Overview

• Guidelines important for health/public health policy
  • Establish clinical practice standards
  • Set behavioral norms/expectations

• Conflicts of interest (COI) or bias can undermine public confidence/support
  • Challenge to detect and mitigate
  • Should be considered up-front, not as afterthought
  • Integral to credibility, especially with contentious issues
Concepts

- IOM definition of COI
  - “A set of circumstances that creates a risk that professional judgment of actions regarding a primary interest will be unduly influenced by a secondary interest.”
  - Financial
  - Nonfinancial (i.e., career advancement, previously stated positions)

- Conflict of interest (COI) implicates, but does not equal bias
Concepts

• Can manage, but not eliminate bias or COI

• Inherently subjective concepts lacking consensus

• Core issue is public trust
  • Balance need for experts while limiting bias
  • Transparency essential
Gaps

- Variation across federal regulations/policies—no standard framework
- How to detect and assess impact of bias on guidelines development/implementation bias up-front
- No criteria for distinguishing between substantial and incidental conflict
- No ongoing monitoring to test various strategies
Criteria

• Bright lines—dollar amounts with upper bounds
  • IRS private benefit—$50,000; PHS—$5000; USPSTF—$1000
  • Clear because limited or no discretion
  • But subject to definitional disputes
Criteria

• Standards—general guidance to be interpreted on a case-by-case basis
  • Sponsoring entity “reasonably determines that [a] significant financial interest could directly and significantly affect the design…” (45 CFR 94.4 (f)) (“direct and predictable effect” —5 CFR 2640.103(a))
  • Sponsoring entity applies standard to facts
  • Allows for discretion to assess whether identified COI indicates potential bias
Standards

• Conflict tolerable where incidental to accomplishing policy objectives
  • Qualitatively incidental—mere byproduct of broader public benefit
  • Quantitatively incidental—insubstantial in amount compared to public benefit
  • Burden on individual to demonstrate that value to committee outweighs incidental COI

• Fiduciary duty standard
Mitigation Strategies

• Disclosure
  • Necessary but not sufficient—consensus that inadequate remedy
  • Part of process to select committee members
  • Need to determine applicable standards and disclosure period
  • Information for selected committee members must be publicly available and accessible when guidelines issues (see, e.g., 42 CFR 50.605)
  • Identify sanctions for non-disclosure

• Divestiture
Mitigation Strategies

- Committee composition
  - Wide variety of voices (i.e., multiple disciplines) is desirable objective
  - Diversity of views attenuates bias
  - Balance among industry and consumer members attenuates bias
  - Chair should be from another field
  - 50% of members should have no or only incidental COI
  - Lead drafters should have no or only incidental COI
  - Can solicit input from advisory panel with special expertise, regardless of potential bias
Mitigation Strategies

• Peer review prior to dissemination
  • Can include experts who might be excluded from committee under COI criteria

• Appoint independent monitor to describe “the impact of the bias...and the plan of action taken to eliminate or mitigate the effect of the bias” (45 CFR 94.5 (a)(3)(iii)) (see also, 42 CFR 50.605)
Conclusion

• No easy or obvious solutions

• Managing and mitigating COI/bias important component for public support