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## *Dietary Supplements*

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## *Section A*

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Overview of Dietary Supplements

## *Dietary Supplements: Definition*

- Products (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: vitamins, minerals, amino acids, herbs or other botanical

# *Dietary Supplements: Definition*

OR

- A dietary substance that supplements the diet by increasing the total dietary intake

# *Dietary Supplements: Definition*

OR

- A concentrate, metabolite, constituent, extract, or combination of any ingredient described above

AND

- Intended for ingestion in the form of a capsule, powder, softgel, or gelcap, and not represented as a conventional food or as a sole item of a meal or the diet

# *Regulation of Dietary Supplements*

- Until 1994, dietary supplements were under the regulatory authority of the FDA (Federal Food, Drug, and Cosmetic Act of 1958—FD&C Act)
- In 1994, the Dietary Supplements Health and Education Act (DSHEA) removed FDA's authority by excluding dietary supplements from the FD&C Act

# *Regulation of Dietary Supplements*

- As a result of these provisions, dietary ingredients used in dietary supplements are no longer subject to the pre-market safety evaluations required of other new food ingredients (or of new uses of old food ingredients)



# *Approval of New Supplements*

- Manufacturers must notify FDA at least 75 days before marketing products containing new dietary ingredients, declaring that a dietary supplement containing the new dietary ingredient "will reasonably be expected to be safe"

- There is no provision under any law or regulation that the FDA enforces that requires companies to disclose the information they have about the safety or purported benefits of their dietary supplement products

- Manufacturers and distributors of dietary supplements are not required by law to record, investigate, or forward to the FDA any reports they receive of injuries or illnesses that may be related to the use of their products

- After the product is marketed, FDA must show that a dietary supplement is "unsafe," before it can take action to restrict, use, or remove the product from the marketplace

# *The Three Types of Claims*

- Health claims
  - “Prevents acne”
- Nutrient content claims
  - “Reduced fat”
  - “Low cholesterol”
  - “Rich in fiber”
- Structure/function claims
  - “Helps keep a healthy, silky skin”

- FDA approval required
- Based on FDA's scientific review

OR

- "Authoritative statement" from a U.S. government body or the National Academy of Sciences
- Subject to continuing advances in scientific knowledge

## *Approved Health Claims—1*

- High-folic acid diet (0.4mg/d) prevents neural tube defects
- Calcium-rich diets reduce risk of osteoporosis
- Diets rich in high-fiber products reduce risk of some forms of cancer
- Low-cholesterol, low-saturated fat diets reduce risk of CVD

## *Approved Health Claims—2*

- Low-sodium diets reduce the risk of high blood pressure
- Low-fat diets reduce risk of some types of cancer
- Fruits, vegetables, and grains that contain fiber reduce risk of CVD
- Soy protein and risk of coronary heart disease
- Plant sterol/stanol esters and risk of coronary heart disease
- Potassium and the risk of high blood pressure and stroke
- Dietary sugars and dental caries



# *Nutrient Content Claims*

- Regulated by FDA
- Must provide product composition data
- Subject to quality monitoring

# Examples of Nutrient Content Claims

<b>CLAIM</b>	<b>REQUIREMENT</b>
Calorie-free	<5 kcal
Light (lite)	30% less calories
Reduced fat	25% less fat
High-fiber	At least 5g
Good source of . . .	10–19% of DV
Rich in . . .	20% or more of DV

# *Structure/Function Claims*

- Not regulated by FDA
- No data on efficacy required
- Must include two disclaimers
  - 1. Not approved by FDA
  - 2. Not intended to diagnose, prevent, or treat a disease

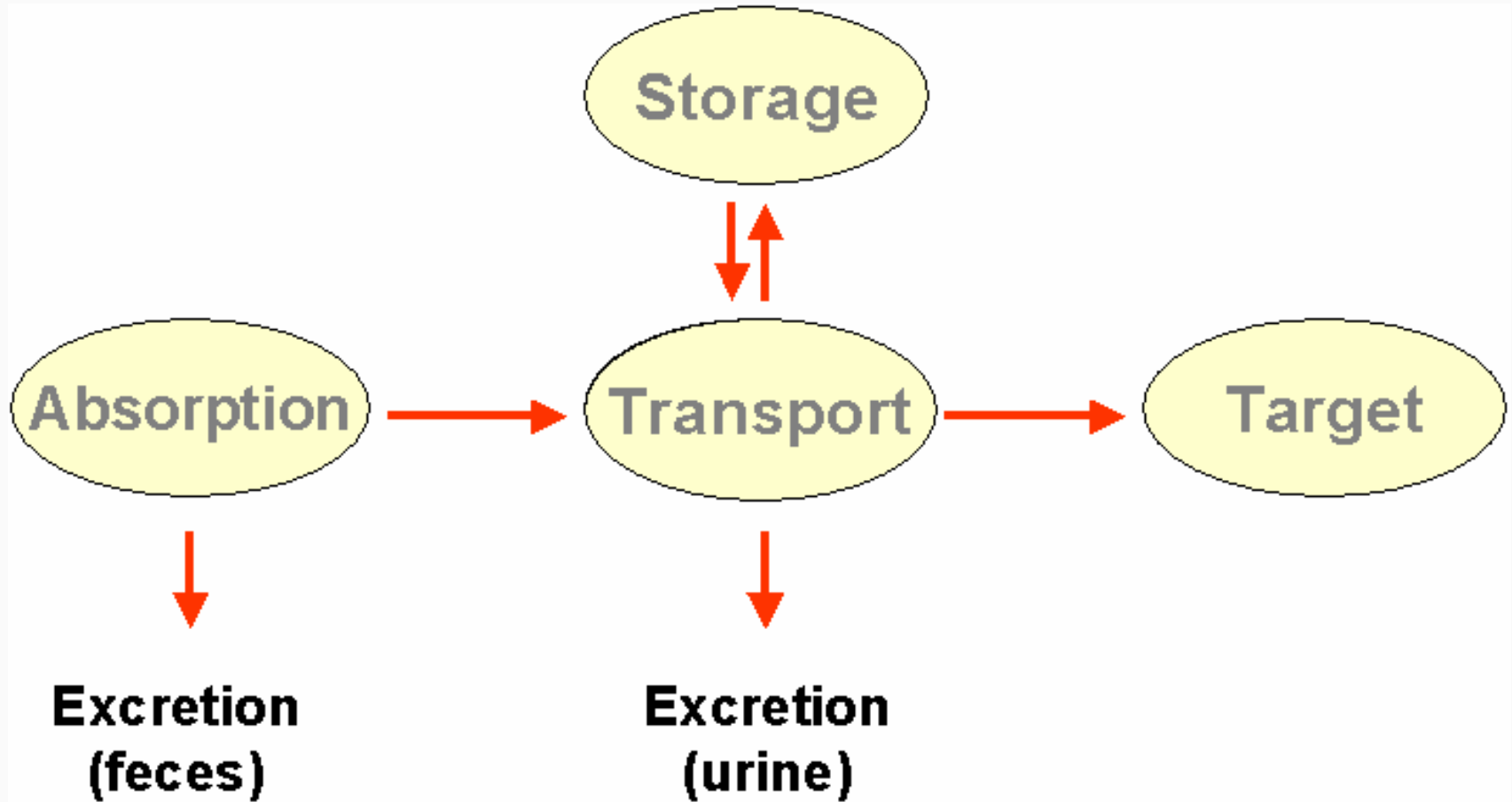


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## *Section B*

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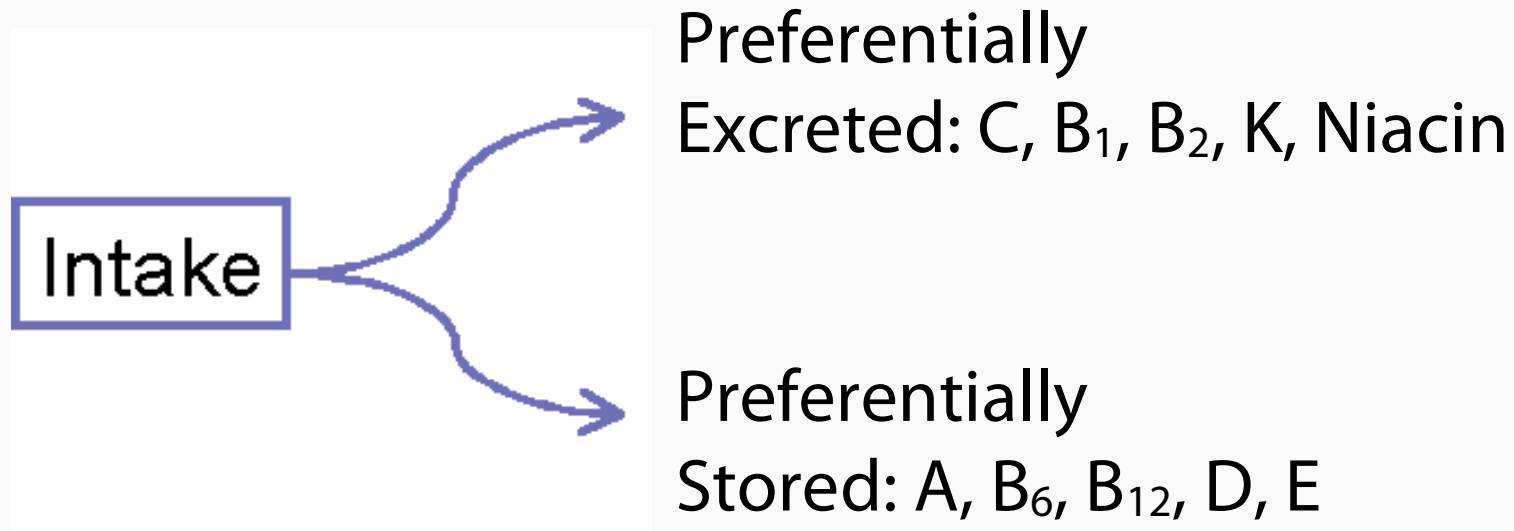
Mechanisms of Action of Supplemental Nutrients



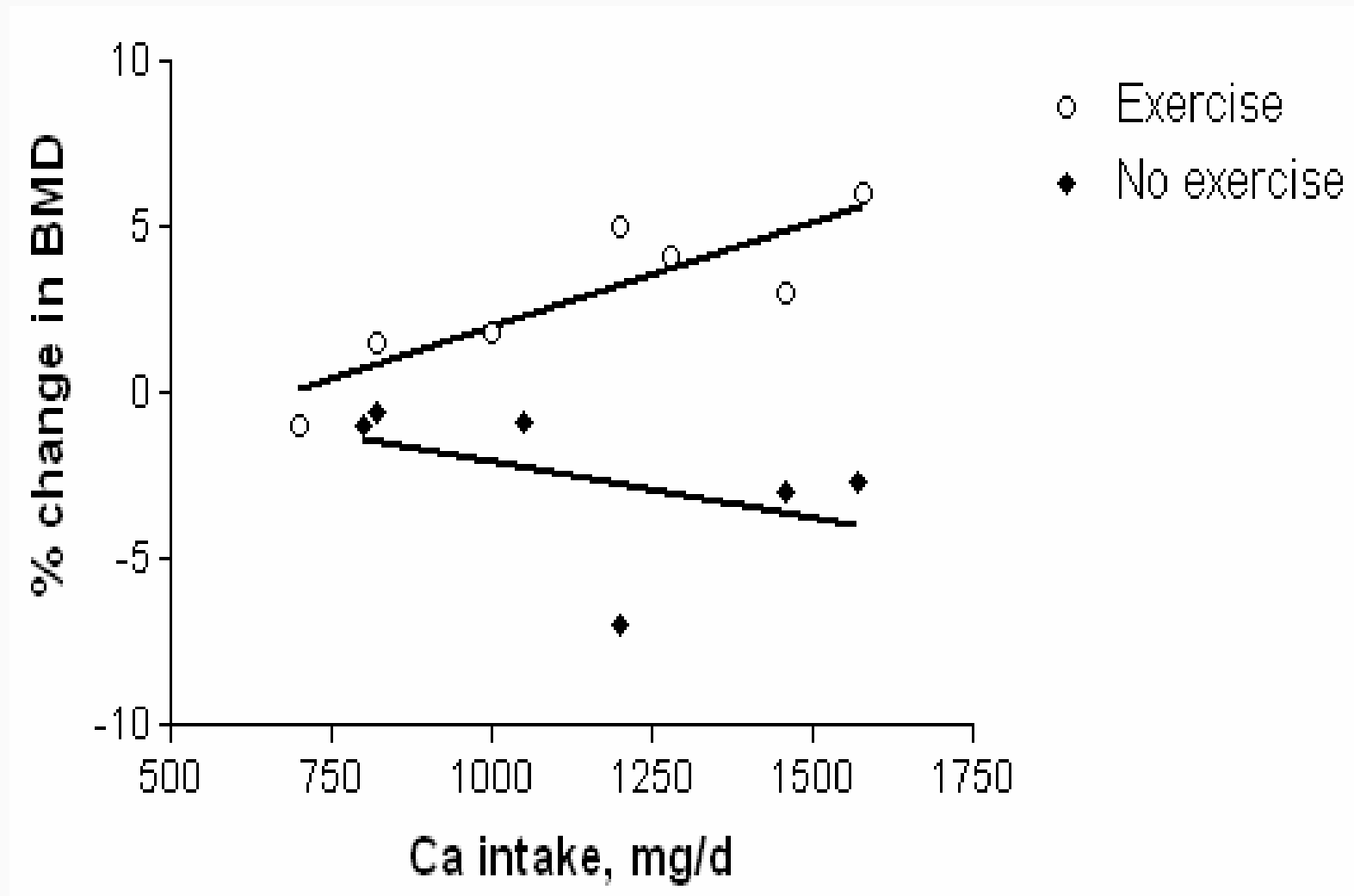
# *Consuming Higher Amounts of Dietary Constituents*

- The “push” principle
  - Increasing intake of a substrate will promote the synthesis or activity of its product
- The “pull” principle
  - An increased synthetic rate of a product will increase the demand for its substrate

# Fate of Excess Vitamin Intake



# Ca Intake and Bone Density





## *Vitamin E Trials: Some Examples*

- Inverse association between intake level and CHD risk (Rimm, 1993; Stampfer, 1993; Kushi, 1996)
- ATBC trial
  - No effect on lung cancer, 50% excess mortality from stroke in the supplemented group (Rapola, 1997)

## *Example of Scientific Rationale for Supplementation: Vitamin E*

- Food and Nutrition Board, NAS (2000)
  - There are insufficient data on which to base a recommendation for supplemental vitamin A to prevent heart disease for the general population
  - Data regarding the protective effects of supplements against cancer are not as yet available



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## *Section C*

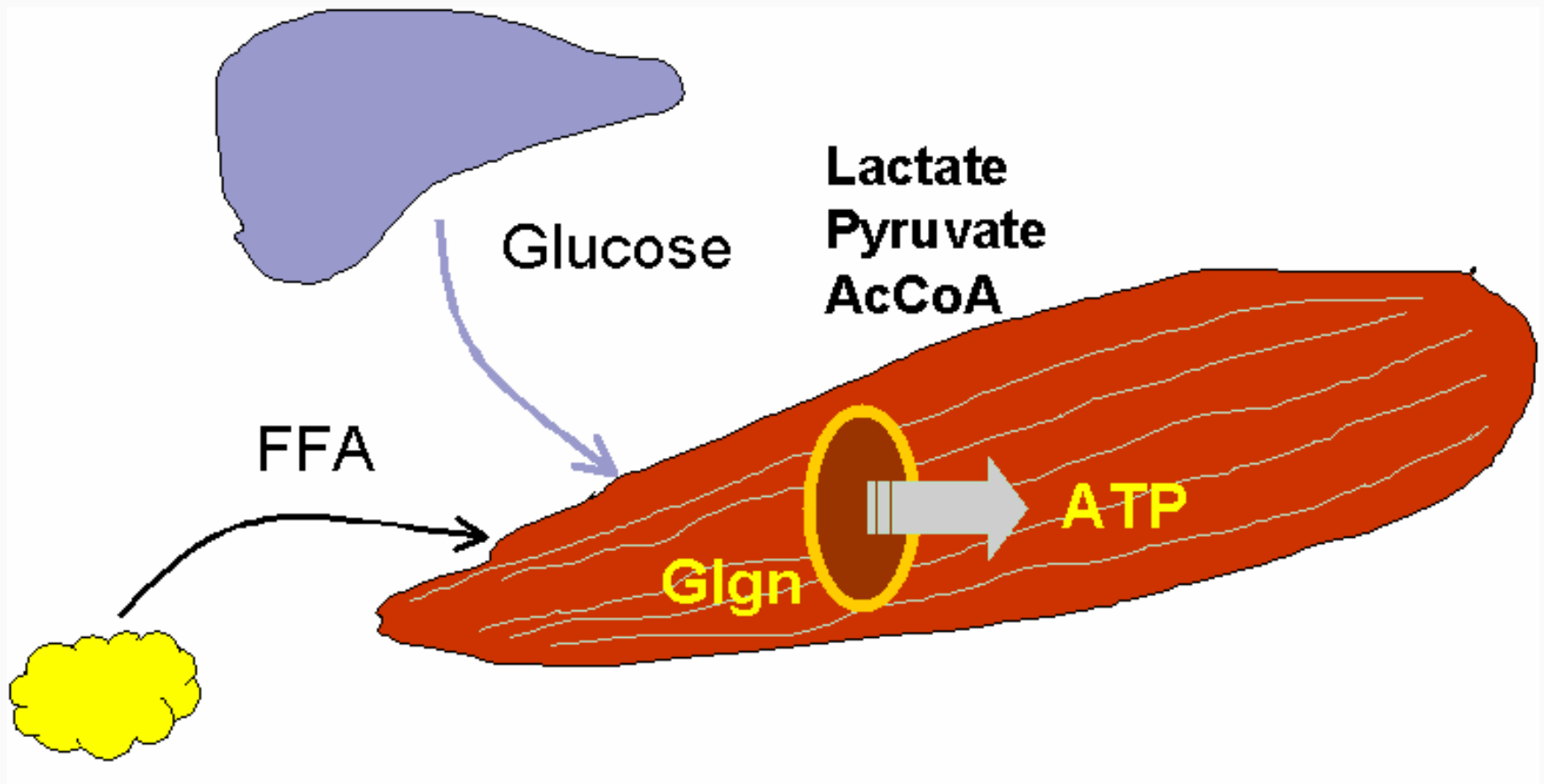
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Dietary Supplements and Physical Performance

## *“Pull”: Supplements and Physical Performance*

- Sales of the “sports” supplement CREATINE reached \$100 million in 1997, \$250 million in 1998, and over \$400 million in 2000 (est.)

# Skeletal Muscle Metabolism



- There is no evidence that athletes need more vitamins and minerals than healthy individuals
- Protein needs may increase for muscle building or repair
- However, this increase is within the range of usual protein intake in developed countries (~150% of RDA)

- Because athletes usually require higher than usual energy intake, fulfilling this need from healthy foods will provide higher micronutrient intakes

- Athletes who restrict their energy intake to comply with professional weight restrictions (wrestling, ballet, etc.) may risk having insufficient micronutrient intake



- Dietary creatine is derived almost exclusively from red meat and fish
- Supplemental creatine (monohydrate) increases muscle creatine levels in most but not all people
- Excess creatine is rapidly excreted in the urine as phosphocreatine

- Inconclusive evidence suggests that creatine may improve performance in repeated bouts of maximal exercise separated by periods of rest, in individuals 18–35 years of age
- No effects on single-bout anaerobic or submaximal aerobic exercises or in older individuals

# *Possible Adverse Effects of Supplements*

- Toxicity
  - Pro-oxidant role of vitamin E, iron
- Nutrient-nutrient interactions
  - Inhibition of nutrient absorption
- Behavioral
  - False belief that taking supplements will make up for unhealthy lifestyle (sedentary, smoking, etc.)

## *Risks of Supplement Use*

- Allergic reactions
- Competitive inhibition of absorption of other nutrients
- Drug-nutrient interactions
- Long-term effects

# *Functional Foods*

- Food modified to enhance health or address a specific diet-related risk
- FDA permits health claims if substantiated by scientific evidence

# Examples

- Orange juice fortified with calcium
- Modified oils (high pro-vitamin A)
- Soy-enriched products
- High-fiber cereals

## **Example—Osteoporosis**

- Calcium, vitamins D, K supplements

OR

- Regular exercise outdoors to promote bone health and enhance endogenous vitamin D synthesis
- Fresh fruits and vegetables to provide vitamin K

# *Indications for Nutritional Supplements*

- When dietary practices put (healthy) individuals at risk of having low micronutrient intake
  - Vegetarian
  - Macrobiotic
  - Other restricted diets



# *Indications for Nutritional Supplements*

- When unlikely that a “regular” diet will provide the RDA for a given nutrient
  - Pregnancy
  - Lactation
  - Breast-fed infants
  - Impaired absorption—GI disorders, bariatric surgery, elderly
  - Persistent anorexia