The InterMune Settlement: Deferred Prosecution Agreements in the Context of Off-Label Investigations

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InterMune Deferred Prosecution Agreement

- Criminal violation of 21 U.S.C. 331(k), 333(a)(2) for "misbranding" of Actimmune from August 2002 through January 2003
  - U.S. stated that "the vast majority of Actimmune sales during the period of August 2002 through January 2003 were attributable to prescriptions for the treatment of idiopathic pulmonary fibrosis (IPF) for which there is no FDA-approved treatment"
- Conduct by former personnel for promoting Actimmune for unapproved indications and making misleading statements
  - Former employees created or approved August 2002 press release, October 2002 fax from a specialty pharmacy, October 2002 patient letter
  - Intermune employed 60 sales representatives primarily focusing on pulmonology and Actimmune, which had not been approved for treatment of pulmonary disorders

InterMune Deferred Prosecution Agreement

- Cooperation and remedial measures
  - Disclosed internal investigation
  - Fully complied with subpoena
  - Made numerous presentations
  - Made current employees available
  - Pledged cooperation for two years
- Compliance Measures
  - Management team (majority hired after the conduct) instituted "numerous and comprehensive compliance changes"

InterMune Deferred Prosecution Agreement

- Civil Settlement for $36.9 million to U.S. ($30.2 million) and Participating States ($6.7 million)
  - Released conduct includes promotion of Actimmune for the treatment of idiopathic pulmonary fibrosis (IPF), an unapproved use
  - Released conduct includes misleading use of Clinical Trial results regarding the survival benefit of Actimmune for treatment of IPF
- Deferred Prosecution for Two Years contingent on cooperation and compliance, and all conditions of DPA
  - Department of Justice will not indict InterMune for promotion of Actimmune during the period 2000 through 2003
- Corporate Integrity Agreement

Prior Off-Label Criminal Resolutions

- Schering Plough (August 2006) (Boston)
  - Plea Agreement involved one-count conspiracy to make false statements to FDA regarding promotional activity and to HCFA regarding Best Price
  - Total payment to U.S. and States, $435 million -- $180 million criminal fine, $225 million civil settlement
  - - Amendment to Corporate Integrity Agreement
  - Conduct alleged included illegal off-label promotion, and kickbacks and Medicaid Best Price violations
  - Government alleged Schering illegally promoted the drug Temodar for types of brain cancer for which it was not then approved, and illegally promoted hepatitis and cancer drug Intron A for superficial bladder cancer
  - Government alleged a national plan in which Schering salespeople were trained how to obtain off-label sales, and used tactics including "illegal remuneration" to doctors for "sham advisory boards" and "lavish entertainment"

Prior Off-Label Criminal Resolutions

- Eli Lilly & Co. (December 2005) (Indianapolis)
  - Plea Agreement involved one-count of misdemeanor violation of the Food, Drug, and Cosmetic Act for misbranding its drug Evista
  - Agreement to pay $36 million, including $6 million criminal fine, forfeiture of $6 million to the United States, and payment of $24 million in equitable disgorgement
  - Agreement to enter into a consent decree of permanent injunction

Prior Off-Label Criminal Resolutions

- Warner –Lambert (May 2004) (Boston)
  - Agreed to two counts of violation the Food, Drug and Cosmetic Act, and payment of $240 million criminal fine and $190 million civil settlement
  - Corporate Integrity Agreement
  - Allegation of off-label promotion of Neurontin, kickbacks

Prior Off-Label Criminal Resolutions

- Genentech (May 1999) (San Francisco)
  - First criminal prosecution of a drug company for illegal promotion of a drug for unapproved uses
  - Payment of $50 million ($30 million criminal fine , $20 million civil settlement) to settle allegations
  - Admission of illegally marketing the drug Protropin (somatrem for injection) for unapproved uses, i.e. treating children who were short for reasons other than the lack of adequate growth hormone, children with a rare form of juvenile obesity, and a small number of burn patients
  - Conduct was from 1985 until 1994, government agreed that conduct stopped in 1994
  - In 1995, Genentech came under new management, which FDA concluded took additional steps to prevent violations of the law, including educating its sales force on proper drug promotion

Prior FDCA Criminal Resolutions

- Guidant (June 2003) (San Francisco)
  - Subsidiary EVT agreed to plead guilty to 10 felony counts, including nine for shipping misbranded products and one count of a former employee making false statements to the government
  - EVT agreed to a criminal fine of $43.4 million and a $49 million civil settlement
- LifeScan (December 2000) (San Francisco)
  - LifeScan, Inc., entered a plea of guilty to three misdemeanor charges relating to a federal government investigation of its SURESTEP® Blood Glucose Meter
  - LifeScan paid a criminal fine of $29.4 million and $30.6 million in civil settlement
  - Problems were corrected in 1997 and early 1998, and in June 1998 LifeScan offered to replace all affected SURESTEP® meters free of charge

Analysis

- DPAs and Consent Decrees provide flexibility to the Government and corporations – risks and benefits
  - January 2003 Deputy Attorney General Memorandum (the "Thompson Memorandum") on charging guidelines for prosecuting corporate fraud
  - December 12, 2006 Deputy Attorney General Memorandum revised the "Thompson Memorandum" guidelines
- FDA position may be dynamic and evolving
  - December 12, 2006 remarks by outgoing Deputy Commissioner Gottlieb
- Districts may have different approaches
- Different models for investigation, prosecution, resolution
- Post-2004 conduct may receive higher scrutiny
- Pure "off-label" speech has not been tested
- Judicial guidance is scarce

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