The Thirteenth Annual
Pharmaceutical Regulatory and Compliance Congress
and Best Practices Forum

Compliance 101

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Agenda

- State and Federal Laws
- OPDP/Food, Drug, Cosmetic Act
- Summary of Recent CIAs
- Foreign Corrupt Practices Act
- Compliance Program Elements
  - Training, Policies, Communications
  - Auditing & Monitoring
  - Investigations and Remedial Actions

State and Federal Laws

Seven Major Federal Laws

1. Anti-Kickback Statute
2. False Claims Act
3. Food, Drug, and Cosmetic Act >>> Lucy
4. Prescription Drug Marketing Act
5. Health Insurance Portability and Accountability Act (HIPAA)
6. Foreign Corrupt Practices Act >>> Mike
7. Sunshine Act

Anti-Kickback Statute – The Law

Criminal Statute

- Makes it illegal to offer or pay "remuneration" to induce customers to purchase or prescribe products
- "Remuneration" has a wide definition and can include gifts, discounts, free goods, coupons, cash, etc.

Anti-Kickback Statute – The Purpose

To prevent “bribes” to customers to induce them to purchase products paid for by the government

Anti-Kickback Statute – Safe Harbors

The government has established "safe harbors" to protect certain conduct. Four safe harbors are particularly significant to pharmaceutical manufacturers:

1. The **Discount Safe Harbor** - protects certain price reductions, provided they are set in advance and properly disclosed and reported to the government.
2. The **Personal Services Safe Harbor** - allows a manufacturer to enter into contracts with HCPs for services such as speaking engagements, consultancies, and advisory boards.
3. The **Group Purchasing Organization ("GPO") Safe Harbor** - protects certain administrative fees paid to GPOs.
4. The **Managed Care Safe Harbors** - protect certain discount arrangements with managed care organizations.

Fee for Service Arrangements
(Consultants, Speakers, Advisory Boards)

Requirements Under Personal Services Safe Harbor:

- Company must need the services
- Participants chosen based on their qualifications only
- Payment must be fair market value
- There must be a written contract that includes
  - —Business need for the service
  - —Minimum of a one year term
  - —Qualifications of participants
  - —Payment terms

Fee for Service Arrangements
(Consultants, Speakers, Advisory Boards)

- Fee for service arrangements **may not** be provided to:
  - Encourage off-label use
  - Encourage purchase or use of product
  - Reward “high prescribers”
- Other Limits
  - Company reimburses reasonable expenses of participants only (i.e., not spouses, family members)

Anti-Kickback Statute – Case in Point: Serono 2005*

Physicians were offered an all expense paid trip to Cannes, France in exchange for writing 10 new scripts for Serono's AIDS wasting drug

* Based on facts described in government's press release.

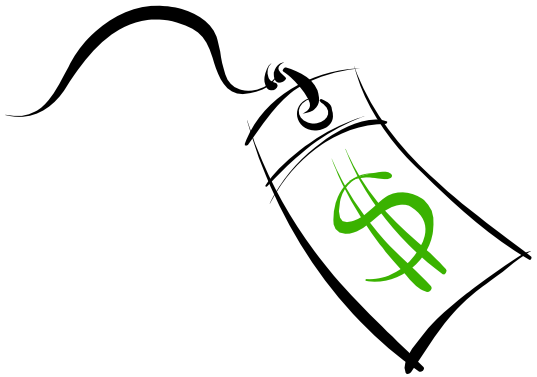
False Claims Act (FCA) – The Law

- It is illegal to make – or assist others in making – false statements or claims to the government

- A claim is "false" if the person or company making the claim actually knows that it is false or acts in "deliberate ignorance" of, or with "reckless disregard" for, whether the statement or claim is actually true.

FCA – The Purpose

To prevent government overpayment due to false or inaccurate pricing information



Whistleblower Provision

- You might know the FCA because of the whistleblower provision
  - Recovery up to 30%
- Under the Federal Civil False Claims Act, individuals with knowledge of false claims may bring suit on behalf of the government.
  - "Qui tam relator"
- There are also 28 State False Claims Acts

FCA - Case in Point: TAP*

Sales representatives encouraged physicians to bill for free samples of an injectable cancer drug.

- A false claim to the federal government
  - i.e., to reimburse for free goods
- Activities of both the physicians and the sales representatives may have violated the FCA

* Based on facts described in government's press release.

Food, Drug & Cosmetic Act – The Law

- Even after a drug receives approval, Company must control how its drug is promoted.
- A manufacturer may only **promote** a drug for its approved use, even though prescribers may use their professional judgment in determining how to **prescribe** the drug.
- Promoting a drug for an unapproved use is known as "**off-label promotion**," meaning that the manufacturer is promoting the drug for a use not indicated in the drug's approved labeling.

What Is the Approved Labeling?

- A drug's "labeling" includes all information contained on its label, packaging, and full prescribing information ("FPI"), as well as any other materials distributed by the manufacturer about the drug and oral statements about the drug's intended use.

- All such materials and statements must contain only information related to the drug's approved use(s) as set forth in the FPI.

Food Drug & Cosmetic Act – Fair Balance

- In addition to promoting a drug only for its approved uses, pharmaceutical companies must promote medications in a way that is **truthful and not misleading** and that gives a "**fair and balanced**" description of the drugs' risks and benefits.

- This means that risk information must be presented with prominence and readability comparable to any safety or efficacy information.

- Fair balance must exist in both printed materials as well as any oral communications of a promotional nature.

Claims

In order to make a claim, there must be **substantial evidence/clinical trials** supporting the claim.

- Comparative Claims
- Superiority Claims
- Convenience Claims
- Quality of Life Claims
- Implied Claims

Unsubstantiated superiority claims – explicit or implied – are part of a significant number of Warning and Untitled Letters in the past several years.

Penalties for Off-Label Promotion

- Untitled Letter
- Warning Letter
- Require Company to take corrective action such as:
  - "Dear Doctor" letters
  - Cease distribution of materials
  - Submit plan for remediation
- Product Seizure
- Loss of Right to Market

Prescription Drug Marketing Act (PDMA) – The Law

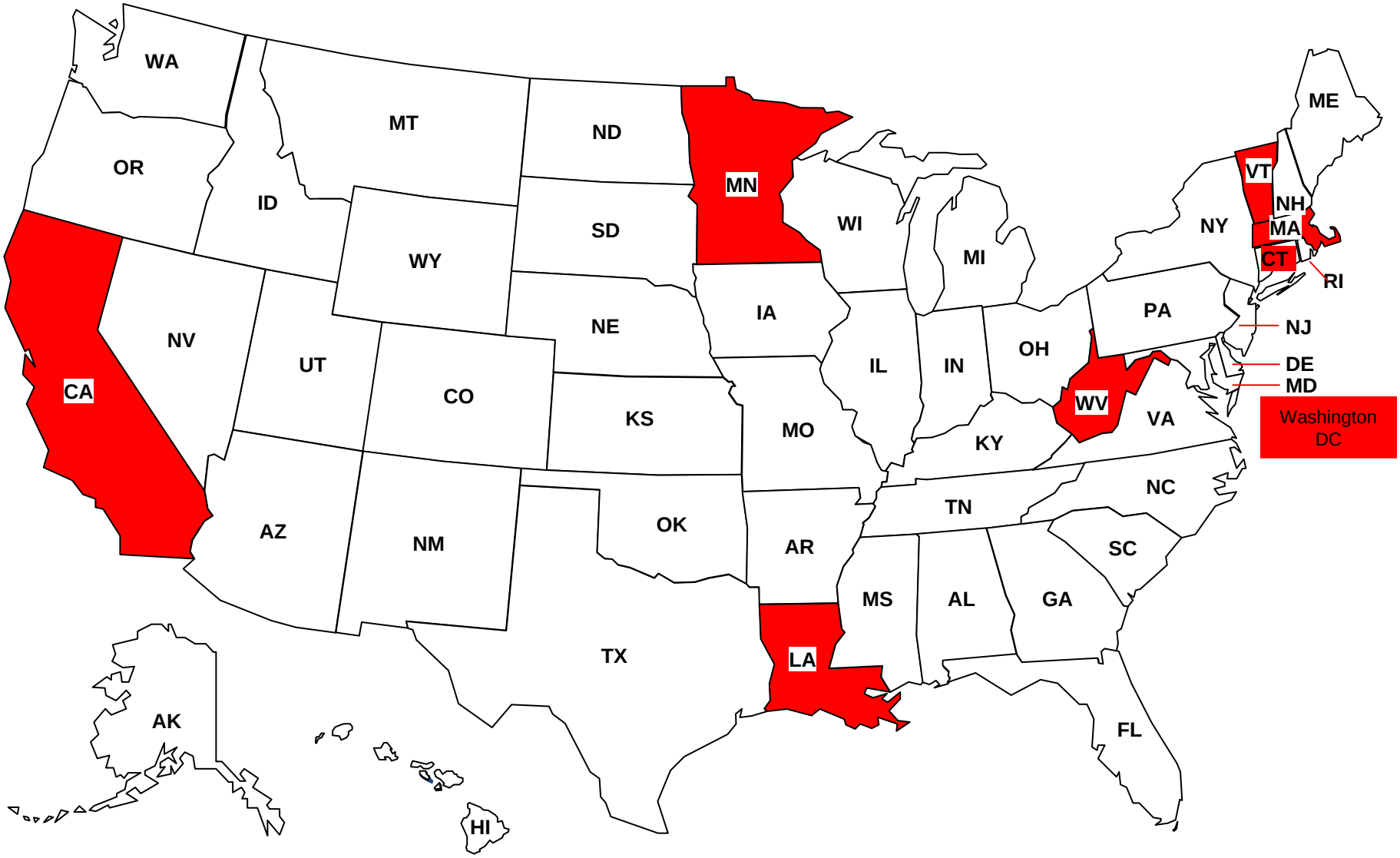
- Part of the Food, Drug and Cosmetic Act
- Addresses sampling practices
  - Written request must be obtained from each physician with whom samples are left
  - Receipt upon delivery of samples

- Not Allowed:
  - Excessive Quantities
  - Rewarding "High Prescribers"
  - Suggesting that physicians sell or seek reimbursement
  - Selling or trading of Samples

Health Insurance Portability and Accountability Act (HIPAA)

- Privacy
  - The use or disclosure of protected health information (PHI) may require written permission
- Governs activities of covered entities
  - - Physicians
  - - Hospitals
  - - Clinics
  - - Nursing homes
- Pharmaceutical companies, for purposes of manufacturing and marketing prescription drugs, are NOT considered covered entities

State Laws & Sunshine Act



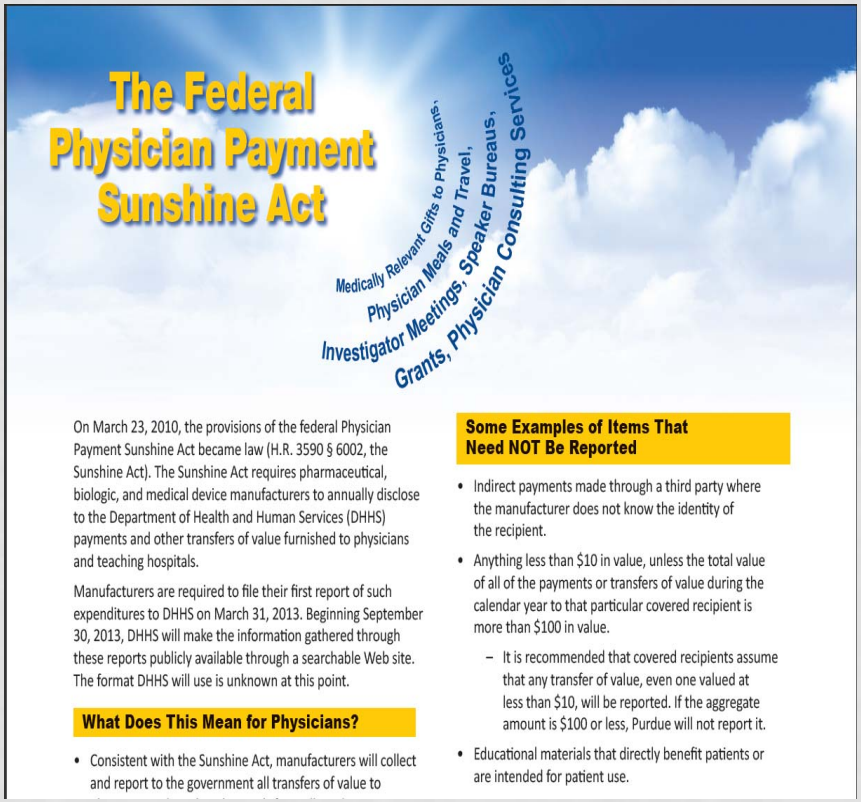
STATE LAWS

California	$750/Healthcare Practitioner (HCP) spending limit; must certify to Compliance Program; prohibits provision of certain gifts to HCPs
Connecticut	Requires pharmaceutical, biological, and medical device companies to adopt and implement a marketing code that is at least as restrictive as the PhRMA Code or AdvaMed Code by January 1, 2011
D.C.	Company required to report aggregate marketing costs and gifts to physicians, as well as advertising costs for prescription drugs annually; Sales Reps required to be licensed and complete continuing education training
Louisiana	Sales reps must register as lobbyists if spend >$500/year on Executive Branch Officials (i.e., practitioners employed or working in a voluntary capacity for the State)
Maine	Company required to report aggregate marketing costs and gifts to physicians, as well as adver[illegible] disclosure and clinical trial disclosure laws in effect
Massachusetts	Company required to certify and audit Compliance Program; required to report marketing costs to prescribers of at least $50.
Minnesota	Gifts to practitioners prohibited (up to aggregate $50/practitioner/year permissible); Company must annually report non-prohibited payments in excess of $100
Nevada	Company required to certify and audit Compliance Program
Vermont	Total ban on gifts to Vermont-licensed HCPs who "regularly practice" in VT except in limited cases; Sales Reps must report AWP per pill of each marketed drug and prices of other drugs in therapeutic class when marketed to VT physician or other prescriber
West Virginia	Company required to report aggregate advertising costs for prescription drugs Annually; Company must annually report non-prohibited payments in excess of $100

Maine Law Repealed!!

SUNSHINE ACT TEAR SHEET

- Sunshine Act Tear Sheet available on our internet page



OPDP and
The Food, Drug & Cosmetic Act

BREAK

Summary of Recent CIAs

Recent Activity

AMGEN

$750 million

MERCK
Be well

$950 million

Boehringer Ingelheim

$95 Million

gsk GlaxoSmithKline

$3 billion

Johnson & Johnson
Celebrating 125 Years

$270 million

Abbott
A Promise for Life

$1.5 billion

SANDOZ

$150 million

- With many more CIAs to follow
- And over 150 “whistleblower” cases

From the Headlines

Corporate Integrity Agreements

- A CIA is an agreement with the Office of Inspector General
- CIA is included in almost all civil settlements and provides a "probation" period of generally 5 – 7 years
- CIAs help organizations move toward and maintain, ethical behavior
- They reflect the government's view of the requirements of an effective compliance program in view of a companies underlying conduct
- CIAs do not create any new legal or regulatory requirements

Corporate Integrity Agreements

- Compliance Officer and Committee
- Written standards
  - Code of Conduct
  - Policies and Procedures
- Training and Education
- Internal and Third Party Reviews of Compliance polices and adherence to policy
  - Independent Review Organization

Corporate Integrity Agreements

- Disclosure Program and Self Reporting
  - Confidential Helpline
  - Investigations Process and Documentation
- Ineligible Persons Screening
- Notification of Government Investigations or Legal Proceedings
- Notification of Communications with FDA
  - Unlawful or improper promotional activities
- Reports and Certifications
  - Reportable Events

Evolution of CIA Programs: More Onerous Provisions

- Independence of CCO
- Needs Assessment: consulting services
- Board Oversight
- Senior Manager Certification
- Notification to HCPs
- Website Postings: payments to HCPs
- Website Postings: Research/Clinical Studies
- Inquiries Database
- Monitoring-Promotional Issues
- Monitoring—Non-Promotional Issues
- Post-marketing Commitments
- Consultant Monitoring
- Needs Assessments: Research
- Needs Assessment: Publications
- Publications Monitoring
- Grants Monitoring
- Compliance Expert
- Website Posting: Med Ed Grants
- Compliance with ICMJE Standards
- Disclosures for Formulary Committee Members

Major Developments in Recent Pharma CIAs

- Board accountability
- Management accountability
- Compliance officer certifications
- Expansion into medical affairs and R&D
- Monitoring
- Transparency
- Expanded use of exclusion authority
- Compliance Expert

Benchmarking: Requirements in Recent Pharma CIAs

	AZ	OMJPI	Forest	Novartis	Allergan
Ride-Alongs	75	30	40	50	30
Speaker Programs	250	40	175	125	75
Consultants	70	50 (40 speakers)	30	50	30
Publications	50	N/I	30	25	25
Grants	60	N/I	30	30	30
Research-Related Activities	30 (20 must be ISSs)	N/I	30 (20 must be IITs)	20	20

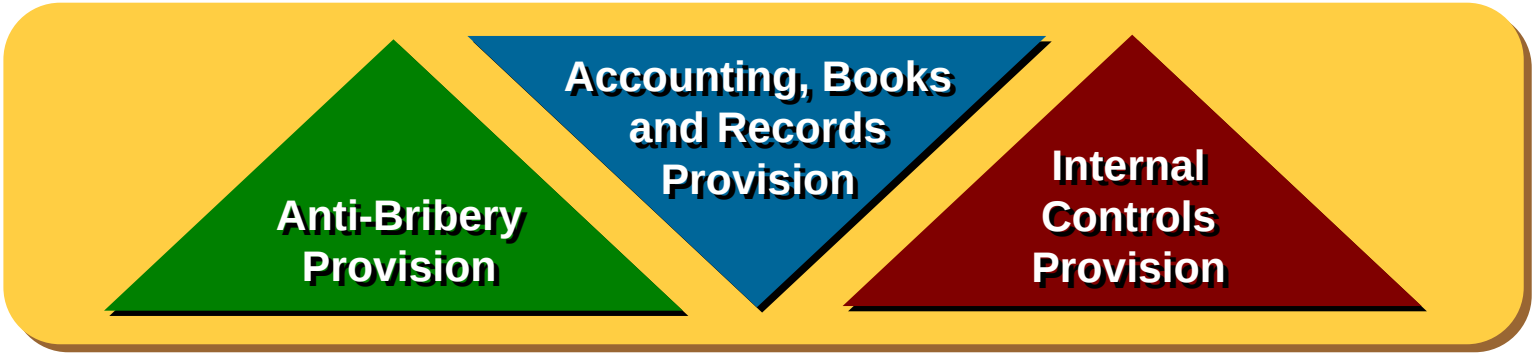
Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act (FCPA)

What is it, and why is it relevant internationally?

The FCPA (15 U.S.C. §§ 78dd-1, et seq.) was passed in 1977. It has three primary provisions:

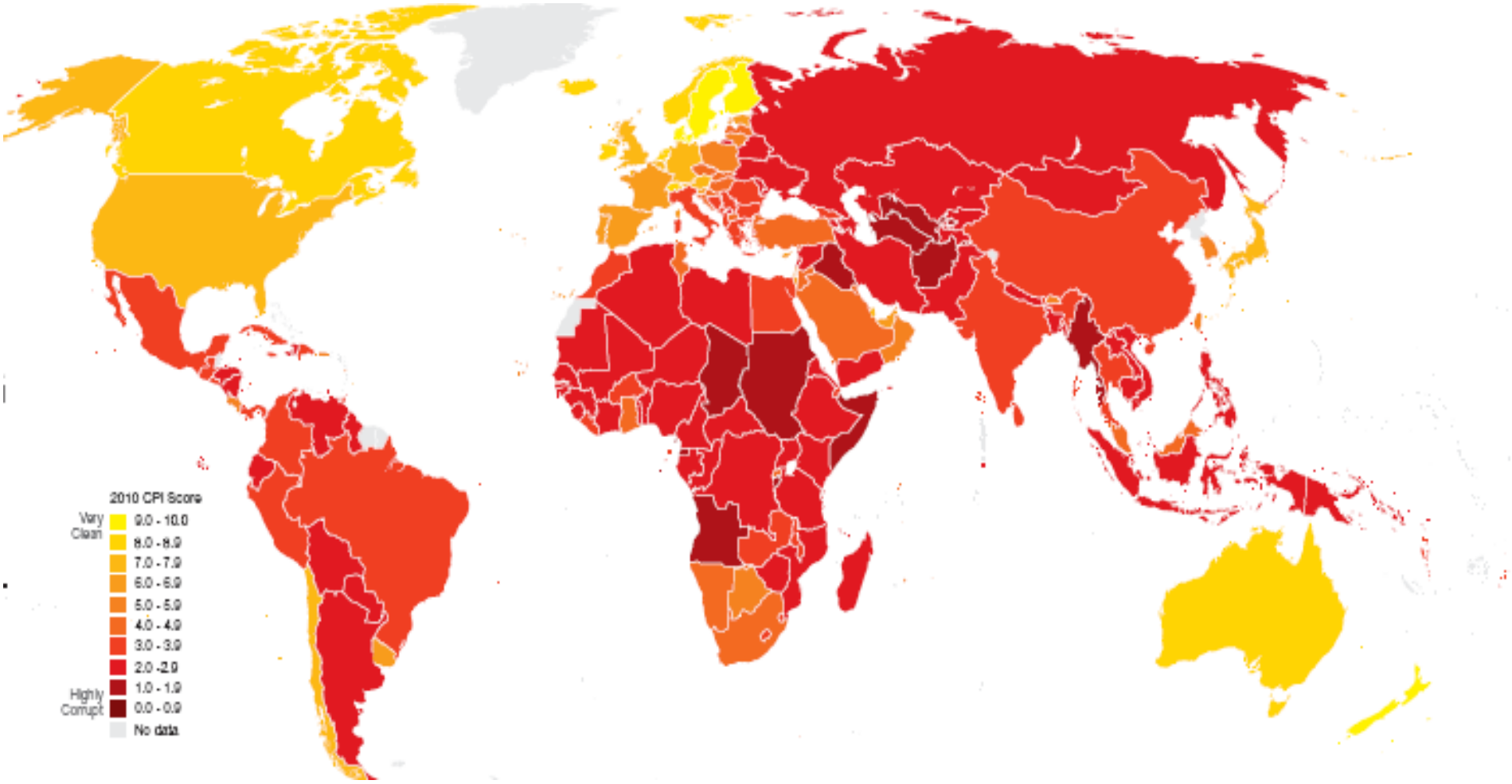
The Accounting Provision requires companies to keep books, records and accounts that accurately and fairly reflect any transaction and disposition of corporate assets in **reasonable** detail.



The Anti-Bribery Provision prohibits any **U.S. Company and its employees** from paying, or giving or promising **anything of value**, **directly or indirectly, to a foreign government official**, political parties or party officials to obtain or retain business, or to gain any improper business advantage.

The Internal Control Provision establishes "standards of conduct and internal control systems that are reasonably capable of reducing the likelihood of violations of laws." These **internal controls** are not limited only to accurate financial reporting, but extend broadly to ensure compliance with all laws.

Global Companies Likely Have High Risk



The Foreign Corrupt Practices Act (FCPA)

What is it, and why is it relevant internationally?

- A "bribe" under the FCPA is:
  - anything of value given or offered to a foreign official
  - intended to improperly influence their decision to award business
  - or to secure a commercial advantage

Government Officials include…

- "Foreign officials" under the FCPA include:
  - Officers or employees of a foreign government,
  - officers or employees of an instrumentality of a foreign government,
  - officials of foreign political parties and candidates for elected office,
  - and persons acting in an official capacity or on behalf of international organizations such as the World Bank or United Nations
- Examples include:
  - Employees at a Ministry of Health
  - Employees of a tendering agency
  - Doctors at government-operated hospitals, universities and clinics
  - A person working on behalf of any such government agency
  - Employees of the International Red Cross, WHO, and World Bank
  - Political Party Officials
  - Candidates for Political Office

Anti-Bribery Provisions

- FCPA violated even if:
  - Bribe paid through third party intermediaries*
  - Bribe resulted in no actual business
  - Bribe was authorized but not paid
  - Bribe was small or immaterial given amount of business awarded
  - Bribe involved excessive travel/hospitality/gifts
  - Bribe given to the friends or family of the foreign official
  - Bribe was charitable contribution that personally benefited official
  - Bribe was political contribution in exchange for official act (or inaction)
  - Bribe not proven but accounting violations shown (for public co's only)
- ***NOTE: Under willful blindness standard, FCPA liability may attach even if you lack actual knowledge of the bribes if you should have known bribes were being paid or if you were a control person.***

The Foreign Corrupt Practices Act (FCPA)

What is it, and why is it relevant internationally?

- The FCPA has a very broad reach in extraterritorial application
  - Domestic concerns: U.S. citizens and residents, wherever located; U.S. companies and entities with principal place of business in the U.S.
  - U.S. issuers: Publicly traded companies listed on U.S. stock exchanges or with SEC reporting requirements, including consolidated foreign subsidiaries
  - Foreign Persons: Foreign persons or companies acting in the U.S. (for example, having meetings in the U.S. to discuss prohibited conduct or using U.S. banks to transfer payments or profits)

FCPA Sanctions for Violations

- Over the last several years, companies have paid hundreds of millions in DOJ/SEC sanctions
  - Siemens (2008): $800 million
  - BAE Systems (2009): $400 million
  - Panalpina and related parties (2010): $226.5 million
  - Halliburton/KBR (2010): $579 million
  - Johnson & Johnson (2011): $78 million
- Individuals also have been prosecuted, and have been subject to increased prison sentences, disgorgement, and fines
  - Joel Esquenazi (Terra Telecom – Haiti): 180 months imprisonment
  - Charles Jumet (Ports Engineering Consultants Corp – Panama): 87 months imprisonment
  - Carlos Rodriguez (Terra Telecom – Haiti): 84 months imprisonment

Other Examples of Anti-Bribery Laws

- UK Bribery Act (2011)
- Inter-American Convention against Corruption (1997)
- Organisation for Economic Co-operation and Development (OECD) Anti-Bribery Convention (1997)
- Council of Europe Conventions on Corruption (1998)
- U.N. Convention against Corruption (2003)
- Local country Bribery and Anti-Corruption Laws

Some include bribery of private individuals as well as government officials

FCPA Enforcement Trends

- Significant increase in FCPA investigations by SEC and U.S. Justice Department with assignment of additional resources
- Aggressively enforced since 2004
- Increased targeting of individuals for prosecution
- Higher settlements and judgments in FCPA cases
- Use of aggressive investigatory tactics (*e.g.*, undercover agents, wiretaps, other covert surveillance)
- Industry-wide focus: When the U.S. Government looks at one company in an industry, it often follows with an industry-wide sweep
- Top enforcement priority for SEC and DOJ with financial sanctions of over $1 billion in 2010 and $650 million in 2011

FCPA Enforcement Trends

- Focus on Due Diligence
  - In advance of mergers and acquisitions
  - In connection with third party agents
- Focus on facilitation payments
- Global investigation cooperation
  - Leveraging U.S. resources
- FCPA Whistleblower program
  - Tips received globally
  - Whistleblowers will follow the money
    - Big dollar sanctions in FCPA cases
- SEC Cooperation program
  - Entices insiders to cooperate

FCPA Enforcement Trends

- Relaxing successor liability
  - Trend of requiring companies to integrate target companies into compliance programs in timely fashion rather than holding acquiring companies accountable for conduct of target
- Reconsidering the definition of a "foreign official"
  - Multiple cases pending in federal court are focusing on the definition of "federal official"; it is likely that the definition will be limited to private entities controlled by a foreign government by ownership or voting rights.
- Unlikely to see any reform with regards to a "compliance defense" like the UK Bribery Act or in the use of deferred prosecution agreements

Focus on Pharma

Lanny A. Breuer
Assistant Attorney General
Criminal Division

Prepared Keynote Address to
The Tenth Annual Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum
November 12, 2009

"I would like to share with you this morning one area of criminal enforcement that will be a focus for the Criminal Division in the months and years ahead – and that's the **application of the Foreign Corrupt Practices Act (or "FCPA") to the pharmaceutical industry.**

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Focus on Pharma

The Department of Justice sees Pharma as being at high risk for encountering corruption due to the nature of our business:

"According to PhRMA's 2009 Membership survey, close to $100 billion dollars, or **roughly one-third, of total sales for PhRMA members were generated outside of the United States…**.

…a typical U.S. pharmaceutical company that sells its products overseas will likely interact with foreign government officials on a fairly frequent and consistent basis."

http://www.justice.gov/criminal/pr/speeches/2009/11/11-12-09breuer-pharmaspeech.pdf

J&J FCPA and UK Bribery Act Settlements

April 2011

- Johnson & Johnson paid $70M and has a Deferred Prosecution Agreement (DPA) with enhanced compliance obligations to settle FCPA bribery allegations related to Greece, Poland, Romania, and Iraq
    - Also paid $8M to settle related charges under the UK Bribery Act
  - Reporting requirements to both SEC and DOJ at 6 month intervals
    - Status of remediation and implementation of compliance measures
    - Must also disclose to the DOJ any “credible evidence” of questionable payments or “transfers of value” and any problematic accounting issues

- Quote from the settlement: "J&J had a pre-existing compliance and ethics program that was **effective** and the majority of problematic operations globally resulted from insufficient implementation of the J&J compliance and ethics program in **acquired companies**."

Emphasis added

- Example allegation:
  - J&J Poland paid publicly-employed Polish HCPs purportedly for lecturing, leading workshops, and conducting clinical trials
  - J&J Poland did not require proof that the work was actually ever performed
  - From January 2000 until June 2006, govt alleges J&J actually paid the HCPs to corruptly induce those HCPs to favorably influence the purchase of J&J products

Pfizer FCPA Settlements

- In August 2012, Pfizer and 2 subsidiaries settled with the SEC and U.S. DOJ for $60.2 million for alleged violations of the FCPA
  - Pfizer admitted to no misconduct
  - Must appoint compliance heads for each of its business units and establish an executive compliance committee chaired by CEO
  - Must maintain a global investigations group to respond to corruption issues
  - Must submit follow-up reports on compliance
- *"Pfizer subsidiaries in several countries had bribery so entwined in their sales culture that they offered points and bonus programs to improperly reward foreign officials who proved to be their best customers*."-- Kara Brockmeyer, chief of the SEC's FCPA unit
- Pfizer H.C.P. Corporation, an indirect wholly owned subsidiary, agreed to $15 million criminal penalty in DOJ settlement with 2-year deferred prosecution agreement
  - Subsidiary accused of paying $2 million in bribes to hospital administrators, regulatory and purchasing committees and health care workers in Bulgaria, Croatia, Kazakhstan, and Russia
  - Used sham consulting contracts, improper cash and travel payments, and "exclusive distributorship" deals to influence the officials
  - Due to "extensive cooperation," base fine of $28.5 million reduced and no corporate monitor implemented
- Pfizer Inc. settled parallel case with SEC, where subsidiary employees were alleged to have bribed officials in Bulgaria, Croatia, Czech Republic, Italy, Kazakhstan, Russia, and Serbia
  - Bribes were improperly recorded as promotional activities, travel/entertainment, clinical trials, and other legitimate business expenses
  - Company to pay $16 million disgorgement and prejudgment interest of $10.3 million
- Wyeth LLC, entity acquired by Pfizer in 2009, charged by SEC for bribes to government doctors in China, Indonesia, and Pakistan, and for improper payments to customs officials in Saudi Arabia
  - Pfizer voluntarily disclosed improper payments following due-diligence review during acquisition
  - Wyeth agreed to disgorgement of $17.2 million and $1.7 million in prejudgment interest

Anti-Corruption Enforcement is International

UK/Greece/US	DePuy (J&J)	UK SFO and US DOJ
Germany	Siemens	Foreign Law Enforcement then DOJ
Germany	MAN	Coordinated raid of 40+ facilities
Sweden	Novo Nordisk	Foreign Law Enforcement
Switzerland	Alsto	French/Swiss law raid businesses and homes
Mexico	Syncor	Improper pmts to doctors/hospitals
Poland	Schering	Improper pmts to Health Fund Dir

BREAK

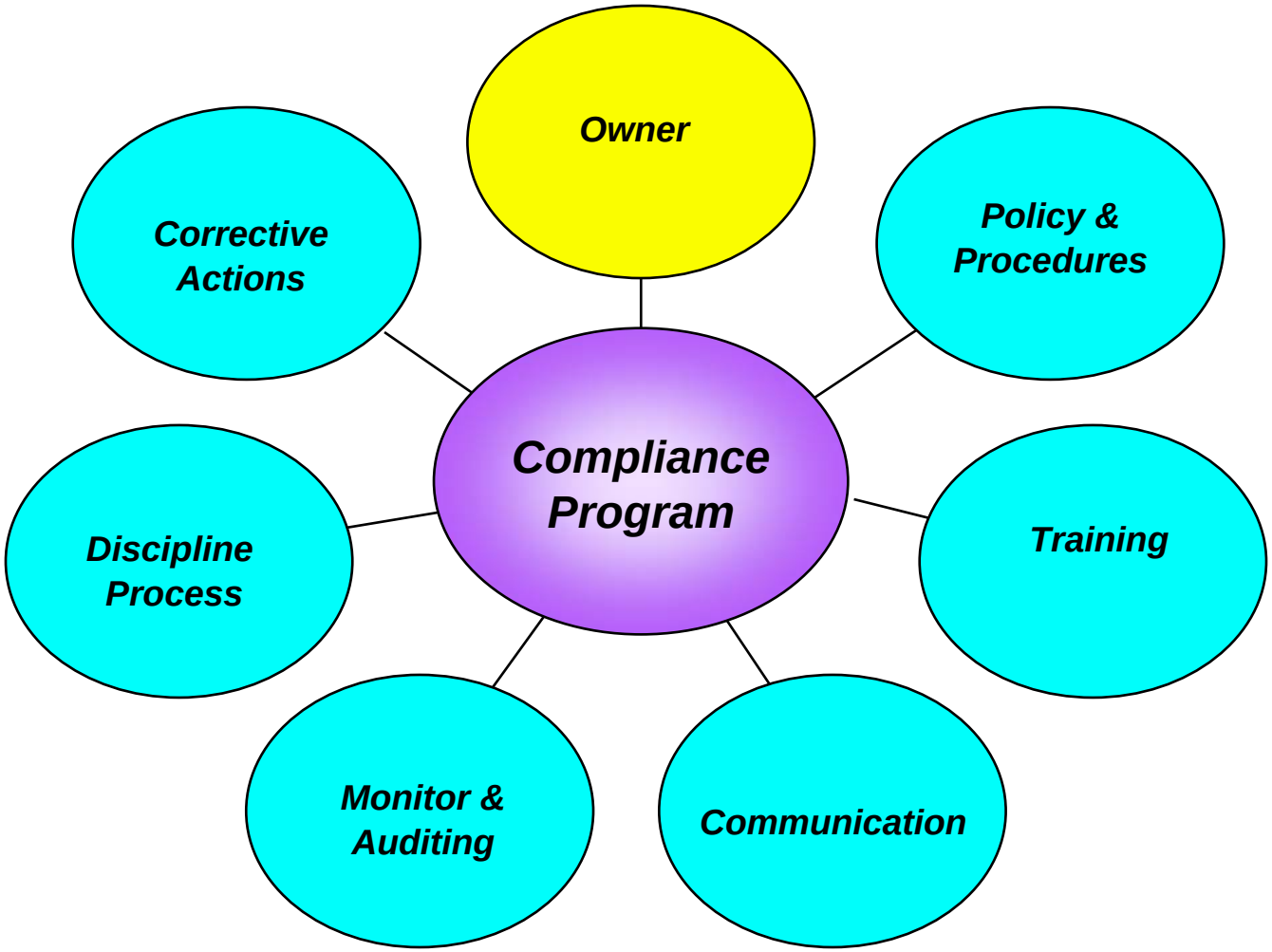
Elements of an Effective Compliance Program

Why is a Compliance Program Essential?

"All companies struggle with a fundamental challenge: the vast array of financial and legal rules that apply to their every activity. These rules are **voluminous**, **multifaceted**, **ambiguous in interpretation and uncertain in application**. I was frankly stunned when I began my tenure at GE in 1987 and began to get a sense of the complexity the company faced… The problems of complexity, ambiguity, uncertainty and mutual inconsistency are multiplied a hundredfold in a multinational company like GE, which is subject not only to international law, but also to the laws of more than one hundred nations."*

- Ben W. Heineman, former General Counsel of GE and author of *"High Performance with High Integrity" *pp.37-38*

Seven Elements of a Compliance Program



Owner

Compliance Officer

- Senior leader reporting to President or CEO and Board with access to Legal Counsel

Compliance Committee

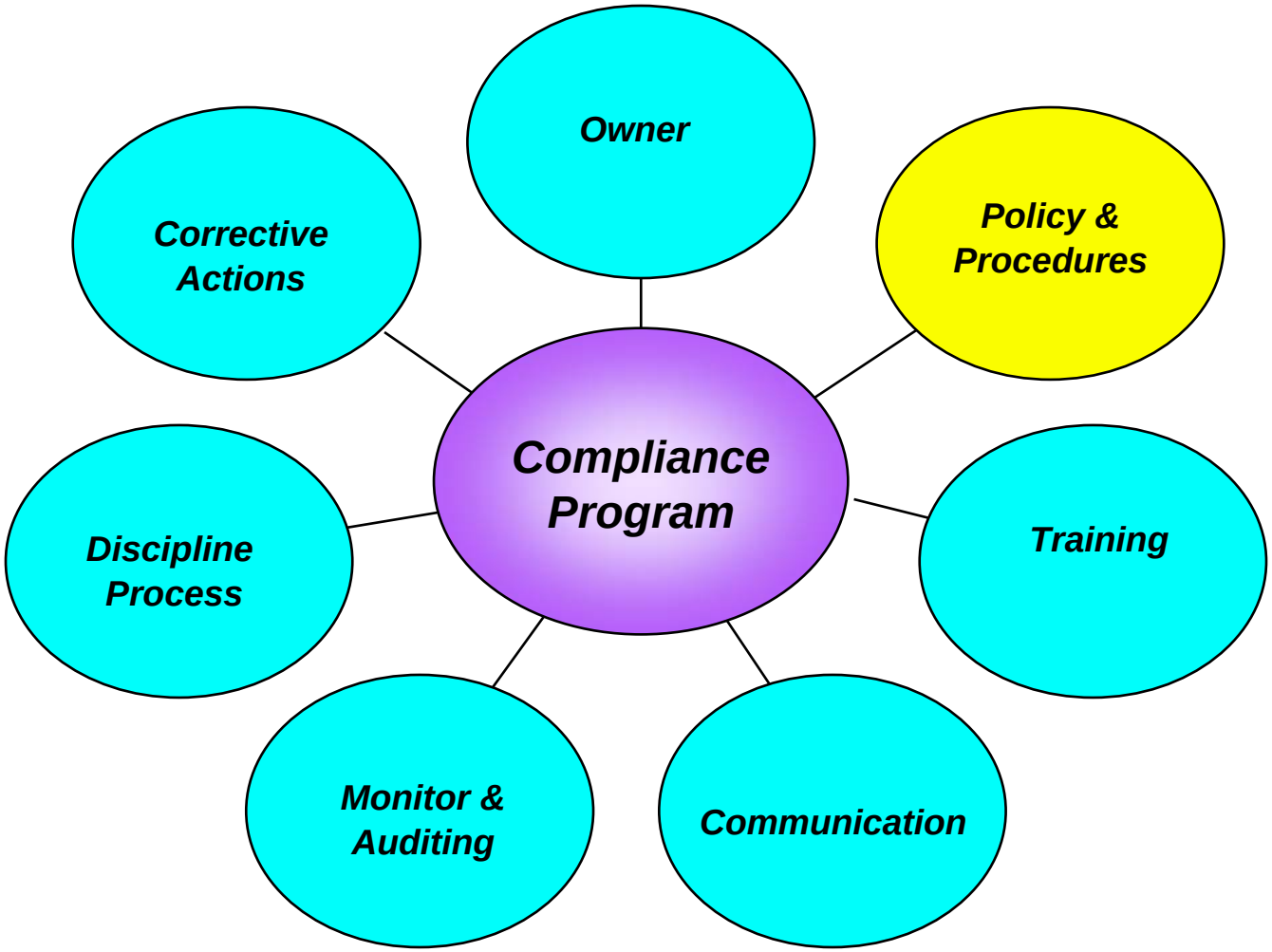
- Support the Compliance Officer
- Senior Leaders
- Set the tone and guide the program

Success of the program depends on the “Tone at the Top”

- Consistent, Frequent Demonstration of Senior Leadership Commitment
  - Personal Integrity that Walks the Talk
- CIA requirements
  - Board of Directors resolution
  - Compliance Officer and Management Certifications

Compliance Program Elements: Training, Policies, Communications

Seven Elements of a Compliance Program



Identify the RISK AREAS

- Promotional Materials
- Sales Personnel
- Medical Information
- Medical Science Liaisons
- Publications
- Press Releases
- Educational Grants/CME
- Charitable Contributions
- Clinical Trial Services
- Clinical Research Grants and Activities
- Product Support Services
- Preceptorships
- Advisory Boards / Consulting
- Speaker Programs and Speaker Training
- Formulary Committees
- PBMs, GPOs, Payers
- Pricing and Discounts
- Coupons
- Exhibit Booths
- Symposia
- Honoraria and Expense Reimbursement
- Call Plans
- Disciplinary actions
- Ineligible Persons
- Off-label Promotion
- False or Misleading Statements Re Efficacy or Safety of Product
- Kickbacks
- Switching
- Unsolicited Requests
- Access Fees
- Value-added Services
- Contracts and Rebates
- Integrity of Price Reporting Data
- Samples and Sample plans
- Sales Force compensation
- Educational Items
- Business Meals
- Nominally Priced Drugs
- Patient Privacy
- Adverse Event Reporting
- Ghost-writing
- Conflicts of Interest
- Compendia
- Patient Advocacy Organizations
- Vendors acting on your behalf
- Market Research
- Fee-for-Service Arrangements
- Post-marketing Research and Investigator-sponsored studies

WORDS MONEY PRIVACY

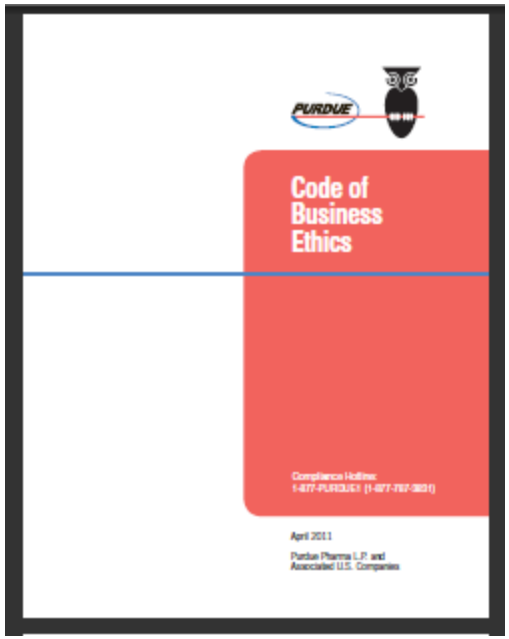
Policies and Procedures

Company Code of Conduct

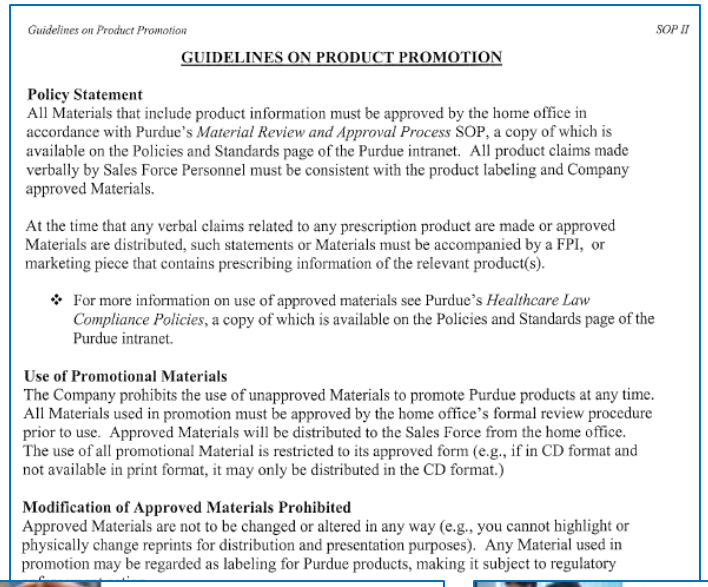
- Many companies are posted on the web
  - http://www.purduepharma.com/wp-content/pdfs/CBE.pdf
- Address key business areas and legal/regulatory risks
- Articulates our ethics and compliance expectations
- Keep it Principle-based

Departmental Policies and Procedures

- Policies are the **What's**
- Procedures are the **How's**
- Translate "legalese" into everyday language
- Order procedural steps in sequence
- Controlled process for managing exceptions



Standards of Conduct & Procedures



Guidelines on Product Promotion SOP II

GUIDELINES ON PRODUCT PROMOTION

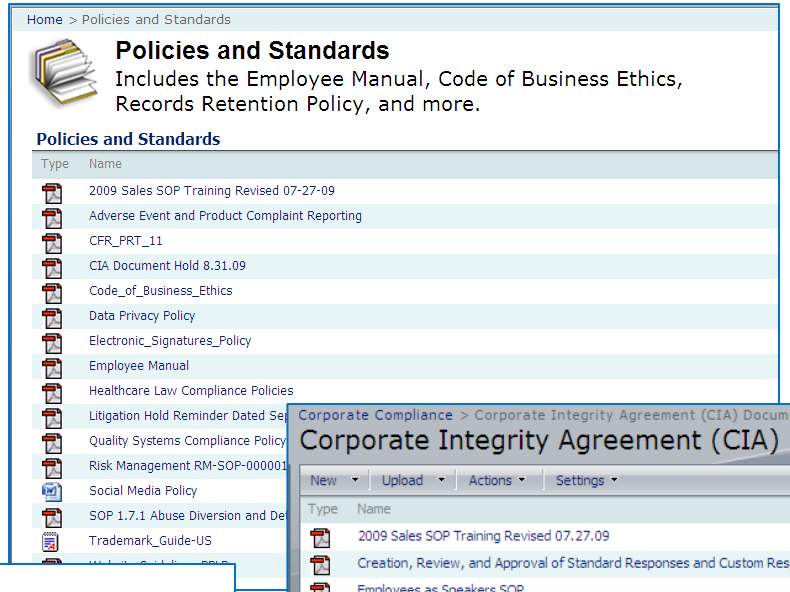
Policy Statement
All Materials that include product information must be approved by the home office in accordance with Purdue's *Material Review and Approval Process* SOP, a copy of which is available on the Policies and Standards page of the Purdue intranet. All product claims made verbally by Sales Force Personnel must be consistent with the product labeling and Company approved Materials.

At the time that any verbal claims related to any prescription product are made or approved Materials are distributed, such statements or Materials must be accompanied by a FPI, or marketing piece that contains prescribing information of the relevant product(s).

- For more information on use of approved materials see Purdue's *Healthcare Law Compliance Policies*, a copy of which is available on the Policies and Standards page of the Purdue intranet.

Use of Promotional Materials
The Company prohibits the use of unapproved Materials to promote Purdue products at any time. All Materials used in promotion must be approved by the home office's formal review procedure prior to use. Approved Materials will be distributed to the Sales Force from the home office. The use of all promotional Material is restricted to its approved form (e.g., if in CD format and not available in print format, it may only be distributed in the CD format.)

Modification of Approved Materials Prohibited
Approved Materials are not to be changed or altered in any way (e.g., you cannot highlight or physically change reprints for distribution and presentation purposes). Any Material used in promotion may be regarded as labeling for Purdue products, making it subject to regulatory

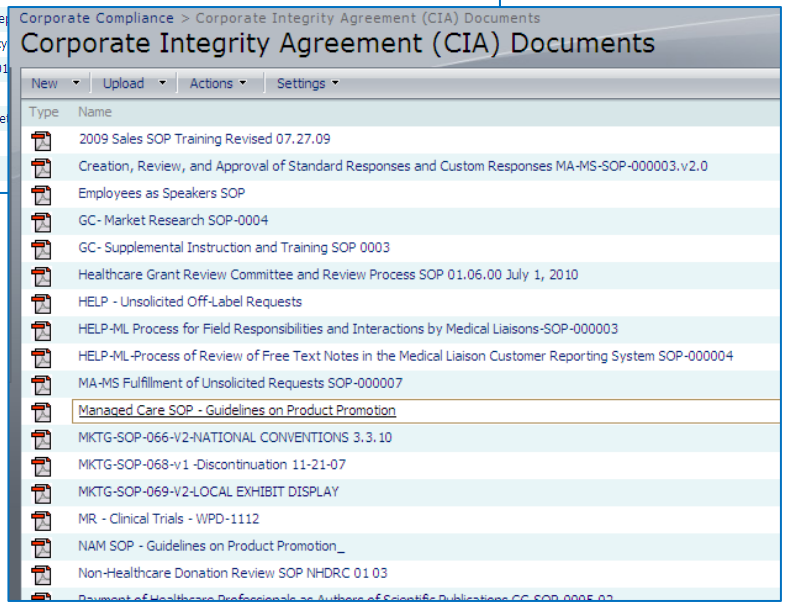


Home > Policies and Standards

Policies and Standards
Includes the Employee Manual, Code of Business Ethics, Records Retention Policy, and more.

Policies and Standards

Type	Name
	2009 Sales SOP Training Revised 07-27-09
	Adverse Event and Product Complaint Reporting
	CFR_PRT_11
	CIA Document Hold 8.31.09
	Code_of_Business_Ethics
	Data Privacy Policy
	Electronic_Signatures_Policy
	Employee Manual
	Healthcare Law Compliance Policies
	Litigation Hold Reminder Dated Se
	Quality Systems Compliance Policy
	Risk Management RM-SOP-000001
	Social Media Policy
	SOP 1.7.1 Abuse Diversion and De
	Trademark_Guide-US

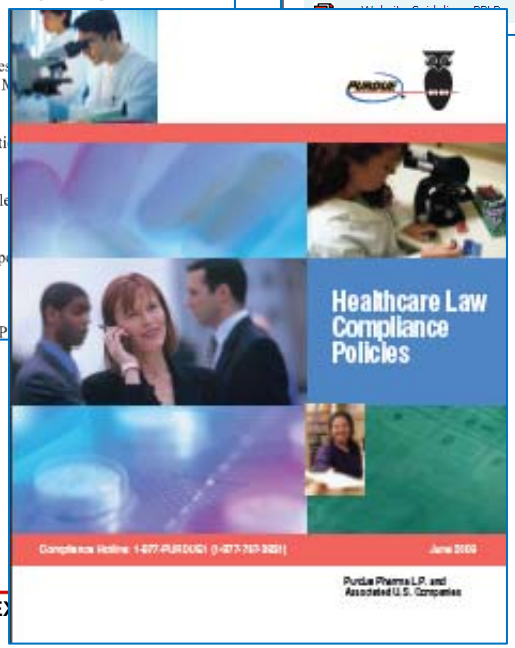


Corporate Compliance > Corporate Integrity Agreement (CIA) Documents

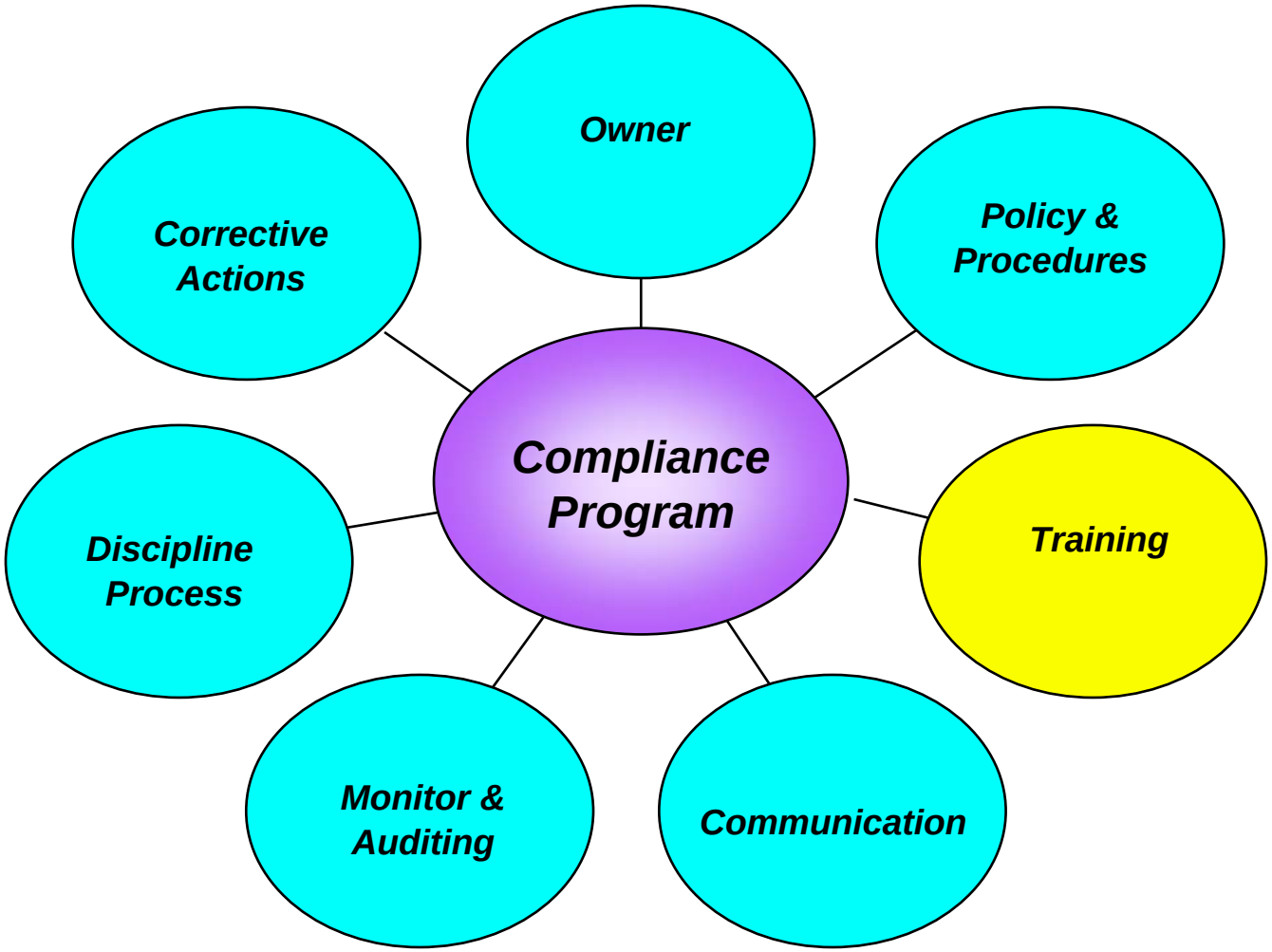
Corporate Integrity Agreement (CIA) Documents

New | Upload | Actions | Settings

Type	Name
	2009 Sales SOP Training Revised 07.27.09
	Creation, Review, and Approval of Standard Responses and Custom Responses MA-MS-SOP-000003.v2.0
	Employees as Speakers SOP
	GC- Market Research SOP-0004
	GC- Supplemental Instruction and Training SOP 0003
	Healthcare Grant Review Committee and Review Process SOP 01.06.00 July 1, 2010
	HELP - Unsolicited Off-Label Requests
	HELP-ML Process for Field Responsibilities and Interactions by Medical Liaisons-SOP-000003
	HELP-ML-Process of Review of Free Text Notes in the Medical Liaison Customer Reporting System SOP-000004
	MA-MS Fulfillment of Unsolicited Requests SOP-000007
	Managed Care SOP - Guidelines on Product Promotion
	MKTG-SOP-066-V2-NATIONAL CONVENTIONS 3.3.10
	MKTG-SOP-068-v1 -Discontinuation 11-21-07
	MKTG-SOP-069-V2-LOCAL EXHIBIT DISPLAY
	MR - Clinical Trials - WPD-1112
	NAM SOP - Guidelines on Product Promotion_
	Non-Healthcare Donation Review SOP NHDRC 01 03



Seven Elements of a Compliance Program



Training

It has to be documented but it needs to be more than just “checking the box”

- Impact and Retention
- Behaviors

It’s about the Learner’s needs

- Learning styles
- Engaging
- Management training

Reinforcing good behaviors or implementing new ones

Explain the “whys” behind the rules

- Understanding “Why” fosters compliance in new situations
- Explain where policies come from (laws, regulations, codes)

Give a man a fish; you have fed him for today.
Teach a man to fish; and you have fed him for a lifetime.

Compliance Training Development

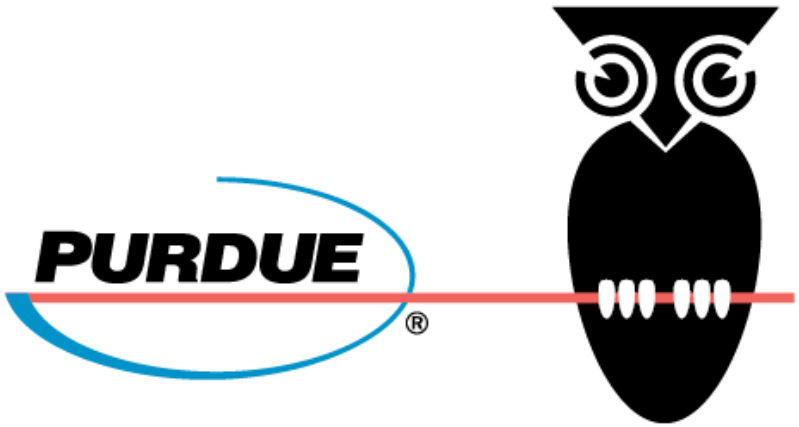
It needs to be a partnership between Compliance and the Training Dept.

- Compliance personnel are the Subject Matter Experts
- Training Personnel are the Experts on Training

Use adult learning principles

- Tell them, and tell them the WIFM (What's in it for me?)
- Develop Practical Scenarios and Case Studies
- Use a range of training formats
  - Self-study
    - Read the local Policies and Procedures
    - Computer-Based courses
  - Group sessions
    - Live sessions with a trainer
    - Video or DVD presentation with group discussion

Online Workplace Learning = OWL



OWL training includes:

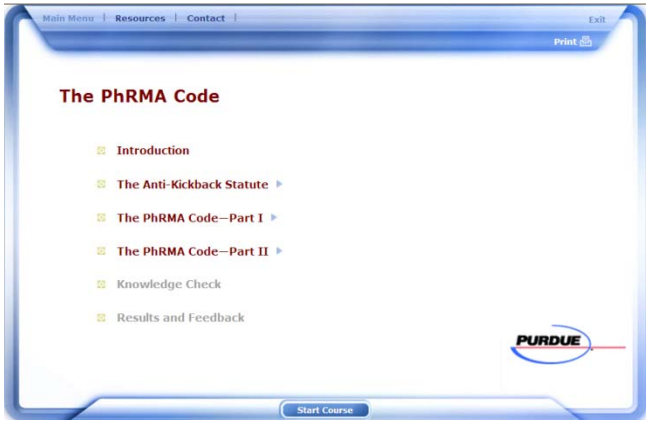
Purdue's Code of Business Ethics, Healthcare Law Compliance Policies, Purdue's CIA, Adverse Events & Product Complaints, PhRMA Code, Preventing Workplace Harassment, Antitrust, Careful Communication, Ethical Leadership and Conflicts of Interest

CIA-Required OWL Training Modules

Code of Ethics
– 1 hour

Healthcare Law Compliance Policies
Part 1 – 1 hour

Healthcare Law Compliance Policies
Part 2 – 1 hour



PhRMA Code
– 1 hour

Corporate Integrity Agreement
– 1 hour

Adverse Events, Product Complaints
~15 minutes

Live Training Sessions – In House

- All new sales and marketing staff participate in live training sessions on HCLC Policies.

- These training sessions address laws and regulations of the FDA, CMS, and other regulatory agencies.

- Trainers are evaluated by participants

Level	Attendees	Content	Training Dates
100	New Sales Representatives	(1) HCLC Policies - standard slide deck and hand out folder; (2) Scenarios	September 27 and 30, October 18-29, November 8-19
150	Sales Representatives with 6-9 months experience	Snowball Fight	November 2-5
200	Sales Representatives with approx. 24 months experience	Start with Snowball Fight, finish with Gladiators	November 4
300	Sales Representatives with 3+ years experience	Gladiators; last 15 minutes = scenario development in teams	October 14
400	Sales Representatives with ?+ years experience	Discussion and Gladiators	November 15-19 (cancelled)
500	District Field Trainers - 1 per district	In Development	November 3
600	New DMS, Part I	Phoenix/Compliance Training to include: Call Note Review and Annotation, Field Contact Reports, etc. (see below)	October 18-19, November 15-18
610	New DMs, Part II	General Compliance Background; FCRs, Ride Alongs, Call Note Review, Call Annotations - Part II	
620	New DMs, Part III	Gladiators	
710	SMBA with focus on Coaching, Hiring & Recruiting	Current issues in compliance world; key points, Gladiator	November 8-11
720	SMBA with focus on Communication Skills	Current issues in compliance world; key points, Gladiator	
730	SMBA with focus on Business Acumen	Current issues in compliance world; key points, Gladiator	October 25-28

Level 200 Sales Development Class Speaker Evaluations

November 2 - 6, 2009

Rating Scale:

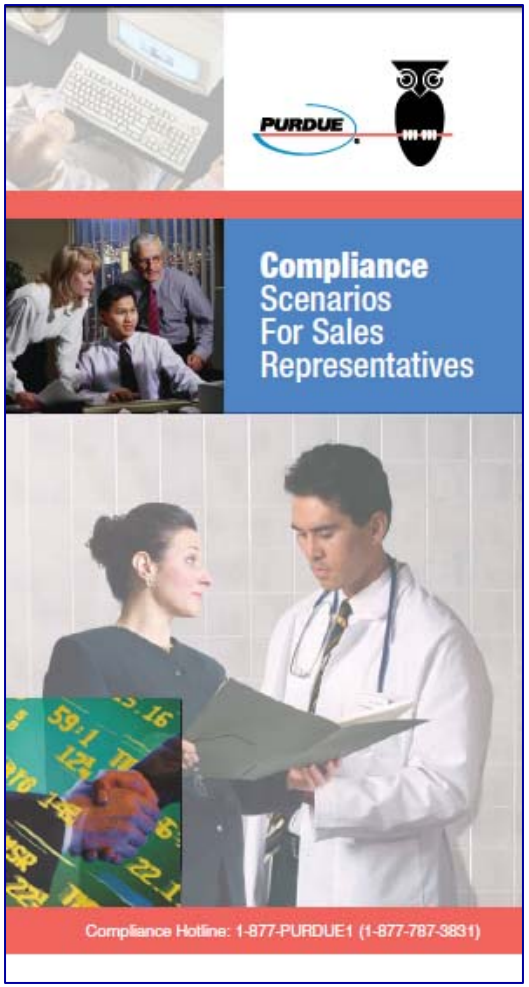
Rating: 1 = Poor; 2 = Fair; 3 = Average; 4 = Good; 5 = Excellent

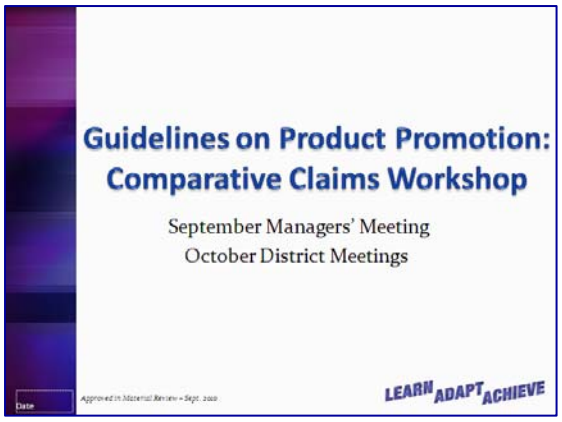
*** Comments are required for a rating of less than 3.**

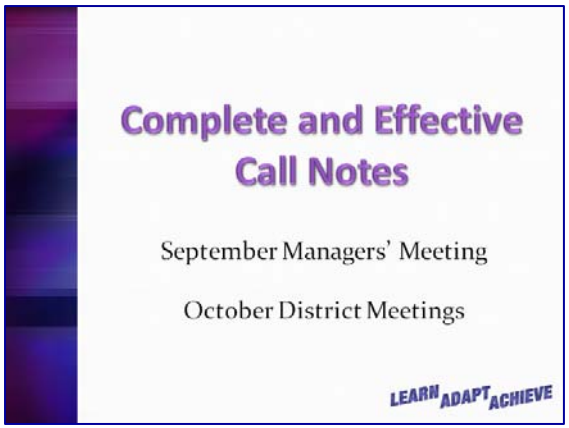
Presentation/Speaker(s)	Rating for Speaker Delivery	Rating for Presentation Content	* Comments
Healthcare Compliance *Maggie Feltz*	**4.8**	**4.8**	Fun exercise, very real world info. Like snowball method to start activity.

Compliance Training In the Field

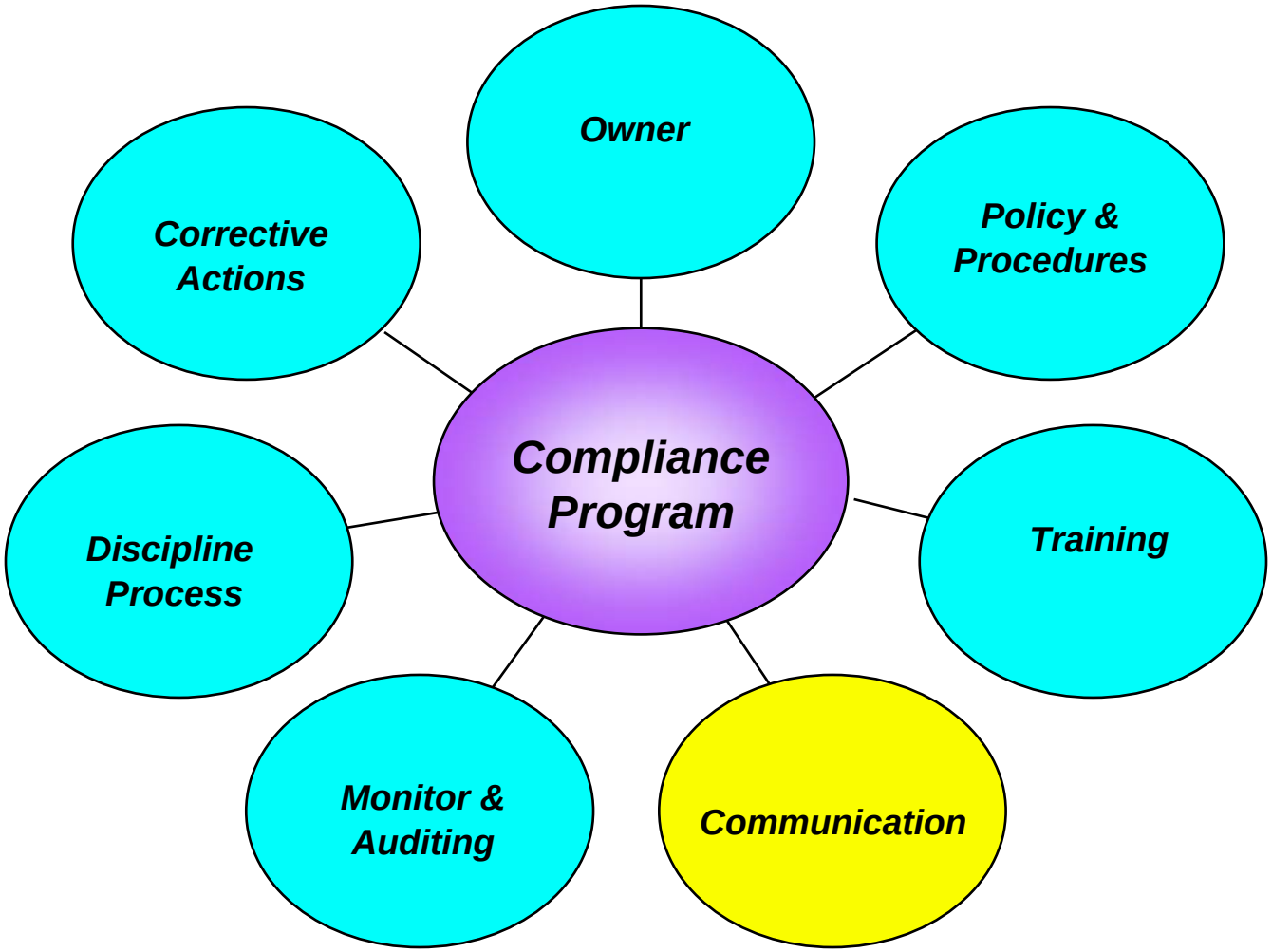
- Significant live compliance training is conducted in the home office and the field:
  - Regional and District Meetings
  - Manager Meetings
  - National Sales Meetings
  - Ride-alongs
- Training is also conducted by Sales Trainers, District and Regional Field Trainers, and by DMs and RDs. This helps to make Sales “owners” of compliance.







Seven Elements of a Compliance Program



Communications

Vehicles to identify risks or potential violations

- Hotline or other mechanism
  - For reporting of potential violations
  - Assure broad awareness (newsletters, posters, wallet cards)
  - Allow option of anonymous reporting
  - Non-retaliation policy for good-faith reporting
  - Use by International employees – Understand local law considerations
  - Use by External parties (HCPs, consumers)
- Surveys
- Exit Interviews

Communications

Provide resources for questions, guidance, best practices

- 1-800 number to reach compliance team
- Intranet Website
- E-mail
- Conference calls
- Compliance Liaisons – local department experts
- Purdue's Vice Presidents' Compliance Council

Create opportunities for dialogue

- Attend meetings – and stay for breaks and meals
- Attend trainings
- Routinely scheduled interactions
  - Coffee or Lunch with business partners
  - Rides with Reps, MLs

Communications

- Purdue maintains a 24 hour toll-free confidential Ethics and Compliance Hotline with “The Network,” a third party vendor
  - Callers may remain anonymous
  - Every matter is logged into our tracking system, no matter how important (or not)
  - Electronic files of every matter are maintained in track system
  - Disclosure Log - reviewed at weekly team meetings, by Law Department, others
- Purdue policy expressly prohibits retaliation or retribution against any employee for making a good faith report of suspected misconduct or improper behavior
- We regularly publicize our compliance program and our Disclosure Program through training, presentations, e-mails, posters, Purdue’s newsletter, and other items

Consultations

A major part of your role

Be the **Advisor**, not the **Approver**

- They know their business
- They might not give you all the facts
- The business must retain accountability

Help them understand **WHY**, so they can apply to new but similar situations without your assistance

Sample Publicity Materials

Just as a reminder: To raise any ethical concerns or to report any suspected violations of law, regulations, or Purdue policy, you may contact Bert Weinstein, Vice President, Corporate Compliance, at (203) 588-8288, any attorney in the Office of General Counsel, the Human Resources Department, your supervisor, or the Company's Ethics and Compliance Hotline toll free, 24 hours a day. Callers may choose to remain anonymous and will be protected from retaliation in any form.

ETHICS & COMPLIANCE HOTLINE

1-877-PURDUE1
(1-877-787-3831)

PURDUE

ANONYMOUS 24/7

The Purdue Ethics & Compliance Hotline

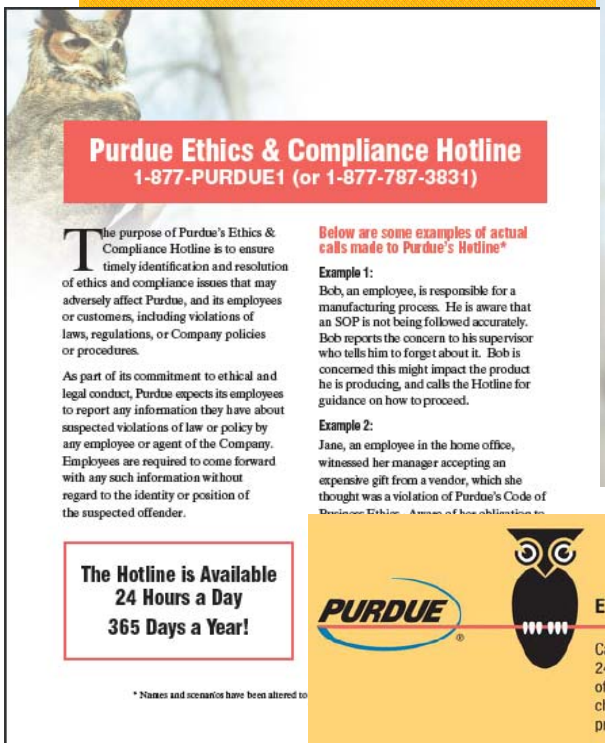
Report suspected **ethics concerns** or **violations of laws, regulations or Purdue policy** to the toll-free hotline.

Report Concerns:
- 24 Hours a Day
- Anonymously, If You Choose
- Without Retaliation or Retribution

Your Call Matters

1-877-PURDUE1
(787-3831)

Si Usted habla español, por favor llama



Purdue Ethics & Compliance Hotline
1-877-PURDUE1 (or 1-877-787-3831)

The purpose of Purdue's Ethics & Compliance Hotline is to ensure timely identification and resolution of ethics and compliance issues that may adversely affect Purdue, and its employees or customers, including violations of laws, regulations, or Company policies or procedures.

As part of its commitment to ethical and legal conduct, Purdue expects its employees to report any information they have about suspected violations of law or policy by any employee or agent of the Company. Employees are required to come forward with any such information without regard to the identity or position of the suspected offender.

Below are some examples of actual calls made to Purdue's Hotline*

Example 1:
Bob, an employee, is responsible for a manufacturing process. He is aware that an SOP is not being followed accurately. Bob reports the concern to his supervisor who tells him to forget about it. Bob is concerned this might impact the product he is producing, and calls the Hotline for guidance on how to proceed.

Example 2:
Jane, an employee in the home office, witnessed her manager accepting an expensive gift from a vendor, which she thought was a violation of Purdue's Code of

The Hotline is Available 24 Hours a Day 365 Days a Year!

* Names and scenarios have been altered to

PURDUE

ETHICS AND COMPLIANCE HOTLINE

Call **1-877-PURDUE1** (1-877-787-3831) toll free, 24 hours a day, to report any suspected violations of ethics, law, or Purdue policy. Callers may choose to remain anonymous and will be protected from retaliation in any form.

The OWL's Nest

Creating an Environment Supporting Compliant and Ethical Behavior

The Corporate Compliance department is growing, and its newest members – Anna Boccuzzi, Greg D'Onofrio, and Rore Middleton – recently sat down to reflect on their new roles and what it means to be a part of the Compliance team.

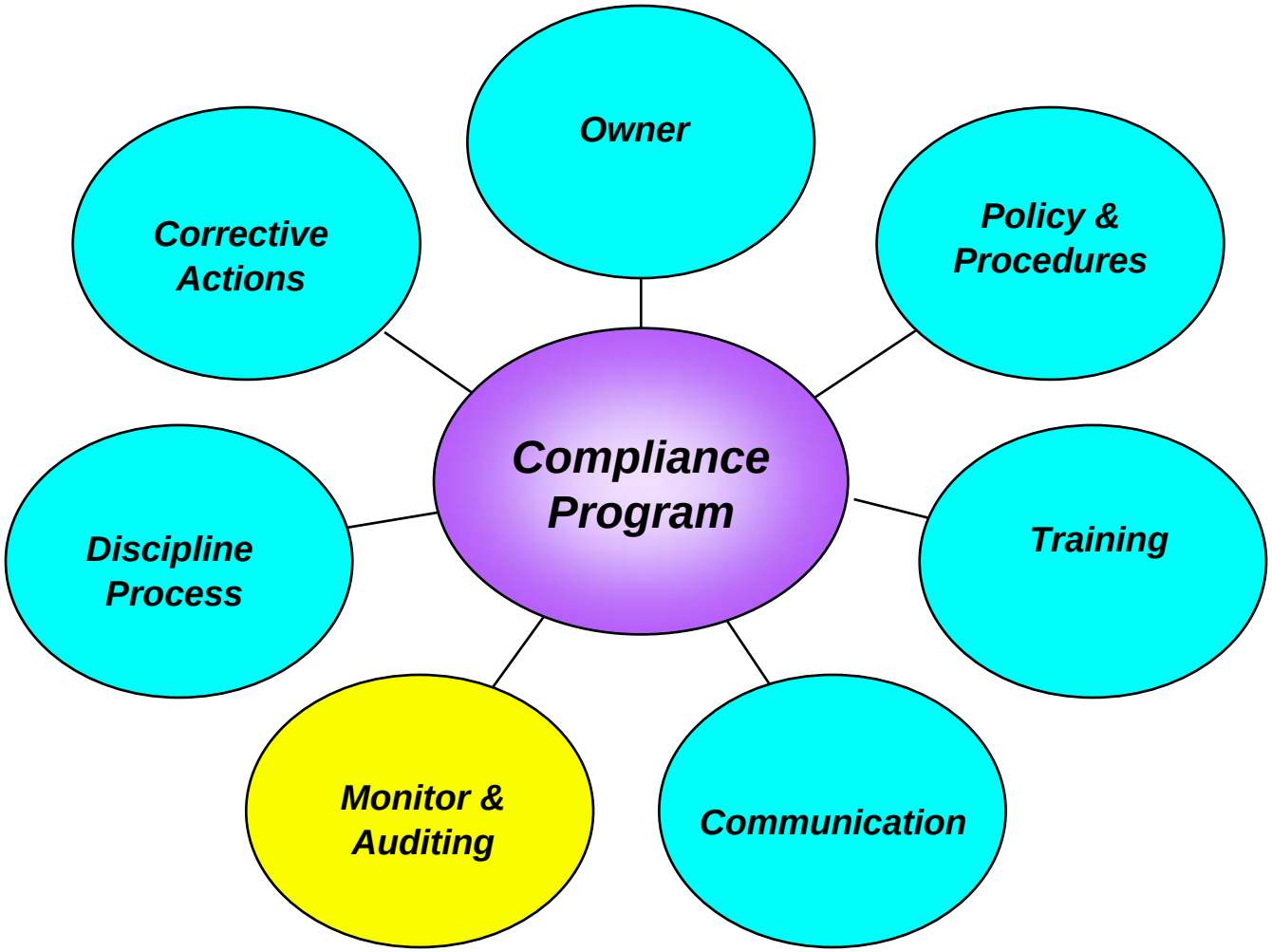
Compliance Program Elements: Auditing & Monitoring

Considerations for Monitoring and Auditing in a Compliance Program

Kelly B. Freeman, Ph.D.
Ethics and Compliance Officer

Lilly
Answers That Matter.

Seven Elements of a Compliance Program



Monitoring vs. Auditing

Monitoring

- Conducted by personnel affiliated with Compliance Program
- Broad sample of activities
- Part of on-going, continuous improvement process

Auditing

- Independent personnel - whether internal or external
- Focused engagements
- Report findings for management action plans

Different but Complementary Processes

Benefits of Monitoring and Auditing

Assure compliance with policies

- Document that policies are being followed
- If they aren't, you want to find it and fix it yourself

Feedback loop on effectiveness of other program elements

- Policy Language
- Training
- Communication programs

Foster relationships with business partners

- Putting a face with the compliance program
- Opportunities to coach and share the learning
- Opportunities to understand business challenges
- It's not an "ivory tower" compliance program

Considerations for Designing A Monitoring Program

Voluntary or mandatory?

-Corporate integrity agreements

Internal or external?

-Resources to execute it (people/money)

-Independence

Direct observations or indirect?

-Complementary reviews for certain activities

Scope: Promotional or beyond?

-Sales, Marketing, R&D, Medical, Corporate Affairs, etc.

Coordination with Audit activities

Monitoring Plans

Live Event Monitoring and Record Reviews

- Number should reflect volume of business activities
- Assure coverage across risk areas, business units, and brands
- Use Risk-based approach to sampling for selection of events

Non-promotional Activities included in CIAs

- Consultant arrangements
- Research arrangements
  including Investigator-sponsored studies
- Publications
  - Authorship
  - Scope of disclosures
- Medical Education Grants
- Ride-alongs with Field Medical personnel

Monitoring Plans

Field Force Monitoring included in CIAs

- Rep Ride-alongs
- Speaker Programs
- Record Reviews
  - Expense reports
  - Sample records
  - Medical Information requests
  - Preceptorships/Tutorials
  - Promotional Materials
  - Call notes
  - E-mail
  - Manager coaching notes
  - Message recall studies

Monitoring Process

Protocols and checklists directly from policies

- "Open book" test

Unpredictable notification for live events

Compliance reviews are unique from traditional financial or GXP auditing

- Intent, content, and context are as important as following procedures

Document what is going well

Investigate any findings and do a root cause analysis

- An isolated finding or an indicator of broader issues?

Take corrective actions as appropriate

- Disciplinary action
- Adjust policy and/or training to provide clarity and consistency
- Document corrective action

Sales Rep Ride-along

Selected by Compliance Department

Observations

- Current promotional materials and package inserts
- Interactions with customers
- Adverse event and product complaint reporting
- Sampling
- State requirements, e.g. Vermont price disclosure, state payment reporting

Assess rep's knowledge of policies

- Opportunity to answer their questions
- Feedback loop for improving training program

Opportunity to Explain the Benefits of the Compliance Program

- Enhanced relationships with Field personnel

Speaker Programs

Observations

- Invitations
- Venue
- Business Meal policies
- Appropriate Attendees
- Presentation
  - Speaker statements
  - Were all mandatory slides used?
  - Proactive presentation was on-label
  - Fair balance safety information was presented
  - Proper handling of unsolicited questions
- Current package insert and promotional materials
- Educational Items
- Honoraria and expenses
- Sales rep activities and certification

Payment Reviews

Observations:

- Ability to locate records
- Financial transactions
- Business case for services
- Selection criteria for the service provider
- Approvals
- OUS – Anti-corruption due diligence
- Fair market value
- Contracts executed before work begins
- Documentation of services received
- Payment matches services provided

Monitoring Results

Integrate Partnership with the Business

- Provide on-going Dashboard metrics for Business units

Compile quarterly and annual monitoring results for Senior Management Reviews

Look for trends and patterns

- Use as feedback loop for training and policy adjustment
- Findings may identify need for in-depth audit

Other things you need to consider:

How do you apply your Compliance Program:

- To Third Parties who are acting on your behalf
  - Vendors
  - Contract Sales Forces
  - Contracted HCPs – Speakers
- To Joint Ventures
- To Mergers and Acquisitions
  - Due Diligence
  - Integration
- In a Global Multi-National Company
  - International Laws

Case Study

Sofia, a sales rep in Fargo, has heard that her company is working on a Fair Market Value analysis for physician speaker payments. She wants to be sure that the new rates won't put her at a disadvantage as compared to her competitors. The sales reps in the area have created a group page on Facebook where they share information about things like the doctors' office hours, rep rules, etc. She posts a message asking everyone to share how much each company pays physicians to do a speaker program. Since it's supposed to be fair market value, she thinks this is a great way to be sure the rates really are fair.

What considerations does this situation raise for you as a Compliance Officer?

Case Study

Do you have a policy on Social Media?

Do you have a policy on Interacting with Competitors?

Do you have a policy on Confidential Company Information?

Is there an appropriate way to do benchmarking?

Would you provide Training on these topics?

Are you able to do Monitoring to detect this activity?

If you discovered this situation, what would you consider for corrective action?

A. What if Sofia “self-reported” because she called to share the rates she got with you to “help with the company’s FMV analysis” ?

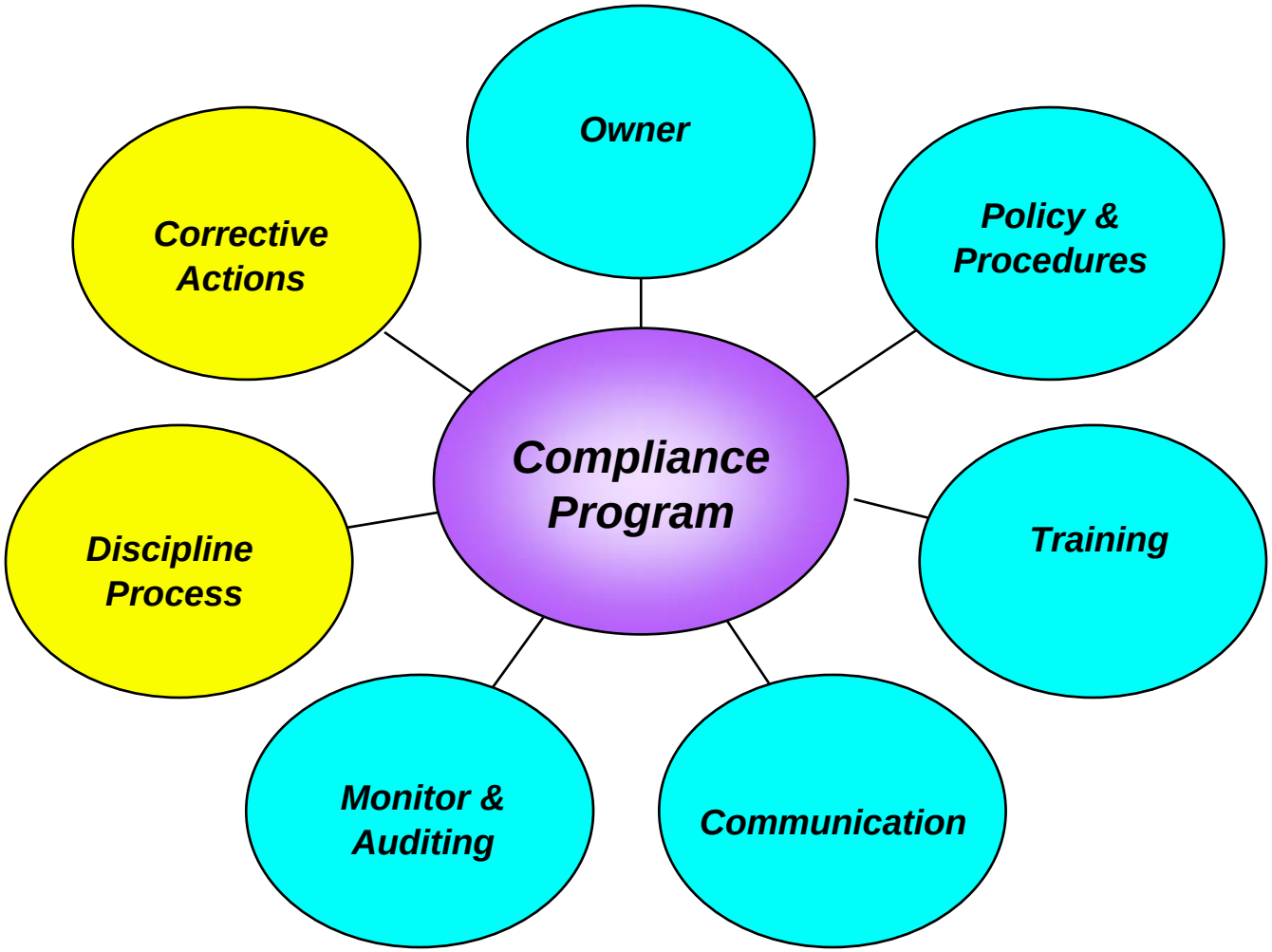
B. What if it was reported to you anonymously through your hotline?

What do you think about the role of Sofia’s management?

Compliance Program Elements: Investigations & Remedial Actions

GARY'S SLIDES HERE

Seven Elements of a Compliance Program



Discipline Process

- OIG Guidance for Pharmaceutical Manufacturers
  - " A pharmaceutical manufacturer should consistently undertake appropriate disciplinary action across the company in order for the disciplinary policy to have the required deterrent effect. Intentional and material noncompliance should subject transgressors to significant sanctions."
  - " Disciplinary action also may be appropriate where a reasonable employee's failure to detect a violation is attributable to his or her negligence or reckless conduct."
  - " Each situation must be considered on a case-by-case basis, taking into account all relevant factors, to determine the appropriate response."

Disciplinary Process

Clear disciplinary policies setting out consequences of violating the law, regulations, or company policies

Consequences for management failure to detect

Roles of Human Resources and Line Management

Each situation must be considered on a case-by-case basis with all relevant facts

Corrective Actions

OIG Guidance for Pharmaceutical Manufacturers

- Expectation for “responding promptly to detected problems and undertaking corrective actions.”
- “Upon receipt of reasonable indications of suspected noncompliance, it is important that the compliance officer or other management officials immediately investigate the allegations to determine whether a material violation of applicable law or the requirements of the compliance program has occurred, and, if so, take decisive steps to correct the problem.”
- “Detected but uncorrected misconduct can endanger the reputation and legal status of the company.”

- **It’s not “bad” to find issues; it’s bad to find an issue and not correct it**
- **Corrective actions are intended to prevent future issues**
  - **Even if discipline was deemed necessary**

Corrective Action

"Learn and Grow"

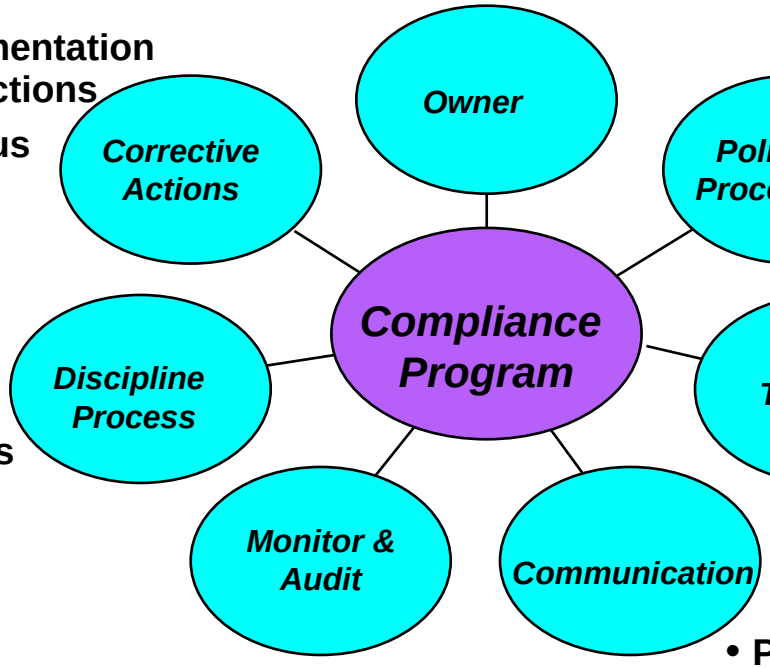
Does it require reporting to the government or law enforcement?

- CIA Reportable Events

Do you understand the root cause?

How do you make sure it doesn't happen again?

Seven Elements of a Compliance Program



- Ownership by Business
- Support from E&C
- Influence external environment

- Track trends
- Support implementation of corrective actions
- Seek Continuous Improvement

- Watch for external environment changes
- Develop and maintain policies

- Partner with HR and mgmt
- Investigate potential violations
- Promote accountability

- E&C provides Subject Matter Experts (SMEs)
- Business implements training program

- Monitor key risk areas
- Conduct assessments
- Coordinate with Audits

- Provide ways to report violations
- Answer questions on policies
- Share best practices
- Solicit feedback

Other things you need to consider:

How do you apply your Compliance Program:

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  - Contract Sales Forces
  - Contracted HCPs – Speakers
- To Joint Ventures
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