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Pharmaceutical Industry Compliance:

The Future and Its Challenges

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Overview

- Where Are We In the Health Care Fraud Cycle?
- What's Different This Time -- And How Does It Matter?
- What Are the Near Term Challenges?
- What Are the Longer-Term Challenges?
- Where Is Compliance Profession Headed?

Pharma Fraud -- Just Another Round in the HC Fraud Cycle?

- Health care fraud is not a new issue.
  - 1993 -- Attorney General Reno makes HC fraud a top priority
  - 1996 -- HIPAA is enacted, providing new tools and resources
  - 2000 -- HC fraud collections top $1 billion
- Other sectors were targeted in the 1990s (hospitals, clinical laboratories, DME suppliers, nursing homes).
- Given increased spending on pharmaceuticals in recent years, it was inevitable that government scrutiny -- investigations and prosecutions -- would increase.
- Key drivers for HC fraud cases are still in place:
  - Whistleblowers
  - Resources under the HIPAA statute
  - Public outrage at healthcare fraud

But There Are Key Differences

- Generally, pharmaceutical cases involve more $ than other types of HC fraud cases (making them much more attractive to relators)
  - Columbia/HCA $1.7 billion
  - TAP Pharmaceuticals $875 million*
  - Fresenius $486 million
  - AstraZeneca $355 million*
  - Bayer $250 million*
- Unlike in the provider context, there's no way of addressing minor problems through overpayment process
  - For pharmaceutical companies, every discrete violation of the anti-kickback statute is a criminal offense punishable by jail time for individuals and exclusion for organizations
- The "implied certification theory" -- under which FDA and other regulatory violations form the "predicate" violation under the False Claims Act -- exposes the industry to significant liability.

Key Differences (cont'd)

- Sarbanes-Oxley has added to the regulatory/compliance risks:
  - New obligations on Boards of Directors (particularly Audit Committees)
  - New obstruction of justice statute (making it a crime to destroy documents or records "in contemplation of" a government investigation)
  - New whistleblower provisions -- making it a federal crime to retaliate
  - New SEC lawyer reporting rules
- Greater involvement of State Attorneys General (and now Counties) -- using lessons learned from earlier HC cases and tobacco litigation
- Negative image of the pharmaceutical industry
  - There is a hospital in every congressional district, often with a non-paid Board of Trustees
  - Medicare covers hospital bills -- but many individuals have significant out-of-pocket costs for drugs

So, What Does This Mean?

- There is no reason to think that investigations/prosecutions of pharmaceutical companies will decrease over the next three-to-five year period.

- Government prosecutors, OIG officials, and whistleblower lawyers all have indicated that there are many cases "in the pipeline" -- and, if history is a guide, these cases will take several years to resolve.

- The financial incentives for whistleblowers and their lawyers -- which are the biggest drivers of health care fraud enforcement actions -- will only increase over time.
  - And court cases may make the environment even more friendly for such suits (*e.g.,* the recent Parke-Davis decision).

- Compliance programs will become even more important to the long-term financial health of pharmaceutical manufacturers

What Does This Mean? (cont'd)

- The imposition of Corporate Integrity Agreements will establish *de facto* standards or benchmarks for compliance programs in the pharmaceutical industry:
  - The Compliance Officer will be a member of or report directly to senior management and will not be in the GC's office
  - High-level codes of conduct and detailed policies and procedures in key risk areas
  - Comprehensive education and training programs -- including specialized training for identified functions (*e.g.,* price reporting)
  - Hotlines and internal reporting/disclosure programs -- including procedures for self-reporting to the government for "reportable events"
  - Systematic monitoring and auditing programs
  - Disciplinary and performance standards
  - Procedures for corrective actions

What Are the Near-Term Challenges?

- Responding to the HHS OIG's Guidance for Pharmaceutical Manufacturers:
  - Most companies are still analyzing and digesting the Guidance and in the middle of adopting new or revised policies and procedures.
  - Not surprisingly, the areas of greatest challenge are:
    - Revising price reporting practices
    - Revising policies and procedures for consulting relationships
    - Separating sales and marketing from education and research funding
    - PBM relationships
    - Compensation of sales representatives

Near-Term Challenges (cont'd)

- Responding to the HHS OIG's Guidance (cont'd)
  - Revising price reporting practices
    - This remains perhaps the greatest near-term compliance challenge
    - This problem is unlikely to go away soon due to Government's failure to define key terms/requirements
      - Situation unlikely to be resolved even if a Medicare Rx drug benefit is enacted
  - Revising policies and procedures for consulting relationships
    - Companies are finding it very difficult to structure consulting relationships within the personal services safe harbor
    - Outside of the safe harbor, strict compliance with the PhRMA Code's criteria is essential
    - Companies are still grappling with rigorous identification of purpose; numbers appropriate to meet the purpose; documentation of collection and use of consulting feedback

Near-Term Challenges (cont'd)

- Responding to the HHS OIG's Guidance (cont'd)
  - Some companies are adopting a narrow view of the Guidance's recommendations on "separation" of functions -- limiting their review only to education and research funding.
    - The implicit message in the Guidance, however, is broader
    - The Guidance cautions against assigning the sales/marketing organization responsibility for activities whose legitimacy is based on non-sales and marketing purposes. Examples:
      - Preceptorships (training)
      - Certain consulting relationships (market research)
    - Companies are well advised to review such activities, identify the legitimate purpose, and assign primary ownership/responsibility (including budget authority) to the appropriate function
      - Example: Assigning preceptorships to the sales training organization
    - The remaining challenge is to develop processes that allow for appropriate input/expertise from the sales/marketing units

What Are the Longer-Term Challenges?

- Medicare Rx Drug Benefit Legislation
  - There is simply no way that the Federal government will spend $400 billion over the next 10 years without substantial strings attached -- either now or later, by regulation or litigation
  - Any system that relies directly on manufacturer-reported data will expose manufacturers to charges of manipulation
    - And we'll still be left with many state systems that are based on AWP or similar formulas
  - Compliance issues surrounding manufacturer relationships with PBMs -- already a challenging area -- will increase given the central role that PBMs will play in the Medicare drug benefit

Longer-Term Challenges

- From “fraud/abuse compliance” to “comprehensive regulatory risk management”
  - Sarbanes-Oxley (and its aftermath) is forcing the Boards and Senior Management to take direct responsibility for compliance issues
    - Example: NYSE Listing Standards require the Audit Committee to have a charter that includes “legal and regulatory compliance”
    - Internal controls report from Senior Management, assessment by outside auditors
  - From Board/CEO perspective, makes little sense to have siloed compliance activities
    - Pushing for compliance programs that address and manage all forms of regulatory risk (e.g., fraud/abuse, GMP, EH&S, global issues)

Longer-Term Challenges

- Impact of Sarbanes-Oxley
  - Great emphasis on response to detected violations
    - Handling of whistleblowers
    - Conduct that can give rise to obstruction charges
      - Destruction of documents
      - Witness tampering (e.g., DOJ view on payment of counsel fees)
      - Scope/process for internal investigations by outside counsel
  - Given breadth of responsibilities, and limited resources (time and money), necessarily requires a strategy that identifies major regulatory risks, prioritizes such risks, and lays out plans to manage such risks
    - Requires constant assessment of effectiveness for existing risks and re-assessment to identify new/emerging risks
  - This shift moves compliance away from legal and more toward process and business practices

Longer-Term Challenges

- From “fraud/abuse compliance” to global risk management
  - Companies are looking to their compliance programs to manage and control the full range of regulatory requirements. Examples:
    - Advertising and promotion
    - Antitrust/competition
    - Environmental health & safety
    - Export/import
    - Foreign corrupt practices
    - Fraud/abuse
    - GMP
    - Research & development/clinical trials
    - Workplace discrimination

- A critical challenge is how to integrate these into a coherent corporate compliance program while supporting/enhancing the roles of existing functions (e.g., regulatory affairs, EH&S, global supply chain, etc.)

Longer-Term Challenges

- Going Global
  - While some programs are global in scope, many are focused primarily on the US
  - The evolution toward “regulatory risk management” will lead to an increasing focus on foreign regulatory compliance
  - We are seeing signs of stepped up enforcement activities in EU member states
  - Significant challenges to going global:
    - Legal and regulatory differences among foreign countries
    - Cultural differences
    - Language and time barriers

Challenges for the Profession

- Demonstrating the "value" of compliance programs to management -- not just in a theoretical sense, but in showing that spending time/money on compliance will produce tangible results.
  - Demonstrating how compliance programs can advance business objectives
    - Faster decision-making
    - Better relations with customers
    - More rigorous analysis of costs/benefits
  - Demonstrating how compliance programs contribute to the bottom line

- Implementing "effective" compliance programs -- ones that work in practice, not just on paper -- and whose effectiveness can be measured.
  - Identification of measurable performance indicators
  - On-going validation of performance indicators

Challenges for the Profession

- Fostering a “compliance culture”

> We have open doors and e-mails, and anybody who sees a problem can raise his hand, blow a whistle, and stop the whole process. But then when you look at how it really works, it's an incestuous, [top-down] system, with invisible rankings and a very strict informal chain of command. They all know that. So even though they've got all the trappings of communication, you don't actually find communication. It's very complex. But if a person brings an issue up, what caste he's in makes all the difference. Now, again, [The Company] will deny this, but if you talk to people, if you really listen to people, all the time you hear 'Well, I was afraid to speak up.'

- What company/organization is this?

Challenges for the Profession

- Understanding the limits of compliance programs -- and educating Management on such limits -- and adopting mechanisms to address wrongdoing when it does occur.
  - Procedures for internal investigations
  - Corrective action plans to prevent wrongdoing a second time

- Spurring further dialogue between industry and the government on compliance issues.
  - Compliance is an area that cries out for collective action on regulatory issues
  - The PCF is a natural forum for such dialogue