ASHP Statement on the Use of Dietary Supplements

Position

The American Society of Health-System Pharmacists (ASHP) believes that the widespread, indiscriminate use of dietary supplements presents substantial risks to public health and that pharmacists have an opportunity and a professional responsibility to reduce those risks. ASHP recognizes that patients may choose to use legally available dietary supplements, but believes that the decision to use substances that may be pharmacologically active should always be based on reliable information about their safety and efficacy. The current regulatory framework governing dietary supplements does not provide consumers or health care providers with sufficient information on safety and efficacy to make informed decisions. Furthermore, standards for product quality are currently inadequate. ASHP recognizes the concerns raised by the dietary supplement industry regarding regulating dietary supplements as nonprescription drugs because of the industry's inability to patent product ingredients. Still, ASHP urges Congress to amend the Dietary Supplement Health and Education Act of 1994 (DSHEA) to require that the Food and Drug Administration (FDA) develop a regulatory scheme to ensure that dietary supplements are safe and effective. ASHP believes that dietary supplements, at a minimum, should (1) receive FDA approval for evidence of safety and efficacy, (2) meet manufacturing standards for identity, strength, quality, purity, packaging, and labeling, and (3) undergo mandatory postmarketing reporting of adverse events, including drug interactions.

ASHP strongly encourages in vitro and clinical studies of interactions between dietary supplements and medications. Because of the demonstrated risk of these interactions, ASHP discourages the concurrent use of dietary supplements and drug therapy, especially those therapies for which failure may have irreversible consequences (e.g., immunosuppressive therapy, cancer chemotherapy, treatment for human immunodeficiency virus infection, anticoagulation therapy, and hormonal contraceptive therapy).

ASHP believes that the criteria used to evaluate dietary supplements for inclusion in health-system formularies should be as rigorous as those established for nonprescription drugs and that the self-administered use of dietary supplements during a health-system stay may increase risks to patients and liabilities to health care professionals and institutions.

ASHP urges pharmacists and other health care practitioners to integrate awareness of dietary supplement use into everyday practice and encourages pharmacists to increase efforts to prevent interactions between dietary supplements and drugs. ASHP also supports the education of pharmacists and other health care practitioners in the taxonomy, formulation, pharmacology, and pharmacokinetics of dietary supplements and believes that such education should be required in college of pharmacy curricula.

Background

Dietary supplements are defined in DSHEA as products "intended to supplement the diet" that contain vitamins, minerals, herbs or other botanicals, amino acids; "a dietary substance for use by man to supplement the diet by increasing the total daily intake"; or "a concentrate, metabolite, constituent, extract, or combinations of these ingredients."[1]

Evidence of variability in dietary supplement content[2–8] has spurred efforts to standardize products. Current federal regulations regarding the manufacture of dietary supplements are not adequate.[9] Some manufacturers voluntarily follow good manufacturing practices (GMPs) devised by their own trade groups (e.g., the National Nutritional Foods Association GMP Certification Program[10]), and the U.S. Pharmacopeia (USP) has created voluntary standards for a handful of dietary supplements.[11] Manufacturers that wish to carry the "USP approved" seal on their product labels have to subject their products to testing by USP. The creation of these voluntary programs reflects a widespread concern, even on the part of dietary supplement manufacturers, that production processes must be regulated. Although FDA has had the authority to establish dietary supplement GMPs for almost a decade, it issued its first proposed rule on the topic in 2003. [12]

DSHEA does not require FDA to review evidence of the efficacy or safety of dietary supplements, so manufacturers have no burden to prove that their products are effective or safe. Although dietary supplement labeling cannot claim activity in the treatment of a specific disease or condition, claims that suggest an effect on the "structure or function of the body" are allowed.[1] For example, dietary supplements containing echinacea can be labeled as supporting immune health (as a "function") but cannot be labeled as preventing or ameliorating colds (treating a disease). Regardless of this distinction between function and treatment, consumers are bombarded by the lay press (and even some scientific literature) with what can only be described as specific-disease indications for dietary supplements (e.g., glucosamine for osteoarthritis, black cohosh for menopausal symptoms, and St. John's wort for depression).

The health claims allowed in dietary supplement labeling by current interpretation of DSHEA create further confusion for consumers. FDA's attempt to hold these health claims to the same scientific standard required for conventional foods was struck down in *Pearson* v. *Shalala,* so FDA must permit dietary supplement labels to carry "qualified" health claims based on equivocal scientific evidence.[13]

Although DSHEA does require that dietary supplements be safe, it does not require prospective testing to ensure safety. To remove a product from the market, FDA must prove that the product is unsafe. Under DSHEA, some dietary supplements that were banned from the U.S. market because of concerns about their safety have been allowed to return (e.g., sassafras tea, dehydroepiandrosterone). Demonstrably unsafe products have made their way onto the market, and fatal adverse reactions have been reported.[14,15]

Establishing the safety record of dietary supplements has been complicated by the lack of systematically collected data about their adverse reactions. The MedWatch system has been used to a limited extent to report adverse events related to dietary supplement use, but, nine years after the passage of DSHEA, FDA is still developing an adverse-reaction-reporting system for dietary supplements. Despite the limited data, however, the number of case reports of interactions between dietary supplements and medications is growing.[16–21] The safety of dietary supplements for special populations (e.g., children, pregnant women, people with impaired organ or immunologic function) has also not been demonstrated.

Dangers to Public Health

It has been estimated that 40% of the U.S. population uses dietary supplements often and that almost twice as many have used at least 1 of the estimated 29,000 dietary supplements on the market.[22] Out-of-pocket expenditures on dietary supplements total approximately $18 billion annually.[23] Such widespread and indiscriminate use of dietary supplements presents five dangers to the public health:

1. Some dietary supplements are inherently unsafe when ingested orally (e.g., chaparral, ephedra, comfrey, tiractricol, aristolochic acid, pennyroyal).[24–28]
2. Lax regulation of dietary supplement manufacturing presents the risk of contamination or adulteration with harmful substances, including carcinogens,[29–32] and of dangerous variability in active ingredient content among products.[2–8]
3. The use of dietary supplements may compromise, delay, or supplant treatment with therapies of proven efficacy.[16–21,25]
4. Dietary supplements may present dangers to special populations (e.g., children, pregnant women, patients undergoing surgery, patients with impaired organ or immunologic function).
5. Spending on dietary supplements represents an enormous health-related expenditure of unsubstantiated value.[33]

Since the mid-19th century, the federal government has exercised its responsibility to protect Americans from hazardous or adulterated foods and medicines. ASHP believes that, with the passage and implementation of DSHEA, the federal government has abandoned its duty to create a regulatory scheme for dietary supplements that adequately protects the health of consumers. Under DSHEA, consumers and health care practitioners are not provided with the information they need to use dietary supplements safely. To reduce the dangers posed by the current regulatory framework, Congress should amend DSHEA to

1. Require that dietary supplements undergo FDA approval for evidence of safety and efficacy,
2. Mandate FDA-approved dietary supplement labeling that describes safe use in a clear, standardized format, including the potential for interaction with medications and cautions for special populations,
3. Require FDA to promulgate and enforce GMPs for dietary supplements,
4. Require that dietary supplements meet FDA-established standards for identity, strength, purity, and quality, and
5. Empower FDA to establish and maintain an adverse-event-reporting system specifically for dietary supplements, and require dietary supplement manufacturers to report suspected adverse reactions to FDA.

Implications for Practice

Although examples of persons rejecting potentially life-saving medical interventions in favor of alternative therapies can be found in the medical and lay press,[34] the presumption that most users of dietary supplements reject traditional treatments is unfounded. One survey found that most individuals who use alternative therapies for a specific symptom or disease are also receiving care and prescription medications from a physician or surgeon.[35] In a more recent nationwide survey, almost 20% of adults taking prescription drugs reported that they were taking at least one dietary supplement, not including vitamin or mineral supplements.[36]

Pharmacists and other health care practitioners therefore have an opportunity to reduce the risks associated with dietary supplement use. Health care providers face unfamiliar challenges in this effort, however, because much of the information they typically use to establish pharmaceutical treatment regimens is lacking for dietary supplements. Product content is not standardized, therapeutic goals are vague, and evidence of efficacy and safety is absent or ambiguous. ASHP believes that pharmacists, as medication-use experts and accessible members of the health care team, are uniquely qualified and positioned to counsel patients using or considering the use of dietary supplements. Despite their professional responsibility to provide patients with sound advice, pharmacists (like other health care providers) are frustrated by the lack of reliable information about the safety and efficacy of dietary supplements. Pharmacists have shown that they can improve medication safety by identifying and preventing adverse drug events,[37] and they could play a similar role in preventing adverse events due to dietary supplement use if they had sound, evidence-based professional resources.

Incorporate Awareness of Dietary Supplement Use into Practice. ASHP urges pharmacists and other health care practitioners to integrate awareness of dietary supplement use into everyday practice. ASHP believes that all health systems should have an institutional policy regarding the use of dietary supplements. Such policies should allow pharmacists and other health care practitioners to exercise their professional judgment and try to balance patient autonomy and institutional concerns.

Patient Counseling. Although most consumers of alternative therapies also take prescription medications,[35] one survey found that 72% of respondents who used alternative therapies did not report that use to their health care providers.[38] Pharmacists and other health care practitioners must therefore routinely inquire about a patient's current or planned use of dietary supplements, providing examples so that patients understand what is meant (e.g, asking "Do you use dietary supplements, such as St. John's wort or gingko?").[39] This information will allow pharmacists and other health care practitioners to counsel the patient about dietary supplement use and monitor for adverse reactions and drug interactions.

When counseling patients about dietary supplements, the concept of *caveat emptor* (buyer beware) must be emphasized because the content and safety of dietary supplements are not well regulated. ASHP believes that all pharmacists, at a minimum, should be familiar with the pharmacology and pharmacokinetics of common dietary supplements that might contraindicate concurrent use with a therapeutic regimen (i.e., proven and potential pharmacokinetic and pharmacodynamic interactions with prescription and nonprescription medications) to the extent that sound evidence exists. To provide informed counsel to patients using or considering the use of dietary supplements, pharmacists further need to be familiar with the following:

- The typical uses of common dietary supplements and the scientific literature regarding their efficacy and safety,
- The proven and potential interactions between common dietary supplements and prescription and nonprescription medications,
- The methods of therapeutic monitoring for common dietary supplements, including signs and symptoms of potential adverse effects and toxicities,
- The proven and potential effects of certain disease states on supplement absorption, distribution, and elimination, and
- The safety of using dietary supplements before or after surgery.

Despite the shortcomings of the data on dietary supplements, the limited references on the topic that are available should be consulted.[40–45]

Patients stabilized on a combination of a supplement and medication should be cautioned not to suddenly discontinue the use of either without first consulting with the prescriber. The potential for adverse effects from an interaction exists both when a dietary supplement is discontinued and when it is initiated.

Dietary supplement sales have a very high potential for profit. Despite the expectation that pharmacies should receive a profit from the sale of products, professional ethics mandate that any recommendations or purchasing suggestions be made with the well-being of the customer or patient as the primary concern. Pharmacists should also review promotional and reference materials promulgated in or by their workplaces to ensure that these materials are evidence based and not misleading or deceptive. The scientific literature about the safety and efficacy of dietary supplements is updated continually. Pharmacists have a responsibility to continually monitor that literature and incorporate the evolving knowledge into their care for and advice to patients.

Inclusion in Formularies. ASHP believes that the criteria used to evaluate dietary supplements for inclusion in health-system formularies should be as rigorous as those established for prescription and nonprescription drugs. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has recommended that medical staff weigh the patient care implications of dietary supplements with the same rigor applied to prescription and nonprescription medications,[46] and all JCAHO medication management standards apply to dietary supplements, as well as prescription and nonprescription drugs.[47] ASHP believes that the decision to include any product in a health-system formulary should be based on comparative data regarding efficacy, adverse effects, cost, and potential therapeutic advantages and deficiencies.[48] The lack of definitive evidence of efficacy and safety and the demonstrated variability in product content make most dietary supplements unsuitable for inclusion in health-system formularies.[49] More research is needed to determine the relative effectiveness of dietary supplements and their safety for all patient populations, especially drug–supplement interactions.

The shortcomings that make most dietary supplements unsuitable for inclusion in formularies also argue strongly against their self-administered use by patients during a health-system stay. ASHP believes that the use of self-administered medications should be avoided to the extent possible[50] and that pharmacists should identify all drug products before their use.[15] There is currently no way to definitively determine the content of dietary supplements brought into health systems. In addition, discontinuing supplement use may be advisable as part of the diagnostic workup, and the possibility that supplement use may have contributed to hospitalization should be considered.

If an institution decides, as a matter of patient autonomy, to allow the use of dietary supplements, such use should require a prescribed order for the specific dietary supplement in the patient medical record and pharmacist review and verification of the order. Health systems should be aware that the use of dietary supplements may expose patients to risks, and the health system and staff should take steps to reduce potential liability (e.g., require patients to sign a liability waiver for dietary supplement use) and decrease those risks.

Conclusion

Current regulation of the manufacture and labeling of dietary supplements fails to address substantial risks to the public health. As the activity of some dietary supplements has become apparent, so have their dangers and the shortcomings of the current regulatory framework. These laws and regulations should be revised, with the primary goal of providing consumers and health care practitioners with the information they need to use dietary supplements safely and effectively. In short, dietary supplements should be regulated in a manner that ensures that they are safe and effective. Regardless of the shortcomings of the current regulatory framework, pharmacists have an opportunity and a professional responsibility to reduce the risks presented by dietary supplement use.

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This statement was reviewed in 2014 by the Council on Pharmacy Practice and by the Board of Directors and was found to still be appropriate.

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