National Pharma Audioconference:
Pharmaceutical Drug Pricing and Reporting Issues

Overview of Department of Justice Prosecution of Drug Pricing and Reporting Cases

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Agenda

1. Structure of DOJ enforcement.
2. Pending federal enforcement.
3. Theories of liability.
4. State enforcement.
5. Future enforcement.

Addendum: List of recent federal criminal and civil resolutions of enforcement actions against pharmaceutical manufacturers involving pricing or reporting allegations.

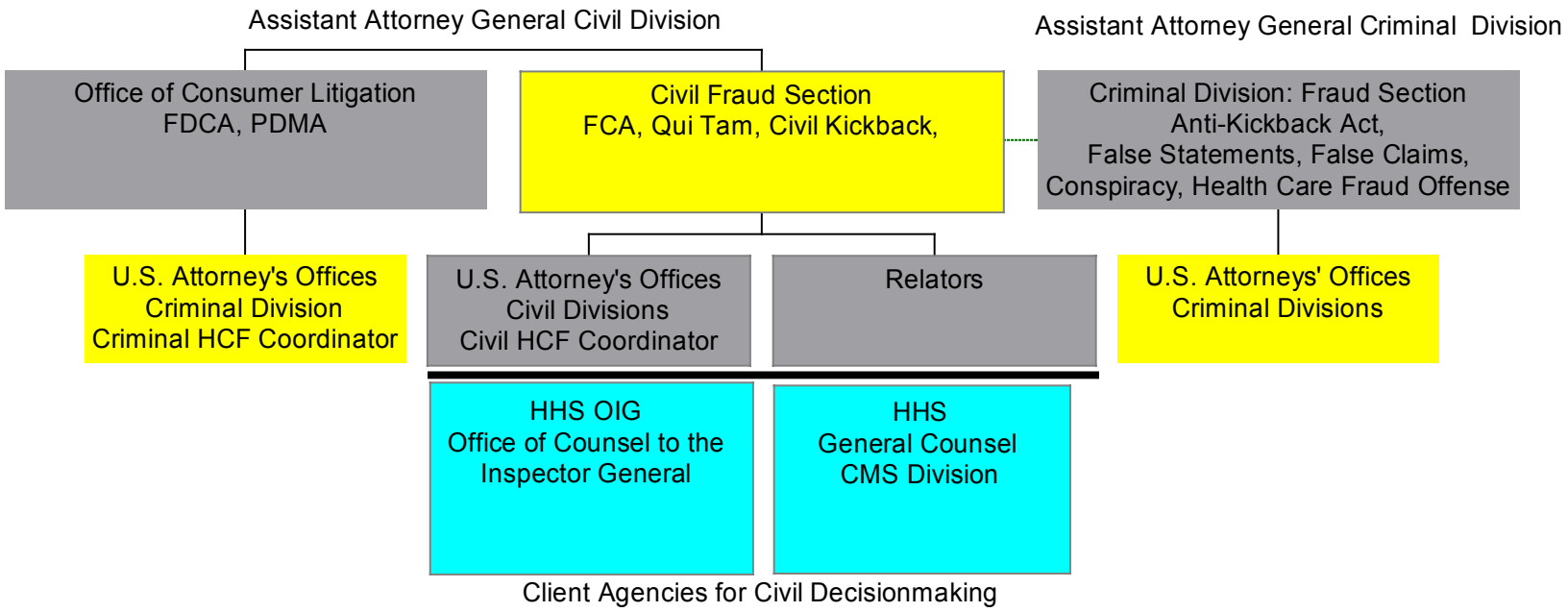
Department of Justice Overview

- Pharmaceutical enforcement is not part of the President's Corporate Fraud Task Force, but same principles apply.
  - "Prosecuting corporate fraud criminally" against corporations and individuals.
  - "Aggressively pursuing civil and regulatory enforcement actions."
- DOJ/HHS health care fraud and abuse report for FY2003.
  - AstraZeneca, GlaxoSmithKline, Bayer, and Parke-Davis (Lipitor®) are listed as top achievements.
  - Pharmaceutical enforcement is very high visibility, whether action is taken or no action is taken.
  - Relators have been pursuing aggressively pharmaceutical manufacturers, even before high-profile cases in areas of marketing the spread, kickbacks and off-label promotion.
  - Virtual flood of *qui tam* filings in most recent years.
- Pharmaceutical allegations are high visibility in Deputy Attorney General's and Associate Attorney General's Offices.

Enforcement Machinery: DOJ

- Special Counsel for Health Care Fraud (in Deputy Attorney General's office).
- Criminal Division.
  - Fraud section, PhRMA enforcement headed by Deputy Chief..
    - Coordination of "PhRMA task force" along with Civil Division.
- Civil Division.
  - Fraud section, PhRMA enforcement headed by Deputy Director.
    - False claims act investigations and litigation.
    - *Qui tam* investigations and litigation.
  - Office of Consumer Litigation, with criminal and civil authority.
- Executive Office of United States Attorneys ("EOUSA").
  - Affirmative Civil Enforcement ("ACE") coordinator.
  - Criminal Health Care Fraud Coordinator.

Enforcement Machinery: DOJ



Pending Federal Enforcement

- Civil and even criminal cases driven largely by *qui tams*.
- "PhRMA task force" provides for high level of coordination through the Department and among districts.
- Over 125 federal *qui tam* (whistleblower) actions involving over 500 products in many judicial districts against pharmaceutical manufacturers.
  - Range of allegations with four clusters: marketing the spread, kickbacks, off-label marketing, and medicaid rebate.

Pending Federal Enforcement (cont'd)

- No federal civil action alleging drug price or cost fraud against a pharmaceutical manufacturer in litigation (or intervened and unsealed) by Department of Justice.
- No pharmaceutical manufacturer currently under federal criminal indictment for these four allegations.
- Enormous amount of current federal investigative activity will give rise to decisionmaking: settlement, suit, or declination.

Theories of Liability: AWP and "Marketing the Spread"

- No federal civil complaints filed yet by the United States allege "marketing the spread" as a theory of fraud.
- Theory is spelled out in federal civil settlements, and is also set forth in suits by states and complaints by *qui tam* litigants.
- Federal legal guidance from AWP private litigation in Boston.
- AstraZeneca and TAP are civil settlements as part of global resolution, including criminal plea for other conduct.
- Other civil settlements also provide guidance, e.g Warrick, Dey.

Theories of Liability: AWP and "Marketing the Spread"

- Factual triggers include intent to gain market share, competitive manipulation, "RTP" and other explicit sales conduct, concealed discounting, other factors.
- Government investigation may identify appropriate corporation, drug, competitive market for pursuit of a civil case alleging "marketing the spread" fraud.
  - Premise may be "false claim."
  - Premise may be "kickback tainted" claim, under U*rbanek* theory.
  - Premise may be "fraudulent" claim, under 31 U.S.C. 3729(a)(1).
  - 3729(a)(1) creates liability if person "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."

Theories of Enforcement: Medicaid Rebate/Best Price

- Medicaid Rebates have been driver for significant criminal and civil resolutions, e.g., GlaxoSmithKline (Boston), Bayer resolution (Boston), Parke-Davis/Lipitor® (Texas), Schering-Plough/Claritin (Philadelphia).
- Very concrete theories of prosecution, and well-defined theories of damages.
- *E.g.,* Schering-Plough transactions with Cigna and Pacificare had specific components that in the "context and content of the deal" were alleged to be non-price programs designed to substitute for product discounts.

State Enforcement

- Suit by the Texas against manufacturers alleging violations of state price reporting law.
  - Sued 12 drug manufacturers for ignoring a three-year-old state law that requires the companies to report the average manufacturer price (AMPs) of Medicaid-covered drugs.
- Suit by Florida against manufacturers alleging violations of "marketing the spread."
  - False Claims Act lawsuit against Sandoz, Inc., Ivax Pharmaceuticals, Inc., and Purepac Pharmaceutical are "marketing the spread" The generic drugs named are used to treat depression, schizophrenia, seizures, angina and other serious ailments.
- Many other states have filed suits against dozens of companies alleging AWP/WAC fraud.

Future Enforcement
Part B: Reimbursement Changes

- Average sales price (ASP) plus 6% beginning in 2005.
  - Manufacturers are required to report ASP data.
  - False ASP information may be False Claims Act violation.
- Competitive bidding option begins in 2006.

Future Enforcement
Part D: Reporting of Drug Pricing

- A plan's negotiated prices are to take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered Part D drugs.
- Plans sponsors must disclose the aggregate negotiated price concessions.
- Potential Anti-Kickback and False Claims Act application.

Addendum: Recent Federal Criminal and Civil Resolutions of Enforcement Actions Against Pharmaceutical Manufacturers Involving Pricing or Reporting Allegations

- Schering-Plough Corporation – Claritin Best Price/Adulterated Drugs (E.D. Pa. July 28, 2004) (Criminal, Civil).
- Parke-Davis Division of Warner Lambert Corp. – Neurontin Off-Label (D. Mass. May 13, 2004) (Criminal, Civil).
- Warrick Pharmaceuticals –Albuterol Marketing the Spread (State of Texas) (April 30, 2004) (Civil).
- Dey Inc. – Albuterol, et al., Marketing the Spread (State of Texas) (June 11, 2003) (Civil).

Addendum: Recent Federal Criminal and Civil Resolutions of Enforcement Actions Against Pharmaceutical Manufacturers Involving Pricing or Reporting Allegations

- Astrazeneca Pharmaceuticals, LP – Zolodex AWP and Kickbacks (D. Mass. June 2, 2003) (Criminal, Civil).
- Bayer Corporation – Cipro and Adalat CC Private Label/Best Price (D. Mass. April 11, 2003) (Criminal, Civil).
- GlaxoSmithKline – Flonase and Paxil Private Label/Best Price (D. Mass. April 9, 2003) (Civil).
- Parke-Davis Division of Warner Lambert – Lipitor Best Price (E.D. Tex. May 16, 2002) (Civil).

Addendum: Recent Federal Criminal and Civil Resolutions of Enforcement Actions Against Pharmaceutical Manufacturers Involving Pricing or Reporting Allegations

- TAP Pharmaceuticals – Lupron AWP and Kickbacks (D. Mass. Sept. 27, 2001) (Criminal, Civil).
- Bayer Corporation – Blood Factor, Marketing the Spread (S.D. Fla. June 23, 2001) (Civil).

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