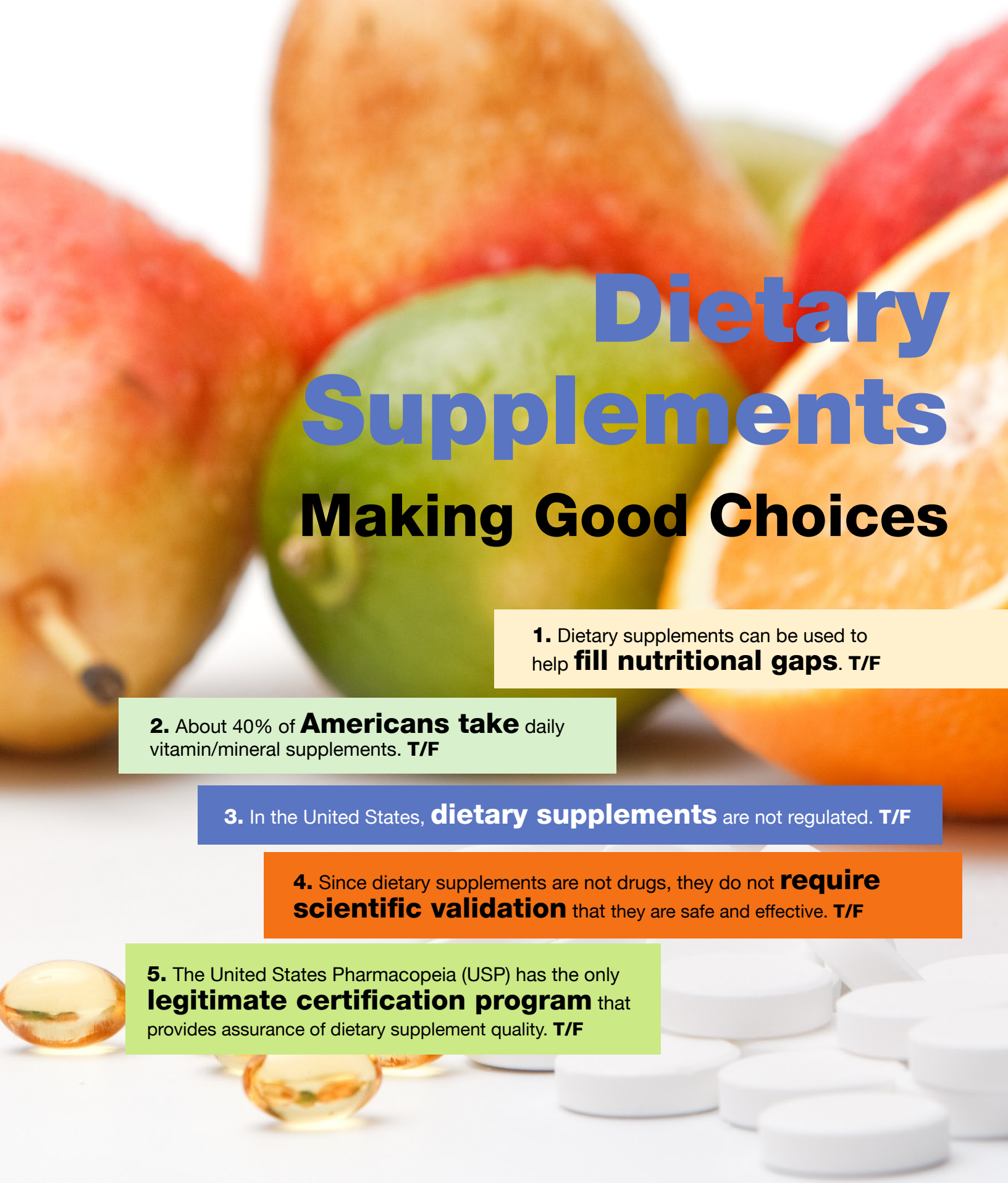


Dietary Supplements

Making Good Choices

1. Dietary supplements can be used to help **fill nutritional gaps**. **T/F**

2. About 40% of **Americans take** daily vitamin/mineral supplements. **T/F**

3. In the United States, **dietary supplements** are not regulated. **T/F**

4. Since dietary supplements are not drugs, they do not **require scientific validation** that they are safe and effective. **T/F**

5. The United States Pharmacopeia (USP) has the only **legitimate certification program** that provides assurance of dietary supplement quality. **T/F**

By Robert A. Sinnott and Jane E. Ramberg

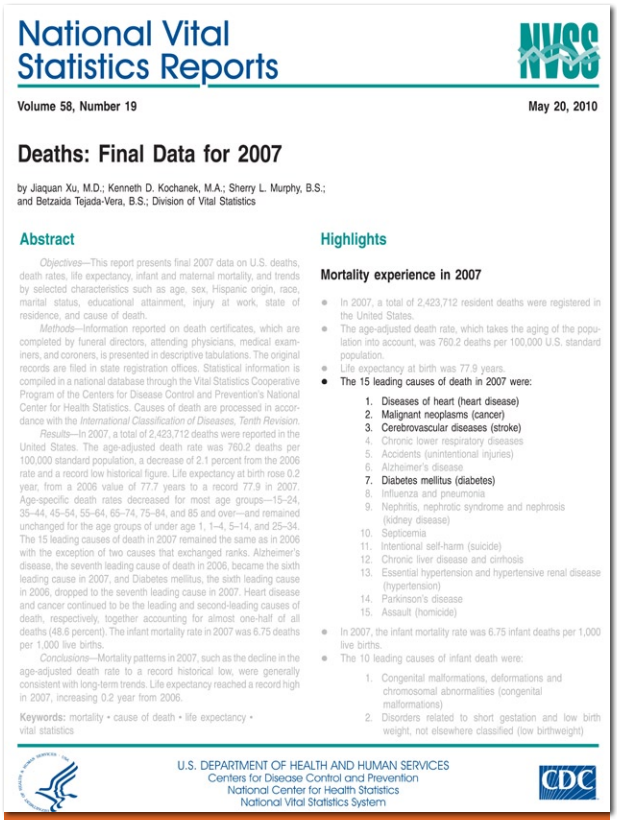
Answers

1. True. Dietary supplements are products intended to augment, or supplement, nutrients that may be missing in the daily diet.
2. True. Over 50% of American adults take dietary supplements, and about 40% take vitamin/mineral supplements.
3. False. In the U.S., dietary supplements are regulated by the Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) as a subcategory of food.
4. False. Supplement manufacturers must maintain appropriate scientific product claim substantiation and must submit product claims to FDA no later than 30 days after the product is sold.
5. False. Both USP and NSF International have legitimate certification programs that can provide further assurance of product quality.

The Inadequate Diet of Many Americans has Significant Health Consequences

There is no question that a healthy diet is necessary to support good health. Nutritionists agree that a healthy diet should include abundant fruit and vegetable intake, lean protein, whole grains, and healthy oils. Despite substantive efforts by experts to encourage healthy habits, American adults and children continue to make poor choices, eating inadequate amount of these foods and an excess of processed foods laden with unhealthy fats and sugars.[1]

Today, many Americans have significant micronutrient deficiencies. For example, the United States Department of Agriculture (USDA) considers the inadequate intake of calcium, vitamin D, fiber and potassium to be a public health concern for children and adults.[2] The consequences of poor diets are clear: fewer "quality life" years[3] and increased risks of developing four diseases that are among the fifteen top leading causes of death—heart disease (#1), cancer (#2), stroke (#3), and diabetes (#7).[4]



National Vital Statistics Reports

Volume 58, Number 19 — May 20, 2010

Deaths: Final Data for 2007

by Jiaquan Xu, M.D.; Kenneth D. Kochanek, M.A.; Sherry L. Murphy, B.S.; and Betzaida Tejada-Vera, B.S.; Division of Vital Statistics

Abstract

Objectives—This report presents final 2007 data on U.S. deaths, death rates, life expectancy, infant and maternal mortality, and trends by selected characteristics such as age, sex, Hispanic origin, race, marital status, educational attainment, injury at work, state of residence, and cause of death.

Methods—Information reported on death certificates, which are completed by funeral directors, attending physicians, medical examiners, and coroners, is presented in descriptive tabulations. The original records are filed in state registration offices. Statistical information is compiled in a national database through the Vital Statistics Cooperative Program of the Centers for Disease Control and Prevention's National Center for Health Statistics. Causes of death are processed in accordance with the *International Classification of Diseases, Tenth Revision*.

Results—In 2007, a total of 2,423,712 deaths were reported in the United States. The age-adjusted death rate was 760.2 deaths per 100,000 standard population, a decrease of 2.1 percent from the 2006 rate and a record low historical figure. Life expectancy at birth rose 0.2 year, from a 2006 value of 77.7 years to a record 77.9 in 2007. Age-specific death rates decreased for most age groups—15–24, 35–44, 45–54, 55–64, 65–74, 75–84, and 85 and over—and remained unchanged for the age groups of under age 1, 1–4, 5–14, and 25–34. The 15 leading causes of death in 2007 remained the same as in 2006 with the exception of two causes that exchanged ranks. Alzheimer's disease, the seventh leading cause of death in 2006, became the sixth leading cause in 2007, and Diabetes mellitus, the sixth leading cause in 2006, dropped to the seventh leading cause in 2007. Heart disease and cancer continued to be the leading and second-leading causes of death, respectively, together accounting for almost one-half of all deaths (48.6 percent). The infant mortality rate in 2007 was 6.75 deaths per 1,000 live births.

Conclusions—Mortality patterns in 2007, such as the decline in the age-adjusted death rate to a record historical low, were generally consistent with long-term trends. Life expectancy reached a record high in 2007, increasing 0.2 year from 2006.

Keywords: mortality • cause of death • life expectancy • vital statistics

Highlights

Mortality experience in 2007

- In 2007, a total of 2,423,712 resident deaths were registered in the United States.
- The age-adjusted death rate, which takes the aging of the population into account, was 760.2 deaths per 100,000 U.S. standard population.
- Life expectancy at birth was 77.9 years.
- The 15 leading causes of death in 2007 were:
  1. Diseases of heart (heart disease)
  2. Malignant neoplasms (cancer)
  3. Cerebrovascular diseases (stroke)
  4. Chronic lower respiratory diseases
  5. Accidents (unintentional injuries)
  6. Alzheimer's disease
  7. Diabetes mellitus (diabetes)
  8. Influenza and pneumonia
  9. Nephritis, nephrotic syndrome and nephrosis (kidney disease)
  10. Septicemia
  11. Intentional self-harm (suicide)
  12. Chronic liver disease and cirrhosis
  13. Essential hypertension and hypertensive renal disease (hypertension)
  14. Parkinson's disease
  15. Assault (homicide)
- In 2007, the infant mortality rate was 6.75 infant deaths per 1,000 live births.
- The 10 leading causes of infant death were:
  1. Congenital malformations, deformations and chromosomal abnormalities (congenital malformations)
  2. Disorders related to short gestation and low birth weight, not elsewhere classified (low birthweight)

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
National Center for Health Statistics
National Vital Statistics System

Poor diets are associated with four of the fifteen top leading causes of death in the United States.

Many Experts Recommend Dietary Supplements

While efforts will certainly continue to urge consumers towards better dietary choices, there is growing recognition that dietary supplements can be used to help fill nutritional gaps. In a surprising reversal of their long-standing position that supplements are not necessary, physicians at Harvard Medical School recommended in 2002 that all adults take a vitamin supplement.[5] Their recommendation was based on a thorough review of the scientific literature which confirmed that inadequate intake of certain vitamins is a risk factor for numerous chronic diseases. Since then, a growing number of organizations—including the American Dietetic Association and the American Academy of Pediatrics—have also acknowledged the benefits of dietary supplementation. Today, over 70% of physicians take supplements, their top choices being multivitamins, vitamin C, B-complex vitamins, vitamin D, calcium, and vitamin E. Almost 80% of physicians recommend supplements to their patients, most frequently for overall wellness benefits, healthy cholesterol levels, or bone, joint or heart health.[6] Over 50% of American adults take dietary supplements, and 40% take vitamin/mineral supplements.[7] In 2007, the most commonly used non-vitamin/mineral supplements used by adults for health reasons were fish oil products (37.4%), glucosamine (19.9%), echinacea (19.8%), flaxseed oil or pills (15.9%) and ginseng (14.1%).[8]

In the U.S., over 70% of physicians take dietary supplements and close to 80% recommend them to their patients.

What are Dietary Supplements, and How are they Regulated?

Dietary supplements are products intended to augment, or supplement, nutrients that may be missing in the daily diet. Their specific definition, and what manufacturers may say about them, depends on the country in which they are sold. Country-specific dietary supplement regulations thus strongly impact the consumer's access to particular products, and their understanding of product effects.

In the U.S., dietary supplements are regulated by the Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) as a subcategory of food. Dietary supplement products include vitamins, minerals, botanicals, sports nutrition supplements, weight management products and specialty supplements. Allowed statements about the effects of most supplement products are limited to structure/function claims (e.g., calcium supports healthy teeth), and product labels must clearly indicate that they should not be used to diagnose, prevent, mitigate, treat or cure a specific disease. In response to supplement industry petitions, the FDA has granted more robust health claims for some products (e.g. omega fatty acids may decrease the risk of cardiovascular disease and folic acid reduces the risk of neural tube birth defects).

In Canada, the Natural Health Products Directorate regulates dietary supplements, most of which (Natural Health Products [NHPs]) are regarded as a subcategory of drugs. These products include vitamins and minerals, herbal remedies, Homeopathic medicines, traditional medicines (such as traditional Chinese medicines), probiotics, and other products (such as amino acids and essential fatty acids). A smaller percentage of products are regulated as foods. If appropriate human clinical studies have been conducted, disease treatment claims may be made for NHPs.

In Australia, the Therapeutic Goods Administration regulates supplements as Listed Medicines and, as is the case in Canada, therapeutic claims are allowed if the evidence is sufficient. In EU countries, supplements are regulated as food, and only structure/function/health maintenance claims are permitted. Each member state has an agency that oversees foods and supplements. The primary agency in the EU that is the most involved in developing legislation (but not enforcement) is the European Food Safety Authority (EFSA).

dietary supplements In the U.S., dieatary supplements include vitamins, minerals, botanicals, sports nutrition supplements, weight management products and specialty supplements.

A Brief History of Dietary Supplement Regulations in the United States

In the early 1900s, many unregulated health products were frequently prepared in unsanitary conditions, adulterated, mislabeled, and sold with outrageous therapeutic claims. Over the past 100 years, the U.S. Congress has enacted legislation to protect consumers against such egregious products. Key legislation includes:

- The Food and Drug Act of 1906, which prohibited the sale of misbranded and adulterated products;
- The Food, Drug and Cosmetic Act of 1938, which required that all foods, beverages, drugs and cosmetics be proven safe; and
- The Nutrition Labeling and Education Act of 1990, which gave the FDA

Department of Health and Ageing
Therapeutic Goods Administration

FDA

Health Canada Santé Canada

Definitions of dietary supplements, what they can contain and how they are regulated depends on the country in which they are sold.

S. 784

One Hundred Third Congress
of the
United States of America

AT THE SECOND SESSION

Begun and held at the City of Washington on Tuesday, the twenty-fifth day of January, one thousand nine hundred and ninety-four

An Act

To amend the Federal Food, Drug, and Cosmetic Act to establish standards with respect to dietary supplements, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; REFERENCE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Dietary Supplement Health and Education Act of 1994".

(b) REFERENCE.—Whenever in this Act an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act.

(c) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

Sec. 1. Short title; reference; table of contents.
Sec. 2. Findings.
Sec. 3. Definitions.
Sec. 4. Safety of dietary supplements and burden of proof on FDA.
Sec. 5. Dietary supplement claims.
Sec. 6. Statements of nutritional support.
Sec. 7. Dietary supplement ingredient labeling and nutrition information labeling.
Sec. 8. New dietary ingredients.
Sec. 9. Good manufacturing practices.
Sec. 10. Conforming amendments.
Sec. 11. Withdrawal of the regulations and notice.
Sec. 12. Commission on dietary supplement labels.
Sec. 13. Office of dietary supplements.

SEC. 2. FINDINGS.

Congress finds that—

(1) improving the health status of United States citizens ranks at the top of the national priorities of the Federal Government;

(2) the importance of nutrition and the benefits of dietary supplements to health promotion and disease prevention have been documented increasingly in scientific studies;

(3)(A) there is a link between the ingestion of certain nutrients or dietary supplements and the prevention of chronic diseases such as cancer, heart disease, and osteoporosis; and

(B) clinical research has shown that several chronic diseases can be prevented simply with a healthful diet, such as a diet that is low in fat, saturated fat, cholesterol, and sodium, with a high proportion of plant-based foods;

(4) healthful diets may mitigate the need for expensive medical procedures, such as coronary bypass surgery or angioplasty;

Unanimously approved by Congress in 1994, the Dietary Supplement Health and Education Act (DSHEA) clarified the regulation of dietary supplements by the FDA.

authority to approve disease prevention claims for foods, including dietary supplements.

When, in the early 1990s, the FDA Commissioner announced his intention to aggressively restrict public access to dietary supplement ingredients other than essential vitamins and minerals, the supplement industry mobilized a grassroots campaign that is regarded by some as one of the most successful political movements in American history. Health food stores and consumers throughout the country campaigned for action to stop FDA. Congress responded by unanimously passing the Dietary Supplement Health and Education Act of 1994 (DSHEA). DSHEA, which acknowledged that appropriate nutrition is a cost-effective means of preventing many chronic diseases, included these key features:

- Requires supplement manufacturers to maintain appropriate scientific product claim substantiation and to submit product claims to FDA no later than 30 days after the product is sold.
- "Grandfathered" products and dietary supplement ingredients sold before 1994. Such products were assumed to have a history of safe use.
- Requires manufacturers of products with new ingredients to provide FDA notice and safety information 75 days before intended sale. If FDA has any concerns, it can request more information or deny the product's entry into the marketplace.
- Provided FDA with additional enforcement authority, including the ability to remove from the market products deemed unsafe.
- Gave FDA authority to establish Good Manufacturing Practice (GMP) regulations for supplements, which were issued in 2007.

The Dietary Supplement and Nonprescription Drug Consumer Protection Act of 2006 required manufacturers to notify FDA of all serious adverse events they are aware of associated with an over-the-counter drug or a dietary supplement. And, finally, if approved by Congress, the Dietary Supplement Full Implementation and Enforcement Act, currently under consideration by Congress, would ensure that FDA has additional resources to accomplish important regulatory mandates set out by DSHEA.

Making Good Dietary Supplement Choices

Before we begin, it's important to remember that assessing the effects of nutrition on human health presents unique challenges. When evaluating the effects of dietary supplements, healthcare providers often expect "gold" standard double-blind, placebo-controlled clinical trials. This type of study was, however, developed to evaluate the effects of drugs on humans. In such studies, the drug is given to one group of patients and not to another group, and the difference in response is noted. When applied to the study of foods or dietary supplements, unique confounders arise. People are typically getting the nutrient(s) being studied in their daily diets, which makes it difficult to evaluate the effects of added amounts, or to know exactly how much they are actually consuming. Further, nutrients are expected to play a role in the prevention of disease, not its treatment. Most clinical trials examine people who either have a disease, or are at high risk for developing the disease. Such trials are testing treatment, rather than preventive effects. The effects of

nutrients would be expected to take years to become apparent—much longer than the duration of most clinical trials.

While nutrient studies usually measure small effects within a single body system, the public health impact may be large, and effects across multiple body systems can be large. That is, over time, small effects can have big consequences. For example, people with a negative calcium balance of just 30 milligrams per day can experience 10% bone loss each year, which means they can develop osteoporosis in 30 years. Or, normal weight people who consume an extra 70 calories each day (less than a 6 ounce Coke) can gain roughly 7 pounds per year, and thus become overweight in 10 years.

Consumers are faced with an overwhelming variety of supplement choices.

Practical Tips for Consumers

Consumers are faced with an overwhelming variety of supplement choices. Before purchasing any dietary supplement, smart consumers will increase their chances of success by considering the following guidelines:

- Remember that no supplement can be expected to overcome a poor diet or other poor health habits.
- If you have a health challenge, be sure to discuss the product with your healthcare provider, pharmacist or registered dietician.
- Be clear about the reason(s) you want to take the product.
- Are the benefits of the product you are considering validated by published human oral studies?
- Are the sources and amounts of nutrients in the product reasonable? Numerous studies suggest that intake of high dose, synthetically derived nutrients can be harmful. Look for products containing RDA-levels of nutrients, preferably from whole food sources.
- Is the product appropriately labeled?

  The FDA requires that dietary supplement product labels include a "Supplement Facts" box and an Ingredients Section. The Supplement Facts box must include the amount (if present) of calories, fat, cholesterol, sodium, carbohydrates and protein in a product. If vitamins or minerals are present at or above 2% of their Recommended Dietary Intake (RDI), they must also be listed. The Ingredients Section lists specific product ingredients in descending order (from the highest to the lowest percentage).

  While manufacturers have some freedom regarding the presentation of Ingredient information, consumers should look for specific, detailed nutrient information followed by a list of excipients (ingredients necessary to manufacture the product) in an "Other Ingredients" section.

  Products with a box entitled "Nutrition Facts" are considered to

How do you read a supplement label?

Supplement Facts

Serving Size 1 tablet

Suggested Use: Adults, take one tablet per day with meal

Amount Per Serving	% Daily Value
Vitamin A 5000 I.U.	
50% as Beta Carotene	100%
Vitamin C 250 mg	417%
Vitamin D 400 I.U.	100%
Vitamin E 200 I.U.	667%
Vitamin K 80 mcg	100%
Thiamin 5 mg	333%
Riboflavin 5 mg	294%
Niacin 20 mg	100%
Vitamin B_6 5 mg	250%
Folic acid 400 mcg	100%
Vitamin B_{12} 6 mcg	100%
Biotin 150 mcg	50%
Pantothenic Acid 10 mg	100%
Calcium 200 mg	20%
Iron 18 mg	100%
Phosphorus 200 mg	20%
Iodine 150 mcg	100%
Selenium 35 mcg	50%
Magnesium 200 mg	50%
Zinc 15 mg	100%
Copper 2 mg	100%
Boron 150 mcg	*

* Daily Value not established

Ingredients: vitamin A acetate, beta carotene, vitamin D, dl-alpha tocopherol acetate, ascorbic acid, thiamin mononitrate, riboflavin, niacinamide, pyridoxine hydrochloride, vitamin B12, biotin, d-calcium pantothenate, potassium chloride, dicalcium phosphate, potassium iodine, ferrous fumarate, magnesium oxide, copper sulfate, zinc oxide, manganese sulfate, sodium selenate, chromium chloride, sodium molybdate, microcrystalline cellulose, calcium carbonate, sodium carboxymethyl cellulose

Storage: Keep tightly closed in dry place; do not expose to excessive heat

KEEP OUT OF REACH OF CHILDREN

Expiration date: JUN 2013

Company V, Cityville, New York 01010

Council for Responsible Nutrition®
The Science Behind the Supplements®

Updated 10/08

How do you read a supplement label? **(a)** Serving size is the manufacturer's suggested serving expressed in the appropriate unit (tablet, capsule, softgel, packet, teaspoonful). **(b)** Amount Per Serving heads the listing of nutrients contained in the supplement, followed by the quantity present in each serving. **(c)** Percent Daily Value (DV) tells what percentage of the recommended daily intake for each nutrient for adults and children ages 4 and up is provided by the supplement. **(d)** International Unit (IU) is a standard unit of measure for fat soluble vitamins (A, D and E). **(e)** Milligram (mg) and microgram (mcg) are units of measurement for water soluble vitamins (C and B complex) and minerals. A milligram is equal to .001 grams. A microgram is equal to .001 milligrams. **(f)** An asterisk under the "Percent Daily Value" heading indicates that a Daily Value is not established for that nutrient. **(g)** The list of all ingredients includes nutrients and other ingredients used to formulate the supplement, in decreasing order by weight. **(h)** All supplements should be stored in a cool, dry place in their original containers, out of the reach of children and should be used before the expiration date to assure full potency. **(i)** The manufacturer's or distributor's name and place of business or phone number are required to appear on the label.

NSF International and the United States Pharmacopeia (USP) have legitimate certification programs that can provide further assurance of product quality.

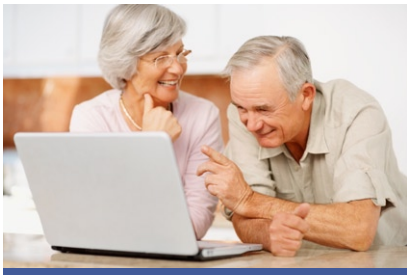
be foods, but the label should provide the same types of information provided for dietary supplements.

- Look for a seal that indicates the product has been evaluated by an independent laboratory. NSF International and the United States Pharmacopeia (USP) have legitimate certification programs that can provide further assurance of product quality.
- Does the company that sells the product have a website with a phone number for customer questions?
- Does the company that sells the product have a good track record? Has it been marketing products for at least a few years?
- Trust your instincts. Avoid products that have claims that sound too good to be true. Such products probably *are* too good to be true.
- Don't expect overnight results. Supplements aren't drugs, so immediate effects shouldn't be expected.

Tips for Educating Yourself About Nutrition and Dietary Supplementation

For those who like to educate themselves about the benefits of nutrients, here are a few guidelines:

- If you use the internet, try .org, .edu, .gov and .net websites. Such sites are more likely to be non-commercial and have more objective information. Suggested reliable websites:
  - National Institute of Health's Office of Dietary Supplements
  - The U.S. National Library of Medicine and the National Institutes of Medical Literature
  - Natural Standard
  - The Council for Responsible Nutrition (a trade organization that represents the dietary supplement industry)
- Look for information supported by studies published in reputable scientific journals. The highest quality dietary supplements will often have published studies supporting their safety and effectiveness.
  - Take more seriously studies which include larger numbers of people, but pay attention to the dose given (is it reasonable?) and the health of the people taking it (this can have a big impact on response).
  - Be wary of test tube (*in vitro*) studies, animal studies, or human studies that are not oral studies. Such studies may tell you little about what a supplement does when a human consumes it.



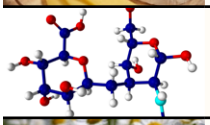
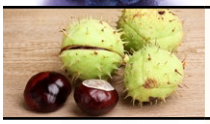
Saavy consumers make better dietary supplement choices.

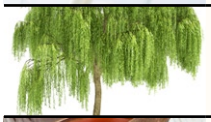
Some supplements that can be part of the integrative health paradigm

Despite the difficulties associated with studying nutritional ingredients, scientific knowledge regarding their use to support healthy body functioning, reduce the risk of disease or reduce disease symptoms is progressing. The table below lists scientifically-validated ingredients that can be included in the integrative health paradigm.

TABLE 1

Scientifically validated supplement ingredients

	Ingredient	Benefits
	Alpha-lipoic acid	Diabetes, nerve damage
	Beta-glucans	High blood lipids
	Beta-sitosterols	High blood cholesterol
	Calcium	Bone density, osteoporosis
	Chondroitin sulfate	Osteoarthritis
	Feverfew	Migraine headaches
	Folate	Prevention of pregnancy complications (neural tube defects); high blood homocysteine
	Garlic	High blood presure, high blood lipids
	Gingko biloba	Memory
	Glucosamine sulfate	Osteoarthritis
	Glyconutrients	Immunity, mood, memory
	Grape seed	Chronic venous insufficiency
	Horse chestnut	Chronic venous insufficiency
	Iodine	Goiter
	Kava	Anxiety
	Melatonin	Jet lag

	Ingredient	Benefits
	Niacin	High blood lipids
	Omega-3 fatty acids	High blood pressure, high blood triglycerides, cardiovascular disease
	Peppermint	Irritable bowel syndrome
	Plant soluble fibers	Gut health, high blood cholesterol
	Plant sterols	High blood cholesterol
	Probiotics	Diarrhea, atopic dermatitis
	Red yeast rice	High blood lipids
	Saw palmetto	Benign prostatic hypertrophy
	Soy	High blood lipids
	Vitamin A	Acne
	Vitamin B_{12}	Pernicious and megaloblastic anemias
	Vitamin C	Scurvy
	Vitamin D	Rickets
	Willow bark	Osteoarthritis
	Zinc	Stomach ulcers

The Future of Dietary Supplements

If existing regulations are appropriately enforced, the future is bright for dietary supplements to play an important role in the enhancement and preservation of human health. Reputable companies in the industry and major industry trade associations actually support stronger enforcement that would remove poor quality products from the market, and also those products that make claims without adequate scientific proof. Fortunately, consumer's access to information has improved greatly and more consumers are taking a keen interest in preserving their health and quality of life by the prudent use of dietary supplements as part of an integrative health approach. Some experts believe that the United States will move toward requiring a higher level of substantiation and some level of premarket approval for dietary supplement products, similar to the Canadian and Australian models. The benefit will be that scientifically validated dietary supplements will probably be allowed to make some level of meaningful treatment and prevention claims that would be valuable to the consumer but are currently disallowed under current regulations.

The Top Five Points to Remember

1. Today, many Americans have significant micronutrient deficiencies. The United States Department of Agriculture (USDA) considers the inadequate intake of calcium, vitamin D, fiber and potassium by children and adults to be a public health concern. The consequences of poor diets are clear: fewer "quality life" years and increased risks of developing four diseases that are among the fifteen top leading causes of death—heart disease, cancer, stroke, and diabetes.

2. Dietary supplements are products intended to augment, or supplement, nutrients that may be missing in the daily diet. Their specific definition, and what manufacturers can say about them, depends on where they are sold. In the U.S., dietary supplements are regulated by the Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) as a subcategory of food.

3. The Dietary Supplement Health and Education Act (DSHEA): 1) requires supplement manufacturers to maintain appropriate scientific product claim substantiation and to submit product claims to FDA no later than 30 days after the product is sold; 2) "Grandfathered" products and dietary supplement ingredients sold before 1994; 3) requires manufacturers of products with new ingredients to provide FDA notice and safety information 75 days before intended sale; 4) provided FDA with additional enforcement authority, including the ability to remove from the market products deemed unsafe; and 5) gave FDA authority to establish Good Manufacturing Practice (GMP) regulations for supplements, which were released in 2007.

4. Before purchasing a dietary supplement, consumers should: 1) be clear about the intended purpose of the product, 2) be informed about what to look for on the product label, including confirmation of product quality by an independent laboratory, such as USP or NSF International, and 3) select companies that have a good track record, a website, and a phone number for customer questions. Consumers with health challenges should always discuss their planned supplement use with their healthcare provider.

5. A growing number of scientifically validated dietary ingredients can improve health. To learn more about legitimate products, smart consumers avoid commercial websites and look for products that have been validated by human oral clinical studies.

Test Yourself

1. According to the USDA, inadequate intake of which of the following nutrients by children and adults is a public health concern?
   a. Calcium.
   b. Vitamin E.
   c. Folate.
   d. All of the above.

2. When choosing a dietary supplement, it is important to:
   a. Determine if it is appropriately labeled.
   b. Confirm that the company has a good track record.
   c. Confirm that reasonable amounts of nutrients are included.
   d. All of the above are correct.

3. People who have health challenges:
   a. Should not take dietary supplements.
   b. May take dietary supplements because they are safe.
   c. Should discuss their planned use of dietary supplements with their health care provider, pharmacist, or registered dietician.
   d. b and c are correct.

4. The best way to assess the safety and efficacy of dietary supplements is through:
   a. Excellent *in vitro* or test tube studies conducted in modern laboratories.
   b. Well-designed human clinical trials.
   c. Studies on at least 500 chimpanzees.
   d. Any of the above will do, as long as the researcher is a Ph.D.

5. DHSEA, passed by the U.S. Congress in 1994, includes these features:
   a. Requires manufacturers to submit product claims to the FDA no later than 30 days after the product is sold.
   b. "Grandfathered" products and dietary ingredients sold before 1994.
   c. Allows the FDA to remove unsafe products from the marketplace.
   d. All of the above.

Answers

1. (a) The USDA considers the inadequate intake of calcium, vitamin D, fiber and potassium to be a public health concern for children and adults.
2. (d) All of these criteria are important for individuals planning to purchase dietary supplements.
3. (c) Dietary supplements can be beneficial for individuals with health challenges, but their planned use should always be discussed with a qualified healthcare provider.
4. (b) Well-designed human clinical trials are the best validation of dietary supplement safety and efficacy.
5. (d) DSHEA includes all of these features, and also requires manufacturers of products with new ingredients to provide FDA notice and safety information 75 days before intended sale, and gave FDA authority to establish Good Manufacturing Practice (GMP) regulations for supplements, which were released in 2007.

Web Resources

Information about dietary supplements

- National Institute of Health's Office of Dietary Supplements: http://ods.od.nih.gov/Research/PubMed_Dietary_Supplement_Subset.aspx
- The U.S. National Library of Medicine and the National Institutes of Medical Literature: http://www.ncbi.nlm.nih.gov/sites/entrez/
- Natural Standard (subscription required): http://naturalstandard.com/index.asp
- The Council for Responsible Nutrition (a trade organization that represents the dietary supplement industry): http://www.crnusa.org/

Governmental agencies that regulate dietary supplements

- United States: Food and Drug Administration (FDA): http://www.fda.gov/Food/DietarySupplements/default.htm
- Australia: Therapeutic Goods Administration (TGA): http://www.tga.gov.au/cm/cm.htm
- Canada: Health Canada: http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index-eng.php

Other U.S. governmental agencies that monitor and report on human health and nutrition issues

- Centers for Disease Control and Prevention (CDC): http://www.cdc.gov/
- Department of Agriculture (USDA): http://www.usda.gov/

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Credits

Page 5, bottom right: Council for Responsible Nutrition;

Page 6, top: NSF International (nsf.org) wrote the American national standard for dietary supplements and certifies supplements to this standard. The NSF standard requires toxicology and label claim reviews, and ongoing testing to ensure NSF certified supplements do not contain unsafe levels of contaminants or other undeclared ingredients.