Published on *The National Law Review* https://natlawreview.com

The Apotex Case: Current Good Manufacturing Practices (cGMP) violations

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Here is a company you probably never heard of, Apotex. Chances are good, however, they manufactured a vaccine you received from your doctor. The company generates a billion dollars a year in sales, manufacturers more than 300 different pharmaceutical drugs and sells many of those drugs in the United States.

Generic drug companies are usually not on the public's radar but when you read some of the stories about how they are made, they should be. According to a January 30th warning letter, the FDA warned the company's Bangalore, India subsidiary, Apotex Research Private Limited, of serious manufacturing violations.

Although Apotex is headquartered in Canada, much of its manufacturing occurs in India. On January 30th, the FDA cited the company's Indian operation for a variety of cGMP violations.

Short for "***current good manufacturing practices***," cGMP looks at the quality control practices of pharmaceutical companies. The FDA wants to insure that products sold in the United States are not adulterated, contain the appropriate amount of active ingredients and are not contaminated.

The January 30th warning letter claims Apotex has lapses in its data control, written procedures and information systems. Fortunately, the FDA did not find that any drugs were actually compromised but in our experience, shoddy practices lead to tragic results.

In its warning letter, the FDA says, "During our June 23, 2014 through July 1, 2014, inspection of your pharmaceutical manufacturing facility, ***Apotex Research Private Limited (ARPL)*** located in Bangalore, India, investigators from the ***U.S. Food and Drug Administration (FDA)*** identified significant violations of ***current good manufacturing practice (CGMP)*** regulations for finished pharmaceuticals."

The FDA also said that the violations cause drugs manufactured there to be adulterated. In one instance, inspectors found that sometimes the company disregarded test data from certain samples and only submitted the most favorable results to the FDA. That’s akin to asking a teacher to only base your report card on tests you passed and ignore any failing grades.

When confronted about the violations, the FDA says that Apotex officials claimed there was no "intentional activity to disguise, misrepresent or replace failing data with passing data." That response, however, still doesn't address the serious violations found and what the company was doing to correct them.

The company did admit that some employees panicked during the inspection and that an analyst "directed [a] lab technician to immediately remove petri plates from the microbiology lab … in an utterly misguided and ill-conceived attempt to clean up the microbiology lab prior to the start of the FDA inspection."

Prescription drugs must be manufactured in sterile environments. Many companies rely on high tech clean rooms. The thought of workers scurrying to remove dirty dishes and glassware, however, simply to placate the FDA concerns us.

The FDA ultimately concluded that Apotex's Indian facility has serious cGMP violations and that the company can't ensure the integrity of quality control data. Bad data, of course, means there is no way of ensuring the safety of the drugs manufactured and sold by the company.

Unfortunately for patients, the FDA is spread very thin. A handful of inspectors must cover factories throughout the entire world. Because pharmaceutical quality issues are so rampant in India, the FDA has assigned a team of inspectors there but even with a beefed up presence, drug manufacturers typically only get visited every couple years and the there are no surprise inspections.

One industry executive recently confided to us that quality drops off immediately after an inspection. Another told us in February that an entire “factory” was built just to help the company pass its inspection. It was dismantled in just 24 hours after inspectors had left.

The key to combatting dangerous drugs finding their way into people's medicine cabinets is enhanced inspections once drugs enter the marketplace and whistleblowers. The federal False Claims Act pays whistleblowers up to 30% of whatever is collected by the government from wrongdoers. Several pharma whistleblower cases have netted the government in excess of $1 billion meaning huge paydays for whistleblowers.

In 2013, a former employee of Indian pharma company Ranbaxy, received almost $49 million from the government for his information about cGMP violations. Last year we helped a whistleblower collect almost $50 million in a different whistleblower case. Awards this big are the exception but these exceptions often occur in pharma fraud cases.

To qualify for an award, a potential whistleblower must have inside information about fraud and the drug must be eligible for Medicare or Medicaid reimbursement. In some cases, a claim arises if the government purchased the drug directly for use by the military or a V.A. hospital.

Although cGMP violations are very serious, a recent court decision suggested that information about the violation alone isn't enough to earn an award. There must also be proof that the drug itself was misbranded, adulterated or contaminated. Often the two go hand-in-hand, however.

Present and former employees of Apotex and their vendors and consultants may qualify for an award. The whistleblower need not be a U.S. citizen or resident.

National Law Review, Volume V, Number 64