AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS®
Pharmacists in health systems helping people make the best use of medications

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May 28, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 99N-1174: Dietary Supplements; Center for Food Safety and Applied Nutrition Strategy; Public Meeting

TO WHOM IT MAY CONCERN:

The American Society of Health-System Pharmacists (ASHP) is pleased to provide comments on the Food and Drug Administration's (FDA) May 13, 1999, *Federal Register* notice announcing a public meeting to solicit comments that will assist the Center for Food Safety and Applied Nutrition (CFSAN) in developing an overall strategy for achieving regulation of dietary supplements. ASHP is the 30,000-member national professional association representing pharmacists who practice in hospitals, health maintenance organizations, long-term care facilities, home care organizations, and other components of health care systems. Although ASHP will not be represented at the June 8, 1999, public meeting, we are submitting the following comments for the meeting record.

ASHP's members have observed that dietary supplements are being used therapeutically by a growing number of patients with whom they have contact. ASHP supports the FDA's objective in developing a strategy for regulating dietary supplements as stated in the May 13 *Federal Register* notice: "to ensure consumer access to safe dietary supplements that are truthfully and not misleadingly labeled."

The *Federal Register* notice refers to three themes that emerged from a stakeholder meeting sponsored by the CFSAN in June 1998:

- The need to maintain a credible FDA program, including compliance, enforcement, and consumer outreach activities;
- The need to maintain a solid, science based program;
- The recognition that FDA's assistance to consumers and the regulated industry is important.

99N-1174

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ASHP agrees. At its Annual Meeting in June 1998, ASHP adopted the following policy, entitled *"Regulation of complementary and alternative substances,"* which coincides with the above-noted themes:

> To support Food and Drug Administration (FDA) regulatory authority over complementary and alternative substances for which claims -- even indirect and general claims -- are made by manufacturers or distributors about their usefulness in preventing and treating disease; further,
>
> To support the principle that complementary and alternative substances not having proven efficacy but having no appreciable toxicity should be allowed to be marketed (but not as drugs or biologics) with labeling that clearly states their lack of proven efficacy; further,
>
> To support the routine reporting and monitoring of product defects and adverse effects associated with complementary and alternative substances through the FDA MedWatch and United States Pharmacopeia reporting programs.

ASHP developed this policy stance because it recognized that in addition to substances already classified as drugs or biologics, there are many other substances (identified by the FDA as "dietary supplements, but which ASHP has identified in its policy statement as "complimentary and alternative substances") that are used by consumers with pharmacologic intent. There is abundant literature and promotional information about these products, but ASHP's members are concerned that much of this information is not scientifically based.

In general, ASHP agrees with the prioritization of elements delineated in dietary supplement section of the "CFSAN 1999 Program Priorities" document. The first element, determining boundaries between dietary supplements and foods and between dietary supplements and drugs, is an important one, because in today's marketplace it is inextricably tied to the second element of the list – claims. Obviously, any substance used with pharmacologic intent has a potential for therapeutic benefit as well as harm. Given the origins of many dietary supplements, the variety of suppliers, and the lack of regulatory production standards, it is logical to anticipate that the products have inconsistent ingredients, uncertain contaminants, and variable concentrations. Due to these circumstances, as well as the vigorous promotion and sizable economic market of these products, and the fact that many patients entering care in health systems are increasingly found to be users of such products, ASHP believes that there is a substantial potential for eventual public harm.

As a means of ensuring the efficacy, potency and purity of medicines, ASHP believes that it is in the best interest of the public that all substances marketed with pharmacologic intent be classified

as drugs or biologics. Substances for which claims are made by manufacturers or distributors about usefulness in treating disease should be subject to the clear regulatory authority of the FDA, state boards of pharmacy, and other agencies having routine jurisdiction over these products.

In regard to the second element on CFSAN's list, claims, ASHP believes that existing and new dietary supplements that are marketed with health claims should be required to demonstrate scientific evidence of efficacy and safety as a condition of their marketing as drugs or biologics. Substances scientifically shown to lack efficacy, but which have no appreciable toxicity could continue to be marketed (as is now the case), but not as drugs or biologics, and they should be required to bear labeling that clearly states their lack of proven efficacy.

ASHP supports other elements on the CFSAN list, particularly review and agency follow-up of adverse event reports relating to dietary supplements, and appropriate enforcement of any dietary supplement regulations that CFSAN may develop.

Finally, one of the questions that the FDA asks commenters to address in the May 13 *Federal Register* notice is: "In addition to ensuring consumer access to safe dietary supplements that are truthfully and not misleadingly labeled, are there other objectives that an overall dietary supplement strategy should include?"

ASHP adopted another policy at its June 1998 Annual Meeting. Entitled *"Pharmacists as a source of information about dietary supplements and alternative or complementary substances,"* that policy is:

> To support the principle that pharmacists should be informed about dietary supplements and alternative or complementary substances, and capable of providing sound advice to patients about their use; further,
>
> To support the principle that pharmacists and pharmacies should foster public confidence that they are accessible sources of available authoritative information about dietary supplements and alternative or complementary substances; further,
>
> To support the principle that pharmacists' recommendations about the use of dietary supplements and alternative or complementary substances should be based on scientific evidence of safety and efficacy.

This policy is somewhat forward-looking, in that many pharmacists require more information about dietary supplements than they now receive in order to provide the best professional advice

to patients. The first two parts of the policy are intended to stimulate improvements in the availability of such information. Because dietary supplements are being used to a significant extent as drug therapy, ASHP encourages the FDA to seek out and utilize the expertise of knowledgeable pharmacists in developing regulations and disseminating information to ensure public benefit and safety from this class of products.

In September 1998, as part of its consumer outreach program, ASHP conducted a survey about "alternative therapies" of over 1,000 health-system pharmacists who have are involved in assessing, applying, or conveying drug information. Some of the information that we elicited included the percentage of consumers who report to physicians or pharmacists that they are taking alternative therapies. The survey shows that consumers often have misconceptions about the safety and efficacy of these products, and that pharmacists are concerned about the potential for serious side effects from the use of dietary supplements. A copy of the results of that survey is attached.

ASHP appreciates the opportunity to respond to the FDA's request for comments on its proposal to develop a strategy for effectively regulating dietary supplements. Many of our members are seriously concerned about a situation with dietary supplements that they perceive as a dangerous public health risk. They believe that appropriate regulation will be effective in reducing the number of exaggerated claims that manufacturers of dietary supplements can make. Feel free to contact me if you have any questions regarding our comments.

Sincerely,

Gary C. Stein, Ph.D.
Director, Federal Regulatory Affairs

Attachment

AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS®

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NEWS RELEASE

FOR IMMEDIATE RELEASE

PN9902
March 17, 1999

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CONSUMERS UNDERESTIMATE POTENTIAL DANGERS OF ALTERNATIVE MEDICINES

BETHESDA, Md. — Patients using alternative medicines, such as herbal remedies and dietary supplements, often underestimate the potential for serious side effects and drug interactions, according to a recent survey by the American Society of Health-System Pharmacists (ASHP).

The poll of 1,000 consumers and 300 health-system pharmacists was designed to assess perceptions about the safety of alternative medicines. The survey revealed that forty-two percent of respondents do not believe that alternative medicines can cause serious side effects. This finding concerns pharmacists because the use of some alternative medicines have been linked to dangerous drug interactions and side effects, including high blood pressure and kidney and liver damage.

The increased use of alternative medicines to treat and prevent a variety of medical conditions is well documented, but many gray areas exist in consumers' minds about what constitutes "safe" when it comes to alternative medicines. Nearly all pharmacists surveyed who have discussed alternative medicines with patients say patients have misconceptions about these products.

"While our survey shows that the majority of consumers understand the importance of discussing alternative medicines with their pharmacist or physician, it also shows that a fundamental confusion exists about the definition of 'alternative medicine,'" said ASHP President Bruce Canaday, Pharm.D., FASHP. "There also seems to be a general assumption that 'natural' means 'safe,' but this is not the case in all instances."

The survey revealed that consumers were more likely to consider a substance safe when the words "natural" or "plants" were used. For example, when asked about alternative medicines, the majority of respondents said they believed that potential side effects and drug interactions could be

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"serious" or "very serious." However, the majority of respondents agreed with the statement that side effects were relatively minor since most alternative medicines are made from "natural" ingredients. Seventy percent of consumers surveyed felt that alternative medicines are safe to use since they are made from plants, herbs, and other natural products.

ASHP wants consumers to know that alternative medicines, which can include products like dietary supplements, herbal remedies, and vitamins, can sometimes cause very serious side effects and drug interactions.

- Ephedra, an herbal remedy that has been used as a decongestant, energy booster, and weight loss aid, can intensify symptoms of heart disease and seizure disorders, in some cases causing heart attacks.
- Comfrey (used as a digestive aid), germander (used as a weight loss aid), and chaparrel (used as an antioxidant and anticanacer treatment), have all been shown to cause liver damage and should be avoided completely.
- St. John's Wort, a popular herbal treatment for depression, can cause tremors, nervousness, and insomnia when taken in conjunction with prescription antidepressants.

ASHP recommends that consumers discuss all alternative medicines with their physician or pharmacist. This is especially important for patients entering a hospital or health system or for those who are taking any prescription or over-the-counter medications.

"With the increasing use of alternative medicines, it is more important than ever that consumers and health professionals work together to ensure the safe use of these products," said Canaday.

ASHP is the 30,000-member national professional association that represents pharmacists who practice in hospitals, health maintenance organizations, long-term care facilities, home care and other components of health care systems. ASHP believes that the mission of pharmacists is to help people make the best use of medications. Pharmacists have a minimum of five years of pharmacy education, making them the health care team's medication-use experts. Many health-system pharmacists have a doctoral degree in pharmacy (Pharm.D.) and may also participate in post-graduate residency programs and train in specialized areas such as kidney dialysis, asthma management, and long-term care.

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ALTERNATIVE MEDICINE PERCEPTIONS
RESEARCH SUMMARY

Pharmacist Survey Results

- 89 percent of pharmacists surveyed are aware that patients in their hospital/health-system are using alternative medicines.
- Of those pharmacists who had discussed alternative medicines with their patients, 91 percent report that their patients have misconceptions about the use of alternative medicines.
- 88 percent of pharmacists surveyed believe that interactions between alternative medicines and prescription medicines can cause serious or very serious problems.
- 84 percent of pharmacists surveyed believe that alternative medicines can have potentially serious or very serious side effects.
- According to pharmacists surveyed, the five alternative medicines most frequently discussed with patients are, St. John's Wort, Gingko Biloba, Echinacea, Ginseng, and Glucosamine.
- 78 percent of pharmacists surveyed believe that the use of alternative medicines will increase over the next five years.

Consumer Survey Results

- 58 percent of consumers surveyed believe that alternative medicines can have potentially serious or very serious side effects.
- 34 percent of consumers surveyed felt that it is safe to take alternative medicines while taking prescription drugs.
- 57 percent of consumers surveyed agreed with the following statement: "Because most alternative medicines are made from natural ingredients, side effects from such products are relatively minor."
- 70 percent of consumers surveyed agreed with the following statement: "Alternative medicines are safe to use since they are made from plants, herbs, and other natural products."
- 85 percent of consumers surveyed believe that it is important for people using alternative medicines to inform their pharmacist, doctor, and other health care professionals about their use of such products.

Pharmacist Survey Methodology

The purpose of the American Society of Health-System Pharmacists (ASHP) Alternative Medicine Survey was to assess pharmacist awareness of alternative medicines. Patient usage and misconceptions were queried as well as the need for patients to inform physicians about alternative medicine usage. In addition, drug interactions between prescription medicines and alternative medicines were queried.

On September 16, 1998, 1,052 surveys were faxed to a random sample of ASHP members. Of those, 758 fax numbers were correct and 284 surveys were returned for a response rate of 37.4%.

The maximum sampling error associated sample does not exceed ±5.8% at the 95% confidence level. The value of the therapeutic position statements and therapeutic guideline were rated on a five point scale using Top Two Box analysis. "Top Two Box" analysis looks at the percent of respondents giving a "4" or "5" rating.

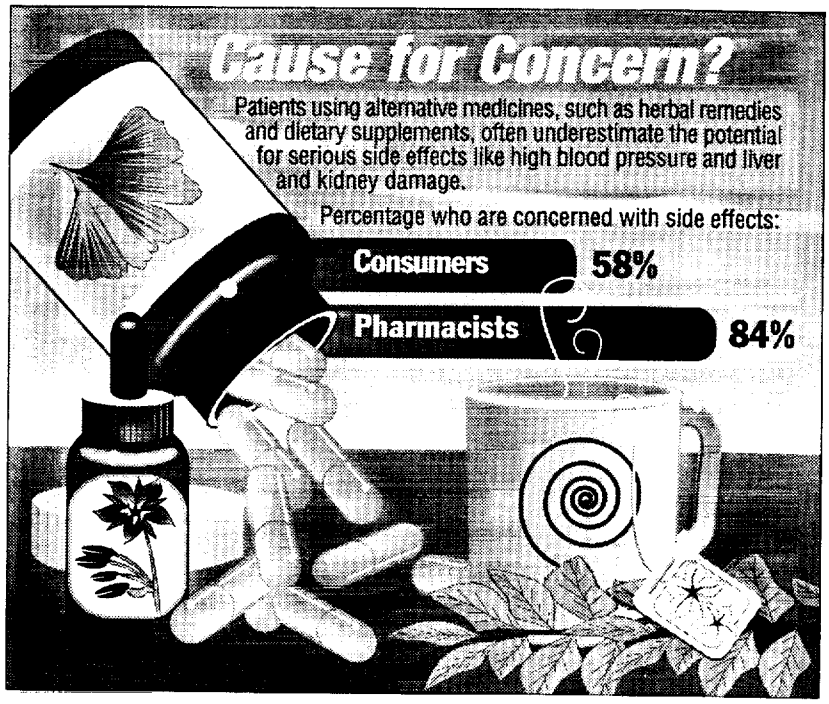
The average pharmacist in this report has been in practice for 16.5 years.

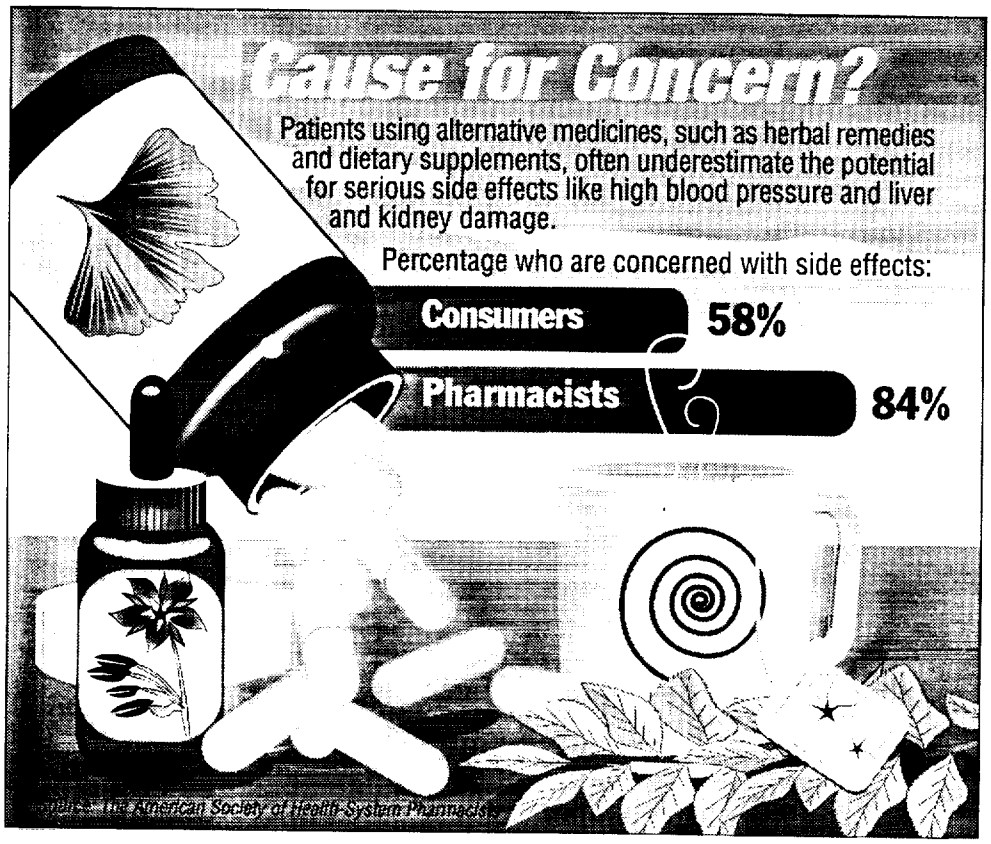
Consumer Survey Methodology

The American Society of Health-System Pharmacists (ASHP) is interested in gauging public attitudes towards alternative medicine. To accomplish this objective, a telephone survey was conducted by International Communications Research (ICR) from Wednesday, January 27, 1999 through Sunday, January 31, 1999, with 1,006 adults age 18 and over.

The sample is based on a methodology designed to produce a representative sample of the U.S. adult non-incarcerated population. This representative sample makes use of random-digit selection procedures that assure sample representation of persons in households that are "listed" in telephone directories, as well as persons in households that are "unlisted" in telephone directories. Within each sample household, one adult respondent is randomly selected using a computerized procedure based on the "Most Recent Birthday Method" of respondent selection. The data were weighted to the Census Bureau's latest population parameters on region, education, sex, race, and age.

The results achieved from all sample surveys are subject to sampling error. Sampling error is defined as the difference between the results obtained from the sample and those that would have been obtained had the entire relevant population been surveyed. The sampling error for the total sample of this survey (n=1,006) is plus or minus three percentage points. Please note that when comparing smaller subgroups, such as respondents divided by age categories or gender, the margin of error increases.





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