US Compliance Risks and Strategies: An Overview

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The Attraction

- **United States health care market is enormous, and expanding**
  - **Spending in 2004 estimated at ~$1.9T**
- **Health conscious consumers, interested in innovative treatments and technology**
- **Significant discretion over treatment choices**
- **Well understood regulatory path to market entry**

Some Risks Associated With US Market Are Well Understood

- **Business risks**
  - Aggressive competition
  - Increasing cost sensitivity among payors, both private and governmental
  - Increasing focus on demonstrated efficacy
- **Legal risks**
  - Stringent antitrust laws
  - Complicated FDA approval process
  - Products liability claims

New Landscape, New Risks

- **Disclosure Risks – Sarbanes Oxley et al.**
- **Class action products cases**
- **Regulatory and enforcement actions**
  - **Financial relationships throughout the chain of distribution**
  - **Pricing calculations and communications**
  - **Promotional activity, especially off-label directed at new indications**

Emergence of New Regulators

- Traditional role of FDA and HHS
- The Department of Justice as a "regulator"
- State Attorneys General as "regulators"
- Office of Inspector General as a "regulator"
- Plaintiffs lawyers as "regulators"

Why Has This Happened?

- Concerns about soaring government expenditures
- Concerns about soaring health insurance costs
- Concerns about over utilization
- Concerns about the exercise of independent medical judgment by physicians
- Concerns about patient safety
- Concerns about patient privacy

How Has This Happened?

- **Broad criminal statutes**
  - **Anti-kickback statute**
  - **Misbranding statute**
- **“Whistleblower” laws**
  - **How they work**
  - **Incentives for bounty hunters**
  - **Why they matter**
- **Exclusion authority**

Key Milestones

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- **2001 TAP settlement a "wake up" call**
  - $875 payment was unprecedented
  - Extensive corporate integrity agreement
  - Criminal and civil elements
  - Individual charges
- **Widening corporate scandals post-Enron placed increased focus on compliance and governance**
- **July 2002 – issuance of PhRMA code**
- **May 2003 – issuance of OIG compliance guidelines for pharmaceutical companies**
- **January 2004 – Pfizer settles criminal and civil cases relating to off label promotion of neurontin with payment of $430M**

Industry Response

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- **In light of PHRMA and OIG codes, boards and senior management sought assurances**
- **Compliance program model in place from other segments of health care system, but little experience with organizations on the scale of Pharma**
- **Early generation compliance programs**
  - **Driven by law departments**
  - **Rules based**
  - **Focus on education and training**
  - **Reporting avenues**
- **Successful in raising consciousness, but difficult to alter ingrained business practices**

Enforcement Drives Compliance

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- **As many suspected, there were many more TAP like cases in the pipeline, most of them initiated by whistleblowers**
- **A series of large settlements followed, each with an accompanying corporate integrity agreement**
- **CIA agreements increasingly imposed requirements for intensive outside reviews focusing on various business practices such as consulting or grants**
  - **Outside reviewers asked both to review systems and to audit particular transactions**
- **Enforcement and oversight trends reflected increasing sophistication about and insight into the way pharmaceuticals are developed and marketed**

Impact of OIG Agreements

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- **OIG has required execution of corporate integrity agreements as a condition for its decision to refrain from seeking exclusion**
  - **As a practical matter, exclusion from federal health programs would be financially ruinous**
- **Integrity agreements contain many standard provisions, but there has been a steady evolution in those elements dealing with required policies and outside review**
  - **E.g., compare the Pfizer CIA with the recent Purdue CIA**
- **Integrity agreements have become important benchmarks for compliance professionals because they presumably reflect OIG views on certain topics**
  - **Yet as the product of a particular negotiation, they are a poor substitute for regulatory guidance**

Next Generation Compliance Plans

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- **As the materiality of the risks became more apparent, the compliance investment changed**
- **Companies moved to appoint dedicated compliance officers**
  - **Although the regulatory complexity affecting pharmaceuticals makes legal training essential for effective compliance, some companies moved to separate compliance from the legal function**
- **Expanded resources allowed greater visibility within key business units**
- **Increased focus on structural issues, e.g., control and direction of medical education, and on broad risk areas, e.g. large scale consulting programs**

Impact of State Law Reporting

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- **Lead initially by California (of course), a number of states have adopted laws directed at the activities of pharmaceutical companies and their representatives**
- **Many of these state laws require tracking and reporting of certain payments to physicians in the state**
- **These legal requirements forced the development, often for the first time, of systems that could capture the amount of spending to a particular physician**
- **Particularly challenging given the multiplicity of relationships that may exist with physicians – consultant, speaker, researcher, etc.**
- **Although compliance with these requirements has been expensive and burdensome, the data that has emerged can be useful in terms of analyzing broad trends or spotting problems**

Current Compliance Trends

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- **Increasing focus on business operations**
  - **Rules are important, but they are not enough**
  - **Focus on business procedures can imbed compliance into regular operations**
- **Increasing focus on the content of communications with physicians, especially through medical education and other "non-promotional" channels**
- **Increasing focus on developing monitoring tools**
  - **What are the broad trends of spending and what are the implications**
- **Increasing focus on developing audit tools**
- **Increasing emphasis on global standards of conduct**

Case Study: Consulting

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- **Consulting identified as a major risk area – too many physicians being paid too much to do work that no one uses or that looks a lot like promotion**
- **Key control responses**
  - **No consultant may be hired unless there is written brief explaining the need for the consultant and the expected work product**
  - **No payment without a signed agreement entered into a contracts database**
  - **Establishment of standard payment terms**
  - **No payment without certification that work has been performed with appropriate work product**
  - **Tracking overall consulting payment for particular physicians**

Case Study: Speakers

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- **Speakers identified as a major risk area – too many speakers, being paid too much money, to talk about off-label topics, to small groups or not at all**
- **Key control responses**
  - **No speaker may be used unless they are in a database of approved speakers**
  - **To be in the database, a speaker must go through training and there must be an executed agreement**
  - **No event that does not take place in approved venue**
  - **No event that does not meet minimal attendance**
  - **Payment governed by established schedule**
  - **No payment if event does not take place**
  - **No payment without certification from sales rep of compliance with all requirements**

What Comes Next?

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- **Increased emphasis on systems to control and monitor**
- **More reporting requirements from various governmental authorities**
- **Increased emphasis on global standards and benchmarking**
- **More sophisticated efforts to match compliance resources to risk**
- **Continued concern about the right way to respond to the enforcement emphasis on off-label**

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Closing Thoughts

- **The current compliance scene in the US pharmaceuticals market would have been unimaginable in the late 1990s**
- **Because the changes have been driven more by enforcement than regulation, it is still hard to judge the extent to which there has been a true transformation of the business**
- **Also, the importance of enforcement means that the relevance of the US experience to other jurisdictions is hard to assess**
- **Many of the operational changes driven by compliance considerations represent best business practices and deserve consideration regardless of jurisdiction or regulatory scheme**