

SAPRAA Presentation

INTERACTIONS WITH HCP'S

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Video



Video



The unUsual Suspects

Pfizer

SEPT 2009

Pfizer was fined \$2.3 billion, then the largest health care fraud settlement and the largest criminal fine ever imposed in the United States. Pfizer pled guilty to misbranding the painkiller Bextra with "the intent to defraud or mislead", promoting the drug to treat acute pain at dosages the FDA had previously deemed dangerously high. Bextra was pulled from the market in 2005 due to safety concerns. The government alleged that Pfizer also promoted three other drugs illegally: the antipsychotic Geodon, an antibiotic Zyvox, and the antiepileptic drug Lyrica.

[See Pfizer in Dollars For Docs](#)

Merck

NOV 2011

Merck agreed to pay a fine of \$950 million related to the illegal promotion of the painkiller Vioxx, which was withdrawn from the market in 2004 after studies found the drug increased the risk of heart attacks. The company pled guilty to having promoted Vioxx as a treatment for rheumatoid arthritis before it had been approved for that use. The settlement also resolved allegations that Merck made false or misleading statements about the drug's heart safety to increase sales.

[See Merck in Dollars For Docs](#)

GlaxoSmithKline

JULY 2012

GlaxoSmithKline agreed to pay a fine of \$3 billion to resolve civil and criminal liabilities regarding its promotion of drugs, as well as its failure to report safety data. This is the largest health care fraud settlement in the United States to date. The company pled guilty to misbranding the drug Paxil for treating depression in patients under 18, even though the drug had never been approved for that age group. GlaxoSmithKline also pled guilty to failing to disclose safety information about the diabetes drug Avandia to the FDA.

[See GlaxoSmithKline in Dollars For Docs](#)

Sanofi-Aventis

DEC 2012

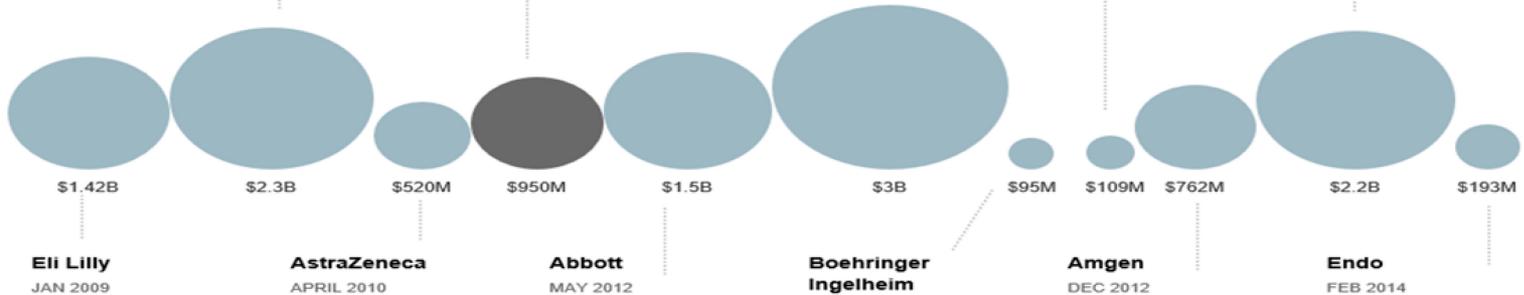
Sanofi-Aventis agreed to pay \$109 million to resolve allegations that the company gave doctors free units of Hyalgan (an injection to relieve knee pain) to encourage those doctors to buy their product. Sanofi lowered the effective price by promising these free samples to doctors, but at the same time got inflated prices from government programs by submitting false price reports, alleged the United States. Medicare and other government health care programs "paid millions of dollars in kickback-tainted claims for Hyalgan," according to the DOJ announcement.

Johnson & Johnson

NOV 2013

Johnson & Johnson agreed to pay a \$2.2 billion fine to resolve criminal and civil allegations relating to the prescription drugs Risperdal, Invega and Natrecor. The government alleged that J&J promoted these drugs for uses not approved as safe and effective by the FDA, targeted elderly dementia patients in nursing homes, and paid kickbacks to physicians and to the nation's largest long-term care pharmacy provider, Omnicare Inc. As part of the agreement, Johnson & Johnson admitted that it promoted Risperdal for treatment of psychotic symptoms in non-schizophrenic patients, although the drug was approved only to treat schizophrenia.

[See J&J in Dollars For Docs](#)



What we did

- We took internal accountability

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➤ WE CHANGED THE WAY WE INTERACT WITH HCP'S

- Policy review
- GPIHCP was the starting point
 - Restricted method of spend.
 - Record keeping. Justification
 - Reviewed Honoraria values.
 - Fair Market Value benchmark
 - All payments reviewed
 - Hospitality must be reasonable and appropriate
 - No sporting or leisure activities.



The Process



Video

Why is Ethics and Integrity Important to You

1. Your role

Regulatory Pharmacist

2. Gatekeepers or Business Enabler

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3. Code of Marketing Practice:

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14.1 Appointment of person(s) responsible as Company Code Compliance Officer for approval of promotional material, meetings or activities.

