THE CASE FOR COMPLIANCE

Theme – Corporate compliance – is not a static concept. Pharma faces evolving standards and policies of corporate responsibility in reaction to pressure on the federal budget and prior bad acts of corporate parties. Societal walls frame environment.

- Legacy of Enron, et al. – real impact on people's lives – loss of retirement investment, heighten call for policing corporate misconduct.
- GM + TARP – "Too big to fail" – Are bailouts for the fat cats? Struggling small business, unemployed, those facing mortgage foreclosure feel abandoned.
- AIG bonuses – rewarding of failure - populist rhetoric that we punish success.
- Healthcare reform – Congressional proposals balance funding requirements for expanded coverage on promise of recouping billions of dollars by preventing "waste, fraud and abuse." Large Pharma likely target of scrutiny.

- DOJ/HHS-OIG – Repetition of corporate misconduct; competitors blowing through the regulatory stop signs – increases pressure for more draconian penalties and more stringent compliance requirements, especially on previous violators.

All of the above play into creating an environment where big business is a target of regulators.

"There are a host of Sheriffs in Town" – jurisdiction to oversee Pharma business creates multiple governmental entities with authority. This can create confusion about role of regulators or simultaneous inquiries from many fronts.

- Prosecutorial discretion is a dynamic concept – DOJ, HHS-OIG, SEC, FDA, FTC can act – not necessarily coordinated.
- 94 U.S. Attorneys – differing levels of engagement with some - (Ma, EdPa, SDNY, NJ, FLA, ILL, NDCA) – particularly engaged.

- State Attorneys General independently elected/appointed. Attempts to reach global resolutions via NAMFUCA, et al. can be like herding cats.
- Congressional oversight –

From perspective of a U.S. Attorney, DOJ guidelines create basis upon which uniformity and consistency in exercise of prosecutorial discretion can be encouraged –

He's Back! One-time DAG Holder is now the General.

- Holder memo – (1999 sets baseline) – Principles of Federal Prosecution of Business Organization.
    - nature and seriousness of offense, pervasiveness of wrongdoing and history of similar conduct are relevant to all charging decisions.
    - existence and adequacy of a corporation's compliance program is a critical consideration.
    - at heart of inquiry – does the compliance program work?
        - is it adequately designed to prevent wrongdoing?

        - is it sufficiently staffed and communicated?
        - does it encourage self-policing?
        - are guidelines enforced or just on paper?
        - assess frequency, extent, duration of misconduct.

- U.S. Sentencing Guidelines; Sarbanes-Oxley; In re Caremark are additional sources for direction on what constitutes a robust compliance effort.
    - Common themes
        - growing responsibility on Boards of Directors and senior executives to oversee compliance directly.
        - independent reporting systems and audits to assure informed decision making.
        - real time response to misconduct, false information.
- Post Enron, very integrity of nation's securities markets at risk. Creation of the President's Corporate Fraud Task Force; aggressive investigation/prosecution of signature entities (Arthur Anderson); re-drafted charging guidance – Thompson memo – are each examples of heightened era of corporate scrutiny.

- The Thompson memo (2003) – interestingly a paramount feature of the guidance was an emphasis on a robust and comprehensive compliance program; directive further shifted consideration to assessing the nature and scope of "cooperation" from corporate representatives in ferreting out wrongdoing and wrong doers.
- Cooperation assessment came to include the willingness of the corporation to waive "attorney-client privilege" and to make available "work product" from results of internal investigations.
- Waiver issue incited vigorous pushback from defense bar and corporate counsel yet, in reality, those concepts were first explicitly introduced in the Holder memo. Other controversial considerations Holder set forth included:
    - whether culpable employees were disciplined or terminated.
    - whether there were joint defense agreements.

- whether witnesses/subjects were provided counsel at corporation's expense.

"The Empire Strikes Back" – the extent to which the government was improperly intrusive became the defining skirmish between defense counsel and the DOJ.

It is interesting question whether "waiver" demands were actually as pervasive as suggested. Many cases generated by whistle blowers who supply some documentation and a road map into alleged misconduct.

Nevertheless, the re-drafting of guideline principles in successive clarifications from Deputy Attorney's General McNulty and Filip, and a rebuke of SDNY tactics by the 2nd Circuit in the KPMG matter, have settled, at least for now, the protections to which parties are entitled, without there being an inference of non-cooperation in any investigation.

Filip Memo – (Aug. '08)

- For cooperation, credit is not dependent upon waiver of attorney-client or work product privilege.
    - "just the facts Ma'am" – charging will consider extent to which the relevant facts and evidence are disclosed – the cooperation is paramount, not how it was obtained.
    - Government is prevented from demanding privileged attorney-client communication or non-factual attorney work product – this includes protected notes or interview memoranda generated during internal investigations.
    - Also government is not to credit corporation that does waive. This allows non-waiving party to proceed without prejudice.
    - Joint defense agreements or sharing of information among investigated parties and payments of attorneys fees or providing attorneys to employees, not to influence discretion.
    - Internal discipline or termination of culpable employees not to influence discretion.
    - New distinction re: criminal conduct – the presence of criminal acts by employees despite presence of compliance

program does not in itself suggest that management/Board has not been sufficiently attentive to compliance oversight obligations.

- "Good faith" now rewarded – an additional factor in charging discretion is whether a compliance program is being applied earnestly and in good faith; ("You'll know it when you see it.")
- "Extent" of cooperation recognizable and pertinent to prosecutor's judgment – timely disclosure of relevant "facts".

- Stein (Aug. 2008) - – The Sheriff gets taken to the woodshed -
  - 2d Circuit finds that government insistence on limiting indemnification protections afforded to witness employees constitutes a deprivation of 6th Amendment right to assistance of counsel. Reaffirms sanctity of attorney-client relationship and ability of corporation to underwrite defense.

- The Case for Compliance – "a tightening noose" – the evolution of increasingly more punitive resolutions for corporate misconduct as

demonstrated by three recent "off label marketing" cases involving the Eastern District of PA:

- Eli Lilly
- Pfizer
- Synthes
  - Trend growing toward 1) increasing fines and monetary penalties; 2) more demanding Corporate Integrity Agreements; and 3) criminal sanctions against corporations and criminal prosecution of responsible individuals – principal executives, officers, Board of Directors not immune.

- Baseline – Medco (Oct. '06)
  - $155M to FEHB to settle false claims allegations regarding drug switching, record destruction and kickbacks;
- Corporation Integrity Agreement. (CIA")
  - Compliance officer with direct access to Board of Directors (not reporting to legal)
  - Code of Conduct and Training

- Hotline.
    - Prompt internal investigation of allegations of misconduct.
- Voluntary self-reporting procedures for fraud or misconduct.
- HHS-OIG extensive inspecting and audit rights of banks and records of plan pertaining to costs, price concessions.
- Independent Review Organization.
- CEO, CFO, or their delegate MUST request payment and CERTIFY accuracy, completeness and truthfulness of all data related to payment and allowable costs.

The requirements place on Pharma defendants are increasingly more demanding.

- Eli Lilly – (January '09)
    - Off label marketing – anti-psychotic drug Zyprexa marketed for sleep disorders and dementia.

- Allegations of marketing use despite written caution from FDA.
- Criminal misdemeanor – commerce in misbranded drugs.
- Criminal fine - $615 million.
- Civil settlement - $438 Million to U.S. - $362 to various state medical programs
- Collective $1.4 Billion – largest settlement in DOJ history at that time.

- CIA – Board of Directors and top management have duty to make reasonable inquiry into operations of company's compliance program and regularly certify that company obeys the law and has an effective compliance program. In the past, it was permissible to have that certification made by the Chief Compliance Officer.
  - Board level committee, with at least three independent directors, provides oversight of compliance program and meet quarterly to review it.
  - Letters to doctors advising them of resolution with way to report misconduct of sales force.

- Payments to doctors listed in websites.

- Pfizer (September '09) (led by U.S. Attorney - Mass.)
  - Off label promotion of anti-inflammatory drug Bextra. Drug promoted for uses and dosages that FDA specifically declined to approve due to safety concerns.
  - Criminal Felony (Pharmacia and Upjohn Company) – misbranding of drug with intent to defraud or mislead.
  - Criminal fine - $1.3 Billion.
  - Civil fine - $1 Billion – false claims and kickbacks.
- Collective $2.3 Billion – largest settlement in DOJ history
  - Pfizer general counsel no longer oversees compliance program. Chief Compliance Officer reports directly to CEO.
    - "Not whether you can do something but whether you should" – Lew Morris – HHS/OIG
- Independent Review Organization to audit performance under CIA.
  - Audit Committee of Board of Directors – annually review compliance program and certify to effectiveness.

- Notice to doctors of settlement and means to report sales misconduct to corporation.
- Post on website – payments to doctors.

- First CIA requiring corporation to proactively identify potential risks of individual products and requires plan to mitigate those risks.
- 3 previous DOJ settlements.
  - 2002 – Pfizer subsidiary - Warner Lamber/ Parke Davis, $49 million – Lipitor - "best price" allegation
  - 2004 – Warner Lambert - $430 million – Neurontin - off label marketing.
  - 2002 Pfizer subsidiary – Pharmacia and Upjohn - $34 million Deferred Prosecution Agreement - Genostropen re: kickbacks/off label marketing.
- Synthes/Norian – (June '09)
  - Allegations of conducting clinical trials of a medical device without FDA authorization and contrary to FDA warning about certain use.

- Allegation of false statements in connection with an FDA inspection.
- (Subsidiary) – Norian – 103 felony count indictment
- (Parcel) Synthes – 44 misdemeanor count indictment
    - President of Synthes subsidiary;
    - President of Synthes division;
    - Vice President of Global Strategy;
    - Director of Clinical Affairs – each charged with 1 count criminal misdemeanor – shipping misbranded drug.

- Hand Grenade in the Room – will DOJ et al pull the pin?
    - How close is the evolving response to resolving misconduct allegation with an exclusion from federal programs?
    - Increasing health care expenditures and national debate on scope of federal role in delivery of health care will only increase scrutiny of provider conduct.
- Conclusion: "Defense wins titles" – increasing oversight responsibility on Board; direct reporting and certification responsibilities on Board and senior management; requirement for

independent auditing and government access to corporate records; growing use of hotlines and continued success of whistleblower/qui-tam litigation all compel diligence to relevant and effective corporate compliance systems.