

GETNICK & GETNICK LLP

Fraud in the Pharmaceutical Industry

The United States *qui tam* Whistleblower Law

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Outline

- ▶ Pharma Fraud Overview
- ▶ The False Claims Act *Qui Tam* Whistleblower Law
- ▶ FCA *Qui Tam* Pharma Fraud Settlements 2000-2012
- ▶ Who are the Whistleblowers?
- ▶ Case Study: *U.S. ex rel. Eckard v. GlaxoSmithKline*, 04 CV10375 (JLT) (D.Mass.)
- ▶ 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

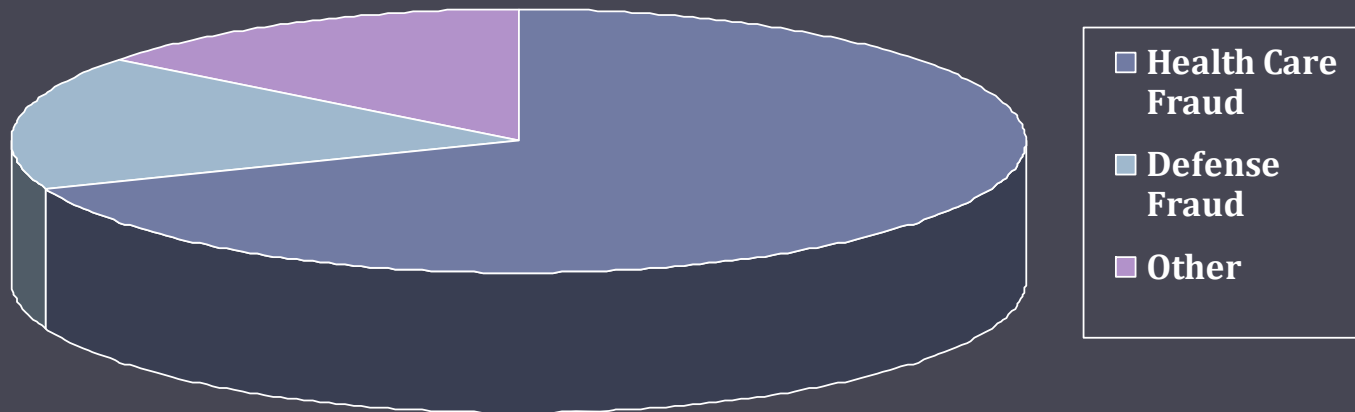
- ▶ Creates a civil cause of action for fraud on the government
- ▶ Treble damages and penalties of \$5,500-\$11,000 per violation
- ▶ Action can be brought both by the government and by a private citizen in the name of the government (the *qui tam* “relator”)
- ▶ Relator is entitled to receive up to 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”

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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

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

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

Company	Year	Relator	Recovery
Columbia/HCA	2003	Divisional Reimbursement Supervisor/Hospital CFO	\$881M
TAP	2001	TAP V-P of Sales/HMO Medical Director	\$875M
GlaxoSmithKline	2010	Global Quality Assurance Manager	\$750M
Columbia/HCA	2000	V-P of affiliated home health company/Others	\$745M
Merck	2008	Merck District Sales Manager/Physician	\$650M
Allergan	2010	Allergan Policy Manager and Account Manager	\$600M
Gambro	2004	Chief Medical Officer	\$350M
Schering Plough	2004	Three Schering Senior Managers	\$345M
SmithKlineBeecham	1997	SKB Medical Director/Senior Billings System Analyst	\$325M
Bayer	2003	Bayer Corporate Marketing Executive	\$257M
National Health Labs	1992	NHL Sales Manager	\$149M
King	2004	King Director of Contracts and National Accounts	\$124M
Pfizer	2002	Pfizer National Account Manager	\$49M

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

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Questions?

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