

PHARMACEUTICAL REGULATORY AND COMPLIANCE CONGRESS

QUI TAM SUITS: BAROMETER OF FUTURE ENFORCEMENT ACTIONS

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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):

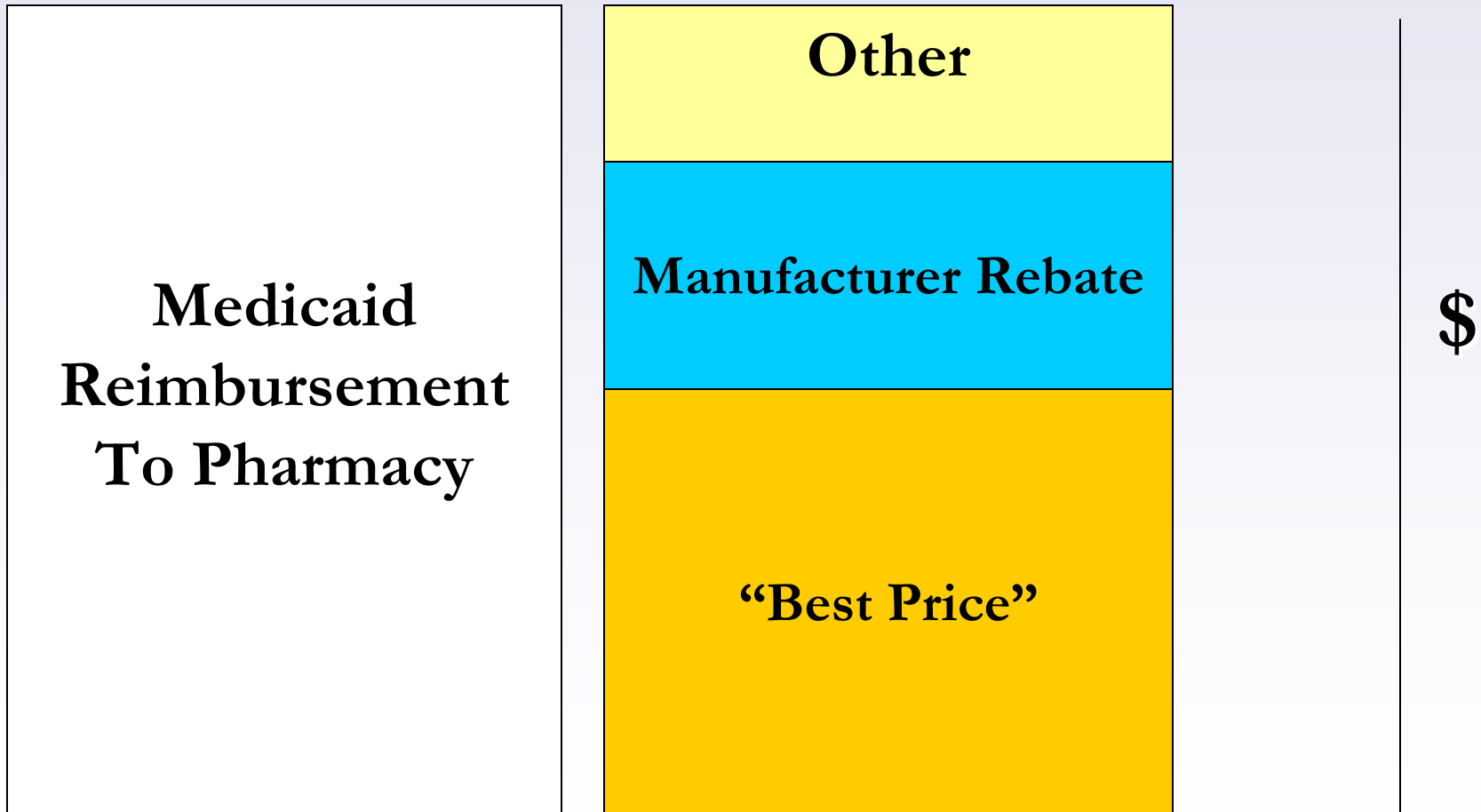
 - ✧ 15.1% of AMP

-or-

 - ✧ Difference between AMP and “best price”

- ✧ Causes Medicaid to receive smaller rebate

Medicaid Rebate



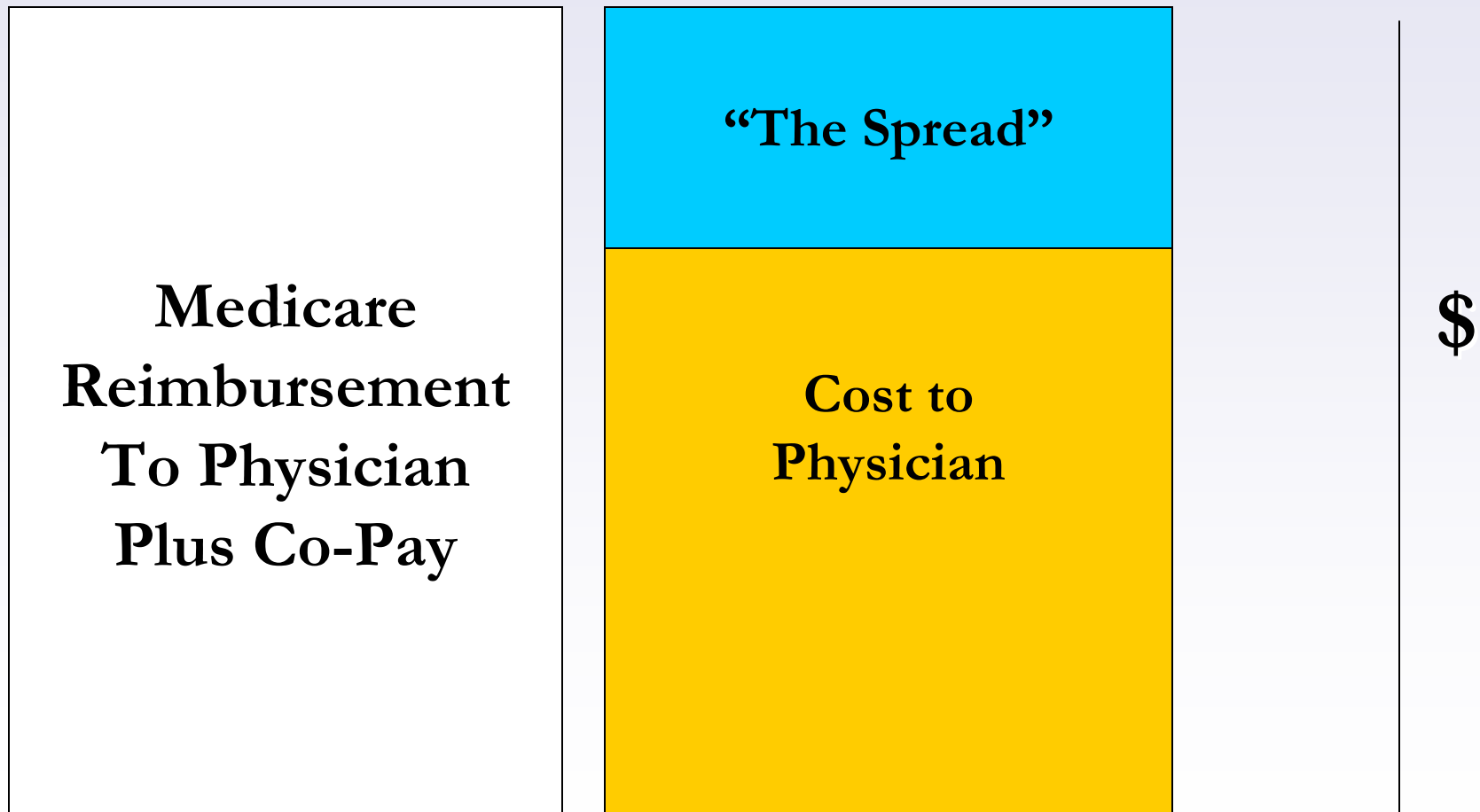
Marketing “The Spread”

- ❖ 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

TOP 15 DRUG CASES*

As of August 25, 2006

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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

Company	Product	Date	Total Recovery	Whistleblower Share	Whistleblower
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

Company	Product	Date	Total Recovery	Whistleblower Share	Whistleblower
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

Company	Product	Date	Total Recovery	Whistleblower Share	Whistleblower
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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