

GlaxoSmithKline, a behemoth drug manufacturer, has agreed to pay \$750 million to settle criminal and civil complaints that the company knowingly sold contaminated drugs, including contaminated baby ointment and an ineffective antidepressant. The settlement is the result of a whistleblower suit filed by a former quality control manager with the company. The safety issues arose at a Puerto Rico plant that was purportedly rife with contamination. GlaxoSmithKline sold 20 drugs with questionable safety. The whistleblower had been sent to the plant in 2002 to lead a team of quality control experts in fixing problems noted by the Food and Drug Administration (“FDA”) earlier that year. At the time, the manufacturing facility was one of Glaxo’s largest, producing \$5.5 billion worth of product each year.

After arriving at the plant to help fix quality control problems, the whistleblower found a number of disconcerting issues: the water system was contaminated; the air system allowed for cross-contamination between products; the warehouse was so overcrowded that rented vans were used for storage; the plant could not maintain the sterile nature of intravenous drugs used for treatment of cancer; and pills of differing strengths were sometimes mixed in the same bottles. The FDA found that Paxil CR produced at the plant was ineffective for a couple different reasons: some pills were ineffective because a layer of active ingredient split from a layer of barrier chemical during manufacturing and some other lots contained only the barrier chemical.

The quality control manager complained top company executives regarding the severity of the issues at the Puerto Rico plant. However, she was ignored, even after warning that she would call the FDA. She was terminated, and then reported the problems to the FDA and filed the whistleblower lawsuit. In 2005, the FDA began a criminal investigation and seized nearly \$2 billion worth of products, the largest such seizure in history. Unable to fix the problems at the plant, GlaxoSmithKline closed it in 2009.

An article relating to the whistleblower suit and the \$750 million in fines imposed against GlaxoSmithKline was recently published in **The New York Times**.