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United States *ex rel.* Cheryl Eckard v. GlaxoSmithKline

Safeguarding cGMP Compliance for Patients and the Public

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The False Claims Act *Qui Tam* Law

- Creates a civil cause of action for fraud on the government.
- Allows an action to be brought both by the government and by a private citizen in the name of the government (the *qui tam* "relator").
- Relator is entitled to receive up to 30% of the proceeds plus attorneys fees and costs.

The False Claims Act *Qui Tam* Law

- Passed by the Lincoln Administration in 1863.
- Strengthened by the Reagan Administration in 1986 and the Obama Administration in 2009 / 2010.
- The *qui tam* law is "firmly rooted in the American legal tradition."
- The *qui tam* law is a "public-private partnership."

Recoveries for Taxpayers

Total *qui tam* recoveries since 1986

$18 billion

Total *qui tam* recoveries from pharma companies since 2000

$11 billion

A New Role for the *Qui Tam* Law: Safeguarding cGMP Compliance

- U.S. *ex rel.* Eckard v. GlaxoSmithKline and SB Pharmco Puerto Rico, 04 CV10375 (JLT) (D.Mass.)
- GSK agreed to pay $750 million to the United States and the 50 States
- GSK subsidiary SB Pharmco pled guilty to distributing adulterated drug products

Relator, Plant and Products

- Relator: Cheryl Eckard, GSK Global Quality Assurance
- Plant: Cidra, Puerto Rico.
  - $5.5 billion annually
- Products: Solid oral dosage forms (Paxil, Avandia, Avandamet, Coreg and others), creams, ointments, injectibles and suspensions.

Areas of Non-Compliance Reported to Management

- Areas of “high risk” reported April 2003:
  - Mix-ups
  - Validation
  - Investigations
  - Sterile manufacturing
  - Documentation quality
  - Microbial contamination in water system and manufacturing areas

Termination and Report to Compliance Department

- April 2003 reported chronic super-and sub-potency in Avandamet since product launch and suggested possible recall
- Terminated May 2003
- Attempted report to CEO, General Counsel
- Report to Compliance Department, June-October 2003

Report to FDA and *Qui Tam* Case

- GSK Compliance Dept finding: “unsubstantiated”
- Report to FDA - Search Warrants
- FDA inspection and 483 issued Dec 2003
- *Qui tam* filed February 2004
- FDA inspection and 483 issued Nov 2004
- Largest seizure of drug products in FDA history and Consent Decree 2005
- $750 million settlement 2010

Qui Tam Allegations

- Mix-ups and lies to FDA in FARs
- Microbial contamination in products, in the water system and in manufacturing areas, including the sterile facility
- Content uniformity failures not corrected
- Products and processes not validated
- Investigations overdue, inadequate: lab, process and complaint
- Thousands of instruments not calibrated
- Chronic documentation deficiencies
- HVAC deficient/cross contamination

Civil Settlement and Criminal Plea

- $600 million civil settlement resolved allegations that GSK sold the government four products that were adulterated: Bactroban, Kytril, Avandamet and Paxil CR
- $150 million criminal fine and guilty plea: releasing batches of those products in interstate commerce with intent to defraud and mislead

cGMPs and CFRs Cited in Criminal Plea

- Quality Unit
- Contamination and product mix-ups
- Equipment (calibration, inspection, maintenance)
- In-process testing
- End-product testing
- Batch records
- Investigations
- Field Alert Reports
- Annual Reports

cGMP Non-Compliance and False Claims Act Liability

- Substantial compliance with the cGMPs is material to the government's decision to pay
- Drug approvals were obtained via false representations to the FDA
- Drugs did not come with the assurance of strength, purity, quality and identity represented in the NDA
  - Criminal Information also sounds this theme

False Claims Act Damages

- FCA damages are recoverable for the full value of product sold to the government where the government paid for quality assurance that it did not receive
  - Breakdown of Quality System at Cidra
- FCA provides for treble damages
- Government does not have to “trace bad batches”

Lessons

- Drug manufacturing is complex, opaque and rife with opportunities for cGMP non-compliance
- Consumers must rely on drug makers to police themselves
- cGMP compliance is now open to the scrutiny of whistleblowers
- Quality managers and others are empowered to ensure that production does not take precedence over quality

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Questions?

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