# Examining the Latest Developments in Drug and Device CIAs
# How Corporate Integrity Agreements Continue to
# Reshape Compliance

National Pharma Audioconference

August 12, 2010

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# Agenda

- Creating a Culture of Compliance
- Bayer HealthCare ("BHC") November 2008 Corporate Integrity Agreement ("CIA")
- Implementation of the CIA's Requirements
- Focus Arrangements Database
- Compliance Expert Panel
- Management Certifications

# Why Do We Need Corporate Compliance?

- Breaking the law can have far-reaching consequences for the company and its employees

- Careless or improper actions of just one employee can instantly harm the company's reputation

- Each employee is obligated to obey all applicable laws and corporate guidelines in his or her work for the company

- By systematically implementing a Corporate Compliance Program, the company shows its employees, business partners, investors, competitors, and the authorities that compliance is an integral part of its corporate culture

# Key Compliance Objectives

- Embed compliance as a fundamental business operating principle

- Promote correlation between high integrity and high performance

- Avoid compliance failures so that business can be conducted in a sustainable fashion

  - Especially those compliance failures that could result in material risk to the business

# Compliance Focus

- Current enforcement environment requires a focus on three fundamental elements as part of a compliance program

    - Identification of the compliance risk

    - Response

    - Responsibility

- Approach:

    - Accessing knowledge and expertise embedded in the organization

    - Strengthening controls and oversight

    - Increasing: (1) individual understanding of controls and reasons for them; (2) accountability and consequences; and, (3) training effectiveness

    - Integrate compliance awareness and sensibility into business processes

    - Establish awareness for follow-up action

# BHC Compliance Department – Major Roles and <u>Responsibilities</u>

- Act as primary source for interpretation of the requirements of the CIA

- Draft, issue and update BHC Compliance Policies and Procedures

- Draft and issue BHC Code of Conduct

- Develop and provide CIA required training

- Develop and implement monitoring/auditing plans, as well as apply internal and external resources sufficient to not only to address CIA requirements but also to seek to avoid future compliance failures

- Develop consistent responses across BHC to violations of Compliance Policies and Procedures and identify trends that require additional training or procedures

- Develop and maintain the Focus Arrangements Database structure, software and necessary business processes

- Act as primary BHC interface with the Office of Inspector General

- Chair and lead the BHC Compliance Committee

- Assist in BHC risk management and risk assessment programs

- Monitor compliance enforcement environment and advise and update BHC Law & Patents Department and BHC management

- Advise BHC with regard to risks associated with non-compliance with U.S. federal and state healthcare laws

- Maintain "Hot Line" and conduct necessary investigations, as well as work with Bayer Corporation Ombudsman

- Develop and maintain BHC Compliance Intranet site and coordinate other compliance-related communications

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# 2008 BHC CIA
# (effective November 25, 2008)

- 90-120 days to implement CIA requirements

- 5 year term (through Q4 2013)

- Also signed Settlement Agreement with Department of Justice

    - Paid Settlement amount of $97.5 Mio

# 2008 BHC CIA

- Broad business scope – BHC entities that interact with "Government Reimbursed Products"
- Broad definition of "Covered Persons"
- Create and maintain Focus Arrangements Database
- Compliance Expert Panel reporting to BHC Board of Directors
- Annual Management Certifications that department/functional area is in compliance
- IRO review of Focus Arrangements Database
- Compliance Officer cannot be, or report to, General Counsel or CFO
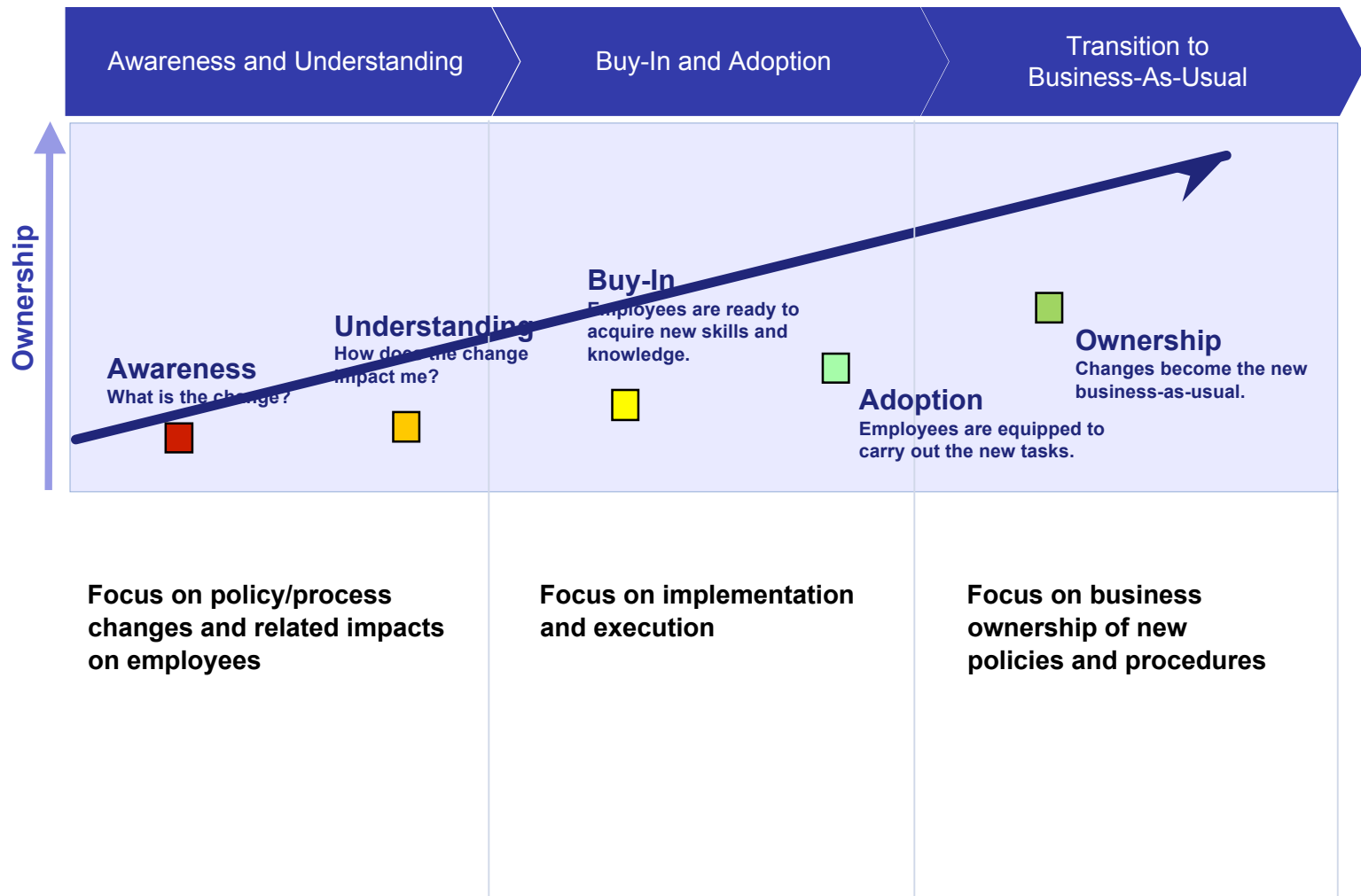
# 2008 BHC CIA

- Compliance Officer

- Compliance Committee

- Code of Conduct / Policies and Procedures

- Employee Compliance Training (initial – 5 hours;
  annual refresher - 4 hours)

   - General Training

   - Arrangements Training

- Confidential Disclosure Program (toll-free number)

- "Ineligible persons" screening and employment restriction

- Reporting obligations

# Implementation Approach

- Ensure that BHC, and its affiliated companies that sell products that are reimbursed by Federal healthcare programs, comply with the November 2008 CIA

- Develop policies, procedures, processes and systems to comply with the obligations, and support the spirit and intent, of the CIA throughout its term

# CIA Implementation Change Management Approach

## A Phased Approach to Driving Business Ownership

| Awareness and Understanding | Buy-In and Adoption | Transition to Business-As-Usual |
|---|---|---|

**Ownership** (vertical axis)

**Awareness**
What is the change?

**Understanding**
How does the change impact me?

**Buy-In**
Employees are ready to acquire new skills and knowledge.

**Adoption**
Employees are equipped to carry out the new tasks.

**Ownership**
Changes become the new business-as-usual.

**Focus on policy/process changes and related impacts on employees**

**Focus on implementation and execution**

**Focus on business ownership of new policies and procedures**

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# Resources to Help

- BHC Compliance Website
    - Updated to include all CIA related materials
- CIA Champions Network
- Job Aids
    - "What is a Focus Arrangement" Job Aid
    - Frequently Asked Questions (FAQs)
    - Focus Arrangement Lifecycle Job Aid
- CIA Compliance Contacts
    - BHC Compliance Department employees
    - BHC Law & Patents Department employees
    - Compliance Assistance Line
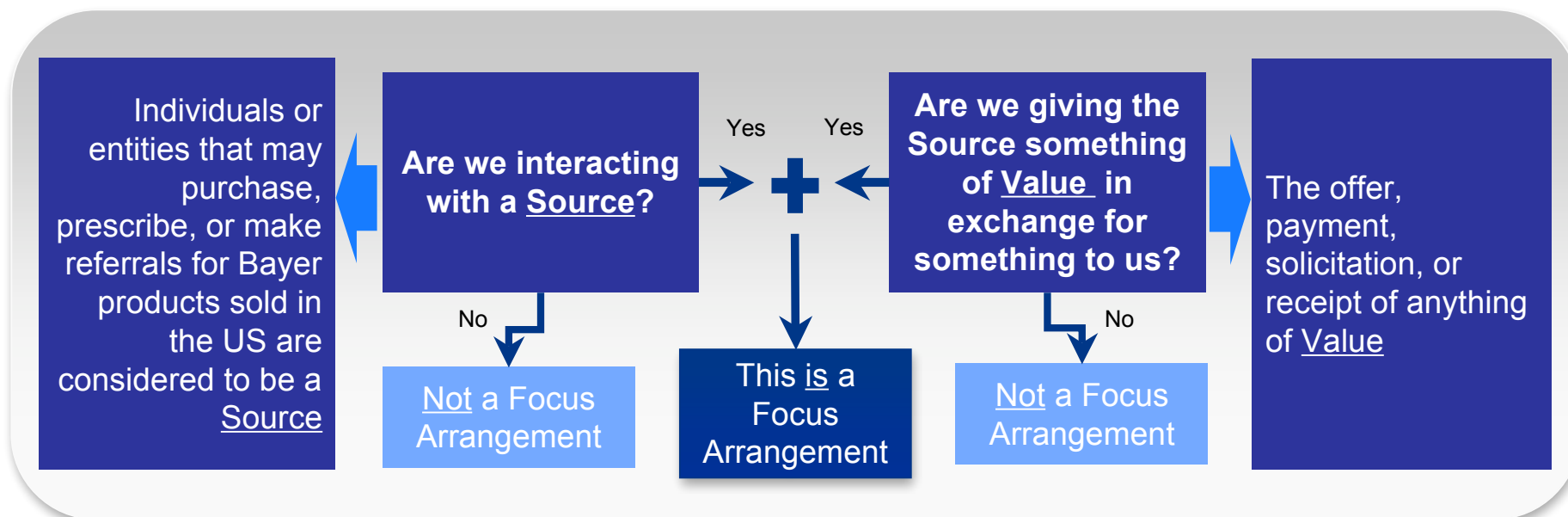    - IntegrityLine

# "Focus Arrangements"

Every Arrangement that is between Bayer or any Bayer Affiliate and any actual source of Government Reimbursed Product referrals or sales and involves, directly or indirectly, the offer, payment or provision of anything of value.
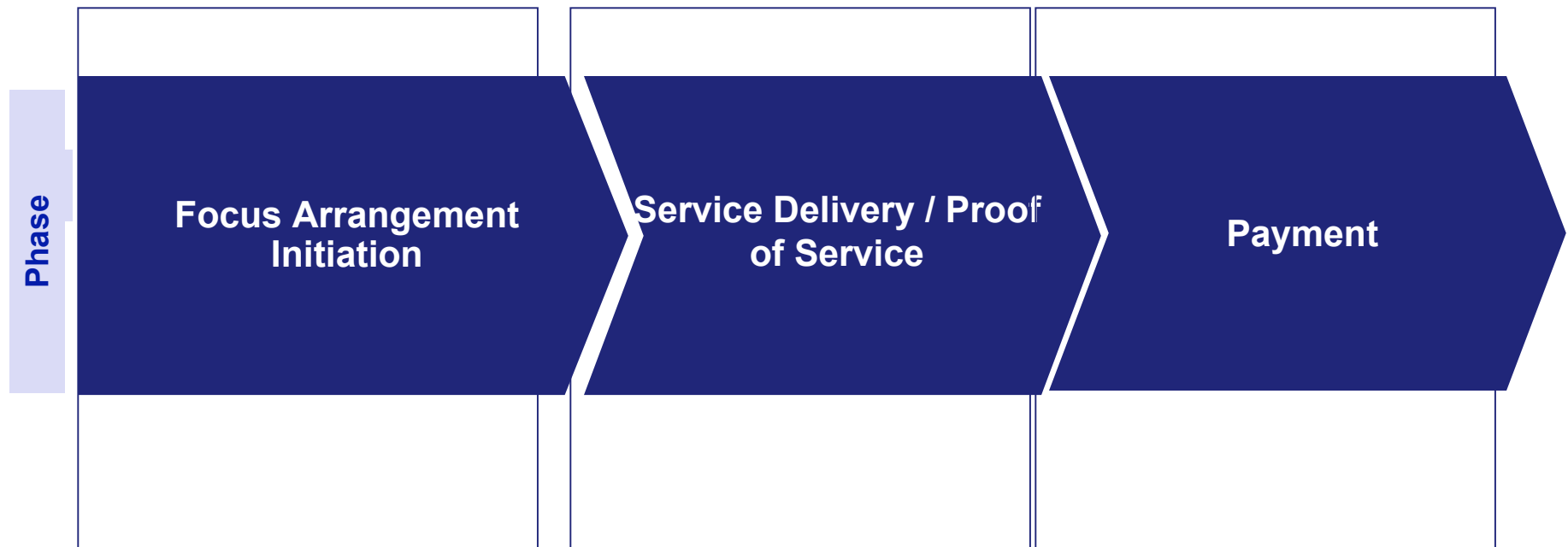
# What is a Focus Arrangement?

A Focus Arrangement is any arrangement between Bayer and a referral source (e.g., a doctor, a nurse, a hospital, a wholesaler) that involves an offer (direct or indirect) of payment or the transfer of anything of value in exchange for service

## Identifying a Focus Arrangement

Individuals or entities that may purchase, prescribe, or make referrals for Bayer products sold in the US are considered to be a <u>Source</u>

**Are we interacting with a <u>Source</u>?**

No → <u>Not</u> a Focus Arrangement

Yes

**+**

This <u>is</u> a Focus Arrangement

Yes

**Are we giving the Source something of <u>Value</u> in exchange for something to us?**

No → <u>Not</u> a Focus Arrangement

The offer, payment, solicitation, or receipt of anything of <u>Value</u>

# Ensuring Compliance Throughout the Focus Arrangement Lifecycle

- ⊕ The Focus Arrangement lifecycle consists of three phases: Focus Arrangement Initiation, Service Delivery / Proof of Service, and Payment

- ⊕ Enhancements made to processes and procedures in each phase to support CIA requirements and record this data in the Focus Arrangements Database

**Phase**

| Focus Arrangement Initiation | Service Delivery / Proof of Service | Payment |

# Focus Arrangements Database

- Comprehensive database of transactions involving payments by BHC in connection with Focus Arrangements -- examples include:

  - Speaker or other consulting fees to doctors

  - Advisory Board compensation

  - Data purchasing agreements with customers

  - CME grants to teaching hospitals

  - Clinical research agreements

- Required to log and track each Focus Arrangement

  - For both existing and new Focus Arrangements (as of November 25, 2008)

  - Ensure that contract initiation is done according to Arrangements Procedures established pursuant to the CIA

  - Ensure services are provided

  - Ensure that payments are made as per the approved contract

# Focus Arrangements Database

- Processes

  - Reviewed, revised and added necessary  business processes

  - Implemented compliance checks and corrective action measures for new/changed business processes and data feeds

- Implemented Communication, Change Management and Training Plan to best fit situational and divisional needs

- Ensure alignment of new business processes and compliance policies and procedures

- Implemented monitoring and control processes and reporting with associated corrective action and disciplinary processes

# Compliance Expert Panel

- BHC Board responsible to retain Compliance Expert Panel (3 independent experts) and instruct to:

  - Annually review BHC Compliance Program effectiveness

  - Create a work plan for the review

  - Provide a written report of its review to Board, including recommendations

- BHC Board responsible to annually adopt a resolution summarizing:

  - Its review and oversight of the BHC Compliance Program

  - Its adoption and its implementation of the Compliance Expert Panel recommendations, or the reasons for not adopting any recommendation

  - The conclusion regarding the effectiveness of the BHC Compliance Program

# Management Responsibilities

- Ensure compliance targets appear in all BHC employees' performance objectives

- Certain management employees must annually certify in writing ("Management Certifications") that, to the best of their knowledge, either

  - their area is compliant, or

  - their area is non-compliant, the reasons for non-compliance and the action plan to achieve compliance

- A certification process, including training, established

# Thank You!