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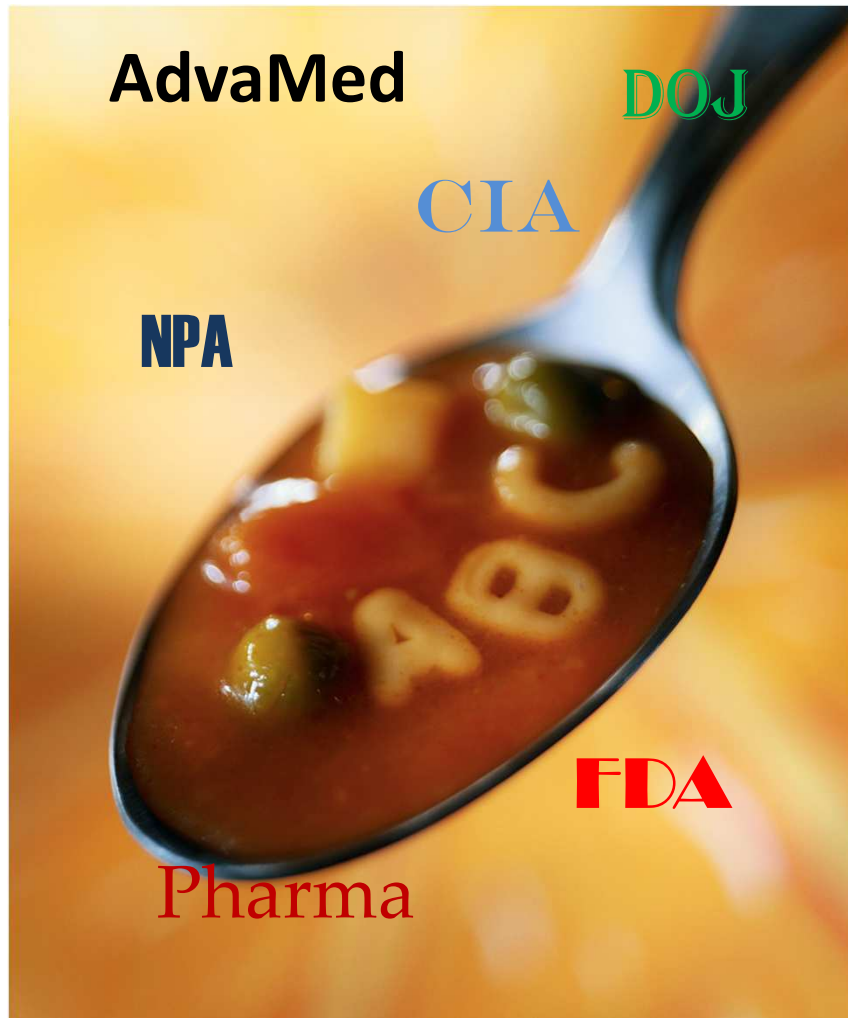
# Considerations for Best Practices

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# Considerations for Best Practices

- External Guidelines
- Internal Guidelines
- Requests for Support
- Q & A

# Considerations for Best Practices



**ALPHABET  
SOUP**

# Considerations for Best Practices

AdvaMed

Promotes policies that foster the highest ethical standards, rapid product approvals, appropriate reimbursement and access to international markets

# Considerations for Best Practices

## Advanced Code

- Provides guidance on
  - Companies Code of Ethics
  - Company conducted product training
  - Third Party Education Conferences
  - Consultant and Research Agreements
  - Sales and Marketing Business Meetings
  - Evaluation and Demonstration Products
  - Charitable Donations

# Considerations for Best Practices

## Advanced Code

- Company conducted product training
  - “Settings that are conducive to the effective transmission of Information”
  - Hands On training “held in training facilities, medical institutions, laboratories or other appropriate facilities”
  - Meals should be “modest”



# Considerations for Best Practices

## Advanced Code

- Third Party Education Conferences
  - Same standards as for Company Conducted Product Training
  - Other considerations
    - Venue
    - Agenda
    - Budget

# Considerations for Best Practices

## Advanced Code

- Consultant and Research Agreements
  - Fulfill a legitimate business need
  - Not based on the value or volume of past, present or future business
  - Modest Meals and Travel

# Considerations for Best Practices

## Advanced Code

- Sales and Marketing Business Meetings
  - Meal is incidental to the presentation
  - Not part of an entertainment or recreational event
  - Only for Health Care Professionals who have “bona fide professional interest” in the information being presented.



# Considerations for Best Practices

## Advanced Code

- Evaluation and Demonstration Products
  - Reasonable amount of time and reasonable quantity
  - Provide documentation and disclose no-charge status
- Gifts and Educational Items
  - Strictly prohibits gift of any kind
  - Educational Items
    - **Caution** – an educational item that can be used for another purpose can be problematic.

# Considerations for Best Practices

## Advanced Code

- Charitable Donations
  - Patient education
  - Public education
  - “bona fide charitable organizations”

# Considerations for Best Practices

## Advanced Code

- Illustrative Meal/Refreshment Provision Best Practices
- Illustrative Third Party Educational Conferences Best Practices & Considerations
- Illustrative Educational Item or Patient Benefit Item Best Practices

# Considerations for Best Practices

## FDA

- Pre Market Activities – New Product Submissions
  - Provide documentation on the safety and efficacy
  - Potential Off Label
- Post Market Activities
  - Requirement to train on the safe and effective use of products
  - Off Label Promotion
    - ACCME allows off label discussions as long as the speaker discloses

# Considerations for Best Practices

## Federal and State Regulations

- Health Care Reform Act 2010
- Massachusetts and Vermont
- Additional States

# Considerations for Best Practices

## Federal and State Regulations

- Health Care Reform Act 2010
  - Report all Payments to
    - Health Care Professionals
    - Teaching Institutions
    - Amount TBD

# Considerations for Best Practices

## Federal and State Regulations

- Massachusetts
  - No Meals allowed “off campus”
  - Except – hospital like setting or in conjunction with a TPEC event or tradeshow
  - \$2000 per year to provide report
  - \$5000 per violation
- Any HCP with an active Massachusetts license

# Considerations for Best Practices

## Federal and State Regulations

- Vermont
  - No Meals
  - Except – at a product training event
    - If a written agreement is in place to purchase/evaluate the products AND
    - If the value of the meal is disclosed in advance
  - \$500 per year to provide report
  - \$10,000 per violation
  - Trial and evaluations limited to 90 days
- Any HCP actively practicing in Vermont

# Considerations for Best Practices

## Federal and State Regulations

- Additional States
  - Require companies have a “Code of Conduct”
  - May be waiting to see what Federal Law covers
- Aggregate Spend
  - Report as a corporation
  - Consolidate reporting
- Currently Health Care Reform Act does not preempt state law if the state law is more prohibitive.

# Considerations for Best Practices

DOJ, CIA's, Monitors

- Requirements Vary
- Previous Rulings
  - Other companies Corporate Integrity Agreements
- Impact all aspects of business
  - Contracts
  - Time lines
  - Code of Conduct
  - Training

# Considerations for Best Practices

## ACCME

- Provide Guidance on conducting unbiased education
  - Restricting Grant Funds
  - No prohibition on location
  - Strict separation of marketing and education

# Considerations for Best Practices

## Internal Guidelines

- Code of Conduct / Compliance
- Professional Affairs
- Supplier / Vendor Agreements
- Budgets

# Considerations for Best Practices

## Internal Guidelines

- Code of Conduct / Compliance
  - Training Requirements
  - Reporting Requirements
    - Sign in Sheets
    - Cost per person
  - Oversight of interactions with HCP
    - Remove interactions with HCP's from Sales and Marketing
- Corporate Culture

# Considerations for Best Practices

## Internal Guidelines

- Professional Affairs
  - Documentation to support payments to Consultants
  - Provide annual evaluations
  - Audit events

# Considerations for Best Practices

## Internal Guidelines

- Supplier / Vendor Agreements
  - Fair Market Value
  - Facility Owners
  - Payment Terms
  - Specimen Providers
  - Evaluations



# Considerations for Best Practices

## Internal Guidelines

- Budgets
  - Moved from Sales and Marketing
  - Payments may require review and approval
- University or Facility
  - Conflict of Interest Policies
  - Vendor Access Policies

# Considerations for Best Practices

## Requests for Support

- Buy or Rent
  - Restrictions
- Location
- 501c3 Organizaion
  - Proposed use of support
    - Education
    - Research
- Education
  - ACCME
  - Other industry education
  - On Label Use
- Indemnification



# Considerations for Best Practices

## Summary

- Balance External & Internal Requirements
- Less Flexible
- Need to document / collect more data
- Ever changing landscape

# Considerations for Best Practices



# Considerations for Best Practices

