Health Products for Seniors

“Anti-Aging” Products Pose Potential for Physical and Economic Harm

Martin Gahart, U.S. General Accounting Office, Health Care Issues

Swindlers, Hucksters and Snake Oil Salesmen…

• …The Hype and Hope of Marketing Anti-Aging Products to Seniors

• U.S. Senate Special Committee on Aging Hearing, Chaired by Sen. John Breaux

• Sept. 10, 2001

(http://aging.senate.gov/events/091001.html)
Background

- Dietary supplements are widely used by seniors
- Seniors may be at particular risk because of chronic health problems and use of prescription drugs
- Dietary Supplements Health and Education Act (DSHEA)
  - No FDA review of safety and efficacy prior to marketing
  - Manufacturers not required to register with FDA or report adverse events
  - FDA can initiate action to remove dangerous products
  - Products can not claim to treat or cure disease
Questions

• Is there evidence that anti-aging and alternative medicine products, particularly dietary supplements aimed at conditions of aging, cause physical harm to seniors?

• Is there evidence that questionable anti-aging and alternative medicine products cause economic harm to seniors?

• What are the state and federal oversight efforts to protect consumers from questionable anti-aging and alternative medicine products?
There are Some Health Risks for Seniors

- Health risks of product use:
  - Some products may have serious adverse events (FDA warnings and alerts)
  - Contraindications for seniors with pre-existing conditions
  - Interactions with prescription drugs
  - Concern that users of alternative therapies will forgo medical treatment

- Product quality:
  - Contamination
  - Variation in amount of active ingredient
Seniors Spend Money on Unproven or Poorly Manufactured Products

- No overall estimates
  - According to FTC, $36 million annually on products for 20 companies that fraudulently marketed unproven health products to seniors
  - For example, “rife machines” for up to $5,000 on the Internet

- Some dietary supplements contain less of the active ingredient than noted on product labels
  - For example, one study from an independent lab found 22% of tested dietary supplements had substantially less of the active ingredient
Government Education and Research Efforts

- **Education**
  - FDA outreach to senior health fairs and conferences with tips to avoid health fraud
  - FTC consumer education materials

- **Research**
  - NIH – National Center for Complementary and Alternative Medicine
Dangerous Products Still Available Despite FDA Enforcement Efforts

- FDA has taken action, on a case-by-case basis against unapproved new drugs or medical devices, and against products claimed to cure disease.

- But problematic products still available because FDA has not prohibited the marketing of dangerous substances:
  - Under DSHEA, FDA must prove an imminent hazard in court.
  - For example, comfrey:
    - July 2001 FDA advisory letter to trade associations: comfrey is dangerous, any product with comfrey is adulterated, stop selling.
    - But, comfrey is still widely available on the Internet.
Other Federal and State Enforcement Efforts

- FTC enforces statutes that prohibit misleading and unsubstantiated advertising
  - 1998 guidance to industry – objective product claims must be substantiated
  - Joint FTC and FDA actions against questionable Internet advertising – “Operation Cure.All”
  - Companies sometimes respond to FTC complaints by altering advertisements, but continue to sell product

- Limited state efforts to protect consumers from fraudulent advertisements for products