

Current Trends in Enforcement

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Current Trends Affecting International Companies

- US Foreign Corrupt Practices Act
- Foreign regulation of financial relationships with the medical profession
- International safety reporting
- Good clinical practice
- Off-label promotion

Foreign Corrupt Practices Act

- Charitable contributions
- Sponsoring government doctors to attend conferences
- When is a foreign doctor a government official for FCPA purposes?
- Abuse of post-marketing studies

FCPA rule of reason analysis

- Sound medical or scientific basis
- No quid pro quo
- Avoid appearance of improper purpose
- Other factors

Financial relationships with doctors

- Investigator-initiated studies
 - Effect of EC Clinical Trials Directive
- Grants
- Advisory boards
- Hospitality, travel expenses, etc.

International Safety Reporting

- Increasingly harmonized requirements
- Increased emphasis on inspections and enforcement
- Effect of FDA proposal
- Nonclinical studies

Good Clinical Practice

- EC Clinical Trials Directive
 - Who is the sponsor?
 - When does ICH GCP apply?
- Inspections and enforcement

Off-Label Promotion

- Increased focus in US
 - First Amendment and FDAMA
 - Recent high-profile cases
- Possible implications for Europe
 - Code enforcement proceedings
 - Private litigation