Fraud in the Pharmaceutical Industry

The United States *qui tam* Whistleblower Law
Outline

- Pharma Fraud Overview
- The False Claims Act *Qui Tam* Whistleblower Law
- FCA *Qui Tam* Pharma Fraud Settlements 2000-2012
- Who are the Whistleblowers?
- Preventing Pharma Fraud
Fraud by Pharma

- Illegal marketing and promotion
- Kickbacks to health care providers and others
- Distributing adulterated drugs
- Overcharging government health programs
- False or misleading clinical data provided to FDA and consumers
- Price fixing and monopoly practices
False Claims Act  *Qui Tam* Law

- Creates a civil cause of action for fraud on the government
- Treble damages and penalties of $5,500-$11,000 per violation
- Action can 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
- 15% minimum share (with exceptions)
A Short History

- Passed by the Lincoln Administration in 1863.
  - The *qui tam* law is “firmly rooted in the American legal tradition.”

- A bi-partisan initiative: strengthened by Reagan in 1986 and Obama in 2009
  - The *qui tam* law is a “public-private partnership.”

- 29 States and the District of Columbia now have *qui tam* statutes.
FCA Recoveries 1987-2012

- Total: $35 billion
  - $24 billion qui tam

- Health Care Fraud: $24 billion
  - $18 billion qui tam

- Defense Fraud: $5 billion
  - Other: $6 billion
Qui Tam Procedure

- Relator files Complaint under seal in federal court and serves the Complaint and statement of material facts on DOJ
- DOJ investigates and decides whether to intervene in the action or decline to do so
- Relator may proceed if DOJ declines
Checks and Balances

- Cases are barred if the allegations are substantially the same as those:
  - on the public record
  - in an existing filed case

- Defendant may recover attorneys fees and costs from relator if case is “frivolous or vexatious”

more …
Checks and Balances (cont.)

- Relator who “planned and initiated” the violations may receive zero, in the court’s discretion

- Relator who is criminally convicted in relation to the violations must receive zero
Potential Collateral Consequences

- Criminal prosecution
- Corporate Integrity Agreements
- Class/shareholder/SEC/private insurer actions
- Exclusion from federal programs
- Foreign Corrupt Practices Act actions
- Cessation of conduct and deterrence
Pharma Fraud *Qui Tam* Cases

More than $20 billion in civil recoveries and criminal fines between 2000 and 2012
<table>
<thead>
<tr>
<th>Pharmaceutical Company</th>
<th>Date Settled</th>
<th>Primary Fraud Alleged</th>
<th>Whistleblower/s</th>
<th>Criminal Fine</th>
<th>Civil Settlement</th>
<th>Total Recovery</th>
</tr>
</thead>
<tbody>
<tr>
<td>GlaxoSmithKline</td>
<td>7/2/2012</td>
<td>Off-label promotion; kickbacks; failing to report safety data; pricing fraud</td>
<td>4 GSK employees, incl. Sr. Marketing Manager and Regional VP</td>
<td>$1 Billion</td>
<td>$2 Billion</td>
<td>$3 Billion</td>
</tr>
<tr>
<td>Pfizer</td>
<td>9/2/2009</td>
<td>Off-label promotion; kickbacks</td>
<td>Several Pfizer sales reps</td>
<td>$1.3 Billion</td>
<td>$1 Billion</td>
<td>$2.3 Billion</td>
</tr>
<tr>
<td>Abbott Laboratories</td>
<td>5/7/2012</td>
<td>Off-label promotion; kickbacks</td>
<td>Several Abbott sales reps</td>
<td>$800 Million</td>
<td>$800 Million</td>
<td>$1.6 Billion</td>
</tr>
<tr>
<td>Eli Lilly</td>
<td>1/15/2009</td>
<td>Off-label promotion; kickbacks</td>
<td>Several Eli Lilly sales reps</td>
<td>$615 Million</td>
<td>$800 Million</td>
<td>$1.415 Billion</td>
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<tr>
<td>Merck</td>
<td>11/22/2011</td>
<td>Off-label promotion</td>
<td>Unidentified whistleblower(s)</td>
<td>$ 321.6 Million</td>
<td>$628.3 Million</td>
<td>$950 Million</td>
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<tr>
<td>TAP Pharmaceuticals</td>
<td>10/3/2001</td>
<td>Marketing the spread; kickbacks</td>
<td>TAP V-P of Sales and HMO Medical Director</td>
<td>$290 Million</td>
<td>$585 Million</td>
<td>$875 Million</td>
</tr>
<tr>
<td>GlaxoSmithKline</td>
<td>10/26/2010</td>
<td>Manufactured and sold adulterated drug products</td>
<td>GSK Global Quality Assurance Manager</td>
<td>$150 Million</td>
<td>$600 Million</td>
<td>$750 Million</td>
</tr>
<tr>
<td>Serono</td>
<td>10/17/2005</td>
<td>Off-label promotion; kickbacks</td>
<td>5 Serono employees (Lab and Sales)</td>
<td>$136.9 Million</td>
<td>$567 Million</td>
<td>$704 Million</td>
</tr>
<tr>
<td>Merck</td>
<td>2/7/2008</td>
<td>Concealing Best Price; kickbacks</td>
<td>Merck District Sales Manager/Physician</td>
<td>$650 Million</td>
<td>$650 Million</td>
<td>$1.3 Billion</td>
</tr>
<tr>
<td>Allergan Inc.</td>
<td>9/1/2010</td>
<td>Off-label promotion; kickbacks</td>
<td>Allergan Managers and consultant</td>
<td>$375 Million</td>
<td>$225 Million</td>
<td>$600 Million</td>
</tr>
<tr>
<td>AstraZeneca</td>
<td>4/27/2010</td>
<td>Off-label promotion; kickbacks</td>
<td>AstraZeneca sales rep</td>
<td>$520 Million</td>
<td>$520 Million</td>
<td>$1.04 Billion</td>
</tr>
<tr>
<td>Bristol-Myers Squibb</td>
<td>7/28/2007</td>
<td>Off-label promotion; marketing the spread</td>
<td>Independent Pharmacy and others</td>
<td>$515 Million</td>
<td>$515 Million</td>
<td>$1.03 Billion</td>
</tr>
<tr>
<td>Schering Plough</td>
<td>8/29/2006</td>
<td>Concealing Best Price; off-label promotion</td>
<td>3 Schering Plough sales reps</td>
<td>$180 Million</td>
<td>$255 Million</td>
<td>$435 Million</td>
</tr>
<tr>
<td>Warner-Lambert</td>
<td>5/13/2004</td>
<td>Off-label promotion; kickbacks</td>
<td>Warner Lambert Medical Liaison</td>
<td>$240 Million</td>
<td>$190 Million</td>
<td>$430 Million</td>
</tr>
<tr>
<td>Cephalon</td>
<td>9/29/2008</td>
<td>Off-label promotion; kickbacks</td>
<td>3 Cephalon sales representatives</td>
<td>$50 Million</td>
<td>$375 Million</td>
<td>$425 Million</td>
</tr>
<tr>
<td>Novartis Pharmaceuticals</td>
<td>9/30/2010</td>
<td>Off-label promotion; kickbacks</td>
<td>Former sales representatives</td>
<td>$185 Million</td>
<td>$237.5 Million</td>
<td>$422.5 Million</td>
</tr>
<tr>
<td>Abbott, B. Braun and Roxane Laboratories</td>
<td>12/7/2010</td>
<td>Marketing the spread</td>
<td>Independent pharmacy</td>
<td>$421.1 Million</td>
<td>$421.1 Million</td>
<td>$842.2 Million</td>
</tr>
<tr>
<td>Elan</td>
<td>7/15/10 &amp; 12/15/10</td>
<td>Off-label promotion</td>
<td>Physician</td>
<td>$100 Million</td>
<td>$317.5 Million</td>
<td>$417.5 Million</td>
</tr>
</tbody>
</table>
Off-label Marketing/Kickbacks

- Marketing FDA-approved drug for non-FDA approved purposes

- Cases:
  - Pfizer
  - Ely Lilly
  - Serono
  - Allergan
  - AstraZeneca
  - Bristol Myers
  - Schering Plough
  - GSK
  - Cephalon
  - J&J
  - Novartis
  - Alpharma
  - Intermune
  - Elan
  - Forest
  - Merck
Pricing/Kickbacks (AWP)

- Inflating the price paid by the government (the “AWP”) while discounting to other purchasers.
- “Marketing the spread”

Cases:

- TAP
- AstraZeneca
- Aventis
- Bristol Meyers Squibb
- Abbott
- Mylan
- GlaxoSmithKline
- Schering Plough
- Teva
- Actavis
- Bayer
- PAR
- Sandoz
Pricing/Kickbacks (“Best Price”)

- Concealing the “Best Price” paid by commercial customers
  - “Private Labeling”
    - Bayer
    - GSK
  - Rebates and grants to HMOs
    - Schering Plough/Pfizer/TAP
- Nominal Pricing
  - Merck
Adulterated Drugs

- Failure to follow current Good Manufacturing Practices (cGMPs) resulting in government paying for adulterated drugs
- Case: GlaxoSmithKline
Who are the Whistleblowers?

- Corporate employees (current, former)
- Customers, e.g., doctors, pharmacists, HMO employees
- Patients
- Competitors
## Executives and Managers

<table>
<thead>
<tr>
<th>Company</th>
<th>Year</th>
<th>Relator</th>
<th>Recovery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Columbia/ HCA</td>
<td>2003</td>
<td>Divisional Reimbursement Supervisor/ Hospital CFO</td>
<td>$881M</td>
</tr>
<tr>
<td>TAP</td>
<td>2001</td>
<td>TAP V-P of Sales/ HMO Medical Director</td>
<td>$875M</td>
</tr>
<tr>
<td>GlaxoSmithKline</td>
<td>2010</td>
<td>Global Quality Assurance Manager</td>
<td>$750M</td>
</tr>
<tr>
<td>Columbia/ HCA</td>
<td>2000</td>
<td>V-P of affiliated home health company/ Others</td>
<td>$745M</td>
</tr>
<tr>
<td>Merck</td>
<td>2008</td>
<td>Merck District Sales Manager/ Physician</td>
<td>$650M</td>
</tr>
<tr>
<td>Allergan</td>
<td>2010</td>
<td>Allergan Policy Manager and Account Manager</td>
<td>$600M</td>
</tr>
<tr>
<td>Gambro</td>
<td>2004</td>
<td>Chief Medical Officer</td>
<td>$350M</td>
</tr>
<tr>
<td>Schering Plough</td>
<td>2004</td>
<td>Three Schering Senior Managers</td>
<td>$345M</td>
</tr>
<tr>
<td>SmithKlineBeecham</td>
<td>1997</td>
<td>SKB Medical Director/ Senior Billings System Analyst</td>
<td>$325M</td>
</tr>
<tr>
<td>Bayer</td>
<td>2003</td>
<td>Bayer Corporate Marketing Executive</td>
<td>$257M</td>
</tr>
<tr>
<td>National Health Labs</td>
<td>1992</td>
<td>NHL Sales Manager</td>
<td>$149M</td>
</tr>
<tr>
<td>King</td>
<td>2004</td>
<td>King Director of Contracts and National Accounts</td>
<td>$124M</td>
</tr>
<tr>
<td>Pfizer</td>
<td>2002</td>
<td>Pfizer National Account Manager</td>
<td>$49M</td>
</tr>
</tbody>
</table>
Case Study: U.S. et al. ex rel. Cheryl Eckard v. GlaxoSmithKline and SB Pharmco Puerto Rico

- *Qui Tam* case filed February 2004 by former Manager of Global Quality Assurance
- $750 million settlement and plea October 2010
  - $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 by SB Pharmco to releasing batches of those products in interstate commerce with intent to defraud and mislead
Preventing Pharma Fraud: which of these strategies will work best?

- Criminally prosecute executives
- Exclude pharma companies and executives from government programs
- Pass more laws and regulations
- Strengthen laws that work
- Give regulatory and enforcement agencies more resources
- Self-regulation and effective corporate compliance programs