EVALUATING THE INTERACTIONS OF HEALTH CARE PROVIDERS, PAYORS, AND PHARMACEUTICAL COMPANIES

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OVERVIEW

- Hypothetical call between compliance officer and outside counsel
- Recent headlines
- Complex legal landscape
- Structuring internal review systems

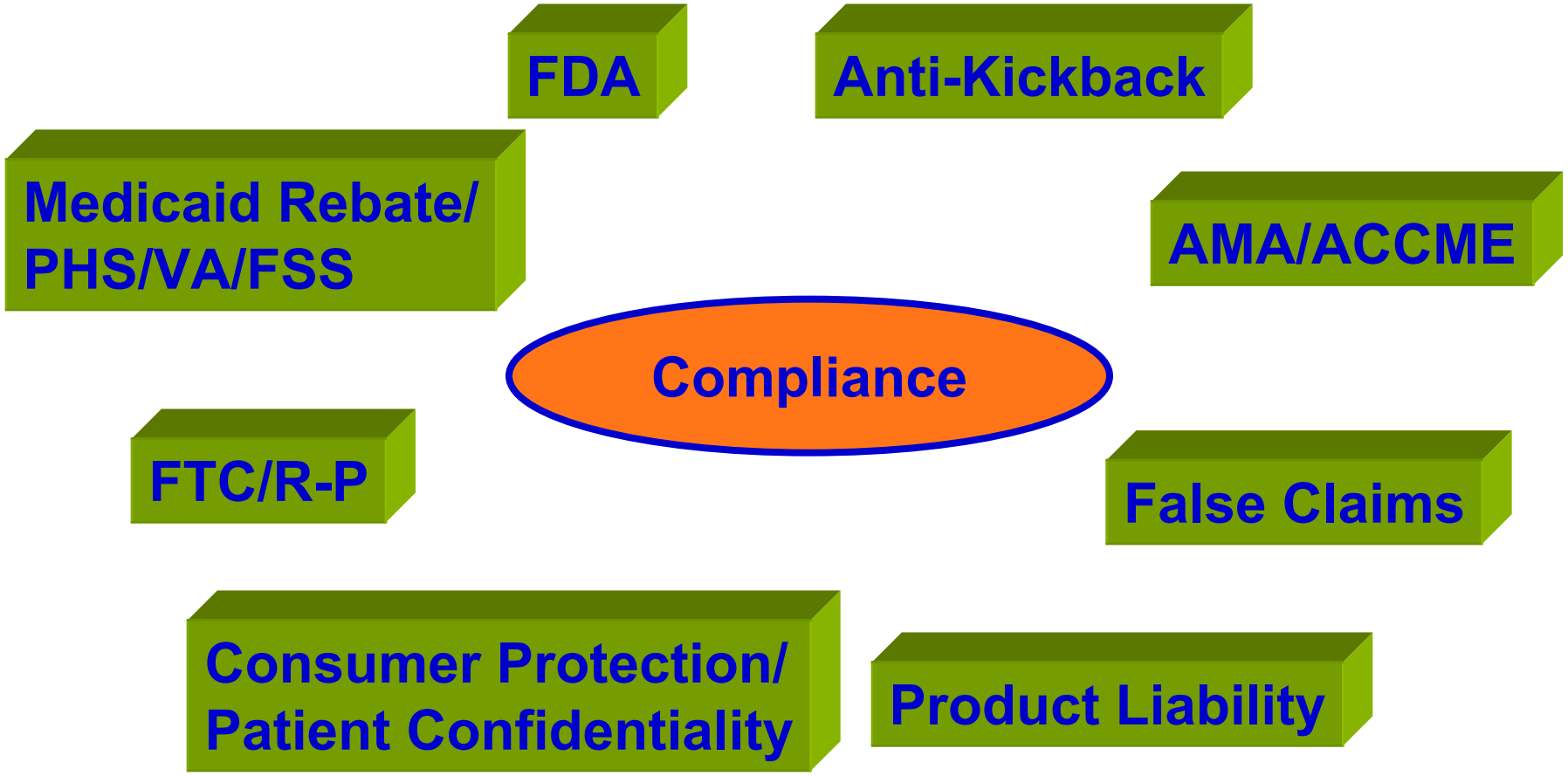
HYPOTHETICAL

[Call from Pharmaceutical Company Compliance Officer to Outside Counsel]

IN THE NEWS ...

- Suit Says Company Promoted Drug In Exam Rooms,
  The New York Times, 5/15/02
- Inquiry Into Drug-Sales Practices Is Widened,
  The New York Times, 5/13/02
- Gifts Seen Effective By Drug Company Reps,
  Globe Staff, 11/17/02
- Ad Agency Helped Push Neurontin, Documents Show,
  The Wall Street Journal, 11/8/02
- Madison Ave. Plays Growing Role In Drug Research,
  The New York Times, 11/22/02
- When Doctors Go To Class, Industry Often Foots The Bill,
  The Wall Street Journal, 12/4/02

The Compliance Challenge: Multiple Legal Standards

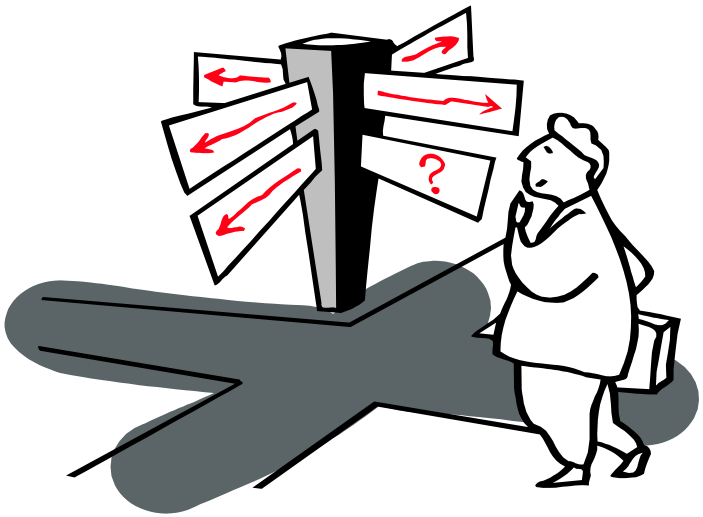


Environmental Check

- The statutes/regulations are broad
- The case law is even broader
- Health care fraud is hot
- The recoveries are staggering
- People are in jail

Key Legal Principles

- Anti-Kickback Laws
- False Claims Act
- FDA Regulations/Guidelines
- PhRMA Code
- OIG Compliance Guidance
- AMA Guidelines on Gifts to Physicians



Federal Anti-Kickback Statute

- Knowingly and willfully
- Offer/pay -- solicit/receive
- Any remuneration, direct or indirect, in cash or in kind
- To induce or in return for
- Referring patients, or purchasing or ordering/recommending or arranging purchasing or ordering
- Items or services covered under federal health care programs

Potential Penalties

- Criminal statute
- Five years in jail
- Criminal fines of $25,000
- Civil fines up to $50,000 and remuneration times three, per violation
- Exclusion (criminal or civil)

Key Exceptions to the Statute (safe harbors)

- Personal services contracts
- Leases of space
- Discounts
- Employment contracts
- GPO fees

Three-Step Analysis

- Is the transaction or practice potentially within the statute?
- If so, is it within a safe harbor?
- If not, what is the risk level, and can the program be modified to reduce the risk?

What Risk?

- Inappropriate influence on medical judgment
- Potential overutilization, misutilization, increased costs
- Impact on quality of care
- Impact on patient access to care
- Impact on competition

Federal False Claims Act

- Prohibits knowingly submitting or causing to be submitted false or fraudulent claims to the government
- Treble damages plus civil monetary penalties for each claim
- Qui tam provisions ("whistle-blowers")

FDA Promotional Principles

- Governs promotion of products by or on behalf of manufacturers
- Consistency with prescribing information
- No false or misleading information
- Fair balance
- Education v. promotion
- Independence

PhRMA Code: Interactions with Health Care Professionals

- Focus of interactions
- Independence of decision-making
- Informational presentations
- Third-party educational/professional meetings
- Consultants
- Speaker/trainer meetings
- Scholarships/educational funds
- Educational/health practice items

OIG Draft Guidelines for Pharmaceutical Manufacturers

- Identifies "major risk areas"
  - Integrity of data used by state and federal governments to establish payment
  - Kickbacks and other illegal remuneration
    - relationships with purchasers
    - relationships with physicians and other health care professionals
      - entertainment, recreation, travel, meals
      - educational seminars
      - scholarships and educational funds
      - research and educational grants
      - gifts, gratuities, and other business courtesies
    - relationships with sales representatives
  - Compliance with laws regulating drug samples

1990 AMA Guidelines on Gifts to Physicians from Industry

[Updated August 2001]

- Modest value patient-care related gifts
- Minimal value items related to physician's practice
- Bona fide service relationships
- Educational grants to program sponsors
- No gifts with strings attached

How Can Pharmaceutical Companies Respond?

Structure Effective

Internal Review Systems

Compliance Programs Generally

- Help to demonstrate that the company is operating under a *state of control*
  - Can demonstrate in practice and in writing
    - Company knows what it is suppose to be doing
    - Company knows what it is actually doing
  - Consistent with USSC Guidelines and require
    - Procedural systems; and,
    - Individual day-to-day transactions based on sound processes
    - Effective monitoring and feedback to management
- Above factors are necessary, but not sufficient!

Compliance Programs Generally

- Companies often structured in silos - variable interchange of information/coordination of efforts
  - Clinical Research
  - Medical Science Liaison
  - Marketing
  - Sales
  - Market Research
  - Regulatory Affairs
  - Finance
  - Legal
- Size of organization is a relevant factor impacting communication/coordination of efforts

Compliance Programs ...

- Government/plaintiff's bar/lay press represent company activities as coordinated efforts
  - Sales, marketing, clinical, regulatory, legal working together to accomplish the company's goals
- Most companies aspire to this, but probably fall short
- Application of AKA & FCA greatly expands number and magnitude of risk areas
- Lack of internal coordination creates "an opportunity for improvement"
- Model of "success" already in place at most companies

It Takes A Village...

- Observation
  - Most companies apply considerable resources to assure that advertising and promotion efforts are consistent with commercial objectives as well as medical, legal and regulatory requirements
    - Review committee comprised of Marketing, Medical, Regulatory, Legal, etc.
    - Appropriate recordkeeping
    - Qualified, experienced vendors
    - Extensive employee training
  - BUT, how about other “risk areas?”

It Takes A Village...

- Other "risk areas" may include
  - Company-supported CME
  - Company-supported post-market 3rd party research and scientific publications
  - Marketing advisory boards and other consulting relationships, etc.
- Are similar resources applied to these [new] risk areas?

It Takes A Village...

- Companies may consider borrowing from existing control systems
  - Individual activities reviewed by appropriate disciplines - Marketing, Clinical, Medical, Market Research, Regulatory, Legal, etc.
  - Proper documentation and support for activities
    - Creation, filing, clarity of facts, mindset
  - Selection of qualified and experienced vendors
  - Employee training

It Takes A Village...

- Other Factors
  - Underestimation/availability of scarce resources
  - Denial/dissatisfaction with current controls
  - Sea of vendors with limited understanding/appreciation for standards of conduct or risks
  - Pervasive myth that you can do indirectly what you can't do directly
  - Staff turn-over
  - Focus on financial transactions v. underlying behavior
  - Understanding the importance of clear documentation of underlying facts supporting activities
  - Complexity of the issues, size and sophistication of the internal audience, unintended consequences

Summary

- Pharmaceutical company interactions with payors and providers are complex and increasingly risky
- Appropriate systems, transactions and monitoring are necessary but not sufficient
- Consider application of lessons learned from advertising and promotion controls
- Don’t underestimate resource demands