

## **Health Products for Seniors**

#### "Anti-Aging" Products Pose Potential for Physical and Economic Harm

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

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# 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 <u>physical harm</u> to seniors?
- Is there evidence that questionable anti-aging and alternative medicine products cause <u>economic harm</u> to seniors?
- What are the state and federal <u>oversight efforts</u> 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 <u>case-by-case</u> basis against unapproved new drugs or medical devices, and against products claimed to cure disease
- <u>But</u> problematic products still available because FDA has not prohibited the marketing of <u>dangerous substances</u>
  - 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 <u>adulterated</u>, 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 <u>advertising</u>
  - 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