



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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OUTLINE

- **Inter-relationship with Kickback Allegations**
- **Fraud and Abuse Enforcement Activity**
 - **Fraud Theory**
 - **Off-label Pharma Cases**
 - **Off-label Device Cases**

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

OUTLINE

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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)
- Harkonen (Sept. 29, 2009 conviction)/Intermune, Inc. (2006)
- Novartis (January 26, 2010)

Pfizer/Parke-Davis/Warner Lambert

United States ex rel. Franklin v. Parke-Davis, 147 F.Supp.2d 39
(D.Mass 2001) – **allegations** →

- “Medical liaisons” employed by sales division of predecessor Warner Lambert
 - *made off-label claims related to indications and dosing*
 - *misrepresented credentials*
- Physicians coached to hide off-label nature of prescription
- Sham clinical studies with no scientific value
- Payments for consultants, preceptors, speakers bureau, access to patient records, gifts (Olympic tickets)

Pfizer/Parke-Davis/Warner Lambert *cont.*

United States ex rel. Franklin v. Parke-Davis cont.

- Decision on 9(b) motion to dismiss by Parke-Davis for failure to plead fraud with particularity
- Neurontin– has many recognized off-label uses (pain, epilepsy) – 50% of sales
- Accupril – approved for hypertension
- Note: Amended Complaint subsequently filed, and unsealed in April 2002

Pfizer/Parke-Davis/Warner Lambert *cont.*

United States ex rel. Franklin v. Parke-Davis cont.

Court found that scheme to promote off-label uses is actionable under the False Claims Act (“FCA”)

- Company concedes that off-label prescriptions are not reimbursable by Medicaid
- Complaint sufficiently alleges “a fraudulent marketing campaign in which kickbacks and unlawful and misleading marketing were allegedly used to encourage doctors to **increase their use** of Neurontin for unapproved purposes.” (Emphasis added)
- Material misrepresentation to obtain a benefit – false statements regarding these drugs and use of kickbacks

Pfizer/Parke-Davis/Warner Lambert *cont.*

United States ex rel. Franklin v. Parke-Davis cont.

- Pfizer/Warner Lambert Settlement (2004)
 - Resolution: \$430 million to settle federal criminal and civil cases as well as state civil cases
 - Criminal plea by Warner Lambert for two counts of distribution for unapproved uses (off-label) & misbranding
 - \$240,000,000 criminal fine
 - \$190,000,000 (plus interest) civil fine to federal and state governments
 - Whistleblower was a Ph.D. microbiologist employed as Parke-Davis medical liaison -- \$26.4 million, plus attorneys fees
 - Corporate Integrity Agreement

Eli Lilly and Company

December 21, 2005 Settlement

- Criminal Plea: Company plead guilty to a criminal count of violating the Food, Drug, and Cosmetic Act by misbranding its drug Evista (osteoporosis).
- Government claims: Lilly's strategic marketing plans and promotion touted Evista as effective in preventing and reducing the risk of diseases for which the drug's labeling lacked adequate directions for use.
- Criminal Penalty: \$6,000,000, plus \$6,000,000 forfeiture
- Civil consent decree of permanent injunction and \$24,000,000 (equitable disgorgement)

Schering-Plough

August 29, 2006 Settlement

- Schering-Plough Corporation (“Schering”) and Schering Sales Corporation (“Schering Sales”)
- Criminal Plea: Schering Sales pled guilty to a one count conspiracy, to, among other things, make false statements to the FDA to avoid scrutiny of its off-label marketing of Temodar and Intron A.

Schering-Plough *cont.*

- Criminal Penalty: \$180 million (Schering Sales)
- Civil Settlement:
 - Schering and its subsidiaries and divisions, including Schering Sales, entered into a civil settlement
 - Civil Settlement Amount: \$255,025,089.60 (Schering)
 - *Federal Settlement*: \$159,502,000
 - *State Settlement*: \$91,602,000
 - *Public Health Service*: \$3,921,089.60
 - Corporate Integrity Agreement
- Exclusion: Schering Sales permanently excluded.

Pharmacia & Upjohn Company LLC

March 27, 2007 -- Pharmacia & Upjohn Company LLC (off-label), Pharmacia & Upjohn Company, Inc. (kickback)

- Pfizer, Inc. acquired in April 2003 and self-disclosed in May 2003.
- Pharmacia & Upjohn Company LLC entered into a Deferred Prosecution Agreement
 - regarding its illegal promotion of Genotropin for such off-label uses as anti-aging, cosmetic use and athletic performance enhancement.
 - \$15,000,000 penalty

Bristol-Myers Squibb

- September 28, 2007 -- BMS and subsidiary Apothecan agreed in *civil* settlement to pay more than \$515 million.
 - *Federal Settlement*: over \$328 million (over \$25 million for disgorgement of profits under FDCA re: off-label promotion)
 - *State Settlement*: over \$187 million
 - *Public Health Service Entities*: \$124,000
- Seven qui tam actions.

Bristol-Myers Squibb (*cont.*)

- Government alleged (false and fraudulent claims):
 - Fraudulent inflation of drug prices.
 - Illegal remuneration to physicians (consulting fee and expenses) and to retail pharmacy and wholesaler customers.
 - Misreported best price for anti-depression drug Serzone.
 - **Off-label promotion of Abilify.**

Bristol-Myers Squibb (*cont.*)

- **Government off-label allegations:** From 2002 through the end of 2005, BMS knowingly promoted the sale and use of Abilify, an atypical antipsychotic drug, for pediatric use and to treat dementia-related psychosis, both “off-label” uses.
- FDA approved Abilify to treat adult schizophrenia and bi-polar disorder, but not use for children and adolescents or for geriatric patients suffering from dementia-related psychosis.

Bristol-Myers Squibb (*cont.*)

➤ Government off-label allegations *cont.*:

- FDA mandated that the package for Abilify carry a “black box” warning concerning its use in the treatment of dementia-related psychosis. Nonetheless, BMS directed its sales force to call on child psychiatrists and other pediatric specialists, and the sales force then urged physicians and others providers to prescribe Abilify for pediatric patients.
- BMS also created a specialized long term care sales force that called almost exclusively on nursing homes, where dementia-related psychosis is far more prevalent than schizophrenia or bipolar disorder.

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

Follow-On State Actions Against Eli Lilly

- States Attorneys General settlements with Eli Lilly under state consumer protection and other state laws for Zyprexa off-label allegations.
 - September 30, 2009 -- Connecticut - \$25.1 million
 - October 12, 2009 -- Utah - \$24 million
 - January 26, 2010 -- Mississippi - \$18.5 million

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."

Follow-On State Actions Against Pfizer

- September 1, 2009 42 states Attorneys General settle with Pfizer under their respective consumer protection laws for Geodon off-label allegations.
- Civil Consent Judgment
- \$33 million

Intermune, Inc.

October 26, 2006 settlement N.D. Cal.

- Criminal Information
- Deferred Prosecution Agreement
- \$36.9 million civil settlement
- Five year Corporate Integrity Agreement

Intermune, Inc. *cont.*

Uncontested facts -- Deferred Prosecution Agreement

- Actimmune (interferon drug) approved for severe malignant osteopetrosis and one other condition
 - Vast majority of sales were for ideopathic pulmonary fibrosis (IPF), i.e., off-label
 - Company conducted a phase III clinical trial for IPF indication, but results were not statistically significant
 - Results presented to FDA → FDA needed more work
 - Company went ahead and marketed Actimmune for IPF making claims using statistical comparisons and at same time conducted FDA-mandated study, later discontinued
- Govt alleged vast majority of use was off-label and annual cost to patients = \$50,000.

Intermune, Inc. *cont.*

Obligations under Deferred Prosecution Agreement

- Past cooperation, including
 - disclosed results of internal investigation and
 - made employees available, etc.
- Compliance changes instituted prior to investigation
- Full cooperation for two years
 - Disclosure of information
 - Documents
 - Reasonable access to facilities and employees
- Not make statements contradicting stipulated facts

Intermune, Inc. *cont.*

- In civil settlement, government alleges that the use of Actimmune for IPF was not a “medically accepted indication”
- CIA provisions of interest related to off-label
 - Policies and procedures
 - Specific training
 - IRO Promotional and Product Services Engagement
- Sept. 29, 2009 -- former CEO, W. Scott Harkonen
 - Convicted of wire fraud
 - Found innocent of FDA misbranding charge

Novartis

- January 26, 2010 Novartis Pharmaceuticals files an SEC Form 6-K announcement
 - It has agreed to plead guilty and pay \$185 million to resolve criminal allegations by the US Attorney E.D. PA regarding off-label promotion of epilepsy treatment drug, Trileptal, and related illegal kickbacks to physicians.
 - It is negotiating civil settlement regarding similar allegations related to five other drugs.

OUTLINE

- **Investigational Device Litigation**
- **Inter-relationship with Kickback Allegations**
- **Fraud and Abuse Enforcement Activity**
 - **Fraud Theory**
 - **Off-label Pharma Cases**
 - **Off-label Device Cases**

Device Off-Label Enforcement Actions

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

Serono

October 14, 2005 Settlement

- Serono: (Serono Laboratories, Inc., Serono S.A., Serono, Inc., Ares-Trading, S.A., Serono Holdings, Inc.)
- Criminal Plea: Serono Laboratories, Inc. pled guilty to conspiracy, 18 U.S.C. § 371 (2 counts), one of which was a conspiracy to introduce and deliver for introduction into interstate commerce, with intent to defraud or mislead, adulterated medical devices.

Serono *cont.*

➤ Government claims:

- Illegal scheme to promote, market and sell its drug, Serostim.
- The FDA granted accelerated approval for Serostim in 1996 solely for use in treating AIDS wasting, which at the time was one of the leading causes of death among AIDS patients. Serostim came on the market at the same time as protease inhibitor drugs, which when used in combination with one another as an “AIDS cocktail,” dramatically curtailed the progress of the AIDS syndrome. As a result, the incidence and prevalence of AIDS wasting began to markedly decline and the demand for Serostim dropped significantly immediately following its launch.

Serono *cont.*

➤ Government Claims *cont.*

- Serono knowingly submitted false and fraudulent claims for Serostim that were not eligible for reimbursement because they were for the unnecessary and/or off-label use of Serostim.
- Serono Labs conspired with medical device manufacturer RJL Sciences to market bioelectrical impedance analysis (BIA) computer software packages for use in calculating body cell mass and diagnosing AIDS wasting. The device had not been approved by the Food and Drug Administration for these uses.
- Serono Labs conspired with RJL to increase the market for the devices/software in order to increase the market for Serostim.

Serono *cont.*

- Criminal Penalty: \$136,936,000
- Civil Settlement:
 - Serono Inc., Serono Laboratories, Inc., Ares Trading S.A. and Serono S.A. entered into a civil settlement.
 - Civil Settlement Amount: \$567,065,000
 - *Federal Settlement: \$305,077,000*
 - *State Settlement: \$261,988,000*
- Corporate Integrity Agreement

Serono cont.

- Norma Muurahainen -- Sorono Medical Director
- July 23, 2008 pled guilty to three FDA misdemeanor counts related to this case
- Admitted to encouraging physicians to write prescriptions for Serostim based on the BIA tests.

United States v. Caputo

- October 16, 2006 N.D. Ill. Sentencing Decision
- 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).
- AbTox got clearance to market small sterilizer, then marketed a larger sterilizer for uses beyond the small sterilizer clearance.
- AbTox President/CEO sentenced to 10 years imprisonment, Chief Compliance Officer sentenced to 6 years.

Caputo *cont.*

Seventh Circuit Appeal – Issues

- Numerous factual (sufficiency of the evidence) and legal issues, including --
- First Amendment Commercial Free Speech
 - Govt. Brief →
 - 1st Amendment does not protect conspiracy to defraud
 - Case does not involve off-label promotion of cleared device, but misbranded sterilizer never approved
 - “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.

Caputo *cont.*

Seventh Circuit Appeal – Issues

➤ First Amendment Commercial Free Speech

▪ Govt. Brief →

- Off-label promotion “is evidence that the device has acquired a new intended use.” *Id.*
- Without new labeling, the device is misbranded.
- “There may, of course, be circumstances in which the dissemination of truthful information about off-label issues is undertaken for non-promotional purposes and cannot be treated of proof of intent [to create a new intended use] without raising First Amendment concerns.” *Br.* At 42

➤ Void for vagueness challenge

Caputo cont.

Seventh Circuit Decision -- February 27, 2008, *United States v. Caputo*, 517 F.3d 935

- The Court upheld the convictions and sentences.
- Free speech analysis --
 - Court found that the large sterilizer at issue in this case had not been approved by the FDA.
 - Court declined to rule on whether a manufacturer selling FDA-approved medical devices has a constitutional right to promote off-label uses.

Caputo *cont.*

Seventh Circuit Decision/free speech analysis *cont.*

- 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?”
 - “[A] court should hesitate before extending an ahistorical reading of the Constitution in a way that injures the very audience that is supposed to benefit from free speech.”

Norian/Synthes, et al. Indictments

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Ablation Device Cases

- July 2009 -- Related *qui tam* case filed by unnamed former Boston Scientific sales rep involving five device companies:
 - Endoscopic Technologies (settlement)
 - Medtronic (Complaint unsealed)
 - Boston Scientific/Guidant (Complaint unsealed)
 - St. Jude Medical/Epicor (Complaint unsealed)
 - AtriCure (settled February 2, 2010)

Ablation Device Cases *cont.*

➤ Allegations →

- FDA has only approved treatment of cardiac ablation catheter devices through outpatient EP procedures for atrial fibrillation.
- Defendants microwave ablation products not approved.
- Defendants illegally marketed these off-label products through more expensive inpatient atrial fibrillation procedures.
- Promotion also through illegal kickback payments to physicians.

Stryker Bone Growth Indictments

SEE VIRGINIA GIBSON MATERIALS

Biliary Stent FCA Cases

- January 11, 2010 *qui tam* case against Abbott Laboratories (Guidant device division) -- ED Texas
- DoJ decided not to intervene
- The relator reportedly has also targeted Boston Scientific Corporation, Johnson & Johnson and Cordis
- February 19, 2010 -- Similar allegations in unsealed *qui tam* Complaint against Medtronic -- D. Mass (23 state FCAs)
- Reportedly FDA has been aware of biliary stent off-label use since 2007 and met with many industry representatives

Biliary Stent FCA Cases *cont.*

➤ Allegations →

- Vascular stents are FDA Class III devices that require PMAs
- Biliary stents only FDA cleared under 510(k) for palliation of malignant biliary strictures
- Off-label promotion to vascular specialists
- Funding studies for off-label use
- Reported they were under investigation for improper promotion of biliary stents for off-label uses



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