



Fraud and Abuse Issues In Off-label Marketing

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AdvaMed

Medical Technology Learning Institute

The A-Z of Off-Label Issues

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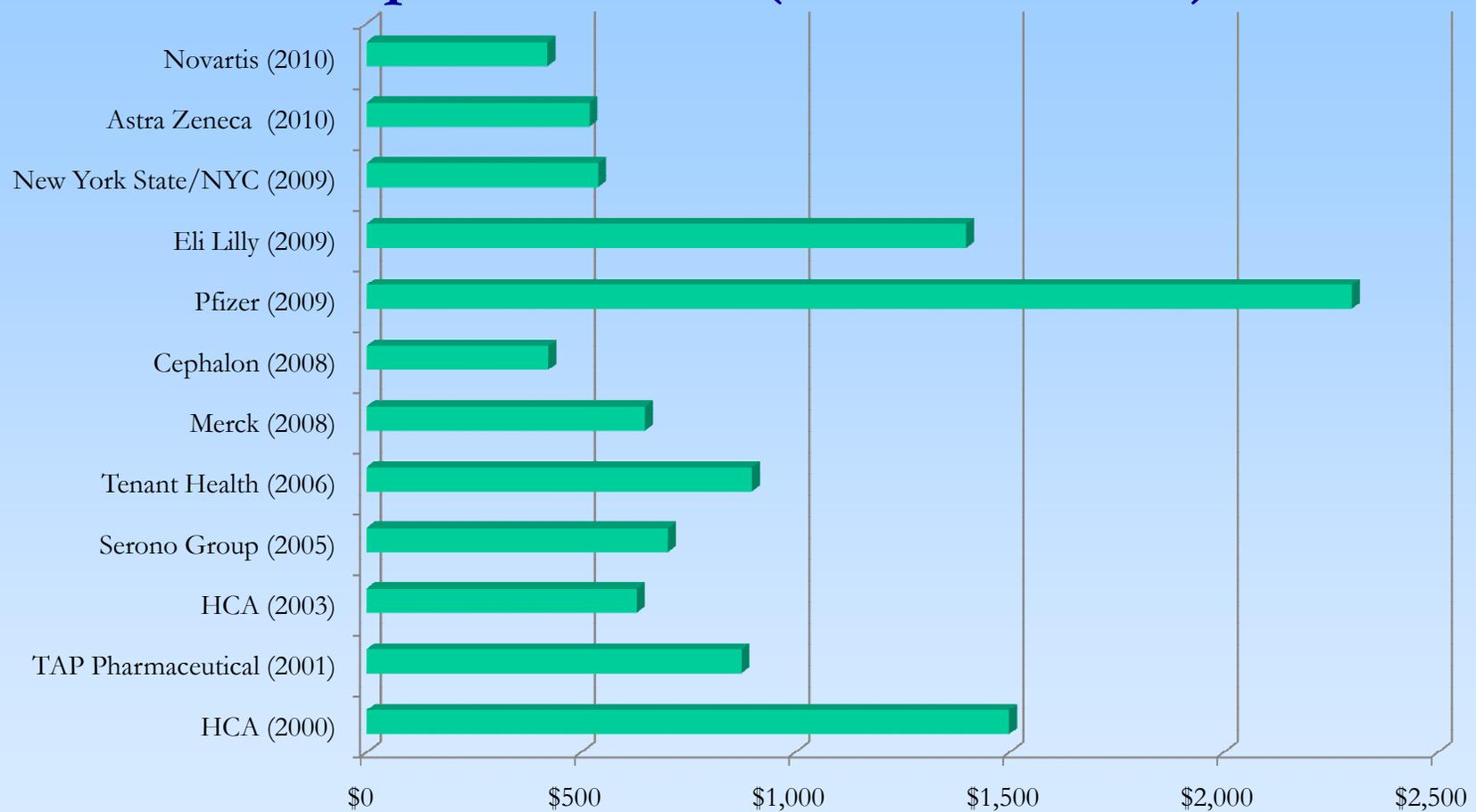
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OUTLINE

- **Increased Fraud Enforcement Activity**
 - **Current Enforcement Climate**
 - **Prosecution and Exclusion of Individuals**
- **Inter-relationship with Kickback Allegations**
- **Off-Label Enforcement Activity**
 - **Fraud Theory**
 - **Off-label Pharma Cases**
 - **Off-label Device Cases**

Federal False Claims Act Top Recoveries (\$\$\$ in millions)



SOURCE: DEPARTMENT OF JUSTICE

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Current Enforcement Climate

- Recent fraud enforcement:
 - FY ending September 2009, DOJ recovered \$2.4b (not including Pfizer settlement)
 - More than \$1b was from healthcare fraud
- Federal Enforcement and Recovery Act of 2009 (FERA)
 - Increased funding for attorneys, investigators
 - Civil Investigative Demand authority expanded
 - Substantial liberalization of the False Claims Act
- Creation of Health Care Fraud Prevention and Enforcement Action Team (HEAT) – May 2009
- Obama Executive Order – Fall 2009
- National Summit on Health Care Fraud – Winter 2010

Current Enforcement Climate (cont.)

- Winter 2010 -- President's 2011 Budget includes 1.7 billion for Health Care Fraud & Abuse Control Program (“HCFACP”)
- \$2.5 billion in recoveries for FY 2010, up from \$1.6 billion for FY 2009
- Presidential Memorandum Regarding Finding and Recapturing Improper Payments, March 10, 2010
 - Expanded the use of Payment Recapture Audits
- 2010 Joint Congressional Hearing on Reducing Fraud, Waste and Abuse in Medicare

Health Reform Legislation

- Patient Protection and Affordable Care Act, Pub. L. No. 111-148
 - Enacted March 23, 2010
- Health Care and Education Affordability Reconciliation Act of 2010, Pub. L. No. 111-152
 - Enacted March 30, 2010
- In this presentation, the two will collectively be “PPACA”

HIPAA Health Care Fraud Statute

- In 1996, HIPAA created a new category of federal criminal offenses—health care offenses
 - Allows subpoenas, freezing of assets, etc.
- Criminal health care fraud:
 - Knowing and willful execution of a scheme or artifice:
 - *To defraud a health care benefit program*
 - *To obtain through false or fraudulent means any money or property from a health care benefit program*
 - *Through Federal Sentencing Guidelines, until now violations of this provision carried greater penalties than anti-kickback statute (“AKS”) violations*

HIPAA Health Care Fraud Statute (cont.)

- Now: Lower level of intent required to prove a violation—a person need not have actual knowledge or specific intent (*Section 10606(b)*)
- Now: The definitions of Health Care Offense include:
 - Violations of the AKS
 - With respect to health care benefit programs --
 - *Violations of the Food, Drug and Cosmetic Act*
 - *Violations of certain sections of ERISA*
- Now: Enhanced penalties under the Federal Sentencing Guidelines

HIPAA Health Care Fraud Statute (cont.)

- PPACA changes the Federal Sentencing Guidelines as they apply to federal health care offenses. Examples include:
 - Changes loss calculation to “the aggregate dollar amount of fraudulent bills submitted to the Government health care program shall constitute prima facie evidence of the amount of the intended loss by the defendant”
 - Enhances penalties for convictions of federal health care offenses relating to government programs
 - *(e.g., for losses between \$1m and \$7m, a 2-level increase)*

- Directs the U.S. Sentencing Commission to:
 - “ . . . ensure that the Federal Sentencing Guidelines and policy statements [among other things]
 - (i) reflect the serious harms associated with health care fraud and the need for aggressive and appropriate law enforcement action to prevent such fraud; and (ii) provide increased penalties for persons convicted of health care fraud offenses in appropriate circumstances.”

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Prosecution and Exclusion of Individuals

- Increased Emphasis
- Washington Legal Foundation (“WLF”) Letter to FDA re: Criminal Prosecution of Executives (2010)
- *United States v. Caputo* (2008)
- Norma Muurahainen (Serono Laboratories) (2008)
- Huggins, Higgins, Bohner and Walsh (Norian/Synthes) (2009)
- Philip, Heppner, Ard, and Whitaker (Stryker Biotech) (2009)
- Lauren Stevens (GlaxoSmithKline) (2010)
- Guilty Pleas:
 - Douglas Donofrio (Exactech, Inc.) (2010)
 - Kenneth B. Beverly (John D. Archobold Memorial Hospital)(2010)
- Scott Harkonen (InterMune) (2011)
- Exclusions of:
 - Friedman, Goldenheim, and Udell (Purdue Frederick Co.) (2010)
 - Jeffrey H. Owen (Surgical Monitoring Systems) (2010)
 - Marc S. Hermelin (K-V Pharmaceutical Co.) (2010)

Increased Emphasis On Individuals *cont.*

- FDA pledges more aggressive use of “responsible corporate officer doctrine” – DOJ is on board
- OIG Exclusion Authority:
 - Recent HHS OIG guidance on exclusions --
http://oig.hhs.gov/fraud/exclusions/files/permissive_excl_under_1128b15_10192010.pdf
 - Exclusions: Section 1128(b)(15)(A)(ii) does not require a knowledge element, setting lower bar for exclusion of officers and managers from federal health care programs
 - Marc Hermelin’s 12/1/10 exclusion a “preview of things to come” – Gregory Demske, assistant inspector general, HHS
- New direction in corporate integrity agreements (CIAs)
 - aimed at increasing individual accountability and transparency to doctors
 - beyond hiring a compliance officer – seeking buy-in and support of boards of directors for policies and training

Washington Legal Foundation Letter to FDA

- October 26, 2010 – called on the FDA to abandon plans to seek increased criminal prosecution of high-level executives for off-label promotional activities
- WLF cautioned this might “adversely affect the nation’s healthcare delivery system by labeling responsible corporate officials as criminals even if they never participated in, encouraged, or had knowledge of the alleged violations”

More information about the letter is available at <http://www.wlf.org>

United States v. Caputo

- October 16, 2006 N.D. Ill. Sentencing Decision
- AbTox President/CEO sentenced to 10 years imprisonment, Chief Compliance Officer sentenced to 6 years.
 - Defendants convicted of conspiracy, mail fraud, wire fraud and introduction of an altered or misbranded device into interstate commerce.
 - Scheme to illegally market AbTox Plazlyte sterilizer (used to sterilize reusable medical devices).
- Seventh Circuit Appeal – Govt’s First Amendment Commercial Free Speech Position
 - FDCA does not protect conspiracy to defraud
 - “The promotion of an approved or cleared device for an unapproved and uncleared use is not per se prohibited by the FDCA.” Br. At 39.
 - Off-label promotion “is evidence that the device has acquired a new intended use.” Id.
 - Without new labeling, the device is misbranded.

Caputo cont.

- February 27, 2008 – Seventh Circuit Decision 517 F.3d 935
 - The Court upheld the convictions and sentences.
- Free speech analysis --
 - Court declined to rule on whether a manufacturer selling FDA-approved medical devices has a constitutional right to promote off-label uses.
 - Court reviewed Supreme Court precedent from *Virginia Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, and *Thompson v. Western States Medical Center*
 - Dicta: “And if a given use is lawful, . . . doesn’t it make a good deal of sense to allow speech by the device’s manufacturer, which after all will have the best information? Why privilege speech by the uninformed?”

Norma Muurahainen (Serono)

- Serono Medical Director (see also discussion of 2005 Serono criminal plea below)
- July 23, 2008 - plead guilty to three FDA misdemeanor counts related to this case
- Admitted to encouraging physicians to write prescriptions for Serostim based on the BIA tests.

Huggins, Higgins, Bohner and Walsh (Synthes/Norian)

- Allegations – Indictment/Information
 - June 2009 – Superseding Information Oct. 2010
 - Synthes, and its wholly owned subsidiary, Norian – 52 Felony counts and 44 misdemeanor counts
 - Individual Defendants
 - *Top executives of Synthes*
 - *Each charged with one misdemeanor count*
 - Unauthorized clinical trials -- surgeries to treat vertebral compression fractures of the spine (“VCFs”)

Huggins, Higgins, Bohner and Walsh (Synthes/Norian) *cont.*

➤ Allegations *cont.*

- Company pilot studies showed the company that the bone cement reacted to cause blood clots
- FDA warning on the FDA-cleared label against this use
- Cautionary internal company memos
- Company proceeded to market the product for VCFs without putting it through FDA-required testing.
- Three patient deaths
- Company then stops marketing the product, but no FDA recall
- Cover-up and false statements to the FDA during an official inspection in May and June 2004

Huggins, Higgins, Bohner and Walsh (Synthes/Norian) *cont.*

➤ Global Settlement

- Norian and Synthes plead guilty to various FDA charges
 - *Over \$23 million in criminal penalties and forfeiture*
- Norian's plea leads to mandatory exclusion
- Agreement between Synthes and OIG enter into Divestiture Agreement -- Synthes must divest Norian by May 25, 2011, with OIG delaying Norian exclusion until that date
- Norian and Synthes enter into a civil settlement -- \$138,000
- Synthes enters into CIA
- Individual defendants awaiting sentencing

Mark Philip, William Heppner, David Ard, and Jeffrey Whitaker (Stryker Biotech)

- Former president and three sales managers at Stryker Biotech, LLC
- October 29, 2009 – along with Stryker Biotech, defendants indicted on charges of promoting the off-label combination of two bone growth products
 - Stryker and Philip also charged with making false statements to FDA
 - Individual defendants indicted on substantive charges, not responsible corporate officer law
 - Some patients experiences adverse affects arising from the combination of products including inflammation, drainage and impaired wound healing, and unwanted bone growth
- Company allegedly manufactured bone growth implants, bone growth putty, and bone void fiber
- September 21, 2010 – Motions to Dismiss filed (briefing complete as of 1/11/11)

Lauren Stevens

- Former VP and Assoc. General Counsel at GlaxoSmithKline
 - November 9, 2010 - indicted for obstructing justice and lying to federal investigators in probe of off-label marketing of Wellbutrin SR
- Accused of obstructing an official proceeding, concealing and falsifying documents to influence a federal agency and making false statements to the FDA
 - Allegedly withheld company slides from presentations “promoting” Wellbutrin for off-label purposes
 - Requested internal legal memo outlining the pros and cons of producing “incriminating” slides for the FDA
- GSK not mentioned or charged in connection with allegations against Stevens

Lauren Stevens (cont.)

Carmen Ortiz, U.S. Attorney for District of Massachusetts

- “There is a difference between legal advocacy based on the facts and distorting the facts to cover up the truth... Federal agencies cannot protect the public health if the entities and individuals they regulate provide false information and conceal true facts”

Tony West, assistant attorney general for DOJ Civil Division

- “Where the facts and law allow, the Justice Department will pursue individuals responsible for illegal conduct just as vigorously as we pursue corporations”

Douglas Donofrio (Exactech)

- Director of Sales for Exactech's Northeast region
- December 7, 2010 – plead guilty to a one-count criminal information in which he allegedly falsified surgeons' work reports to justify fraudulent payments
 - Violation of anti-kickback statute by offering orthopedic surgeons consulting agreements in exchange for use of Exactech's hip and knee reconstruction and replacement products
- Sentencing for Donofrio scheduled for March 14, 2011
 - Faces maximum penalty of 5 years imprisonment and \$250,000 fine
- \$2.99 million related civil settlement and deferred prosecution agreement for Exactech

Kenneth B. Beverly (Archbold Medical Center)

- Former President and CEO of Archbold Medical Center
- December 8, 2010 – found guilty on three counts of Medicaid fraud
 - Conspiracy count for characterizing the hospital as a non-state, government-owned or operated facility in order to receive millions of dollars in additional UPL and DSH Medicaid funds
- \$13.9 civil settlement with hospital resolves qui tam lawsuit alleging receipt of funds between November 2002 and December 2008

Scott Harkonen

- Former CEO, InterMune, Inc. – *See also* InterMune, Inc. settlement discussion below
- Sept. 29, 2009
 - Convicted of wire fraud
 - Found innocent of FDA misbranding charge
- Harkonen initiated an InterMune a press release announcing false and misleading information related to efficacy of Actimmune drug for treatment of idiopathic pulmonary fibrosis

Harkonen cont.

- Sentencing hearing
 - Originally scheduled November 15, 2010
 - Government sought 10-year prison sentence
 - Delayed until March 23, 2011 to allow government time to demonstrate the loss incurred by Harkonen and InterMune's 2002 press statement about the efficacy of Actimmune
 - Judge skeptical – asked government to determine the loss and ordered prosecutors to justify the loss calculations –
 - *“don't just dump a lot of exhibits on me”*
 - *Need “real data”*
 - *Sentence must be “based on reality and not speculations”*
- January 7, 2011 Motion for new trial – Brady violations

Michael Friedman, Paul Goldenheim and Howard Udell - Exclusions

- Executives at Purdue Frederick Company
- Plead guilty under FDA responsible corporate officer law
- December 13, 2010 – decision by District Court (D.C.) to exclude from participation in federal health care programs for 12 years
 - Misdemeanor guilt pleas to charges that they served as “responsible corporate officers” in PFC’s marketing of misbranded drugs
- Plaintiffs sought reversal of exclusion decision, arguing that their pleas under “responsible corporate officer” doctrine do not reflect personal wrongdoing
 - Court upheld exclusion

Jeffrey H. Owen (of Surgical Monitoring Systems)

- Former CEO of Surgical Monitoring Systems
- November 17, 2010 - Agreed to three-year exclusion from federal health care programs
 - SMS and Owen entered into related \$2.7 million civil settlement agreement with DoJ
- Charges involved over-billing of Medicare for excessive hours of intraoperative monitoring services (IOM)
 - SMS technicians perform testing and monitoring of patient's nervous system during surgery
 - Technicians would allegedly bill Medicare for monitoring of patients individually when he/she had actually monitored a group of patients simultaneously

Marc S. Hermelin (K-V Pharmaceutical)

- Former Board member of K-V Pharmaceutical
- November 22, 2010 – excluded from participation in federal health care programs
- Hermelin voluntarily resigned and agreed to broad divestiture plan and schedule as part of settlement agreement
- Early example of OIG “(b)(15) authority,” regarding basis for excluding individuals from participation in federal health care programs: 42 U.S.C. 1128 (b)(15)(A)(ii)
- 2008 – K-V ignored enforcement notice requiring FDA approval before selling time-release drugs containing guaifenesin

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ANTI-KICKBACK STATUTE

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Anti-Kickback Statute

- Makes it unlawful to:
 - (1) Knowingly and willfully
 - (2) Offer or pay, solicit or receive
 - (3) Any remuneration
 - (4) To induce
 - *the referral of an individual to another person or entity for the furnishing of any item or service; or*
 - *to induce the purchasing or ordering of such item or service*
 - (5) Payable in whole or in part by Medicare or Medicaid

Anti-Kickback Statute *cont.*

- Many courts have also ruled that the statute is violated if “one purpose” was to induce referrals.
- Criminal conviction under the Anti-Kickback Statute requires proof of criminal intent or that the person acted with a bad purpose, with knowledge that one’s conduct is unlawful.

Anti-Kickback Statute *cont.*

➤ *Health Reform — Pub. L. 111-148*

➤ *Section 6402(f) — New AKS intent standard —*

“With respect to violations of this section, a person need not have actual knowledge of this section or specific intent to commit a violation of this section.” § 1128B(h)

➤ *Section 10606(b) — Identical new Health Care Fraud intent standard (18 U.S.C. § 1347(b))*

Anti-Kickback Statute *cont.*

- *Linkage to False Claims Act* — Many courts have held under an express or implied certification theory that a violation of AKS is actionable under the False Claims Act
 - Allows for significant penalties
 - Allows for whistleblowers to bring actions
- *Health Reform* — *Section 6402(f), Pub. L. 111-148* makes this explicit —

“In addition to the penalties provided for in this section. . . , a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of the [False Claims Act].” § 1128B(g)

Anti-Kickback Statute *cont.*

Potential Penalties

➤ **Criminal:**

- Fines up to \$25,000 per offense
- Additional fines based on corporate sentencing guidelines
- Five years imprisonment
- If convicted, automatic exclusion from the Medicare and Medicaid programs

➤ **Administrative:**

- Civil Monetary Penalties of up to \$50,000, plus treble damages
- Permissive exclusion (conviction not required)
- Federal debarment

Kickback Allegations In Off-Label Cases

- Many of the off-label cases contain allegations of violations of the anti-kickback statute in the civil settlements. Why?
- Kickbacks may be the economic engine in the corporate behavior.
 - It is one thing to have sales force encourage off-label use
 - The scheme can become more highly potent if physicians become part of the scheme
 - *key opinion leaders*
 - *direct payments disguised as a variety purposes*
- Criminal plea agreement must be confined to FDA violation because conviction for AKS violation → mandatory exclusion

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Fraud Theory

FCA prohibits, among other things, anyone who

- **(1)** knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval;
- **(2)** 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;
- **(3)** conspires to defraud the Government by getting a false or fraudulent claim allowed or paid;

31 U.S.C. §§ 3729(a)(1)-(a)(3)

Fraud Theory (*cont.*)

- Because of payment limitations, an off-label device may not be reimbursable
 - This theory suggests that because of a fraud scheme by a device manufacturer and/or provider, fraudulent information is provided to a government program that makes the claim appear payable
 - Medicaid ties reimbursement for off-label uses to “medically accepted indications” SSA § 1927(k)(3) and (6)
 - False ICDN code
 - Falsification of patient’s medical condition
 - No information that device is being used for an off-label purpose
- Query whether government decision to pay is always at the heart of these govt cases?

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US Attorney's Office D. Mass.

“An area of increasing health care fraud focus is sale of drugs and medical devices for ‘off-label’ or ‘unapproved’ uses.”

Michael K. Loucks, Prosecuting and Defending Health Care Fraud Cases, at 132 (Supp. 2006).

Pharma Off-Label Cases

- Pfizer/Parke-Davis/Warner Lambert (2004)
- Eli Lilly and Company (2005)
- Schering-Plough (2006)
- Pharmacia & Upjohn (Pfizer self-disclosure) (2007)
- Bristol-Myers Squibb (2007)
- Eli Lilly and Company (January 15, 2009)
- Pfizer, Pharmacia & Upjohn (September 3, 2009)
- Intermune, Inc. (2006) (see also Harkonen above)
- Novartis (January 26, 2010)

Eli Lilly and Company

- January 15, 2009 -- Eli Lilly criminal and civil settlement for off-label marketing of the anti-psychotic drug Zyprexa.
 - \$1.415 billion, then record amount
 - \$615 million criminal
 - \$800 million civil settlement
- Civil settlement
 - 4 *qui tam* law suits
 - Includes kickback allegations
- 5-year Corporate Integrity Agreement
- Materials found at: “http://www.justice.gov/usao/pae/eli_lilly.html”

Eli Lilly and Company *cont.*

- Stipulated Facts in Plea Agreement
 - Zyprexa was FDA approved certain indications for
 - *Psychotic disorders*
 - *Schizophrenia*
 - *Bipolar I Disorder (“Bipolar Mania”)*
 - Lilly promoted Zyprexa for unapproved uses in elderly populations
 - *dementia*
 - *Alzheimer's dementia*

Eli Lilly and Company *cont.*

- Allegations in Govt Information and Memorandum for Plea & Sentencing →
 - Illegal promotion included uses for agitation, aggression, hostility, depression, and generalized sleep disorder
 - Targeting providers where almost no on-label use in these markets
 - *Long-term care ("LTC") sales force, targeting nursing homes and assisted living facilities*
 - *Primary care physician ("PCP") sales force*
 - Marketing tied to anticipated revenue loss of Prozac patent expiration
 - Marketing tactics to get physicians to ask “unsolicited” questions about off-label studies

Eli Lilly CIA Off-Label Provisions

➤ *Found at:*

http://www.oig.hhs.gov/fraud/cia/agreements/eli_lilly_and_company_01142009.pdf

➤ ***Policies and Procedures:*** Lilly shall ensure that the Policies and Procedures address or shall continue to address:

- “the materials and information that may be distributed by Lilly sales representatives and account executives about Lilly's Government Reimbursed Products and the manner in which Lilly sales representatives and account executives respond to requests for information about non-FDA approved (or "off-label") uses of Lilly's Government Reimbursed Products;”

Eli Lilly CIA Off-Label Provisions *cont.*

➤ Policies and Procedures *cont.*

- “the materials and information that may be distributed by the Lilly Answers Center (TLAC) and the mechanisms through, and manner in which, TLAC receives and responds to requests for information submitted by sales representatives and account executives about non-FDA approved ("off-label") uses of Lilly's Government Reimbursed Products; the form and content of information disseminated by Lilly in response to such requests; and the internal review process for the information disseminated.”
- Creation of a TLAC data base to track requests for information about Lilly's products that are submitted by Lilly's sales force.

Eli Lilly CIA Off-Label Provisions *cont.*

➤ Policies and Procedures *cont.*

- Systems, processes, policies, and procedures relating to the manner and circumstances for handling responses to unsolicited requests about off-label indications of Lilly's Government Reimbursed Products
- Systems, processes, policies, and procedures relating to the development, implementation, and review of call plans to ensure that Lilly is promoting its Government Reimbursed Products in a manner that complies with all applicable Federal health care program and FDA requirements.
- Similar requirements for distribution of samples

Eli Lilly CIA Off-Label Provisions *cont.*

- Specific Training requirements related to federal health care program requirements, FDA rules, and Lilly policies for Promotional and Product Services Related Functions
- Notification to the OIG within 30 days after the date of any written report, correspondence, or communication between Lilly and the FDA that materially discusses Lilly's or a Covered Person's actual or potential unlawful or improper promotion of Lilly's products (including any improper dissemination of information about off-label indications).

Eli Lilly CIA Off-Label Provisions *cont.*

- **Survey Entity** -- Lilly shall contract with an independent Survey Entity to conduct inquiries into the content and subject matter of the detailing interactions.
 - “Lilly shall review the records obtained from the Survey Entity and shall identify any instances in which the records appear to indicate that Covered Persons may have discussed and/or disseminated information about off-label uses of the Covered Products. Lilly shall make findings based on its review (Off-Label Findings) and shall take any responsive action it deems necessary.”
 - Off-Label Findings to be part of Annual Report.
- **Field Force Monitoring Program** to monitor interactions with HCPs and to identify potential off-label promotional activities.

Eli Lilly CIA Off-Label Provisions *cont.*

- **Independent Review Organization** -- Promotional and Product Services System Review --
 - Lilly's systems, policies, processes, and procedures applicable to requests or inquiries to The Lilly Answers Center relating to information about off-label uses of Lilly's Government Reimbursed Products and the dissemination of materials relating to off-label uses of Lilly's Government Reimbursed Products.
 - Review also includes other Lilly policies. *See above*

Eli Lilly CIA Off-Label Provisions *cont.*

➤ **IRO** -- Promotional and Product Services (“PPS”)

Transactional Review --

- **Internal Review of TLAC Database** -- On a semi-annual basis, Lilly to review its TLAC Database and related information, as appropriate, and shall generate a report summarizing Inquiries received ("TLAC Database Report"). Lilly shall review the TLAC Database Reports to assess whether the information contained in the report suggests that improper off-label promotion may have occurred in connection with any Inquiry(ies). If Lilly suspects that improper off-label promotion may have occurred in connection with any Inquiry, it shall undertake a follow-up review of the Inquiry (hereafter "Off-Label Review"), make specific findings based on the Off-Label Review, and take all appropriate corrective action (including disciplinary action, and disclosing Reportable Events, if applicable).

Eli Lilly CIA Off-Label Provisions *cont.*

➤ **IRO** -- PPS Transactional Review *cont.*

- IRO to review a sample of Inquiries, including Off-label Reviews and to make findings for each Off-Label Review, the basis for Lilly “suspecting that improper off-label promotion may have occurred; the steps undertaken as part of the Off-Label Review; the findings of [Lilly] as a result of the Off-Label Review; and any follow-up actions taken by Lilly based on the Off-Label Review findings.”
- Review of Lilly’s Call Plan
- Review of distribution of samples

Pfizer, Pharmacia & Upjohn Company

- *Materials available at:* “<http://www.justice.gov/usao/ma/Pfizer.html>”
- Sept. 2, 2009 -- Record **\$2.3 billion** settlement with Pfizer and subsidiary Pharmacia & Upjohn Company to resolve criminal and civil liability for off-label promotion marketing of Bextra
 - Bextra -- approved for anti-inflammatory indications
 - Marketed for other indications and dosing -- FDA specifically declined to approve, e.g., general acute pain, surgical pain and DVT prevention. Examples of strategies --
 - *Sham physician requests for medical information*
 - *Use of samples*
 - *CME*
 - Criminal component --
 - *Pharmacia & Upjohn plead guilty to a felony FDA misbranding charge*
 - *\$1.3 billion in criminal fines and forfeiture*

Pfizer, Pharmacia & Upjohn Company (*cont.*)

- Civil resolution - nine separate *qui tam* law suits
- \$1 billion False Claims Act settlement
- Four drugs –
 - Bextra
 - Geodon, an anti-psychotic drug
 - Zyvox, an antibiotic
 - Lyrica, an anti-epileptic drug
- Settlement refers to off-label uses that were not “medically accepted indications.” SSA § 1927(k)(3) and (6)
- Also resolves allegations that Pfizer paid kickbacks to health care providers to induce them, e.g., “Advocate Concierge” and honoraria, to prescribe these, and nine other, drugs.
- OIG Corporate Integrity Agreement, *available at*:
“http://www.oig.hhs.gov/fraud/cia/agreements/pfizer_inc_08312009.pdf”

Pfizer, Pharmacia & Upjohn Company *cont.*

- Comment by the acting U.S. Attorney for the District of Massachusetts, Mike Loucks --

"Pfizer violated the law over an extensive time period. Furthermore, at the very same time Pfizer was in our office negotiating and resolving the allegations of criminal conduct by its then newly acquired subsidiary, Warner-Lambert, Pfizer was itself in its other operations violating those very same laws. Today's enormous fine demonstrates that such blatant and continued disregard of the law will not be tolerated."

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Device Off-Label Enforcement Actions

- Serono (2005)
- Caputo (7th Cir. 2008)
- Ablation Device Cases (July 2009)
- Norian/Snythes Indictments (June 16, 2009)
- Stryker Biotech, et al. Indictments (October 28, 2009)
- Biliary Stent FCA Cases (unsealed January 11, 2010)



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