of Data Reliability; and
        - Appointing a cGMP expert to certify continuing compliance with cGMP requirements.

9. Assistant Attorney General for the Department of Justice's (DOJ) Civil Division, Tony West, characterized the government's action against Ranbaxy as "groundbreaking in its international reach", noting that "it requires the company to make fundamental changes to its plants in both the United States and India. Press Release, Dept. of Justice, *U.S. Files Consent Decree for Permanent Injunction Against Pharmaceutical Ranbaxy Laboratories* (Jan. 25, 2012), *available at* http://www.justice.gov/opa/pr/2012/January/12-civ-105.html.