



Fifth Annual National Congress  
on  
Health Care Compliance

*Pharmaceutical Sales and  
Marketing: Are You Afraid to  
Look Under the Rocks?*

Michael P. Swiatocha

February 8, 2002

RS ♦ MP

# Agenda

---

- Introduction - The US Pharmaceutical Industry
- What's Under the Rocks?
  - Compliance Program Structure
  - Sales and Marketing Activities
- Assessment Methodology
- Q & A



# Introduction

---

### Strategies for Revenue Growth

- Invest in R&D
- Discover and develop new and innovative products
- Develop new indications and line extensions
- Form alliances
- Improve productivity and reduce costs
- Increase share of voice in the marketplace
- Design and execute innovative programs in:
  - Marketing
  - Sales
  - Customer Education

# US Pharmaceutical Industry

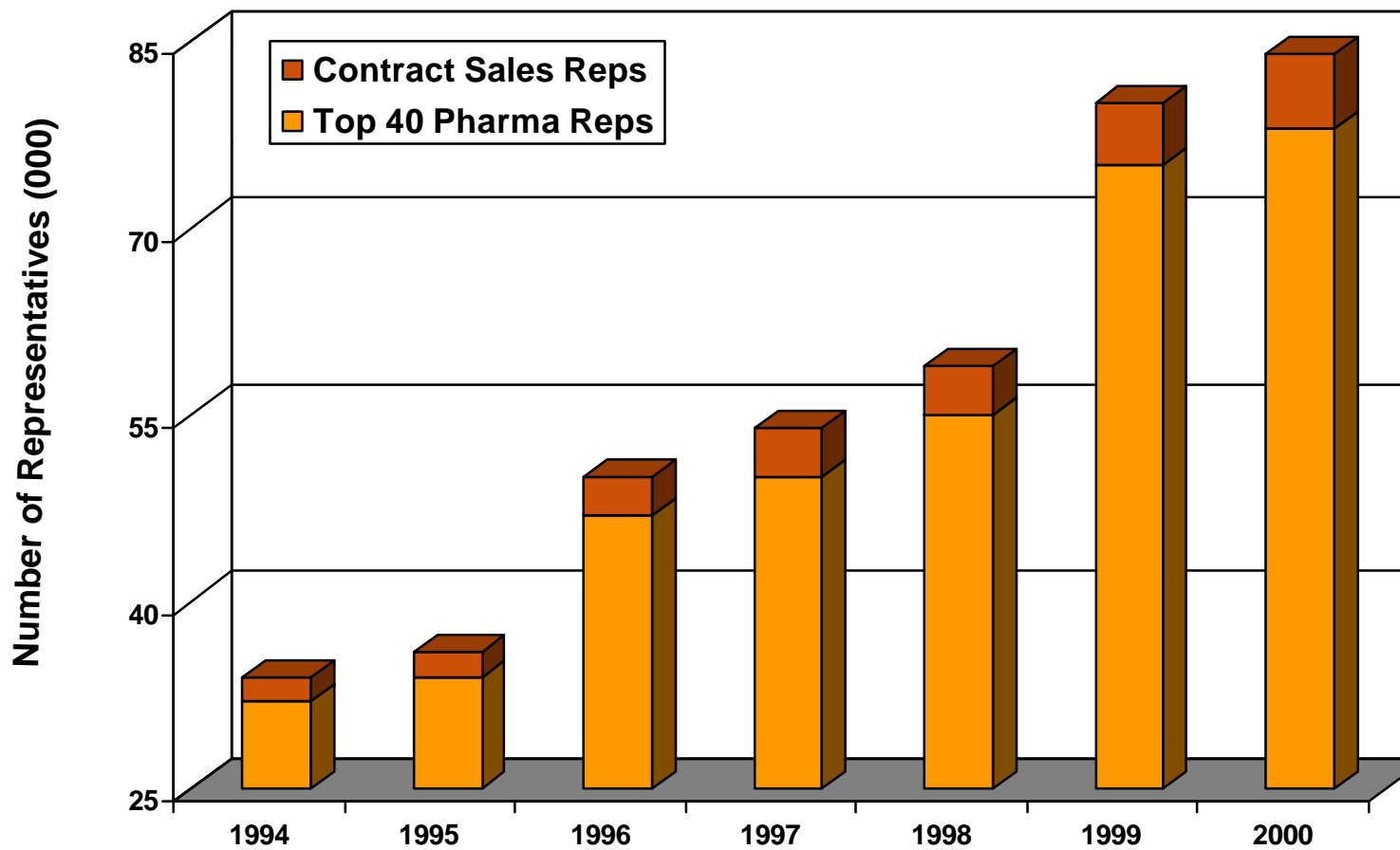
---

## Strategies for Revenue Growth

- Invest in R&D
  - Discover and develop new and innovative products
  - Develop new indications and line extensions
  - Form alliances
  - Improve productivity and reduce costs
- Increase share of voice in the marketplace
  - Design and execute innovative programs in:
    - Marketing
    - Sales
    - Customer Education

# US Pharmaceutical Industry

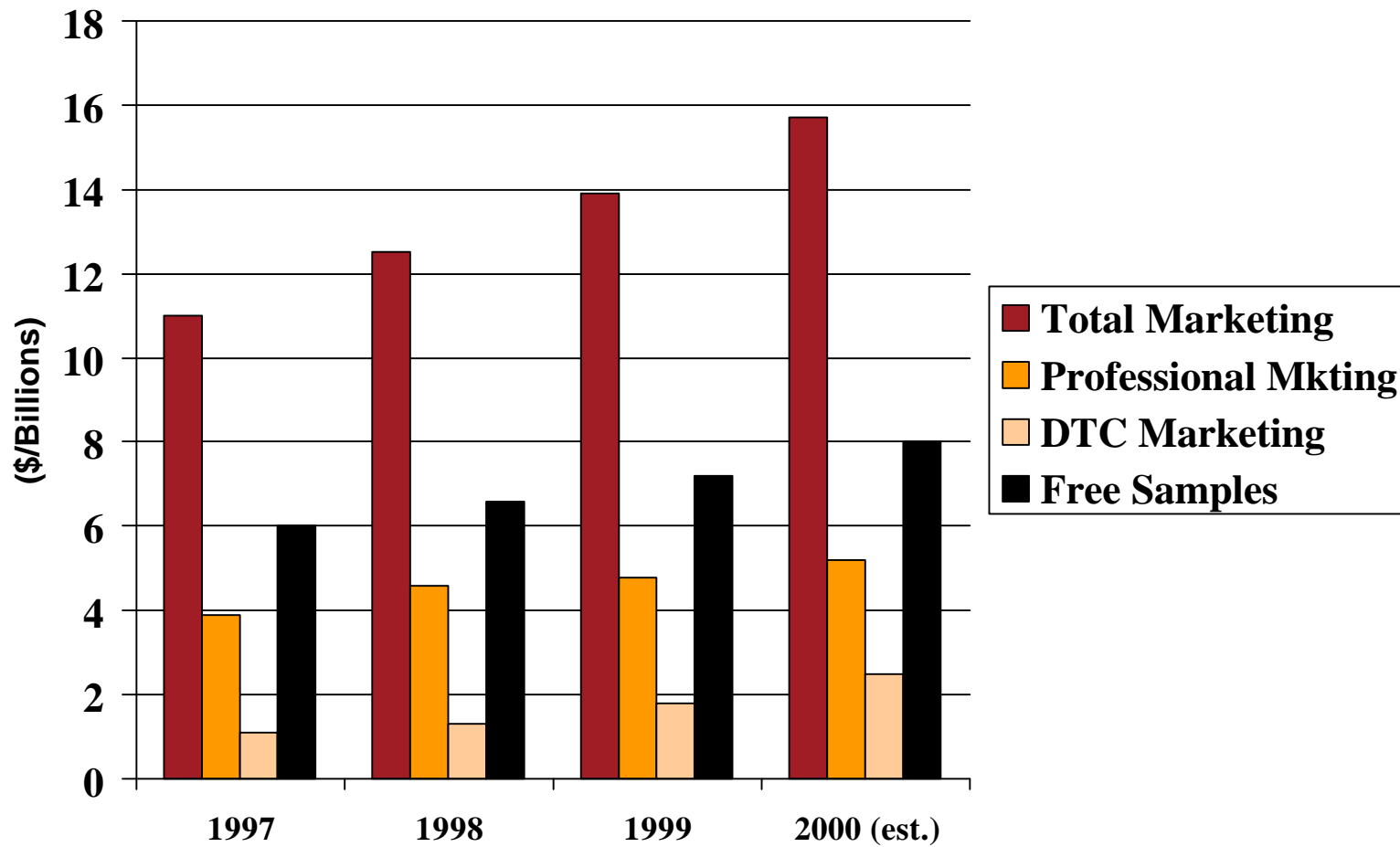
## Accelerated Growth of US Sales Reps: 1994 to 2000



Sources: Scott-Levin, Pharmaceutical Representative and WR Hambrecht + Co Estimates, 2001

# US Pharmaceutical Industry

Overall Growth in Pharmaceutical Marketing Expenditures: ~ 16% Per Year



Source: PhRMA Industry Profile, 2001

## US Pharmaceutical Industry

---

- Rx Sales
  - 1995 - \$61 billion
  - 2000 - \$138 billion
- Marketing Spend on MDs
  - 1995 - \$5.5 billion
  - 2000 - \$13.2 billion
- Professional Spending in 2000
  - Samples - \$ 7.9 billion
  - Office-based promotion - \$4.0 billion
  - Hospital-based promotion - \$770 million

**Sources:** *Scott-Levin, IMS, MedAd News, Pharmaceutical Representative and Datamonitor Plc*

## US Pharmaceutical Industry

---

- Detailing remains the primary marketing tool
- Current marketplace estimates:
  - 78,000 sales representatives (2X 1995)
  - US sales force size – 20 to 8000 representatives/managers
  - 600,000 targeted physicians (static)
  - 390,000 physicians see sales representatives
  - \$150-200 per detail
  - Additional targets:
    - Nurse practitioners
    - Physician's assistants

**Sources:** *Scott-Levin, Pharmaceutical Representative, US Census Bureau, MedAd News and Datamonitor Plc*

## US Pharmaceutical Industry

---

- Shrinking access to physicians in offices
  - 1995 – 12 minutes (average time spent with sales representatives)
  - 2000 – 7 minutes (average time spent with sales representatives)
- Improve sales force ROI
  - Increase access to customers
  - Entertainment-based programs
    - meetings and events
    - dinner programs
  - Meals for office staff
  - Gifts and business courtesies

**Sources:** *Scott-Levin, Pharmaceutical Representative, US Census Bureau and Datamonitor Plc*



What's under the rocks?

---

## What's under the rocks?

---

### Perspective for the Discussion

- Fraud and Abuse
- Anti-Kickback
- False Claims
- FDA
- HIPAA

## What's under the rocks?

---

### Compliance Program Structure

- Compliance officer and committee
- Written policies and procedures (including specific policies for customer activities, clinical research, consultants, grants, etc.)
- Education and training
- Internal reporting
- Auditing
- Compliance-related disciplinary policies
- Reporting of potential misconduct

## What's under the rocks?

---

### Sales and Marketing Activities

- Entertainment, meals and gifts
- Consulting, speaking and advisory fees
- Continuing medical education
- Off-label usage
- Pharmaceutical samples and free goods
- Partnerships
- Fees for detailing
- e-Business

## What's under the rocks?

---

### Entertainment, Meals and Gifts

- 2000 – \$1.9 billion for meetings with customers
- 2000 – 314,000 events
- Control Standards
  - AMA Guidelines
    - [www.ama-assn.org/ceja](http://www.ama-assn.org/ceja)
  - Company policies and SOPs
  - Training and communication
  - Monitoring
    - initial approval
    - expense report
    - corrective action

## What's under the rocks?

---

### Entertainment, Meals and Gifts (continued)

- Examples of industry practices:
  - Strict adherence to AMA guidelines
  - Annual company-wide \$ limit per physician for all entertainment, meals and gifts (multiple divisions)
  - No annual \$ limit per physician (maximum \$ limit per event)
  - Spouse/guest permitted (yes/no)
  - Spouse/guest expense included in \$ limit or 2X \$ limit
  - Annual company-wide \$ limit per physician for medical textbooks (multiple divisions)
  - Guidelines for F/T and P/T government employees
  - \$ limit per occasion for business courtesies

## What's under the rocks?

---

### Consultants, Speakers and Advisory Boards

- Control Standards
  - AMA Guidelines
  - Company policies and SOPs
  - Training and communication
  - Written contract signed by both parties
  - Services are necessary and legitimate
  - HHS OIG's List of Excluded Individuals and Entities
  - Monitoring
    - aggregate compensation to individuals
    - FMV of payments

## What's under the rocks?

---

### Consultants, Speakers and Advisory Boards (continued)

- Examples of Industry Practices
  - Managed by headquarters only
  - Managed at regional and district levels
  - Formal approval process (medical, legal, etc.)
  - Payment ranges based on specific criteria and FMV
  - Reimbursement for travel expense
  - Incidental meals
  - Entertainment (yes/no)

## What's under the rocks?

---

### Consultants, Speakers and Advisory Boards (continued)

- Issues to Consider

- Thought leaders and product advocates

- critical to product launch
- long-term relationships (consulting retainers)
- clinical trials
- publications
- speaker programs
- aggregate compensation
- potential conflict of interest (P&T decision-maker)

## What's under the rocks?

---

### Continuing Medical Education

- Accredited and non-accredited programs
- Control Standards
  - AMA Guidelines
  - Accreditation Council for Continuing Medical Education (ACCME) Guidelines
  - Company policies, SOPs, and training
  - Written agreement signed by both parties
  - Monitoring
    - initial approval
    - documentation (before/after)
    - audit third party activity

## What's under the rocks?

---

### Continuing Medical Education (continued)

- Examples of Industry Practices
  - Managed at headquarters and regional levels
  - Limited to CME accredited programs (yes/no)
  - Non-CME managed through grants and contributions
  - Formal approval and tracking processes
  - Entertainment, meals and gifts subject to other policies
  - No unrestricted grants for educational programs

## What's under the rocks?

---

### Continuing Medical Education (continued)

- Issues to Consider
  - Inducements for purchase or recommendation for use of product
  - Targeting of participants
  - Program agenda and content
  - Venue
  - Vendor management
  - Application of policy to other providers

## What's under the rocks?

---

### Off-label Usage of Pharmaceuticals

- Cost of new product development
- Access to patients for clinical trials
- Control Standards
  - FDAMA “safe harbor”
  - Company policies, SOPs, training and communication
  - Management process to handle unsolicited requests
  - Monitoring
    - approval process for sales promotions
    - customer targeting and call reporting
    - grants for studies and publications

## What's under the rocks?

---

### Off-label Usage of Pharmaceuticals (continued)

- Examples of Industry Practices
  - Managers and representatives trained by legal
  - Strong disciplinary policy
  - Restricted to medical liaisons, specialty representatives and medical affairs
  - Strict guidelines for sales representatives
  - Documentation of requests from customers and responses

## What's under the rocks?

---

### Off-label Usage of Pharmaceuticals (continued)

- Issues to Consider
  - Business plans
  - Incentive compensation programs
  - Thought leader and opinion leader use
  - Support for advocacy groups
  - Product websites – cross-border visits

## What's under the rocks?

---

### Pharmaceutical Samples and Free Goods

- 2000 - \$7.9 billion for samples
- Cost of doing business
- Control Standards
  - PDMA requirements
  - Company policies, SOPs, training and communication
  - Records and reports
  - Monitoring
    - high utilization
    - audits
    - corrective action

## What's under the rocks?

---

### Pharmaceutical Samples and Free Goods (continued)

- Examples of Industry Practices
  - Strong internal/external management program
  - Hardcopy/automated process
  - Disciplinary policy
  - Vouchers and coupons
  - E-requests

## What's under the rocks?

---

### Pharmaceutical Samples and Free Goods (continued)

- Issues to Consider
  - Patient assistance programs
  - FMV for drug delivery devices, laboratory equipment, etc.
  - Phase IV supplies
  - Vendors

## What's under the rocks?

---

### Other Rocks

- Partnerships
- Fees for Detailing
- e-Detailing



# Assessment Methodology

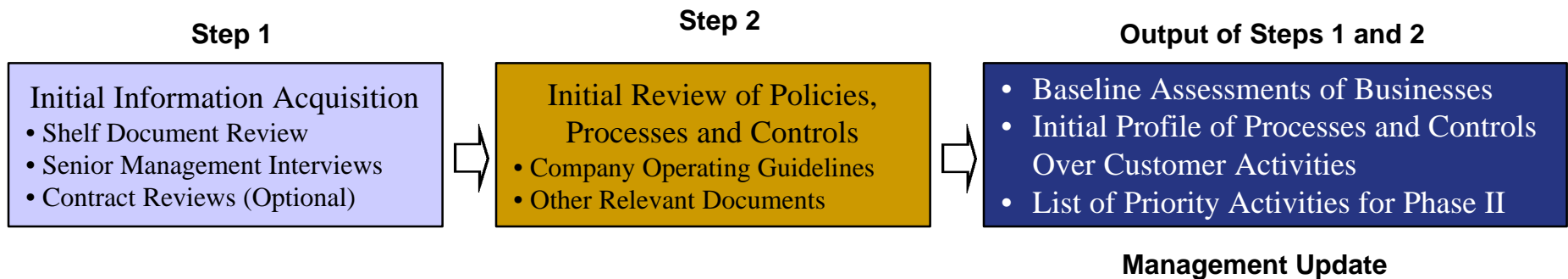
---

# Assessment Methodology

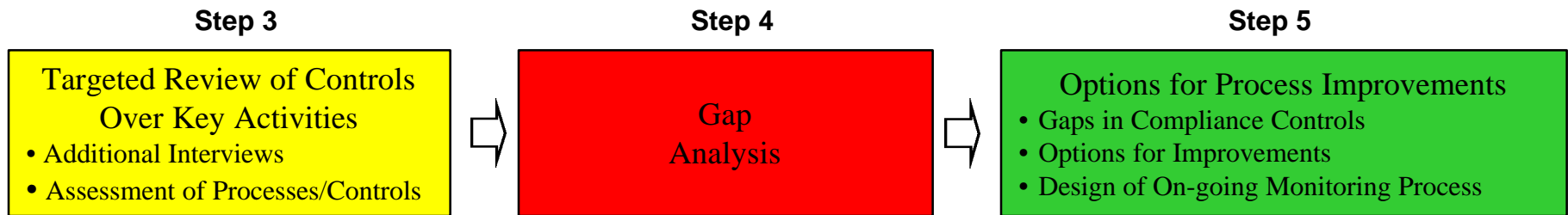
---

## Five Step Process

### Phase I



### Phase II



**Steering Committee**

**Project Team**

**Legal Counsel**





## Q & A

---



## For Further Information

---

### **PricewaterhouseCoopers LLP**

Michael Swiatocha

973-236-4541

[michael.p.swiatocha@us.pwcglobal.com](mailto:michael.p.swiatocha@us.pwcglobal.com)