Dietary Supplements

The Role of Government in Protecting/Enhancing Consumer Welfare

What is a dietary or nutritional supplement?

- Dietary Supplement Health and Education Act (DSHEA) of 1994 definition:
- A dietary supplement is a product taken by mouth that contains a "dietary ingredient" intended to supplement the diet. E.g.,
  - Vitamins
  - Minerals
  - Herbs or other botanicals
  - Amino acids
  - Substances such as enzymes and metabolites
  - Weight loss products

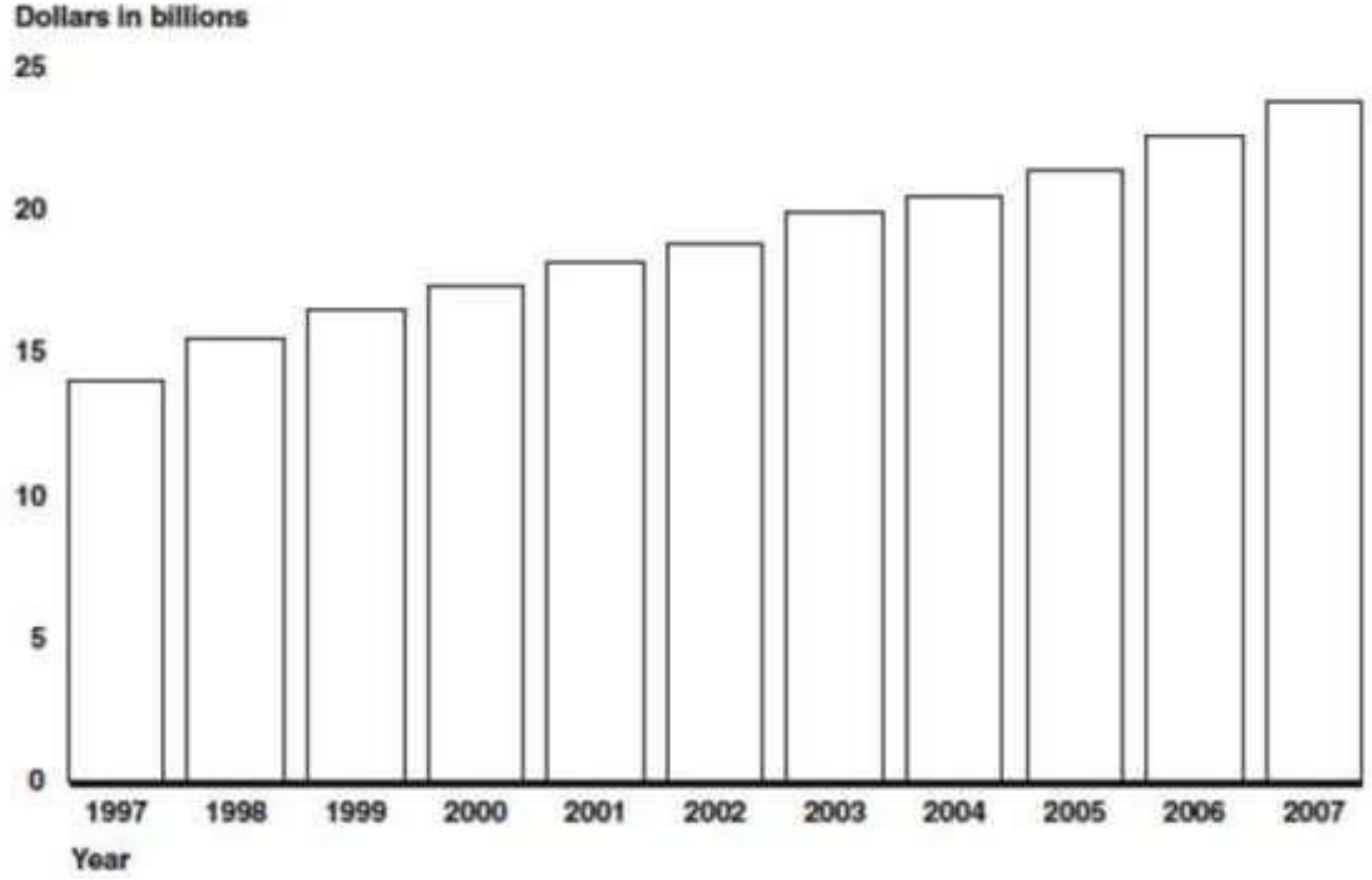
Why do we care about dietary/nutritional supplements?

- Same issues that were raised with prescription drugs
  - Safety: Ingredients are what they claim to be?
  - Effectiveness: Ingredients do what they claim to do?
- Implies asymmetry of information between consumers and manufacturers
- Very large market

What does the dietary supplement market look like?

- $23 billion per year industry in 2008
- 29,000 dietary supplement products on the market (up from 25,000 in 1993)
- More than 150 million Americans take dietary supplements annually

Figure 1: Total Sales of Dietary Supplements in the United States from 1997 through 2007



Source: GAO analysis of *Nutrition Business Journal* data.

Gender and Race/Ethnicity Differences in Dietary Supplement Use

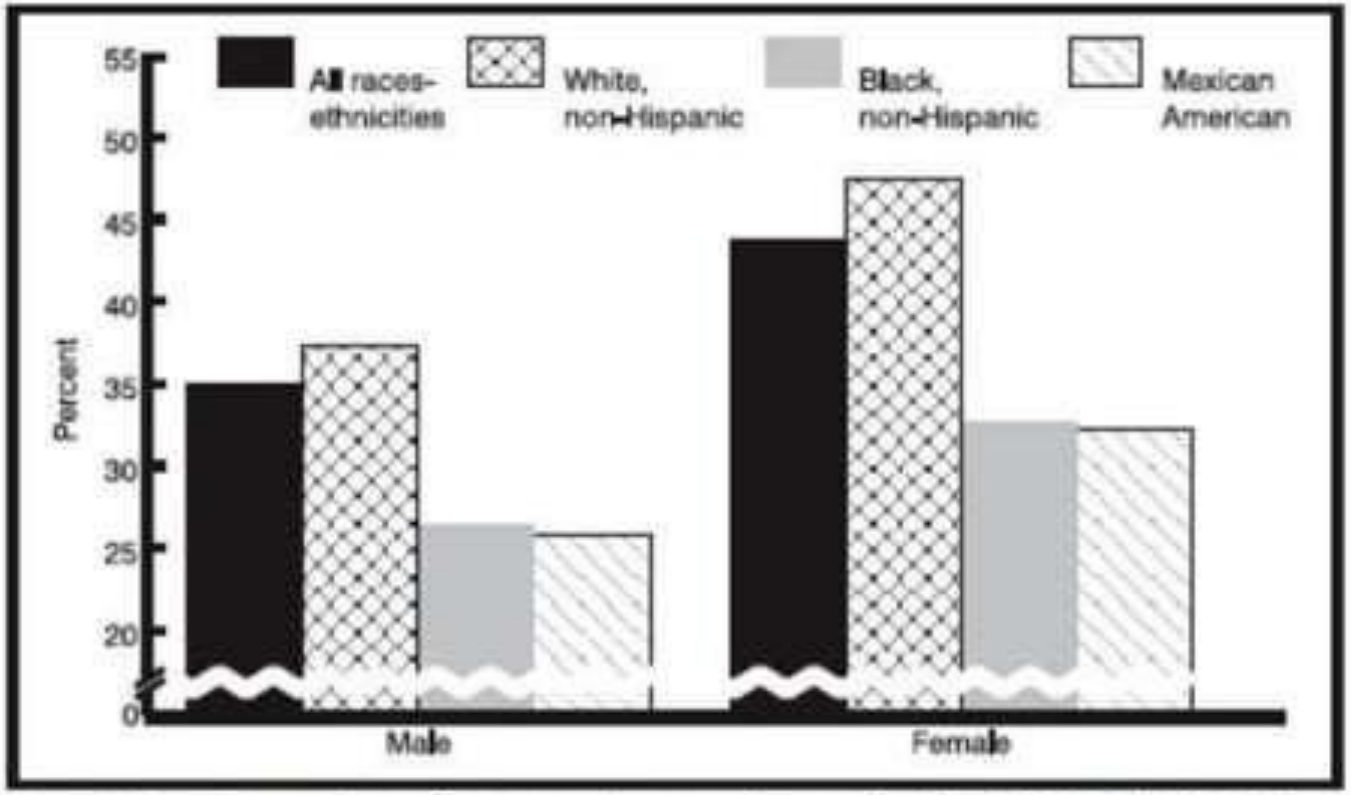


Figure 1. Prevalence of supplement use by sex and race-ethnicity, NHANES III, 1988–94

Source: Use of Dietary Supplements in the United States, 1988-94. NCHS.

Why do people take supplements?

Supplements: Why Taken?			
Vitamins/Minerals	% of Responses	Herbals/Supplements	% of Responses
Health/good for you	35	Health/good for you	16
Dietary supplement	11	Arthritis	7
Vitamin/mineral supplement	8	Memory improvement	6
Prevent osteoporosis	6	Energy	5
Physician recommended	6	Immune booster	5
Prevent colds/influenza	3	Joint	4
Don't know/no reason specified	3	Supplement diet	4
Immune booster	2	Sleep aid	3
Recommended by friend/family/media	2	Prostate	3
Energy	2	Don't know/no reason specified	2
All others	22	All others	45

JAMA, 2002, pp. 337-344.

Why is the dietary supplement market growing?

- Rising health care costs
- Increasing costs of health insurance (and growing numbers of uninsured)
- Growing distrust of the quality of the mainstream health care system

Who should have regulatory authority over dietary supplements?

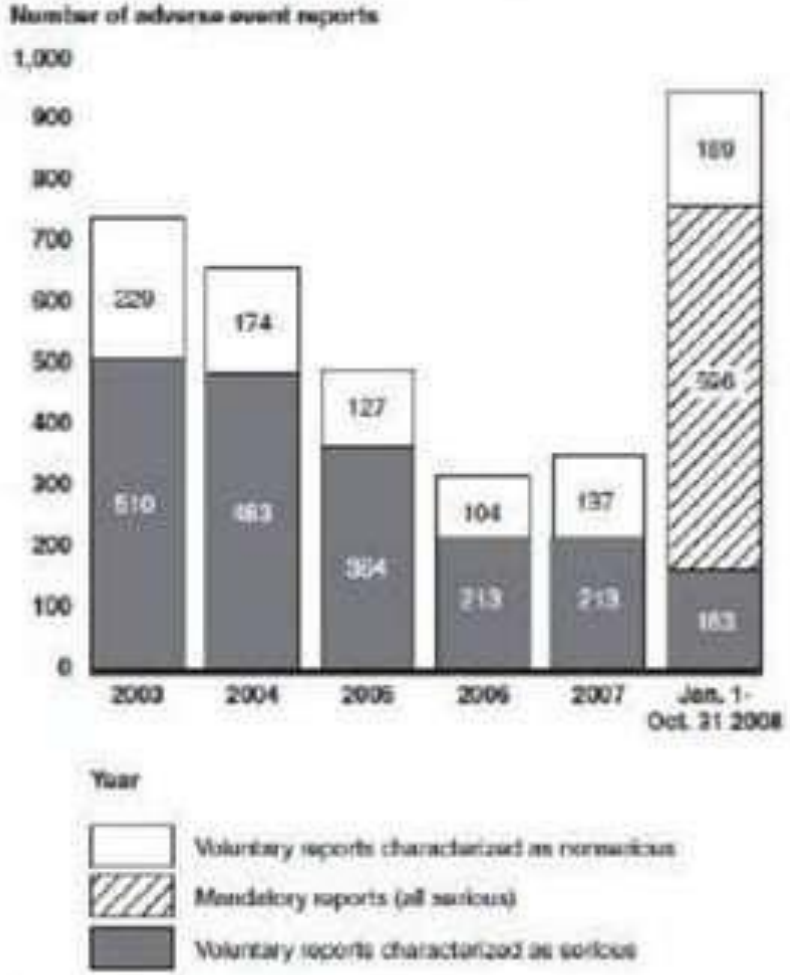
FDA regulates supplements as its own category. This implies…

- Research studies on people to prove a supplement's safety are NOT required
- Manufacturer does NOT have to prove the supplement is effective
- Manufacturer does NOT have to prove the supplement's quality
  - FDA does NOT analyze the content
  - Manufacturer must only meet the requirements of the FDA's good manufacturing practices

Label Claims Regulated by FDA

- Health claims describe a relationship between a food, food component, or dietary supplement ingredient, and reducing risk of disease or health-related condition
- Nutrient content claims describe the relative amount of a nutrient or dietary substance in a product
- A structure/function claim is a statement describing how a product many affect the organs or systems of the body and it can not mention any specific disease

Figure 2: The Number of Dietary Supplement-Related Adverse Event Reports to CAERS from January 1, 2003, to October 31, 2008



Source: GAO analysis of FDA data.

Table 2: Number of Cases with Mandatory Reported Adverse Event Outcomes by Dietary Supplement Product Classification, from December 22, 2007, through October 31, 2008

Dietary supplement product classification	Number of serious adverse events reported, from December 22, 2007, through October 31, 2008	Percentage of all serious adverse events reported
Combination products and products not elsewhere classified	391	65.6%
Vitamin	240	40.3
Mineral	111	18.6
Fats and lipid substances	55	9.2
Herbal and botanical (other than tea)	24	4.0
Fiber	20	3.4
Herbal and botanical teas	15	2.5
Protein	9	1.5
Animal by-products and extracts	1	0.2%
Total	**596[a]**	

Source: FDA

GAO 2009 Report: FDA should request the authority to…

- Issue guidance on new dietary ingredients
- Clarify the boundaries between dietary supplements and foods with supplemental ingredients
- Take steps to improve consumer understanding of dietary supplements

Reviewing…

- Dietary supplement market is large & is growing larger each year
- Consumers have limited information about effectiveness and safety, disadvantage for them in the dietary supplement market
- Justification for regulatory intervention by FDA
  - FDA's regulatory actions are constrained by Dietary Supplement Health and Education Act of 1994
  - Regulatory actions limited to a focus on label and package information and the reporting of adverse events
- Consumers still have little knowledge regarding dietary supplements and what knowledge they do have is questionable. Why?