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FDA Regulation of Promotion & Advertising

Part 8: Handling Promotional Compliance at the Company Level

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Handling Promotional Activity at The Regulated Company

Keys to Implementing A System

- **There is no right way on how to do this; have to create a system that works for you company. But any system should have, at minimum:**
  - Procedure
  - Training
  - Records
  - Audits
  - Validating

Analyze Your Label

- **Analyze your label in advance; prepare a template**
  - What are the key risk info?
  - What is key about indications?
  - What studies support what claims?
  - What should go into a Brief Summary?
- **Substantiate all statements of fact**
  - correlate to source materials

Have a Team

- Medical
- R&D/Clinical – they know what was done to support
- Regulatory – they know what was approved
- Labeling Department
- Marketing
- Legal
- Compliance (if you have a separate function)
- Outside creative agencies
- One person – clearly should own the process

Miscellaneous issues

- **How to handle and resolve comment**
- **Controlling sales reps**
- **Sign-off's when using statements of third-parties**
  - e.g., clinicians, KOL's
- **Reprints – don't forget copyright compliance**
- **Clinicians speaking on your behalf –**
  - training
  - contract to follow your procedures (e.g., on off-label use)
- **Record retention – establish system**

Key Measures to Take to Protect You and Your Company From Liability

How to Protect Yourself and Your Company

- **COMPLY!!**
  - **THE REST IS COMMENTARY …**
  - **But …**

What to Do to Protect/Mitigate Liability

- **Implement an Effective Compliance Program**
- **Written Policies and Procedures**
  - Code of Conduct – on Business Ethics and Compliance
  - Specific procedures for key aspects of operations – not just those related to FDA compliance, but also:
    - vendor contracts
    - marketing
    - pricing
    - deals with doctors
    - interactions with government officials, domestic and foreign
    - reporting of compliance programs

What to Do to Protect/Mitigate Liability …

- **Compliance Officer and Committee –** institute; with authority to:
  - Direct line report to CEO (not to CFO or G.C.) – must be able to act independently and have access to Board of Directors (e.g., if CEO is the bad doer)
  - lead responsibility for compliance
  - adequate resources & budget –
    - side note – Warning Letter – signal to senior management to make resources available to correct violations
- **Communication –** must be avenues within company and to outside directors, if needed

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What to Do to Protect/Mitigate Liability …

- **Training and education**
  - Reading is not enough
  - Must be renewed periodically
    - at Par, we retrained on the code of conduct annually
  - Must be validated
- **Auditing and Monitoring**
  - As with FDA operational audits, all compliance processes must be audited
  - Internal and external are recommended
  - But, must act on what you find

What to Do to Protect/Mitigate Liability …

- **Disciplining Offenses**
  - Have clear guidelines on discipline – up to and including termination
  - Enforce consistently and vigorously
- **Responding to Detected Problems**
  - Do the "right" thing, promptly and comprehensively
  - Investigate and correct (need a procedure for this as with CAPA)
- **Treat Your Employees Fairly –** to minimize the potential for whistleblowers; but remember you can't retaliate

Final Sermon:

Please Teach Vigorous Risk Avoidance Comprehensively and Corporately

- P = Procedures
- T = Training
- V = Validation
- R = Records
- A = Audit
- C = Communications – Open Channels
- C = Compliance Culture from the Top

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End of Part 8:

Handling Promotional Compliance at the Company Level