FDA Regulation of Dietary Supplements: Performance-Enhancing Products

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FDA Authority to Regulate Dietary Supplements

- Food, Drug & Cosmetic Act
- 1994 Amendments: Dietary Supplement Health & Education Act (DSHEA)
- Labels and labeling
Issues

- What fits the definition of a dietary supplement
  - Terms from statute
  - Considerations of “intended use”
- Safety
  - Post-marketing effort / Adverse event system
  - To remove from market
    Burden of proof re: “being unsafe” (significant or unreasonable risk)
- Fraudulent claims
DSHEA: Forms of Dietary Supplements

- Pill, capsule, liquid, powder, caplet, etc.
- But also may be in conventional food form
DSHEA: Dietary Supplement Definition

...a product ... intended to supplement the diet that bears or contains one or more of the following dietary ingredients:

– vitamin, mineral, or amino acid
– herb or other botanical
– dietary substance
– concentrate, metabolite, constituent or combination
Examples of Dietary Ingredients

*vitamin, mineral, amino acid:*
  - Vitamin C, Carnitine

*herb or botanical:*
  - Echinacea

*dietary substance:*
  - Not yet clearly defined: ??? bee pollen

*concentrate, metabolite, constituent:*
  - Not yet clearly defined: ??? melatonin
What Are Hormones?

Unclear --- Drug or ? perhaps a dietary supplement

- It depends on "intended use"
  - If anabolic – Drug ; DEA/Schedule III
  - If precursor to Schedule III (e.g., GBL) -- Drug
  - If "street drug” alternative – Drug
  - If “non-anabolic” for body-building (struc/func – ‘androgenic’)
    - Is it a dietary ingredient intended to supplement the diet?
    - DSHEA does not address; No legislative history
    - FDA has taken no position
    - ?Androstenedione, ?DHEA
Safety of Dietary Supplements

- Pre-market determination is largely role of manufacturer
- FDA’s responsibility is to remove unsafe ingredients or products from the market
  - Demonstrate significant or unreasonable risk
  - Reliance on passive adverse event system
Safety Concerns: P-E Dietary Supplements

- Paucity of data, esp. for chronic use
- Marketing/use by children and adolescents
- Combinations of ingredients may have adverse consequences
- Exercise may change body’s response
- Suggestion that some contain banned substances
Claims Concerns: Fraudulent/Misleading

- Limited resources: “Safety First”
- Claims about effects
- Claims about “proven” safety or “natural” alternatives
- Commitment to address these
Collaborative Effort

- FTC: fraudulent claims
- NIH: effectiveness
- DEA: illicit substances
Needs

- Clarification of definitions
- Research – esp. in view of post-marketing world
- Reporting of adverse events