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FDA/Government Investigations ADVISORY ■

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Generic Manufacturer Ranbaxy Settles Civil and Criminal Claims Based on cGMP Violations: A New Era of cGMP Enforcement Actions?

Yesterday, the Department of Justice (DOJ) announced that it had entered into a $500 million civil and criminal settlement with Ranbaxy USA, Inc. (Ranbaxy), the U.S. subsidiary of the largest generic drug manufacturer in India, Ranbaxy Laboratories Limited. Ranbaxy agreed to pay $350 million to settle a False Claims Act (FCA) lawsuit brought in Maryland by a whistleblower for allegedly selling to federal and state health care programs. The settlement related to, among other pharmaceuticals, Ranbaxy's acne drug Sotret, epilepsy and nerve pain drug Gabapentin, and antibiotic Ciprofloxacin. This case is particularly noteworthy, as it represents one of only two FCA settlements based on failure to comply with cGMPs under the Federal Food, Drug, and Cosmetic Act (FDCA), the other one being the government's $750 million settlement with GlaxoSmithKline in October 2010. In addition, this is the largest drug safety penalty imposed on a generic company.

The Ranbaxy settlement related to activities at two manufacturing facilities in India: Paonta Sahib and Dewas. The facilities were inspected by the FDA in 2006 and 2008 and, during those inspections, the FDA found significant cGMP deficiencies, including incomplete testing records, inadequate drug stability assessment programs and failure to establish appropriate manufacturing controls to prevent cross-contamination. In September 2008, FDA issued warning letters to both facilities and also issued an import alert covering 30 drug products produced at those locations. In January 2012, the FDA obtained a novel consent decree against Ranbaxy, which extended the consent decree's injunctive provisions to Ranbaxy's foreign facilities, a first for the agency.

Claims Against Ranbaxy

In addition to the consent decree, the cGMP violations at Paonta Sahib and Dewas also formed the basis of criminal charges and the FCA settlement. Ranbaxy pled guilty to seven felony counts, including charges related to the company's introduction of adulterated drugs into interstate commerce and failure to file timely reports with the FDA, with the intent to defraud and mislead. Moreover, the government claimed that as the result of this alleged conduct, Ranbaxy caused false claims to be submitted to federal health care programs. The settlement agreement did not, however, protect Ranbaxy from any potential tax liability, debarment from federal agencies or health care programs, liability for personal injuries or property damage, or contractual liability. The agreement also did not protect Ranbaxy's current or former directors, officers, employees or shareholders from criminal liability, foretelling the possibility that additional charges against individuals may be forthcoming.

A Growing Wave of cGMP Enforcement Cases on the Horizon?

It is likely that the Ranbaxy settlement is the beginning of a new FCA and criminal enforcement trend. The government's

aggressive efforts with respect to off-label promotion of drugs and medical devices have had a significant impact on medical product promotional activities. Manufacturing quality issues arguably represent a more significant threat to public health and may be harder to detect than off-label promotion. This is especially true given that most off-label promotion occurs domestically, whereas drug manufacturing is increasingly outsourced, making it more difficult to detect potential violations.

As globalization of the medical products market continues to accelerate, changes in drug and device supply chains continue to outpace the FDA's efforts. There are too few FDA investigators in the international inspection cadre to inspect the growing number of regulated firms outside the United States, and language barriers, cultural issues and economically motivated adulteration have increased the risks associated with regulated products. Possibly for these reasons, in January of this year, DOJ's Deputy Assistant Attorney General for the Consumer Protection Branch of the Civil Division said that enforcement of cGMPs would be one of DOJ's "top areas of focus" in 2013.

The Ranbaxy settlement demonstrates that those comments were not merely aspirational, but made with knowledge that there is an increasing pipeline of cGMP enforcement cases and investigations. All companies that are subject to the Food, Drug, and Cosmetic Act—and not merely drug manufacturers—must be aware that more civil and criminal cases based on cGMP deficiencies will likely be charged and investigated in the months ahead.

Recommendations

We advise that our clients be proactive in their cGMP compliance efforts to minimize the risk of being on the wrong end of an FDA or DOJ investigation. Such compliance measures would include:

- fostering a strong corporate compliance program that stresses the importance of cGMP compliance and ensures accountability;
- devoting sufficient resources to compliance initiatives;
- documenting good faith efforts to comply with regulatory requirements; and
- paying close attention to supplier quality and supply chain management.

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