# MANAGING COMPLIANCE RISKS IN PROMOTIONAL AND INCENTIVE PROGRAMS

# Medical/Commercial Interactions

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- United States
  - No explicit legal, regulatory requirement to separate commercial, medical functions
  - However, U.S. regulators expect that there will be internal structural controls to prevent undue influence of medical over commercial (e.g., reporting, structure, budgets)
  - OIG Compliance Program Guidance (CPG) for Pharma. (2003)
    - Separate decisions for educational grants, research funding, medical affairs consulting arrangements to reduce risk that such arrangements are used to induce, reward product purchases
  - Recent CIAs with OIG also emphasize these boundaries

# Global: Core Principles

- Global regulators expect companies to maintain meaningful boundaries between Commercial and Medical functions and activities
- Failure to maintain boundaries may lead to the perception that Medical activities are no different from sales and marketing activities, and that they are engaged in to promote sales rather than to advance science
- Yet boundaries globally are much less distinct than in the US, reflecting local practices, lack of high risk exposure for off-label, differing management and control styles, ex-US
- Distinctions must be sufficiently reflected in the organization, reporting lines, allocation of projects and budgets and possible contributions of Commercial and Medical.
- How the boundaries are implemented is just as important as the way in which Commercial and Medical are organized
  - Differences in composition of local entities may require compromise; e.g., role of General Managers as Commercial, limitations of medical staffing, compliance review roles, etc.

# Back to Basics

- Commercial personnel should always speak on-label, and their actions should be consistent with on-label uses
- Off-label questions directed at Commercial personnel should be redirected to Medical employees
- Medical personnel should ensure that their statements and actions cannot be construed to be promoting the product

# Commercial Involvement in Medical Activities

- Commercial personnel should not formally or informally direct or influence medical activities, except in clearly defined circumstances
- Commercial personnel may provide high-level input in identifying areas of educational need or charitable donations  and regarding research budgeting and overall priorities
- Commercial personnel may provide administrative assistance to medical projects under the supervision of medical
- Commercial personnel should not play a direct role in soliciting, identifying, or reviewing potential individuals or institutions for medical consulting or grant-making activities

# Interactions with HCPs

- Commercial influence or control over medical consulting and grant-making activities may lead to the perception that such payments are being used improperly
- Medical consulting relationships, grants, and/or advisory board meetings should be offered only to those individuals or institutions that meet a pre-defined need, and should never be offered to enable or facilitate the delivery of a promotional message.
- Commercial should have no role in funding, convening, or selecting Medical consultants or advisors, other than in limited circumstances constituting legitimate market research or when commercial participation is justified by the objective of the discussion in accordance with the needs assessment for the activity

# Clinical Research

- Inappropriate commercial influence over research activities may lead to concern among regulators and other stakeholders that a company is compromising the scientific basis for the research, compromising patient benefit, and using research as a means to reap commercial benefit or advantages from HCPs, and thereby undermining the legitimacy of the resulting data
- Commercial should have no role in developing clinical study protocols, recruiting patients, providing experimental drugs, developing or analyzing data, retaining clinical trial consultants or contract research organizations, or drafting clinical study reports or study publications
- All human interventional and non-interventional clinical research, as well as non-clinical research, should be overseen by the appropriate medical function without commercial input in respect of study design, unless otherwise justified by medical

# Medical HCP Relationships: Landscape

## United States

- Recent cases, enforcement, CIA's focus on Medical activities used to influence or network with HCPs, customers
  - Consulting, advisory boards, honoraria, meals, travel, IIS, etc.
  - Medical budgets, payments to HCPs higher for medical activities
- Bona fide advisory boards, etc.
- Transparency risks (Sunshine, AKS)

## Global

- Largely anti-corruption and publications risk:
  - Selecting HCPs as consultants, meeting sponsorships to influence prescribing
  - Using patient screening, patient assistance and patient support as inducements
  - Improper Commercial involvement with HCP consultants

# Incentives

# Overview of Enforcement-US

- Recent settlements and ongoing qui tams generally focus on incentive compensation (IC) plans, including bonuses, rewards
- Relators/DOJ generally do not go into explicit detail about the specific planning, meetings or activities behind IC plans
  - Some relators have alleged that sales reps had unlimited budgets to provide kickbacks to HCPs, for which the reps received bonuses or IC
  - Such allegations suggest deeper knowledge of planning tied to IC
- Relators/DOJ broadly allege that IC plans are used to encourage or reward field employees to:
  - Promote/sell products for off label uses;
  - Suggest a product is superior to competitors;
  - Meet certain Rx volume, metric requirements, even if not medically necessary or consistent with the label; or
  - Convert or switch a certain number of HCPs from competitors

# Global Issues

- Incentive to disregard boundaries
- Net effect undermining clinical independence
- Blurring distinction between medical and commercial goals
- Evolving enforcement landscape