

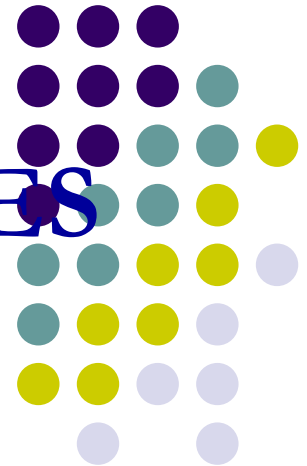
# THE SECOND ANNUAL FDA REGULATORY AND COMPLIANCE SYMPOSIUM

## LESSONS FROM WHISTLE-BLOWER CASES

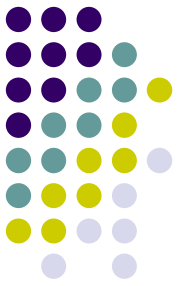
**THOMAS M. GREENE**

Greene & Hoffman

August 25, 2006

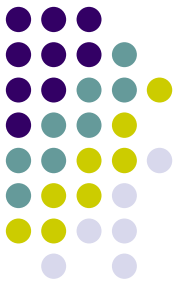


# WHAT IS THE FALSE CLAIMS ACT (FCA)?

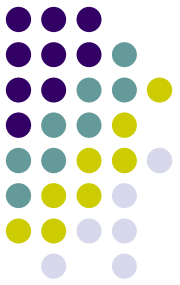


- A primary tool of government to fight fraud
- Enacted in 1863 in response to unscrupulous profiteering during Civil War
- Broad remedial statute intended to reach all types of fraud
- Whistleblower's share = 15% - 30%
- Original source
- Protection against retaliation

# WHAT IS THE FALSE CLAIMS ACT (FCA)?



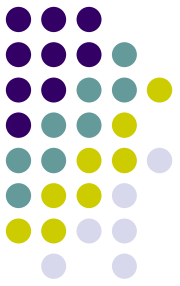
- Imposes liability for any person who –  
Knowingly presents, or causes to be presented, to the United States Government **a false or fraudulent claim for payment** or approval; or  
Knowingly makes, uses, or causes to be made or used, **a false record or statement** to get a false or fraudulent claim paid or approved by the Government
- In addition to federal FCA, 16 states and 3 cities now have false claims acts



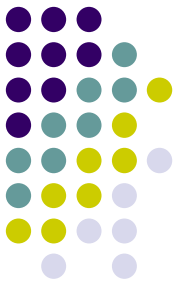
# Monetary Recoveries

- Total recoveries against pharmaceutical companies from top 15 FCA cases = \$3.5 billion
- Whistleblowers have received \$326.3 million

# Types of Whistleblower Cases



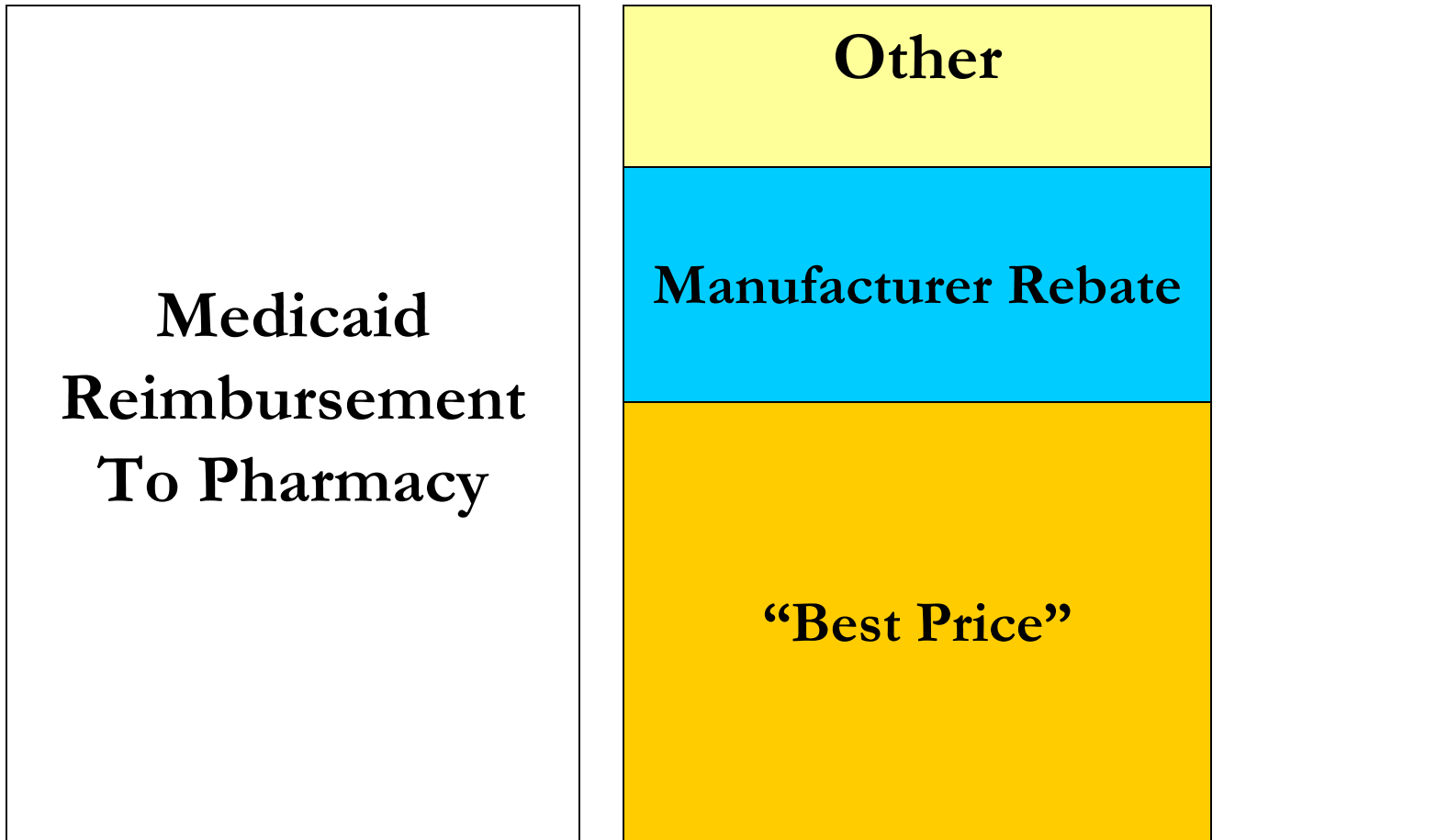
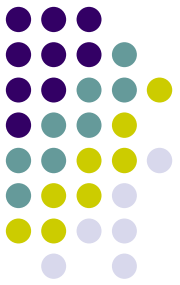
- “Best price” concealment
- Marketing “the spread”
- Kickbacks
- Off-label marketing
- Traditional fraud

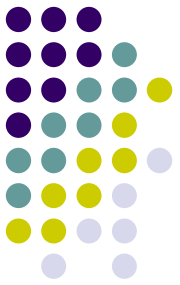


# “Best Price” Concealment

- Medicaid receives rebate (greater of):
  - 15.1% of AMP
  - or-
  - Difference between AMP and “best price”
- Causes Medicaid to receive smaller rebate

# Medicaid Rebate

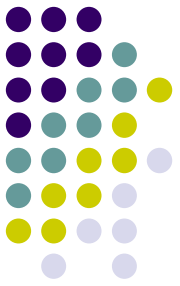




# Marketing “The Spread”

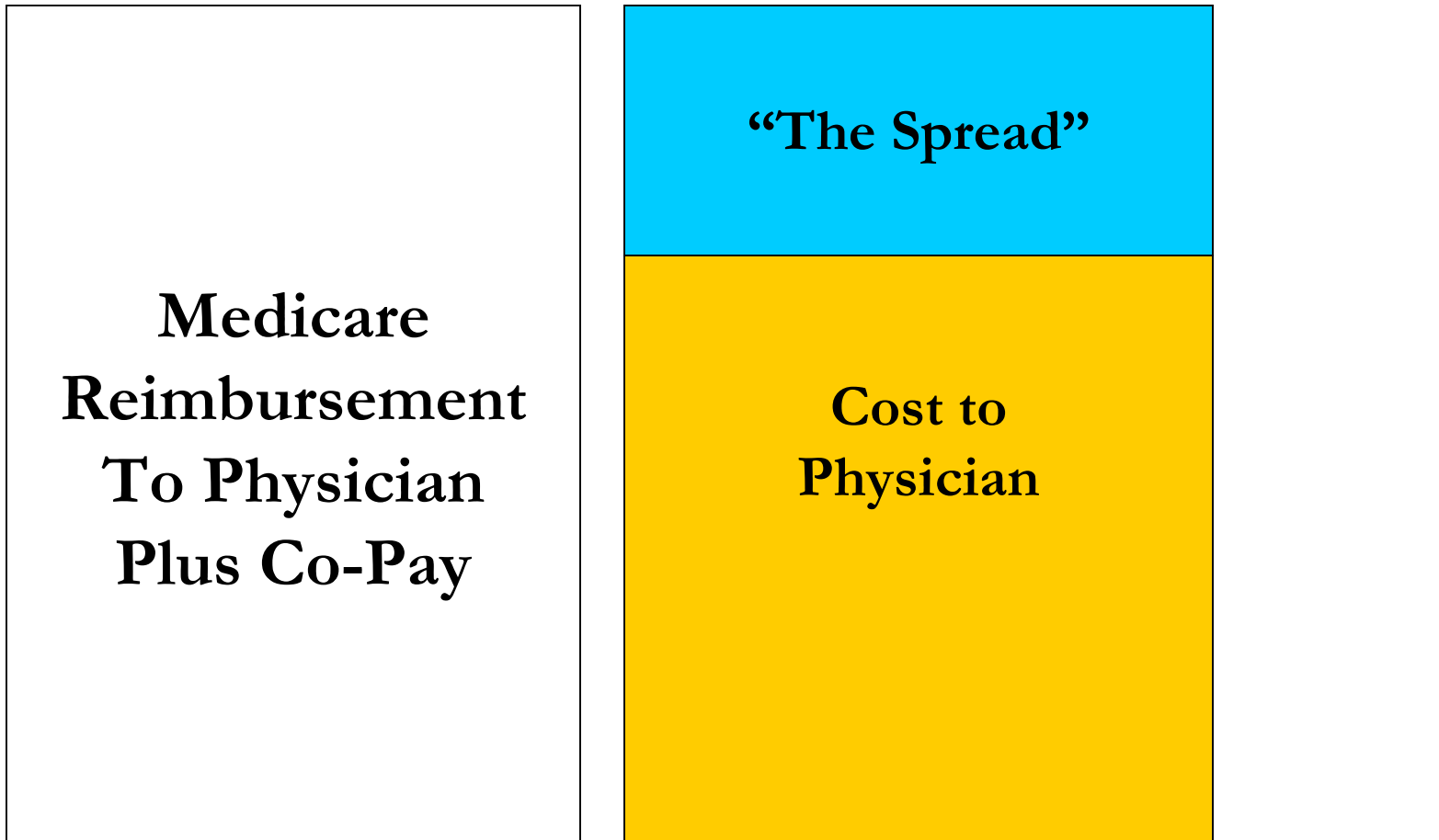
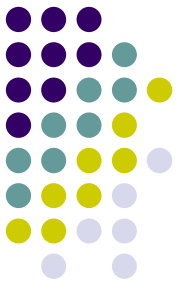
- Drugs administered by physicians
- Medicare pays physician percentage of AWP
- Physician keeps “the spread” between Medicare payment (plus co-pay) and cost of acquiring drug

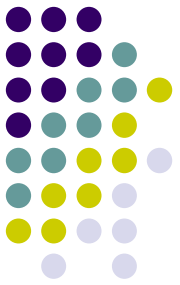
# Marketing “The Spread” (cont.)



- Causes Medicare to overpay
- Causes over-utilization
- Also applies to Medicaid and pharmacy sale of generics

# Medicare & AWP

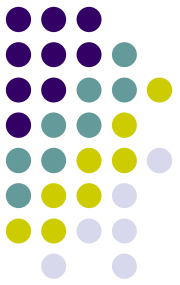




# Kickbacks

- A kickback is defined as:

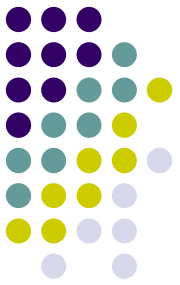
“remuneration . . . to induce [] a person . . .to purchase or recommend purchasing . . . any good for which payment may be made in whole or in part under a Federal health care program” (42 U.S.C. § 1320a-7b)



# Off-Label Marketing

- With limited exceptions, off-label uses are not covered by Medicaid and are not eligible for reimbursement
- Entire amount of prescription reimbursement can be recovered

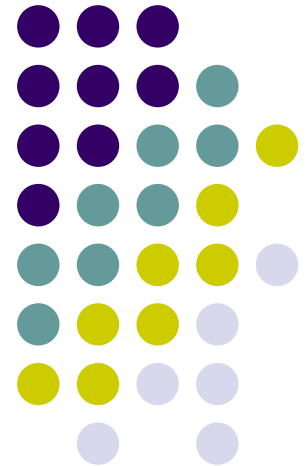
# Traditional Fraud



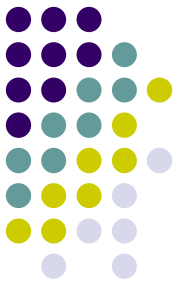
- Examples:
  - Phony tests
  - Double billing

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# TOP 15 DRUG CASES

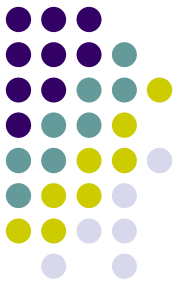


# Concealment of “Best Price”



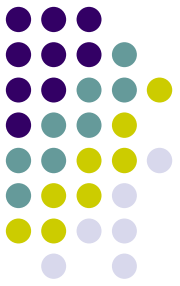
Company	Product	Date	Total Recovery	Whistleblower Share	Whistleblower
Bayer I	Koate-HP Kogenate Gamimmune	1/23/2001	\$14 million	\$1.6 million	Home infusion company
TAP	Lupron	10/3/2001	\$875 million	\$95.1 million	Sales executive Physician
Pfizer I	Lipitor	10/28/2002	\$49 million	\$5.9 million	Account manager
Bayer II	Adalat CC Cipro	4/16/2003	\$257 million	\$34.2 million	Marketing executive
GlaxoSmithKline I	Flonase Paxil	4/16/2003	\$88 million	None	

# Concealment of “Best Price” (cont.)

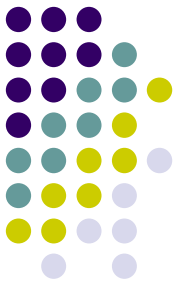


Company	Product	Date	Total Recovery	Whistleblower Share	Whistleblower
Astrazeneca	Zoladex	6/20/2003	\$355 million	\$47.6 million	Competitor
Schering-Plough II	Claritin products	7/29/2004	\$345 million	\$31.7 million	Schering-Plough employees (3)
GlaxoSmithKline II	Kytril Zofran	9/2005	\$150 million	\$26 million	Home infusion company
King	Altace Aplisol Lorabid Fluogen	11/1/2005	\$124 million		Executive
Boehringer Ingelheim	Albuterol	11/25/2005	\$10 million		Home infusion company

# Concealment of “Best Price” (cont.)



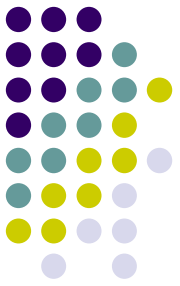
- 10 cases between 2001 and 2005
- Total recovery = \$2.27 billion
- Whistleblower share = \$242.1 million



# Marketing “The Spread”

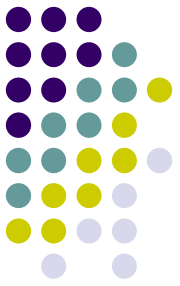
Company	Product	Date	Total Recovery	Whistleblower Share	Whistleblower
Bayer I	Koate-HP Kogenate Gamimmune	1/23/2001	\$14 million	\$1.6 million	Home infusion company
TAP	Lupron	10/3/2001	\$875 million	\$95.1 million	Sales executive Physician
Dey I	Albuterol Sulfate Ipratropium Bromide	6/11/2003	\$18.5 million	\$3.2 million	Home infusion company
Astrazeneca	Zoladex	6/20/2003	\$355 million	\$47.6 million	Competitor

# Marketing “The Spread” (cont.)



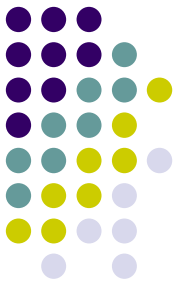
Company	Product	Date	Total Recovery	Whistleblower Share	Whistleblower
Schering-Plough I	Albuterol	5/3/2004	\$27 million	\$5.4 million	Home infusion company
Dey II	Albuterol	8/7/2004	\$2.5 million		Home infusion company
GlaxoSmithKline II	Kytril Zofran	9/2005	\$150 million	\$26 million	Home infusion company
Boehringer Ingelheim	Albuterol	11/25/2005	\$10 million		Home infusion company

# Marketing “The Spread” (cont.)

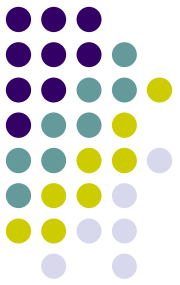


- 8 cases between 2001 and 2005
- Total recovery = \$1.45 billion
- Whistleblower share = \$178.9 million

# Kickbacks



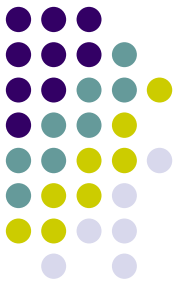
<b>Company</b>	<b>Product</b>	<b>Date</b>	<b>Total Recovery</b>	<b>Whistleblower Share</b>	<b>Whistleblower</b>
TAP	Lupron	10/3/2001	\$875 million	\$95.1 million	Sales executive Physician
Astrazeneca	Zoladex	6/20/2003	\$355 million	\$47.6 million	Competitor
Serono Group	Serostim	10/2005	\$704 million	\$51 million	Serono employees (5)



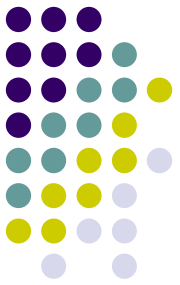
## Kickbacks (cont.)

- 4 cases between 2001 and 2005
- Total recovery = \$1.93 billion
- Whistleblower share = \$193.7 million

# Off-Label Marketing



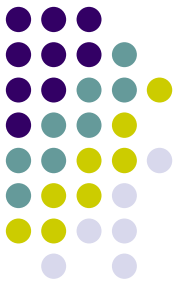
<b>Company</b>	<b>Product</b>	<b>Date</b>	<b>Total Recovery</b>	<b>Whistleblower Share</b>	<b>Whistleblower</b>
Pfizer II	Neurontin	5/13/2004	\$430 million	\$24.6 million	Medical liaison
Serono Group	Serostim	10/2005	\$704 million	\$51 million	Serono employees (5)



# Off-Label Marketing (cont.)

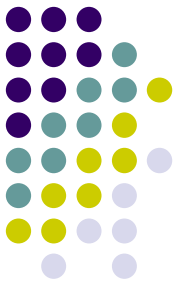
- 2 cases between 2004 and 2005
- Total recovery = \$1.13 billion
- Whistleblower share = \$75.6 million

# Traditional Fraud



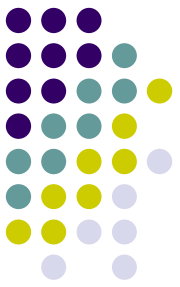
<b>Company</b>	<b>Product</b>	<b>Date</b>	<b>Total Recovery</b>	<b>Whistleblower Share</b>	<b>Whistleblower</b>
GlaxoSmithKline II	Kytril Zofran	9/2005	\$150 million	\$26 million	Home infusion company

# Consequences of Whistleblower Actions

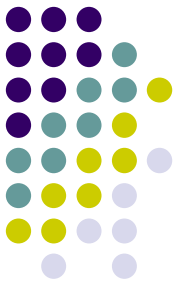


- Government investigations
  - Federal & State
  - Criminal, Civil & Administrative
- Class actions
- Securities litigation

# Consequences of Whistleblower Actions (cont.)



- Personal injury lawsuits
- Physician involvement
  - Indictment (Dr. Gleason)
  - Lawsuit against Company (Dr. Longmire)
  - Depositions and discovery
- Corporate Integrity Agreements



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