Determine Fair Balance when Adding Warnings or Restrictions to Labels

2nd Annual Promotional Review Committee Compliance & Best Practices - Midwest

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Disclaimer

• This presentation does not necessarily represent any position, approach, or policy of Onyx Pharmaceuticals or Amgen

• Opinions expressed are my own and represent my opinions/experiences over the last 15+ years as an industry Medical Affairs director
Perception & Reality
Environment

- OIG Guidance
- PhRMA Code revision
- ACCME update
- Provisions of EU Clinical Trials Directive
- UK Bribery Act of 2010 / FCPA
- COI guidelines / NIH proposed COI Rules
- Sales force restrictions
- State reporting requirements
- Journal publication policies
- Federal/State investigations/judgments
- Corporate Integrity Agreements
- Companies disclosing all payments to KOLs
- Renewed Fair Market Value focus
- Media reporting on “Pharma”
- Etc., etc., etc.
Perception & Reality
Environment

What do these all communicate to our public?

A. We are responsible corporate citizens and partners in driving the preservation and extension of human life

B. We are untrustworthy and must be policed to force compliance while continuing to make obscene profits at the expense of patients…
Fair Balance

- Negative “safety” information to offset claims
- Data limitations from study design/execution
- Contrary data from other studies
WHAT IS PRC?

The internal, multifunctional committee responsible for review and approval of promotional materials intended for use with HCPs and other external customers.
The “Filter” Model
WHAT IS PRC?

The internal, multifunctional committee responsible for review and approval of promotional materials intended for use with HCPs and other external customers

- Responsible for ensuring fair balance
The “Filter” Model

Marketing

Fair Balance

PRC

Sales
WHAT IS PRC?

The internal, multifunctional committee responsible for review and approval of promotional materials intended for use with HCPs and other external customers

- Responsible for ensuring fair balance
- Responsible for ensuring appropriate scope of promotional initiatives
Fair Balance

- Negative “safety” information to offset claims
- Data limitations from study design/execution
- Contrary data from other studies

“Fair Balance” presumes the need to offset purely positive & biased promotional claims
Promotional Review Committee

Medical Affairs

Legal

PRC

Compliance
Fair Balance

- Negative “safety” information to offset claims
- Data limitations from study design/execution
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- “Fair Balance” presumes the need to offset purely positive & biased promotional claims

“Anything a Doctor needs to know in order to make a fully informed & independent treatment decision”
Promotional Review Committee

Medical Affairs

PRC

Legal

Compliance
Fair Balance

“Anything a Doctor needs to know in order to make a fully informed & independent treatment decision”

What if the information that needs to be offset is already negative?
“HYPOTHETICAL” SCENARIO

A Tale of Two Products…
Two Products…

- Same drug class
- Same indication
- Comparable efficacy
- Comparable safety
- Comparable data strength (non-inferiority)
- Launched within 5 months of each other
- Comparable Share of Voice
Tale of Two Products...
Response – Company A

- Updated PI
- Dear HCP Letter
- Sales Training
- Field Medical Training
- Updated Sales Materials
- Updated Medical Information Letters

Who proposes/creates each of these?

What is the role of PRC in this crisis setting?
WHAT IS PRC?

The internal, multifunctional committee responsible for review and approval of promotional materials intended for use with HCPs and other external customers

• Responsible for ensuring fair balance
• Responsible for ensuring appropriate scope of promotional initiatives
What Else?

- Regulatory Affairs?
- Marketing?
- Sales?
- Field Medical?
- Medical Information?
- Market Access/Account Management?
- Alliance Management?
- Clinical Development?
- Clinical Operations?
- Government Relations?
- Legal?
- Updated PI
- Dear HCP Letter
- Sales Training
- Field Medical Training
- Updated Sales Materials
- Updated Medical Information Letters
Response – Company B

- Updated PI
- Dear HCP Letter
- Sales Training
- Field Medical Training
- Updated Sales Materials
- Updated Medical Information Letters
- Updated Speaker’s Bureau Deck
- Speaker’s Bureau Training
- Updated CST Protocols/IC
- Updated IST Protocol/IC Requirement
- Dear Investigator Letter
Response – Company B

- Updated Field Medical Materials
- Marketing Ad Boards
- Medical Affairs Ad Boards
- CME Grant Targeting
- Company-Sponsored Registry
- Company-Sponsored Mechanism Research
- AMCP Dossier Revision/Reissue
- Updated Payer Deck
- Unbranded Customer Education Initiatives
- Updated Budget Impact Model
- Publication Plan Update
Response

Company A
- Updated PI
- Dear HCP Letter
- Sales Training
- Field Medical Training
- Updated Sales Materials
- Updated Medical Information Letters

Company B
- Updated PI
- Dear HCP Letter
- Sales Training
- Field Medical Training
- Updated Sales Materials
- Updated Medical Information Letters
- Updated Speaker's Bureau Deck
- Speaker’s Bureau Training
- Updated CST Protocols/IC
- Updated IST Protocol/IC Requirement
- Dear Investigator Letter
- Updated Field Medical Materials
- Marketing Ad Boards
- Medical Affairs Ad Boards
- CME Grant Targeting
- Company-Sponsored Registry
- Company-Sponsored Mechanism Research
- AMCP Dossier Revision/Reissue
- Updated Payer Deck
- Unbranded Customer Education Initiatives
- Updated Budget Impact Model
- Publication Plan Update
Tale of Two Products...
Epilog

• Product A still on market, but “irrelevant” to physicians

• Product B dominates drug class >5 years out
FAIR BALANCE CONTENT

“Anything a Doctor needs to know in order to make a fully informed & independent treatment decision”
Fair Balance to Negative Safety Info

- Nothing
- Contextual information from same study
  - Efficacy data
  - Design/analysis information
- Label data reiteration
- Description of new/ongoing research (addressing the specific safety signal)

Intent/interpretation cannot be efforts undermine safety information in the label
Epilog 2

Company A

Marketing

Company B

New Initiatives/Claims

New "Pieces"

Marketing

Sales

Clinical Dev

Reg Affairs

Legal

Medical Affairs

Compliance

PRC

MRC

Sales

Marketing
Summary

- Traditional interpretation of Fair Balance is purely the addition of negative information
  - Not appropriate in all cases
  - Under-represents the true Fair Balance information needs of customers
- Traditional PRC structure/role appropriate for “traditional” fair balance
- More inclusive Communications Review Committee structure is more powerful
  - Time commitment may require maintenance of “lower review committee” for the day-to-day
My Own Fair Balance

• Cross-Organizational communications can be and are commonly driven by “Brand Teams”
  – If fully integrated and effective, the integrated PRC concept is not needed

• Brand Teams RARELY include such functions as Clinical Development, Clinical Operations, Compliance, Legal, Patient Advocacy, Government Relations, and others?
Is This You???

Marketing

PRC

Fair Balance

Sales
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