

<http://features.blogs.fortune.cnn.com/2014/02/03/ranbaxys-empty-promises/>

Ranbaxy's empty promises

February 3, 2014: 5:00 AM ET

The big manufacturer of generic drugs—including a non-branded version of Lipitor—has landed in trouble again, and once again it is promising to clean up its act. Should anybody believe the company?

By Katherine Eban



PHOTO: SCOTT EELLS /BLOOMBERG/GETTY

A Ranbaxy scientist in 2007.

FORTUNE -- On Jan. 23, the FDA dropped a heavy hammer on the Indian generic drug giant Ranbaxy Laboratories, announcing it will restrict imports from the company's manufacturing plant in Toansa, India. It was the fourth Ranbaxy factory to be barred by the FDA since 2008. The move came after an unannounced inspection in early January turned up a devastating litany of infractions: a laboratory area littered with flies, a leaking refrigerator for drug samples, and evidence that laboratory technicians were altering data to improve test results. The FDA's action cuts off a vital supply line for the company, given that the plant reportedly makes about 70% of the ingredients that Ranbaxy uses to make its U.S. drugs, including the generic version of Lipitor taken by millions of Americans.

Ranbaxy is already a corporate felon. Last year, it paid a record \$500 million in fines and penalties and pleaded guilty to seven criminal counts related to egregiously falsifying its laboratory data. Since then, Ranbaxy has touted a top-to-bottom house cleaning. At every turn, it has emphasized new management, investments in new technology, and a rigorous new code of conduct for employees. Today a flashing headline on the home page of Ranbaxy's U.S. website emphasizes: RANBAXY HIGHLIGHTS IMPROVED BUSINESS AND QUALITY ASSURANCE STANDARDS.

As word of the latest ban rocketed around the globe, Ranbaxy's shares fell 20%, pulling the stock of its majority owner, Japanese drug company Daiichi Sankyo, down with it. The Japanese company has now been majority owner of Ranbaxy for more than five years, and, at this point, it shares responsibility for the Indian company's multiyear run of serious regulatory and legal problems. Daiichi Sankyo CFO Manabu Sakai told reporters and analysts on a conference call, "We need to grasp how something like this could occur, how extensive the transgressions were and whether they were the fault of a particular person." He also said, "We hope to prepare drastic new measures" to support Ranbaxy.

Meanwhile, the FDA, eager to show that it is cracking down on poor quality generic drugs and ingredients manufactured overseas, released a statement by Carol Bennett, acting director of the Office of Compliance in the FDA's Center for Drug Evaluation and Research: "We are taking swift action to prevent substandard quality products from reaching U.S. consumers. The FDA is committed to ensuring that the drugs American consumers receive -- no matter where they are produced -- meet quality standards and are safe and effective."

Yet as the Ranbaxy melodrama enters its ninth season, the claims of shock, anger, and getting tough are exceedingly shopworn. At this point, it may be useful to ask some bigger questions. Is Ranbaxy a company that is capable of making effective drugs honestly, and if not, why is it still in business? Can the FDA claim to have acted swiftly, when it first learned of systemic fraud at Ranbaxy in 2005? Given the parade of bad medicine coming out of Ranbaxy's laboratories -- pills with unexplained black spots, human hairs, and glass particles in them -- can we believe the FDA's continued reassurance that despite an import alert on four of Ranbaxy's overseas factories, the medicine already on U.S. pharmacy shelves made at those factories is safe to take?

And can Congress continue to sit on its hands, after starting an investigation into the FDA's handling of Ranbaxy in 2008 and then letting it peter out, even though the FDA continued to approve the company's drug applications, and even allowed it to proceed with its exclusive generic launch of America's most popular drug, atorvastatin (better known by the name of the brand version, Lipitor)?

The Ranbaxy debacle crossed a crucial threshold in the fall of 2004, when a senior company executive disclosed to a subcommittee of the Board of Directors that the company had committed a massive and ongoing fraud, and that over 200 drug products in more than 40 countries had been submitted to regulators with elements of fabricated data. (A *Fortune* article, "**Dirty Medicine**," published in May, revealed the saga in depth.) Instead of acting on these findings, the company opted to bury them, and ultimately, Dinesh Thakur, the executive who, at the behest of his boss, had uncovered the deception, left the company. Just months later, in December 2004, FDA inspectors showed up at Ranbaxy's Paonta Sahib manufacturing plant for an announced visit and gave the site a clean bill of health.

The fraud might never have come to light were it not for Thakur, who went on to become a whistleblower. In August 2005, Thakur contacted the FDA and other regulators worldwide to allege that the company was falsifying its laboratory testing data on a massive scale. The FDA, to its credit, was the only agency to vigorously pursue his allegations. In February 2006, FDA inspectors returned to Paonta Sahib. This time, with the benefit of Thakur's inside information, inspectors detected numerous deceptions. They found that raw data

was routinely discarded, patient complaints went uninvestigated, and samples that were supposed to be tested at predetermined intervals, to see if they were stable, were tested at will to produce the desired results.

In June 2006, the FDA issued a scathing warning and said it would not consider any new applications for drugs made at Paonta Sahib until the company made corrections. Publicly, the company did not appear to be unduly concerned. **As a spokesperson told the *Press Trust of India*, many of the FDA's observations "have already been addressed and perceptions cleared up."** (For ease of viewing, we have bolded the company's statements.)

But Ranbaxy had more than a compliance *perception* problem. In February 2007, FDA criminal investigators executed search warrants at Ranbaxy's U.S. headquarters in New Jersey, seizing documents and computers. **In a statement at the time, the company expressed shock: "This action has come as a surprise. The company is not aware of any wrongdoing. It is cooperating fully with officials."**

In July 2008, federal prosecutors filed a motion in U.S. district court in Baltimore, demanding that the company turn over certain documents prepared by an outside auditor. The motion, a bombshell, alleged that the violations at Paonta Sahib "continue to result in the introduction of adulterated and misbranded products into interstate commerce with the intent to defraud or mislead ..." Once again, Ranbaxy protested its innocence. **According to a *Newark Star-Ledger* article at the time, "Ranbaxy said its internal audits 'will demonstrate that no data manipulation, fraud, or dishonesty occurred' in its regulatory filings with the FDA ..."**

For its part, in September 2008, the FDA restricted the importation of drug products from two Ranbaxy plants, Paonta Sahib and Dewas. Oddly, though, an official at the agency took pains to emphasize to reporters that the measures were proactive: "FDA has no evidence that these Ranbaxy products are actually defective," she said. This wasn't true. By that point, the Agency's own testing had shown that Ranbaxy's acne drug Sotret (the generic version of Accutane) degraded far more rapidly than the company claimed.

Meanwhile, the FDA continued to approve new drug applications from Ranbaxy. That gave the company an obvious talking point with investors. **As then-CEO Malvinder Singh stated on a conference call in 2008: "FDA has, however, strongly advised consumers to continue to take Ranbaxy medication, and Ranbaxy remains confident that our pharmaceutical products are safe and effective. And also, I think, this whole measure by the FDA as set by them is based on a precautionary basis."**

Over the next four years, the FDA imposed successively greater restrictions on the company, including a sweeping consent decree that requires the company to prove its integrity through outside monitoring. Ranbaxy professed that it continued to work to improve. **In January 2012, the *Wall Street Journal* paraphrased Ranbaxy CEO Arun Sawhney as saying "the company has made satisfactory progress in upgrading and enhancing the quality of its business and manufacturing processes."**

Meanwhile, in late 2011, the FDA made the still-unexplained decision to allow the company to proceed with an exclusive launch of the first generic version of Lipitor for the U.S. market. In six months, this launch more than paid off Ranbaxy's \$500 million fine and effectively kept the company afloat. Less than a year after that, Ranbaxy was forced to recall numerous lots of the drug, which were found to contain particles of glass.

Last May, after the company announced its guilty plea to seven criminal counts of selling adulterated drugs with intent to defraud, failing to report that its drugs didn't meet specifications, and making intentionally false statements to the government, Ranbaxy emphasized that it was closing the door on past transgressions and starting anew. **"Today's announcement marks the resolution of this past issue," CEO Sawhney said in a**

statement. "While we are disappointed by the conduct of the past that led to this investigation, we strongly believe that settling this matter now is in the best interest of all of Ranbaxy's stakeholders."

Just four months after Ranbaxy resolved its "past issue," the FDA took new action: The agency imposed a ban on imports from Ranbaxy's most modern Indian plant, in Mohali. Regulators had found a black human hair sticking up from one pill, and black oil spots on others. The toilets and sinks in the bathrooms off the main manufacturing area lacked running water. The issues had gone unaddressed for more than a year, even though it was the same plant where millions of the generic Lipitor pills made for the U.S. market had become infused with glass particles.

Facing incredulous investors, the company released a statement, saying, "It is important to take cognizance of the fact that since the last inspection by the U.S. FDA in 2012, Ranbaxy has strengthened its management, manufacturing and monitoring systems and processes to ensure quality and compliance."

And then came last week's revelations regarding a fourth plant, Toansa. The FDA turned up a catalog of egregious lapses. Uncontrolled drug samples left in desk drawers. Windows in a sensitive laboratory that were "uncloseable," leading to an influx of "Too Numerous To Count (TNTC) flies," according to an inspection report.

Very little has changed at Ranbaxy, according to the FDA findings. The inspectors emerged with evidence that Ranbaxy is still *faking it* in the laboratory. Numerous sticky notes bore instructions for making changes to raw data. The inspectors witnessed a technician backdating a form. They determined that laboratory staff had repeatedly retested impure ingredients until they got favorable results. Forms intended to certify test results were left blank, to be back-filled and backdated later. And despite being admonished for the same findings at Toansa a year earlier, the company had done nothing to secure its computer files of raw data. As inspectors noted, they still "can be deleted and all evidence of testing removed."

Oh, and another thing hasn't changed: the company's response. **Here is the statement it issued after the latest FDA findings first became public in January: "Ranbaxy continues to improve its systems and processes, and remains fully committed to upholding the highest standards that patients, prescribers, regulators and all other stakeholders expect from the Company." When that failed to reassure investors, CEO Sawhney added a second statement: "This development is clearly unacceptable and an appropriate management action will be taken upon completion of the internal investigation."**

If "appropriate management action" is taken after an internal investigation, it would certainly be a refreshing change at Ranbaxy. We won't be holding our breath.

Update: The sub-headline of an earlier version of this article described Ranbaxy as "the" maker of a generic version of Lipitor. In fact, Ranbaxy is not the only company to manufacture the medication.