

# GETNICK & GETNICK LLP

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

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- ▶ 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

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- ▶ 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

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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

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- ▶ 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

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- ▶ 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

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- ▶ 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

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- ▶ 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

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- ▶ 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

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- ▶ 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

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- ▶ \$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

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- ▶ 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

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- ▶ 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

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- ▶ 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

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- ▶ 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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