Supplement to
Pharmacy Today

American Pharmacists Association
Improving medication use. Advancing patient care.
APhA

Topics in Patient Care

CONTINUING PHARMACY EDUCATION • OCTOBER 2013

Medication and Dietary Supplements: Safe and Effective Care Through Appropriate Product Selection

Introduction

Nearly 20 years ago, Congress enacted the Dietary Supplement Health and Education Act (DSHEA), which defined dietary supplements as products (other than tobacco) that[1]:

- Are intended to supplement the diet.
- Contain one or more dietary ingredients (including vitamins, minerals, herbs or other botanicals, amino acids, and other substances), or their constituents.
- Are intended to be taken by mouth as a pill, capsule, tablet, or liquid.
- Are labeled on the front panel as being a dietary supplement.

DSHEA placed dietary supplements in a special category under the general umbrella of "foods," not drugs.[2] (While meal replacements, sports nutrition supplements, and homeopathic medicines are technically considered dietary supplements, they will not be addressed in this report.)

Increasing Prevalence

The use of dietary supplements has been steadily growing. In the early 1970s, when the National Health and Nutrition Examination Survey (NHANES) began monitoring supplement use, the prevalence of use among U.S. adults was 28% for men and 38% for women. In the next NHANES, covering the second half of that decade, the prevalence had increased to 32% for men and 43% for women. The 1988–1994 NHANES documented that total dietary supplement use among U.S. adults had grown to 54%, up from 40% overall adult use in the previous survey.[1]

The most commonly used dietary supplements in the United States are multivitamin/multimineral products, calcium, B vitamins (B_1 [thiamin], B_2 [riboflavin], B_3 [niacin], B_5 [pantothenic acid], B_6 [pyridoxine], and vitamin B_{12} [cyanocobalamin]), vitamin C, glucosamine/chondroitin, vitamin D, and fish oil.[3]

A 2011 Harvard Opinion Research Program survey questioned adults about their use of natural products (not including vitamins and minerals). The survey reported that 37.8% of American adults had used these types of products in the previous 2 years. The most popular were[4]:

- Fish oil/omega-3/DHA: 23.9%
- Herbals: 12.5%
- Probiotics: 9.9%

How Supplements Are Used

According to the 2007–2010 NHANES, which surveyed nearly 12,000 adults, the most commonly reported reasons for using supplements were to "improve" (45%) or "maintain" (33%) overall health. Women used calcium products for "bone health" (36%), whereas men were more likely to report supplement use for "heart health" or "to lower cholesterol" (18%). Older adults (≥60 years old) were more likely than younger individuals to report motivations related to site-specific reasons such as heart, bone and joint, and eye health.[5] Only 23% of products were used based on recommendations of a health care provider. Multivitamin/multimineral products were the most frequently reported type of supplement taken, followed by calcium and

Provider: American Pharmacists Association
Target Audience: Pharmacists
Release Date: October 1, 2013
Expiration Date: October 1, 2016
Learning Level: 1

ACPE Number: 0202-0000-13-212-H01-P
ACPE Activity Type: Knowledge-based
CPE Credit: 2 hours (0.2 CEUs)
Fee: There is no fee associated with this activity.

Activity Preview

Rapidly expanding use of dietary supplements has created a need for education to assist health care providers and consumers with product selection. Many consumers believe dietary supplements are alternatives to prescription and nonprescription medications, creating concern that some individuals may be using products with no medicinal value. A recent survey of pharmacists and physicians revealed a lack of understanding about dietary supplements and their relationship to conventional medications. This issue of *Topics in Patient Care* addresses facts instead of anecdotal evidence about the appropriate use of supplements, particularly in cardiovascular disease, and describes how these products are regulated to assist both pharmacists and consumers in selecting appropriate products for safe and effective care.

Learning Objectives

At the conclusion of this knowledge-based activity, the pharmacist will be able to:

1. Define the categories of prescription and nonprescription medications and compare them with dietary supplements.
2. Discuss the critical differences in the regulation of prescription or nonprescription medications and dietary supplements.
3. Explain the use of the Orange Book and its role in appropriate product selection.
4. Access resources to evaluate appropriate use of dietary supplements.
5. Outline the pharmacist's role in educating patients about the appropriate selection and use of dietary supplements.
6. Provide examples of commonly confused supplements and prescription products where using a dietary product in one instance may supplement nutrition and in another where disease management warrants prescription intervention.

Advisory Board

Tommy Johnson, PharmD, BC-ADM, CDE, FAADE
Professor and Chair of Pharmacy Practice
Presbyterian College School of Pharmacy
Clinton, South Carolina

Bella Mehta, PharmD, FAPhA
Associate Professor of Clinical Pharmacy
The Ohio State University College of Pharmacy
Columbus, Ohio

Accreditation Information

The American Pharmacists Association is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education (CPE). The ACPE Universal Activity Number assigned to this activity by the accredited provider is 0202-0000-13-212-H01-P. To obtain 2 contact hours (0.2 CEUs) of CPE credit for this activity, you must complete the Assessment and Evaluation. A Statement of Credit will be awarded for a passing grade of 70% or better on the Assessment. You will have two opportunities to successfully complete the CPE Assessment. Pharmacists who successfully complete this activity before October 1, 2016, can receive CPE credit. Your Statement of Credit will be available upon successful completion of the Assessment and Evaluation, and it will be stored in your "My Training Page" and on CPE Monitor for future viewing/printing.

Development

This home-study CPE activity was developed by the American Pharmacists Association.

American Pharmacists Association®
Improving medication use. Advancing patient care.
APhA

Support

This activity is supported by an independent educational grant from Amarin Pharma, Inc.

AMARIN

Disclosures

Tommy Johnson, Bella Mehta, Gail Dearing, and APhA's education and editorial staff declare no conflicts of interest or financial interests in any product or service mentioned in this activity, including grants, employment, gifts, stock holdings, and honoraria. For complete staff disclosures, please see the APhA Accreditation Information section at www.pharmacist.com/education.

This publication was prepared by Gail Dearing on behalf of the American Pharmacists Association.

omega-3 fish oil supplements.[5] In the survey, supplement users were found to be more likely to report very good or excellent health, have health insurance, use alcohol moderately, abstain from cigarette smoking, and exercise more frequently than nonusers.[5]

Many devoted users of supplements are resolute about continuing to take these products. The Harvard Opinion survey found that most supplement users would be only minimally influenced by government statements contradicting effectiveness, and only one quarter would stop taking their supplements if public health authorities said the supplements were ineffective.[4]

Dietary supplements are designed to supplement the diet, not to replace nutritious foods. They can enhance a diet where there are shortfalls. According to the American Dietetic Association, some people may require supplements because the vitamins and minerals they need are difficult to get in adequate amounts in the diet. These include pregnant women, nursing mothers, vegetarians, people with food allergies or intolerances, elderly adults, and those with diseases such as cancer, kidney disease, cardiovascular disorders, or bone disease.[3]

Dietary supplements are marketed for a wide range of conditions: some promoted benefits are legitimate while other indications are not based on sound scientific study.

Cardiovascular Disease

The two most widely used dietary supplements that address cardiovascular concerns are omega-3 fish oil products and niacin. New clinical trial data and the proliferation of fish oil supplements have contributed to the increasing use of these two supplements. Ongoing research dictates that health care professionals stay current on new efficacy and safety information.

Omega-3 Fish Oil Supplements

Knowledge on the role of omega-3 fatty acids in disease continues to evolve. Numerous studies have suggested that plant-based omega-3 fatty acids may provide some benefits for a wide range of diseases including cardiovascular disease, cancer, asthma, depression, attention deficit hyperactivity disorder, and autoimmune diseases such as rheumatoid arthritis. Development of all these conditions is linked to inflammation, and large amounts of omega-3 fatty acids reduce the inflammatory process that leads to many chronic conditions.[6] Recent cardioprotection studies on the possible role of omega-3 fatty acids failed to demonstrate that supplementation prevented post-surgical atrial fibrillation or reduced the risk of recurrent atrial fibrillation.[7,8]

Omega-3 fatty acids are found in fatty layers of cold-water fish (e.g., tuna, salmon), shellfish, and plant and nut oils. There are many types of omega-3 fatty acids, however the ones that have been shown to be beneficial are[6]:

- Long-chain omega-3 fatty acids: eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). EPA helps reduce inflammation, while DHA is essential for brain health and function.
- Short-chain omega-3 fatty acids: alpha-linolenic acid (ALA), which is converted by the body to EPA and DHA.

Most recommendations for omega-3 fatty acid intake suggest eating a meal of fatty fish at least twice a week. However, most people do not consume fatty fish twice a week, especially with a heightened fear of mercury levels in fish.[3] Therefore, depending on the individual's health needs, fish oil/omega-3 dietary supplements may be recommended or prescription medications, if medically indicated, are prescribed.

Early recommendations advised use of omega-3 fatty acids for patients with coronary heart disease, which led to a rapid proliferation of fish oil supplements. The first prescription product—omega-3-acid ethyl esters containing EPA + DHA—was approved by the U.S. Food and Drug Administration (FDA) in 2004. Studies at that time showed EPA + DHA reduced triglycerides. However, newer data showed that DHA increases low-density lipoprotein (LDL) cholesterol.[9]

Currently, the American Heart Association (AHA) guidelines recommend that patients with diagnosed cardiovascular disease should consume 1 g of EPA + DHA from fish or supplements daily, and patients with high triglyceride levels (≥500 mg/dL) should consume 2 to 4 g of EPA + DHA from prescription capsules daily.[10] However,

these guidelines, which are more than 10 years old and based on evidence that has since changed, are expected to be revised soon.

The expanding use of dietary supplements and the corresponding increase in products to meet the demand have created confusion in both consumers and health care providers. Today, there are hundreds of fish oil supplements on the market plus two FDA-approved prescription products. One prescription product (omega-3-acid ethyl esters) contains EPA + DHA; the other (icosapent ethyl) contains EPA only. Many health care professionals and consumers assume that the supplements are over-the-counter (OTC) products, meaning that they have been approved by FDA and are therefore safe and effective for use without seeking the advice of a health professional. However, there are not any fish oil supplements with OTC status.[9]

A 2013 poll of pharmacists and physicians conducted by PublicMind of Fairleigh Dickinson University explored knowledge and awareness of dietary supplements in general and omega-3 supplements in particular for the treatment of very high triglycerides (Table 1). The survey data demonstrated significant misperceptions among physicians and pharmacists about how FDA monitors and regulates different product classes. The authors also cited "noted confusion" among these health care providers on how omega-3 products affect LDL cholesterol and the appropriate role of omega-3 dietary supplements, specifically that they are not indicated for treatment of a diagnosed disease.[9]

In addition, recent surveys have confirmed that adults in general lack awareness of cardiac conditions and the potential role of fish oil. One survey of adults aged 40 years and older at high risk for cardiovascular disease revealed widespread ignorance about triglycerides, high and low cholesterol, and omega-3 fatty acid products. A study of cardiac patients' knowledge and use of fish oil products similarly found that the vast majority of the patients who were taking a fish oil product were under-educated concerning the product.[11-13]

Niacin

Niacin (vitamin B_3) has been used as a treatment for hyperlipidemia for more than 50 years. It has

Table 1. Misperceptions of Physicians and Pharmacists About Omega-3 Dietary Supplements

Findings of a PublicMind survey show a general lack of awareness on the difference between the OTC and dietary supplement categories as well as confusion about omega-3 products:

- 55% of pharmacists said they have recommended an "OTC" omega-3 product for patients with high cholesterol or very high triglycerides; 37% of pharmacists said they have recommended an omega-3 dietary supplement.
- Pharmacists (79%) were more likely than physicians (50%) to say they have only recommended an OTC omega-3 product.
- 28% of pharmacists and physicians were not sure how many dietary supplement capsules are needed to reach clinical dosage levels. Approximately half of respondents believed that 4 or fewer capsules are needed when, in fact, patients would need more than 12 capsules to reach therapeutic dosage levels.
- 25% of respondents said there are no differences between prescription and nonprescription omega-3 products, or said they do not know the differences.
- Overall, 75% of respondents believed nonprescription omega-3 products can have an impact on LDL cholesterol (80% pharmacists, 70% physicians).
- The majority of those respondents (68%) believed that omega-3 products lower LDL cholesterol levels, however they can elevate LDL levels by 1% to 2%. Only 23% correctly understood that omega-3 products can raise LDL cholesterol levels.

LDL = low-density lipoprotein; OTC = over-the-counter.

Source: Reference 9.

Topic Tip 1

A major difference between dietary supplements compared with prescription and OTC medications is how they are regulated. Supplements do not undergo FDA review for safety and effectiveness and they do not require FDA approval. However, marketing and product labeling for supplements cannot claim to treat or prevent disease.

shown beneficial effects on cholesterol levels by increasing high-density lipoprotein (HDL) cholesterol while reducing LDL cholesterol. Physicians believed that niacin would therefore reduce the risk of heart attacks and strokes. Indeed, numerous trials validated its effects in significantly reducing cardiovascular events and providing a smaller decrease in coronary and cardiovascular mortality.[14,15]

However, those earlier studies were conducted before the use of statins became standard treatment for cardiovascular disease.[15] Results of two recent clinical trials have challenged the clinical efficacy of niacin and called into question its continued use.[16,17]

The Heart Protection Study 2 Treatment of HDL to Reduce the Incidence of Vascular Events (HPS2-THRIVE) found that adding an extended-release form of niacin to statins in patients with cardiovascular disease did not produce worthwhile reductions in the risk of heart attacks, strokes, and invasive interventions. Furthermore, there was a high incidence of adverse effects including those previously known, such as skin rashes and stomach problems, and new ones, specifically infections and bleeding in the gut and brain.[16]

The National Institutes of Health (NIH) sponsored the study Atherothrombosis Intervention in Metabolic Syndrome with Low HDL Cholesterol/High Triglyceride and Impact on Global Health Outcomes (AIM-HIGH), which evaluated the use of high-dose extended-release niacin in addition to statin therapy in patients with a history of cardiovascular disease, high triglycerides, and low levels of HDL cholesterol. Although the trial patients showed significant increases in HDL cholesterol levels and decreases in triglyceride levels, there was no significant reduction in the primary endpoint of cardiovascular events over a mean follow-up period of 36 months.[15,17] Notably, NIH halted the trial 18 months prematurely because niacin offered no additional benefits in the study population.[18] Hence, some experts have suggested that the use of niacin for the prevention of cardiovascular events should be reconsidered.[15,16]

Myth or Fact?

"More is better."

Myth: Using large doses of vitamins to fight disease in humans is not supported by the available scientific evidence. Large doses of some vitamins or minerals have been shown to be toxic.

In addition to omega-3 fatty acids and niacin, a number of other supplements are used to maintain or improve cardiovascular health, including plant sterols, psyllium, red yeast rice, green tea extract, B-complex vitamins (B_6, B_{12}, folic acid), and coenzyme Q10. A meta-analysis published in 2013 concluded that there is no evidence to support the use of vitamin and antioxidant supplements for prevention of cardiovascular diseases.[19]

Other Uses of Dietary Supplements

Daily multivitamins with minerals have long been considered nutritional insurance to cover dietary shortfalls. There are two categories of vitamins[20]:

- Water-soluble vitamins: B_3, B_6, C, and folic acid. These are easily absorbed by the body; the kidneys remove excess amounts.
- Fat-soluble vitamins: A, D, E, and K. The body stores these for use as needed.

These vitamin supplements are generally safe in the recommended doses. However excessive doses of some vitamins and supplements have the potential for harm (Table 2).[20-23]

The most widely used supplements in the United States are: calcium, B vitamins, vitamin C, glucosamine and chondroitin, and D vitamins.[1]

Calcium is one of the minerals most often lacking in the diets of Americans. Ideally, calcium should be obtained from foods, however many

people take calcium supplements to make up for inadequate dietary intake. Calcium citrate and calcium lactate are the forms best absorbed by the body.[3]

B vitamins include thiamin, niacin, riboflavin, pantothenic acid, vitamin B_6, and vitamin B_{12}. Although American diets are plentiful in B vitamins, many people mistakenly believe these supplements will reduce stress. Older adults may need B_{12} supplements because absorption declines with aging.[3]

Vitamin C is often taken to ward off colds or to shorten their duration. The evidence is conflicting, however, with most studies failing to show prevention and some suggesting reduced duration.[3]

Glucosamine and chondroitin are often taken by people with joint pain. Research has shown some pain relief in patients with moderate to severe pain, and these products taken alone or in combination may be beneficial for osteoarthritis.[3]

D vitamins are important for protecting the body against chronic diseases and preventing osteoporosis. Two dietary forms are available: D_2 (ergocalciferol) and D_3 (cholecalciferol), which is more stable than vitamin D_2. Vitamin D_3 is likely to remain active for a longer period of time and has been the most-used form in clinical trials.[24]

Recommendations for use of dietary supplements from the American Heart Association, the American Academy of Family Physicians, and the American Cancer Society are presented in TABLE 3.

Myth or Fact?

"Natural is safe" and "natural is better."

Myth: The term "natural" on labels is not well defined and is sometimes used ambiguously to imply unsubstantiated benefits or safety. Supplements that claim to be "all natural" are not always better or safer than refined or manufactured substances. Some of the most toxic substances in the world occur naturally, such as poison mushrooms.

Table 2. Adverse Effects Associated With Excessive Doses of Dietary Supplements

Supplement	Potential Harms of Excessive Doses
Omega-3 fatty acids	Possible increase in bleeding; increased low-density lipoprotein cholesterol; effect on vitamin E, A, and D levels; possible increased prostate cancer risk.
Vitamin A	Nausea, vomiting, headache, dizziness, blurred vision, clumsiness, birth defects, possible risk of osteoporosis.
Vitamin B_3 (niacin)	Flushing, upset stomach.
Vitamin B_6 (pyridoxine)	Nerve damage to the limbs.
Vitamin B_9 (folic acid)	May mask signs of B_{12} deficiency, which can cause nerve damage.
Vitamin C	Upset stomach, kidney stones, increased iron absorption; may reduce the effectiveness of some types of cancer chemotherapy.
Vitamin D	Nausea, vomiting, poor appetite, constipation, weakness, weight loss, confusion, heart rhythm problems, deposits of calcium and phosphate in soft tissues.
Vitamin E	May reduce the effectiveness of some types of cancer chemotherapy.
Vitamin K	Can reduce the ability of blood thinners to prevent blood from clotting.

Source: References 20–23.

Table 3. Professional Societies' Dietary Supplement Recommendations

Society	Recommendations
American Heart Association	• Do not take antioxidant supplements (vitamins A, C, E); scientific evidence does not suggest that these vitamins can affect blood pressure or blood cholesterol. • Patients with heart disease should consume 1 g of EPA + DHA daily from fish or supplements. • Patients with high triglycerides should consume 2–4 g of EPA + DHA daily from capsules. • Dietary supplements should never be used to treat disease.
American Academy of Family Physicians	• Current evidence is insufficient to assess the balance of the benefits and harms of combined vitamin D and calcium supplementation for the primary prevention of fractures in premenopausal women or in men. • Daily supplementation with ≤400 IU of vitamin D_3 and 1,000 mg of calcium carbonate for the primary prevention of fractures in noninstitutionalized postmenopausal women is not recommended.
American Cancer Society	• Calcium, vitamin D, or a combination, may help protect against colorectal cancer. However men with high calcium intake may incur an increased risk of prostate cancer. • High-dose beta-carotene and/or vitamin A supplements increase—not decrease—lung cancer risk among smokers and should be avoided, especially by smokers. • There is no benefit from taking supplements containing antioxidant nutrients, such as vitamin E or selenium; vitamin E may raise prostate cancer risk slightly. • Fiber supplements are not recommended. • No evidence has shown that phytochemical supplements are as good for health as the foods from which they are extracted. • Selenium supplements are not recommended to lower cancer risk; high-dose selenium supplements should be avoided because there is only a narrow margin between safe and toxic doses. • Vitamin A supplements have not been shown to lower cancer risk; high-dose supplements may increase the risk for lung cancer in current and former smokers. • Vitamin C supplement studies have not shown a reduced risk of cancer. • Vitamin E supplements are not recommended to try to lower the risk of cancer or chronic diseases.

DHA=docosahexaenoic acid; EPA=eicosapentaenoic acid.
Source: References 10, 21, 25, and 26.

Topic Tip 2

There are no OTC omega-3 products. Omega-3 fatty acids are available as dietary supplements and as prescription products. Two FDA-approved prescription omega-3 products are currently available with more on the way.

Nutrient Needs of Older Adults

Eating a variety of healthy foods is the best way to get needed nutrients. However, people aged 50 years and older may need more of some vitamins and minerals compared with younger adults. Dietary supplements are often used to provide nutrients that might be missing from the daily diet. A 2008 survey of adults aged 57 to 85 years old revealed that 49% used a dietary supplement.[27]

The NIH National Institute on Aging has outlined the changing needs of people older than 50 years of age[28]:

- **Vitamin B_{12}:** As people grow older, absorption of vitamin B_{12} naturally found in food diminishes.[3] They can choose fortified foods or use a B_{12} supplement. Recommendation: 2.4 µg/day. Patients taking medication for acid reflux may need to use the injectable form of B_{12}.
- **Calcium:** Bone loss can lead to fractures in both older women and men. Recommendation: Women over 50 years old need 1,200 mg/day; men aged 51 to 70 years old need 1,000 mg/day and men over 70 years old need 1,200 mg, but not to exceed 2,000 mg/day.
- **Vitamin D:** Some people's bodies make enough vitamin D if they are in the sun for 10 to 15 minutes at least twice a week. Older people may not be able to get enough vitamin D that way. Recommendation: 600 IU daily for people aged 51 to 70 years and 800 IU daily for those over 70 years old, but not to exceed 4,000 IU daily.
- **Vitamin B_6:** Recommendation: 1.7 mg/day for men and 1.5 mg/day for women over 50 years old.

Topic Tip 3

Using dietary supplements can have questionable benefits and unwanted effects that can be toxic. They may interact with medications the patient is taking, or their use may stop or delay treatment of a patient's condition. Pharmacists should advise patients to check with their primary health care provider before initiating use of a dietary supplement.

How Do Dietary Supplements Differ From Medications?

Dietary supplements may seem similar to drugs, yet there is a critical difference: dietary supplements do not undergo FDA review for safety and effectiveness before they are marketed.

Regulation

Regulation of dietary supplements differs significantly from prescription and OTC medications, which require comprehensive submissions of clinical trial data to FDA to support safety and effectiveness, identify potential adverse effects, describe drug interactions, and other requirements.[29] TABLE 4 provides an overview for a comparison of the regulation of prescription medications, OTC medications, and dietary supplements.

In 2007, FDA applied its standard good manufacturing practices—which have been in effect for drugs for decades—to dietary supplements as well. The supplements sold today must be produced in a quality manner, cannot contain contaminants or impurities, and must be labeled accurately.[3,30] Once a dietary supplement is on the market, FDA monitors product information such as label claims and package inserts.[29]

Marketing Claims

The other major difference between medications and dietary supplements is the language used to describe their use. FDA provides supplement manufacturers with guidelines for making claims about their products' effects on the body.[3]

FDA-approved medications can claim safety and effectiveness for the specific disease or conditions for which they were tested and approved. FDA

Table 4. Regulatory Differences Between Prescription, Over-the-Counter, and Dietary Supplement Products

Product	Regulator	Requirements
Prescription medications	FDA	• Multi-step, multi-year process of extensive testing before they can be marketed. • FDA continues to monitor after approval. • FDA can withdraw a prescription product from the marketplace.
Over-the-counter medications	FDA	• Cannot be marketed without FDA approval. • Nine-step FDA approval process to evaluate safety and efficacy that includes data review and public comments. • Nonprescription Drug Advisory Committee meets regularly to review products.
Dietary supplements	Congress	• No requirements for safety, efficacy, or consistent/accurate ingredients. • Product labels must state that they are not intended to treat disease. • Advertising and communications are not regulated by FDA.

FDA = U.S. Food and Drug Administration.

Source: References 23 and 29–31.

regulates the labeling of dietary supplements, while the Federal Trade Commission (FTC) restricts and regulates product claims made by manufacturers. Together, FDA and FTC require that all labeling and marketing claims are truthful, not misleading, and scientifically substantiated.

The labels on dietary supplements cannot have claims that they treat, cure, mitigate, diagnose, or prevent disease.[2] However, FDA does allow the makers of dietary supplements to make four kinds of claims on the labels of their products: nutritional claims, claims of well-being, health claims, and structure or function claims.[32,33]

Nutritional claims are statements about the general effects that dietary supplements, vitamins, and minerals have on diseases known to be caused by nutrient deficiency. An example of a nutritional claim is "vitamin C prevents scurvy."[32,33]

Claims of well-being are statements such as "makes you feel better." These claims do not require pre-approval by FDA.[32,33]

Health claims are statements about known health benefits of certain compounds. For example, risk-reduction claims such as "folate may reduce the chance of pregnant women delivering an infant with neural tube defects" fall into this category. FDA must pre-approve all health claims, and requires that these claims be supported by evidence from scientific studies. Risk-reduction claims are not the same as prevention claims.[32,33]

Structure or function claims are the most hotly debated and confusing claims made to consumers. They are claims about the effect of the dietary supplement on the structure or function of the body. FDA has deemed the following descriptions and examples to be structure or function claims that are allowed[32,33]:

Myth or Fact?

"Fish oil supplements elevate LDL cholesterol."

Fact: A common misconception among professionals is that fish oil supplements lower levels of LDL cholesterol in the bloodstream. The DHA in omega-3 products slightly elevates LDL cholesterol by 1% to 2%.

- The product's mechanism of action (e.g., "works as an antioxidant").
- The product's effect on cellular structure (e.g., "helps membrane stability").
- The product's effect on the body's physiology (e.g., "promotes normal urinary flow").
- The product's effect on chemical or lab test results (e.g., "supports normal blood glucose").
- The product's effect on maintenance (e.g., "helps maintain a healthy circulatory system").

Structure or function claims are not reviewed by FDA. Labels or promotional materials that carry them also must include the disclaimer: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease." [32,33]

FDA cautions against assuming that because a product claims to support or promote healthy body function that it prevents or reduces the risk of any disease. FDA notes that although the benefits of some dietary supplements have been documented, the claims of others may be unproven, and offers this age-old advice: if something sounds too good to be true, it usually is. [32,33]

Enforcement

Both FDA and FTC take action when they see fit. When FDA investigators have discovered tainted products marketed as dietary supplements, they have issued warning letters, conducted seizures, and initiated criminal prosecutions. FDA also has issued consumer alerts for hundreds of products deemed deceptively labeled, including those marketed for sexual enhancement, weight loss, and bodybuilding.[34] In July 2013, FDA sent warning letters to 15 companies in the United States and abroad ordering them to stop selling diabetes treatments that violated U.S. drug laws. Some of the offending products claim to be "natural" but were found to contain untested pharmaceutical ingredients. Another made unproven claims to "improve sugar metabolism."[37]

Topic Tip 4

Health care professionals and consumers alike lack understanding about the appropriate selection and use of dietary supplements. Evidence-based information about these products is available and should be consulted. Quality assurance can be ensured by purchasing supplements with a recognized seal of approval on the product package.

Signs of a False Claim for a Dietary Supplement

- Claims such as "extremely beneficial in treatment of rheumatism, arthritis, infections, prostate problems, ulcers, cancer, heart trouble, hardening of the arteries, and more."
- Statements that suggest the product can treat or cure diseases, for example: "shrinks tumors" or "cures impotency." These are drug claims and should not be made for dietary supplements.
- Promotions that use phrases such as "scientific breakthrough," "miraculous cure," "exclusive product," "secret ingredient," or "ancient remedy."
- Personal testimonials by consumers or doctors claiming amazing results.
- Limited availability and advance payment required, for example: "Hurry. This offer will not last. Send us a check now to reserve your supply."
- Promises of no-risk "money-back guarantees."

Source: References 35 and 36.

As part of its ongoing efforts to stop false health claims, FTC challenges claims that promise supplements cause weight loss and treat or prevent colds, flu, allergies, and hay fever. Such challenges have led to recent settlements of $5.5 million that require the manufacturers to refund payments to consumers who purchased the fraudulent products.[38]

Myth or Fact?

"Even though a supplement may not help, at least it won't hurt."

Myth: It is best not to assume that this will always be true. When consumed in high enough amounts, for a long enough time, or in combination with certain other substances, all chemicals can be toxic, including nutrients, plant components, and other biologically active ingredients.

Product Selection

Comprehensive information about prescription and OTC generic medications is included in the FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations*—commonly known as "the Orange Book" or "the List"—however dietary supplements are not included.[31] To locate information about a prescription or OTC medication, individuals can access the Orange Book website at www.accessdata.fda.gov/scripts/cder/ob/default.cfm and enter the proprietary (brand) name or the active ingredient. Thus, searching for omega-3 in the OTC category will produce no results, because it is a dietary supplement—a category not included in the Orange Book.

A few independent organizations offer "seals of approval" that may be displayed on certain dietary supplement products. These indicate that the product has passed the organization's quality tests for features such as potency and contaminants. These seals of approval do not mean that the product is safe or effective; rather, they provide assurance that the product was properly manufactured, contains the ingredients listed on the label, and does not contain harmful levels of contaminants. Three reputable organizations reporting on product testing are ConsumerLab, NSF International, and U.S. Pharmacopeia (USP).

ConsumerLab selects products for testing, including all types of dietary supplements for review. Its reports disclose information such as: which multivitamins failed testing and why; which multivitamins exceed tolerable upper limits for certain nutrients; which low-cost multivitamins provide the same nutrients as more expensive popular brands; head-to-head comparisons of all multivitamins reviewed and rated; and concerns, cautions, and potential adverse effects of the products tested. ConsumerLab is owned by physicians, who test only products they have purchased on the open market. Access to reports requires membership for a cost of $33 for 1 year or $54 for 2 years; the website is www.consumerlab.com.

NSF International is an accredited, third-party certification body that tests and certifies products—primarily athletic supplements—to verify that they meet public health and safety standards. The website for the organization's dietary supplements services is accessible at www.nsf.org/business/dietary_supplements.

U.S. Pharmacopeia is a federally recognized nonprofit standards-setting organization offering voluntary testing and auditing to help dietary supplement manufacturers ensure the production of quality products for consumers. USP grants its seal for use on products that contain the ingredients listed on the label in the declared potency and amounts, do not contain harmful levels of specified contaminants, and have been made according to FDA current good manufacturing practices using sanitary and well-controlled procedures. Access to the USP Dietary Supplement Verification Program website is www.usp.org/usp-verification-services/usp-verified-dietary-supplements.

Questions about a specific brand of dietary supplements can be addressed by contacting the manufacturer of the product. The manufacturer can provide information about the evidence used to substantiate the claims and specifics about tests it has conducted on the safety or efficacy of the ingredients in the product.

Pharmacist Counseling

To make rational judgments about the safety and effectiveness, health care providers—including pharmacists—need to keep current with the medical literature on dietary supplements. As a trusted health care professional, the pharmacist is in a good position to provide safe and effective care through appropriate product selection for patients interested in dietary supplements. The pharmacist can initiate a conversation to cover these points[24]:

- Ask why the patient is considering a dietary supplement.
- Evaluate the diet (e.g., is it a vegetarian or vegan diet?).
- Evaluate situations and medical conditions that may lead to depletion of vitamins and minerals (e.g., gastric bypass).
- Evaluate current prescription and OTC medications for potential contraindications or interactions.
- Inquire about existing diseases or conditions.

Even a brief conversation can make a significant difference to the patient. For example, if a patient asks about omega-3 fish oil, the pharmacist can quickly determine which product is appropriate. If the patient has been diagnosed with heart disease, the AHA guidelines advise that he or she should take 1 g of EPA + DHA daily from fatty fish or supplements. Similarly, the pharmacist may advise a patient with high or very high triglyceride levels to contact his or her primary health care provider to ask about the prescription dosage omega-3 product.[10]

The pharmacist should advise patients to talk to their primary health care provider about the need for dietary supplements and for diagnosis and treatment options. Consultation is particularly important for patients who take prescription or OTC medications. For example, the herbal supplement St. John's wort interacts with many medications, reducing their effectiveness. Careful consideration regarding supplement use is also crucial for patients who are anticipating surgery, are pregnant or expecting to become pregnant, or have diagnosed medical conditions.[29] Patients should not initiate supplement use without talking to their physician and should not substitute a supplement for a medication that has been prescribed for them.[39]

When discussing supplements with patients, pharmacists should point out that exaggerated claims of "miracle" products can have dangerous interactions with other medications a patient may be taking. Patients should be informed that a supplement labeled as "natural" does not necessarily mean that it is safe. For example, the herbs comfrey and kava can cause serious harm to the liver.[29] Pharmacists also should warn patients about the potential harms from taking excessive amounts of supplements (TABLE 2) and advise supplement users not to exceed the recommended daily allowance for vitamins and minerals.

Using the Internet

While the Internet is a rich source of health information, it is also an easy vehicle for spreading myths, hoaxes, and rumors about alleged news, studies, products, or findings. FDA advises against conducting blind searches with a search engine. Instead, contact should be made only with respected organizations such as federal agencies, universities, or professional medical associations.[40] Safeguards to follow include:

- Determine whether the information is written or reviewed by qualified health professionals or experts in the field from academia, government, or the medical community. Is the information from a manufacturer's website whose overriding purpose is to sell a product? Legitimate educational sites should contain references to scientific reports.
- Check the date when the material was posted or updated. Often, new research or other findings (e.g., adverse effects, interactions with other products) are not reflected in old material and new evidence might have changed earlier beliefs. Ideally, health and medical websites should be updated frequently.
- Avoid falling prey to deceptive practices or bogus offers. Be skeptical and watch out for overly emphatic language with uppercase letters, extra exclamation points, and phrases such as: "This is not a hoax" or "Send this to everyone you know."

Purchasing medications or dietary supplements from online pharmacies can be hazardous. According to the National Association of Boards of Pharmacy, only 3% of more than 10,000 online pharmacies reviewed comply with U.S. pharmacy laws. Dietary supplements and medications obtained from online pharmacies may be counterfeit, contaminated, contain the wrong active ingredient, and are seldom FDA approved. FDA advises people to be aware of online pharmacies that[40]:

- Are located outside the United States.
- Are not licensed by a state agency in the United States.
- Allow the purchase of prescription medications without a prescription.
- Offer very low drug prices that seem too good to be true.
- Send unsolicited e-mails offering deep discounts on medications.
- Ship dietary supplements and medications from a foreign country.

FDA operates the BeSafeRx campaign to help patients identify and avoid fraudulent online pharmacies. The website is accessible at www.FDA.gov/BeSafeRx.

Conclusion

As the use of dietary supplements continues to expand, pharmacists will likely face ongoing questions from patients about these products. Unlike prescription and OTC medications, dietary supplements are not approved or regulated by FDA and claims about their benefits are not strictly regulated. Health care professionals need a better understanding of dietary supplements—their benefits and risks, regulatory considerations, and how to identify misperceptions or disallowed claims—to help their patients select appropriate supplements.

Tell Me More

Federal Trade Commission

Consumer Information: Dietary Supplements
www.consumer.ftc.gov/articles/0261-dietary-supplements

Food and Drug Administration

Dietary Supplements
www.fda.gov/Food/DietarySupplements/default.htm

Dietary Supplements Guidance Documents and Regulatory Information
www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/DietarySupplements/default.htm

Using Dietary Supplements
www.fda.gov/Food/DietarySupplements/UsingDietarySupplements/default.htm

Dietary Supplements: What You Need to Know
www.fda.gov/Food/DietarySupplements/UsingDietarySupplements/ucm109760.htm

Consumer Updates
www.fda.gov/downloads/ForConsumers/ConsumerUpdates/default.htm

Orange Book
www.accessdata.fda.gov/scripts/cder/ob/default.cfm

Tips for Dietary Supplement Users: Making Information Decisions and Evaluating Information
www.fda.gov/Food/DietarySupplements/UsingDietarySupplements/ucm110567.htm

National Institutes of Health

National Center for Complementary and Alternative Medicine
www.nccam.nih.gov

National Institute on Aging
www.nia.nih.gov

Office of Dietary Supplements
www.ods.od.nih.gov/factsheets/list-all/

References

1. Gahche J, Bailey R, Burt V, et al. Dietary supplement use among U.S. adults has increased since NHANES III (1988–1994). National Center for Health Statistics, Centers for Disease Control and Prevention NCHS Data Brief No. 61. April 2011. Available at: http://www.cdc.gov/nchs/data/databriefs/db61.pdf. Accessed July 2, 2013.
2. Council for Responsible Nutrition. *Roadmap for Retailers: Safely Navigating What You Say About Dietary Supplements.* Available at: http://www.crnusa.org/roadmap/CRN-RoadMap-Retailers0111.pdf. Accessed July 22, 2013.
3. Zelman KM. The truth behind the top 10 dietary supplements. 2009. Available at: http://www.webmd.com/diet/features/truth-behind-top-10-dietary-supplements. Accessed July 2, 2013.
4. Blendon RJ, Benson JM, Botta MD, et al. Users' views of dietary supplements. *JAMA Intern Med.* 2013;173:74–6.
5. Bailey RL, Gahche JJ, Miller PE, et al. Why US adults use dietary supplements. *JAMA Intern Med.* 2013;173:355–61.
6. Stuart A. What to know about omega-3s and fish. 2008. Available at: http://www.webmd.com/diet/features/what-to-know-about-omega-3s-and-fish. Accessed July 2, 2013.
7. Macchia A, Grancelli H, Varini S, et al. Omega-3 fatty acids for the prevention of recurrent symptomatic atrial fibrillation: results of the FORWARD (Randomized Trial to Assess Efficacy of PUFA for the Maintenance of Sinus Rhythm in Persistent Atrial Fibrillation) trial. *J Am Coll Cardiol.* 2013;61:463–8.
8. Mozaffarian D, Marchioli R, Macchia A, et al. Fish oil and postoperative atrial fibrillation: the Omega-3 Fatty Acids for Prevention of Post-operative Atrial Fibrillation (OPERA) randomized trial. *JAMA.* 2012;308:2001–11.
9. Fairleigh Dickinson University. PublicMind Poll. *Omega-3 Physician/Pharmacist Study.* New York, NY: Makovsky Integrated Communications; March 2013.
10. American Heart Association. AHA Scientific Position. Vitamin and Mineral Supplements. February 2013. Available at: http://www.heart.org/HEARTORG/GettingHealthy/NutritionCenter/Vitamin-and-Mineral-Supplements_UCM_306033_Article.jsp. Accessed July 24, 2013.
11. Dearment A. Survey finds widespread ignorance about triglycerides' role in cardiovascular health. *Drug Store News.* June 15, 2013. Available at: http://www.drugstorenews.com/article/survey-finds-widespread-ignorance-about-triglycerides-role-cardiovascular-health. Accessed July 9, 2013.
12. Joseph N. Most older adults unaware that management of high triglyceride levels is important for health. June 7, 2013. Available at: http://www.researchscape.com/health/triglyceride-awareness-survey. Accessed July 30, 2013.
13. Hawkins EB, Ling H, Burns TL, et al. Perceptions, knowledge, and patterns of use of "fish oil" products in cardiac patients. Poster presented at: Annual Meeting of the American College of Clinical Pharmacy; October 24, 2012; Hollywood, FL. Available at: http://www.accp.com/docs/meetings/am12/PosterScheduleOctober24.pdf. Accessed July 2, 2013.
14. Duggal JK, Singh M, Attri N, et al. Effect of niacin therapy on cardiovascular outcomes in patients with coronary artery disease. *J Cardiovasc Pharmacol Ther.* 2010;15:158–66.
15. Lavigne PM, Karas RH. The current state of niacin in cardiovascular disease prevention: a systematic review and meta-regression. *J Am Coll Cardiol.* 2013;61:440–6.
16. University of Oxford. Niacin can cause serious side effects in heart-risk patients [press release]. March 10, 2013. Available at: http://www.ox.ac.uk/media/news_stories/2013/130310.html. Accessed July 26, 2013.
17. AIM-HIGH Investigators; Boden WE, Probstfield JL, Anderson T, et al. Niacin in patients with low HDL cholesterol levels receiving intensive statin therapy. *N Engl J Med.* 2011;365:2255–67.
18. Nainggolan L. NIH pulls plug on AIM-HIGH trial with niacin. May 27, 2011. Available at: http://www.theheart.org/article/1231453.do. Accessed July 25, 2013.
19. Myung SK, Ju W, Cho B, et al. Efficacy of vitamin and antioxidant supplements in prevention of cardiovascular disease: systematic review and meta-analysis of randomised controlled trials. *BMJ.* 2013;346:f10.
20. U.S. Food and Drug Administration. FDA Consumer Health Information. Fortify your knowledge about vitamins. February 21, 2009. Available at: http://www.fda.gov/consumer/update/vitamins111907.html. Accessed August 15, 2013.
21. American Heart Association. Vitamin supplements: healthy or hoax? Available at: http://www.heart.org/HEARTORG/Conditions/More/ConsumerHealthCare/Vitamin-Supplements-Healthy-or-Hoax_UCM_432104_Article.jsp. Accessed July 24, 2013.
22. Mayo Clinic. Omega-3 fatty acids, fish oil, alpha-linolenic acid. Safety. September 2012. Available at: http://www.mayoclinic.com/health/fish-oil/NS_patient-fishoil/DSECTION=safety. Accessed August 22, 2013.
23. National Institutes of Health Office of Dietary Supplements. Frequently asked questions (FAQ). Available at: http://ods.od.nih.gov/Health_Information/ODS_Frequently_Asked_Questions.aspx. Accessed July 2, 2013.
24. Mehta BH. Evidence-based recommendations for herbal and dietary supplements. Presented at: Annual Meeting of the American Pharmacists Association; March 1–4, 2013; Los Angeles, CA.
25. American Academy of Family Physicians. Vitamin Supplementation. Available at: http://www.aafp.org/patient-care/clinical-recommendations/all/vitamin.html. Accessed July 30, 2013.
26. Kushi LH, Doyle C, McCullough M, et al. American Cancer Society guidelines on nutrition and physical activity for cancer prevention. *CA Cancer J Clin.* 2012;62:30–67.
27. Qato DM, Alexander GC, Conti RM et al. Use of prescription and over-the-counter medications and dietary supplements among older adults in the United States. *JAMA.* 2008;300:2867–78.
28. National Institute on Aging. Dietary supplements for old adults. Available at: http://www.nia.nih.gov/print/health/publication/dietary-supplements. Accessed July 2, 2013.
29. National Center for Complementary and Alternative Medicine, National Institutes of Health. Using dietary supplements wisely. Available at: http://nccam.nih.gov/health/supplements/wiseuse.htm. Accessed July 2, 2013.
30. U.S. Food and Drug Administration. Q&A on dietary supplements. Available at: http://www.fda.gov/Food/DietarySupplements/QADietarySupplements/default.htm. Accessed July 2, 2013.
31. U.S. Food and Drug Administration. Orange Book Preface. *Approved Drug Products With Therapeutic Equivalence Evaluations.* Available at: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm. Accessed July 19, 2013.
32. U.S. Federal Trade Commission, Bureau of Consumer Protection. *Dietary Supplements: An Advertising Guide for Industry.* April 2001. Available at: http://business.ftc.gov/documents/bus09-dietary-supplements-advertising-guide-industry. Accessed July 24, 2013.
33. U.S. Food and Drug Administration. Claims that can be made for conventional foods and dietary supplements. September 2003. Available at: http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm111447.htm. Accessed July 2, 2013.
34. U.S. Food and Drug Administration. Tainted products marketed as dietary supplements. *FDA Consumer Health Information.* December 2010. Available at: http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/UCM236998.pdf. Accessed July 23, 2013.
35. U.S. Food and Drug Administration. Tips for older dietary supplement users. Available at: http://www.fda.gov/Food/DietarySupplements/UsingDietarySupplements/ucm110493.htm. Accessed July 2, 2013.
36. U.S. Federal Trade Commission. Miracle cures: health information for older people. Available at: http://www.consumer.ftc.gov/articles/0327-miracle-cures-health-information-older-people. Accessed July 24, 2013.
37. Perrone M. FDA cracks down on illegal diabetes remedies. EarthLink U.S. News. July 23, 2013. Available at: http://my.earthlink.net/article/us?guid=20130723/ed0f3382-096a-4511-9043-a8d272c5e390. Accessed July 23, 2013.
38. U.S. Federal Trade Commission. Dietary supplement maker to pay $5.5 million to settle FTC false advertising charges [press release]. July 14, 2010. Available at: http://www.ftc.gov/opa/2010/07/iovate.shtm. Accessed July 24, 2013.
39. American Cancer Society. Dietary supplements: how to know what is safe. September 2011. Available at: http://www.cancer.org/acs/groups/cid/documents/webcontent/002385-pdf.pdf. Accessed July 24, 2013.
40. U.S. Food and Drug Administration. Tips for dietary supplement users. Available at: http://www.fda.gov/Food/DietarySupplements/UsingDietarySupplements/ucm110567.htm. Accessed July 30, 2013.

Topics in Patient Care

CPE Assessment

Medication and Dietary Supplements: Safe and Effective Care Through Appropriate Product Selection

Instructions: The assessment questions printed below allow you to preview the online CPE assessment. **Please review all of your answers to be sure you have marked the proper letter on the online CPE assessment.** There is only one correct answer to each question.

1. Congress enacted legislation that regulates dietary supplements as:

a. Flexible manufactured products.
b. Foods.
c. OTC products.
d. Generic equivalents of approved products.

2. In the 2011 Harvard Opinion Research Program survey, the most widely used natural product (excluding vitamins and minerals) was:

a. Ginseng.
b. Glucosamine.
c. Fish oil/omega-3.
d. Green tea.

3. Which ingredient in omega-3 fatty acids helps reduce inflammation?

a. Docosahexaenoic acid (DHA).
b. Eicosapentaenoic acid (EPA).
c. Alpha-linolenic acid.
d. DHA + EPA combined.

4. Which of the following products is recommended for the treatment of cardiovascular disease?

a. OTC omega-3 fish oil products.
b. Fish oil dietary supplements.
c. Prescription fish oil capsules.
d. Generic fish oil products.

5. A PublicMind survey found that most physicians and pharmacists believe nonprescription omega-3 products have an impact on LDL cholesterol. Among that group:

a. The majority believe that omega-3 products lower LDL cholesterol.
b. The majority believe that omega-3 products raise LDL cholesterol.
c. Less than half noted that there are no OTC omega-3 products.
d. More physicians than pharmacists reported recommending an OTC omega-3 product.

6. Manufacturers of dietary supplements are allowed to make which of the following claims?

a. Prevents the pain of arthritis.
b. Makes you feel better.
c. Shrinks tumors.
d. Reduces the risk of cancer.

7. Regulations governing dietary supplements differ from prescription and OTC medications in that:

a. Dietary supplements do not require FDA approval.
b. Health claims must be supported by evidence from scientific studies.
c. Claims in advertisements for dietary supplements are not regulated by FDA.
d. There are no differences between the regulation of supplements and prescription/OTC medications.

8. The claim that a dietary supplement helps maintain a healthy circulatory system is in which category of allowed claims?

a. Nutritional claims.
b. Claims of well-being.
c. Health claims.
d. Structure or function claims.

9. FDA's Orange Book provides information on various products *except:*

a. Approved brand-name prescription medications.
b. Dietary supplements.
c. Generic products with therapeutic equivalences.
d. OTC medications.

10. Pharmacists and consumers can trust statements about the potency of dietary supplements that:

a. Appear in manufacturers' promotional materials.
b. Carry a "seal of approval" from USP, NSF, or ConsumerLab.
c. Are sent in an unsolicited e-mail.
d. Are recommended in a chat room.

11. Omega-3 fatty acids are:

a. Produced in the liver.
b. Secreted by the gall bladder.
c. Readily available in cold-water fish such as tuna and salmon.
d. Abundant in frozen fried fish products.

12. If a patient asks about a product to treat high triglycerides, the pharmacist should:

a. Refer the patient to the primary health care provider for diagnosis and treatment considerations.
b. Dispense the combination EPA + DHA prescription product.
c. Recommend an OTC fish oil supplement.
d. Recommend a fish oil dietary supplement.

13. FDA operates a BeSafeRx website to help consumers:

a. Locate legitimate sellers of prescription drugs online.
b. Identify and avoid fraudulent online pharmacies.
c. Check the ingredients of low-cost medications sold online.
d. Investigate reports of adverse effects of a specific drug.

14. Which of the following statements is *not* a myth?

a. Natural is better.
b. It is safe to take large doses of vitamins.
c. Vitamin C prevents scurvy.
d. Supplements cannot hurt me.

15. The American Cancer Society recommends taking which of the following supplements to protect against colorectal cancer?

a. High-dose beta-carotene.
b. Vitamin E.
c. Selenium supplements.
d. Moderate doses of calcium and vitamin D.

CPE Information

To obtain 2 contact hours (0.2 CEUs) of continuing pharmacy education (CPE) credit for this activity, you must complete the Assessment and Evaluation. A Statement of Credit will be awarded for a passing grade of 70% or better on the Assessment. You will have two opportunities to successfully complete the CPE Assessment. Pharmacists who successfully complete this activity before October 1, 2016, can receive CPE credit. Your Statement of Credit will be available upon successful completion of the Assessment and Evaluation, and it will be stored in your "My Training Page" and on CPE Monitor for future viewing/printing.

CPE Instructions

Log in or create an account at pharmacist.com and select LEARN from the top of the page; select Continuing Education, then Home Study CPE to access the Library.

Enter the title of this article or the ACPE number to search for the article and click on the title of the article to start the home study.

To receive CPE credit, select Enroll Now from the left navigation and successfully complete the Assessment (with randomized questions) and Evaluation.

To get your Statement of Credit, click "Claim" on the right side of the page. You will need to provide your NABP e-profile ID number to obtain and print your Statement of Credit.

Live step-by-step assistance is available Monday through Friday, 8:30 AM to 5:00 PM ET from APhA Member Services at 800-237-APhA (2742) or by e-mailing education@aphanet.com.

13-390