Herbal Rx for prostate problems

Saw-palmetto pills may help—if they contain enough of the right stuff.

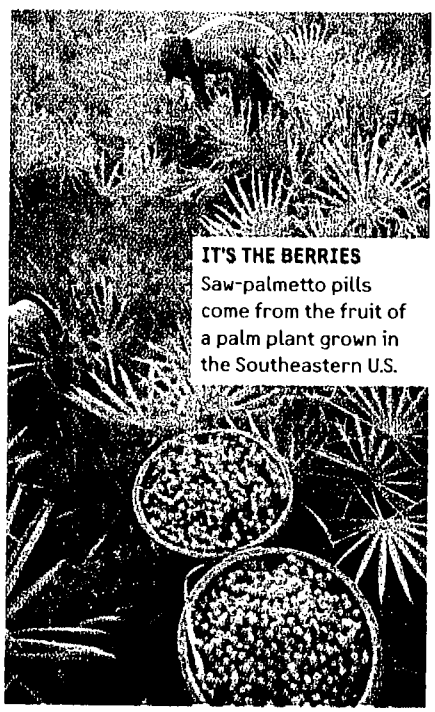
Saw palmetto, a traditional herbal remedy, began its modern comeback in alternative-medicine circles in the early 1990s. Word-of-mouth, marketing, and news of mostly European research showing saw palmetto's benefits have made it one of the top ten best-selling herbal remedies, with sales reaching $140 million in 1999. The remedy is used to treat benign prostate problems, which affect 25 percent of men in their 50s and half of men over age 75. In a recent CONSUMER REPORTS survey, more than a third of men with such prostate problems had tried saw palmetto.

Clinical testing has now begun to catch up with saw palmetto's popularity. Results show that early 20th-century physicians were onto something when they used infusions and potions made from the fruit of the southeastern U.S. palm plant for male genital and urinary problems.

Saw palmetto has had an off-and-on relationship with official listings of plant and pharmaceutical medicines by the United States Pharmacopeia (USP) and its National Formulary (NF). The berry was included as a medicine for prostate problems in the first half of the 20th century, dropped by the 1950s, and reinstated just this year. An April 2000 USP monograph concluded that clinical trials of saw palmetto "provide evidence of moderate scientific quality that commercial extracts of saw palmetto ... are more effective than a placebo in relieving lower-urinary-tract symptoms of BPH [benign prostatic hyperplasia, or noncancerous enlargement of the gland]." The report also found that the herbal remedy has no significant side effects and only rarely causes mild stomach upset or diarrhea. However, it noted that drug interactions and medical contraindications have not yet been studied adequately.)

Now that the report has been published, manufacturers who voluntarily meet USP's standards of potency and purity may place the USP's "NF" seal on their labels.

But unlike modern pharmaceuticals, made with chemicals in a lab, plant-based medicines are notoriously difficult to standardize. Individual plants can vary greatly in their content of key active chemicals. And consumers have virtually no protection against inaccurate labeling or substandard preparation, because of a lack of meaningful government regulation of herbal products.



IT'S THE BERRIES
Saw-palmetto pills come from the fruit of a palm plant grown in the Southeastern U.S.

For that reason, Consumers Union is expanding its herbal-testing program. Over the next few years, working with outside labs that specialize in testing herbal products, we will test representative brands of herbal remedies that are performing well in clinical trials. Our ingredient testing will follow our usual standards, which include anonymous shopping at a variety of retail outlets and, for many products, the testing of several samples of each brand, obtained from different parts of the country.

Of the 13 saw-palmetto brands tested for this report, we found that only 8 had the right amount of the right stuff: The number of pills recommended on the label did supply the desirable amount of berry extract, at prices ranging from 44 cents to $1.44 a day. The other 5 brands fell short—often woefully short, with the recommended pills supplying as little as 1 percent of the desirable daily dosage (see box, facing page).

A PRESSING PROBLEM

Located at the base of the bladder, the prostate gland produces most of the fluid in semen. Normally it's the size of a walnut. But over the years the cumulative effect of the male hormone dihydrotestosterone (DHT) tends to make the gland grow larger, by an average of 175 percent. As a result, it may start to constrict the urethra (the tube that runs through the prostate and carries urine out of the bladder), thereby interrupting normal urine flow. In addition, muscle tone in or near the prostate tends to gradually increase with age; that may eventually trigger recurrent muscle spasms that can restrict the flow of urine. Both processes prevent complete emptying of the bladder, resulting in a frequent, urgent need to urinate, often in the middle of the night; spasms can interrupt the stream as well and sometimes even stop it entirely.

BPH is generally not a dangerous condition, but individuals bothered by any of those urinary symptoms should see a doctor to rule out other diseases such as diabetes, prostate or bladder infection, neurologic disorders, and cancer. If the problem is BPH, a doctor can help you decide whether to treat it, and if so, how.

BPH sometimes improves spontaneously. The decision on what to do—watchful waiting or treatment with saw palmetto, prescription medicine, or surgery—should be driven by how bothersome your symptoms are. If the problem is mild, watchful waiting may be all you need. That means

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seeing the doctor for regular checkups and taking such steps as limiting evening intake of fluids, particularly alcohol and coffee. Make sure to ask the doctor whether any drugs you're taking—especially diuretics (water pills), antihistamines, decongestants, antidepressants, and tranquilizers—might be aggravating the problem.

However, men whose sleep is continually disrupted by the frequent need to urinate at night or whose lifestyle is circumscribed by having to stay within dashing distance of a bathroom should consider treatment.

HERBAL THERAPY

Researchers aren't sure how saw palmetto works, although they have isolated numerous substances, including certain fatty acids, that appear to be active. Some lab studies suggest that the herbal remedy may have a weak antihormonal effect (too weak to blunt the sex drive or cause feminizing changes); others suggest that it may inhibit the proliferation of prostate cells or help fight inflammation. One recent study did find that saw palmetto decreased prostate size, although several other studies found no such effect.

Most clinical trials have tested saw palmetto against a placebo, not against a prescription drug. In 1998 the Journal of the American Medical Association published a review of 18 such clinical trials. The review,

What the pills contain

Our tests indicated whether each brand, taken as directed on the label, would supply at least the amount of saw-palmetto extract (320 milligrams per day) that has become standard. Most brands would—but a significant number fell short.

Ten products claimed they contained a specific dose of saw-palmetto extract. Eight of them supplied somewhat more than enough extract to meet the standard daily dosage if you took the maximum number of pills recommended on the label. (However, there's no evidence that taking more than 320 milligrams per day confers any added benefit.) Two of those eight products—*CVS Premium Quality Herbs* and *Quanterra Prostate*—appeared to be pure extracts. That's a possible plus for people who want to avoid added oils and other extra ingredients. Of the two specific-dose products that fell short, *Puritan's Pride Saw Palmetto Complex* did contain the labeled amount—but it recommended too few pills to supply the standard dosage. The other one, *Ricola Herbal Health Prostate Formula*, contained far less per pill than the label claimed. (It also packed a lot of added sterols—substances present in saw palmetto—but whether that confers any advantage is not clear.)

The remaining three brands—two powdered-berry products and one "concentrated herbal extract"—delivered markedly less than the standard regimen. That suggests that powdered berry probably isn't a satisfactory way to take the supplement. The labels on those three products did not indicate the equivalent amount of extract in the pills.

Recommendation: Consult the table and choose the least expensive brand you can find that delivers the adequate dosage.

BRAND *Listed in order of daily cost of standard dosage*	IF YOU FOLLOW THE LABEL			TO GET THE STANDARD DOSAGE	
Saw-palmetto extract [except where noted]	Pills per day	Do you get standard dosage? [1]	Percent of standard dosage [1]	Pills needed [1]	Cost per day [1]
CVS Premium Quality Herbs Saw Palmetto	2	Yes	110%	2	$0.44
Puritan's Pride Saw Palmetto Complex with Pygeum [blend of herbal extracts]	1 or 2	No	30-60	4	0.44
GNC Herbal Plus Standardized Saw Palmetto	2	Yes	120	2	0.46
Solaray Saw Palmetto Berry Extract 160 mg.	1 or 2	Yes	60-120	2	0.50
One-A-Day Prostate Health with Natural Saw Palmetto and Zinc	2	Yes	130	2	0.58
The Vitamin Shoppe Saw Palmetto 540 mg. [powdered saw-palmetto berry plus some extract]	1 or 2	No	15-30	7	0.63
Nature's Herbs Power-Herbs Saw Palmetto Power 160 Std. Extract	2	Yes	130	2	0.80
Quanterra Prostate Saw Palmetto	2	Yes	110	2	0.82
Your Life Saw Palmetto Standardized Herbal Extract	4	Yes	110	4	0.84
Shaklee Saw Palmetto Plus	2	Yes	130	2	1.44
Ricola Herbal Health Prostate Formula with Saw Palmetto and Natural Vitamin E	2	No	10	18	5.04
Real Health The Prostate Formula with Saw Palmetto [powdered saw-palmetto berry]	3	No	15	24	5.28
Nature's Bounty Herbal Sure Extracts Saw Palmetto 1000 mg. ["concentrated herbal extract"]	1 or 2	No	1-3	60	18.00

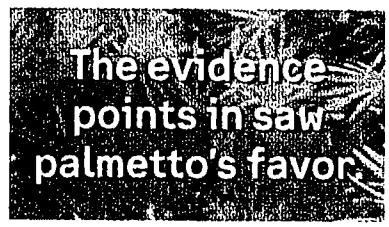
[1] *Based on our test results*

The tests behind the table

We commissioned tests of 13 saw-palmetto brands—including 7 of the top sellers—available at drug or health-food stores or through the Internet. The tests checked whether the products contained the distinguishing chemical constituents of saw palmetto—specific levels of certain fatty acids and sterols. Based on those findings, we calculated the amount of saw-palmetto extract in each pill and used the results to create our table.

If you follow the label refers to what you get when you follow the manufacturer's recommendation. **Pills per day** is the daily number of pills (softgels, capsules, or tablets) recommended by the label. **Do you get standard dosage?** tells whether our tests found that the maximum recommended number of pills will supply at least the standard dosage of 320 milligrams of saw-palmetto extract per day. **Percent of standard dosage** gives the percent of that dosage supplied by those pills. **To get the standard dosage** refers to what's required to get at least the 320 milligrams. **Pills needed** is the number of pills you'd have to take to reach that target. And **Cost per day** tells how much you'd pay if you did take that many pills. (Cost is based on national average selling price.)

by researchers at the Minneapolis VA Medical Center and other institutions, concluded that the evidence points in saw palmetto's favor. Overall, about three-quarters of BPH patients taking the herb reported an improvement in symptoms, compared with about half of those on placebo. (Such a strong placebo response is not uncommon in clinical trials, particularly if the disorder waxes and wanes.) Moreover, saw palmetto appears to relieve several types of symptoms: It boosted the strength of the urine stream, allowed more-complete emptying of the bladder, and reduced the number of nighttime trips to the bathroom. Those benefits added up to a 37 percent improvement in urinary symptoms.



In the world of herbal medicines, where research is usually scanty, that evidence is rather impressive. But it still falls short of what's usually required for drug approval by the Food and Drug Administration (FDA). The clinical trials have typically lasted only six months or less, while prescription prostate drugs have proved their safety and efficacy in studies lasting up to six years. The American Urological Association (AUA), which represents urologists, says it's keeping an open mind while awaiting the outcome of longer clinical trials, including a one-year placebo-controlled study of saw palmetto funded by the National Institutes of Health.

"What worries me is that we don't know about drug interactions," says H. Logan Holtgrewe, M.D., chairman of the AUA's health-care policy committee. In contrast, he says, "we have two families of medications that have been shown efficacious based on good evidence from prospective, randomized, blinded clinical trials."

AS GOOD AS A DRUG?

Saw palmetto costs about $15 to $45 per month (usually not covered by insurance), compared with about $85 for finasteride *(Proscar)* and $45 to $75 for an alpha-blocker such as doxazosin *(Cardura)*, terazosin *(Hytrin)*, or tamsulosin *(Flomax)*. A recent survey found that some 85 percent of urologists would treat moderate prostate problems with one or more of those prescription drugs, whose combined sales approached $1 billion last year.

Finasteride shrinks the prostate by decreasing production of DHT. It works best in the minority of patients with BPH whose gland is greatly enlarged. Few studies have compared finasteride with saw palmetto. But in one six-month trial of more than 1,000 BPH patients, the drug increased urinary flow by 30 percent, while the herbal remedy boosted flow by a comparable 25 percent. What's more, the herbal did not cause the most troublesome side effect of finasteride: erectile dysfunction in about 9 percent of men. And unlike the drug, saw palmetto doesn't interfere with the standard prostate specific antigen (PSA) cancer-screening test. However, the study was too short to draw definite conclusions, since saw palmetto's effects typically kick in within one to two months, whereas finasteride's sometimes take more than six months.

"I think most physicians feel that finasteride's main role in the treatment of BPH is the long-term prevention of complications, such as complete bladder blockage, and of progression to surgery," says Michael Barry, MD, chief of the general medicine unit at Massachusetts General Hospital in Boston. "There's no evidence that saw palmetto conveys that benefit."

SOMETHING FASTER

The other first-line drug treatment for BPH symptoms is an alpha-blocker. Rather than shrinking the prostate, alpha-blockers ease muscle spasms in the prostate and the bladder neck, thus easing constriction of the urethra.

In clinical trials, alpha-blockers have reduced symptoms faster and better than finasteride, although we could find no published data on whether they prevent long-term complications. One published study found that saw palmetto relieved symptoms almost as effectively as an alpha-blocker, but the USP's reviewers concluded that the study was too loosely designed to draw reliable conclusions.

In the recent CONSUMER REPORTS survey, readers with benign prostate problems rated prescription medications, presumably including alpha-blockers, more effective than saw palmetto. As our tests suggest, however, some of those readers probably took pills that supplied relatively small doses of saw palmetto.

Overall, a few points do seem clear. Alpha-blockers work faster than saw palmetto, starting to relieve symptoms in as little as one week. But alpha-blockers, particularly doxazosin and terazosin, can cause reduced blood pressure, necessitating careful monitoring with frequent blood-pressure checks.

While some doctors are starting to recommend saw palmetto for patients with mild symptoms—or at least not flinch when patients want to try it—others are unenthusiastic. Claus Roehrborn, M.D., an associate professor of urology at the University of Texas Southwestern Medical Center in Dallas, considers saw palmetto "nothing but junk food." That's because the FDA regulates herbals as foods, not drugs.

Physicians might be more inclined to recommend the herbal medicine if they could be assured that the pills contain the known or probable active ingredients in the amount shown to work in well-designed studies and that the labeled dosages were accurate and appropriate. But as our tests of saw palmetto show, some herbal products may still contain far too little of the apparently active ingredient.

RECOMMENDATIONS

Although the long-term safety and efficacy of saw palmetto remain unclear, Consumers Union's medical consultants say there's enough evidence to conclude that supplements containing at least 320 milligrams per day of saw-palmetto extract, the amount that worked in clinical trials, might be worth trying for some men with mild symptoms; they should discuss that option with their doctor. If symptoms don't improve after two months of taking the remedy, it's probably time to try another approach.

As our tests indicate, makers of some saw-palmetto products need to do a better job of producing standardized, properly labeled products. And the FDA should act on its promise to define good manufacturing practices for nutritional supplements.

Men with troublesome BPH symptoms that don't respond to evening fluid restriction, drug-regimen changes, and possibly saw palmetto should turn to prescription prostate medication. Because alpha-blockers work so rapidly, they're usually worth trying before finasteride, especially for men with intermittent urinary flow and no more than moderate prostate enlargement. If alpha-blockers don't work, doctors can prescribe finasteride for men with a very large prostate. If all else fails, paring down the prostate via surgery or one of several other invasive techniques can be considered. The latest and best study suggests that those methods do not increase the risks of incontinence or impotence, although some may cause infertility.

How to research a medical topic

Wresting the facts you need from the mass of health information—and misinformation—on the Internet.

In 1997 the National Library of Medicine opened up the world's largest database of medical literature to the public on the Internet. Use of MEDLINE, once the near-exclusive domain of doctors and scientists, soon skyrocketed from 7 million to over 200 million searches a year. "Consumers have powered that explosion," says Eve-Marie Lacroix, chief of the public services division of the National Library of Medicine. "They're starved for medical information."

To satisfy that appetite, a virtual library of textbooks, scientific reports, and peer-reviewed journals is now just a mouse click away from anyone who wants it. Numerous medical societies, such as the American College of Rheumatology, the American Urological Association, and the American Diabetes Association, now post the papers being presented at their annual meetings, allowing patients to learn about new findings and treatments before many doctors do.

The vast amount of current information on the Internet and the relative ease with which it can be searched make it today's best medium for health research. For people without computer access many libraries now provide computers the public can use to reach the Internet. (See "Medical libraries" on page 9 for how to find public libraries with special health resources and medical libraries open to the public.)

"Access to all that information can empower patients [and] give them a sense of control," says George Lundberg, M.D., editor of Medscape.com and CBSHealth Watch.com. "More important, it can improve the care they get, by letting them see for themselves what treatments are out there, and how effective they are, or aren't."

ADS, BIAS, CONFUSION

The challenge of today's wide-open access to information is finding relevant, unbiased, and accurate knowledge about medical conditions in the estimated hundreds of thousands of web sites now devoted to health. Doctors report that they're often swamped by patients bearing computer printouts—and complain about spending valuable office time sorting through irrelevant or erroneous information.

Much of the medical information on the Internet is aimed at health-care professionals, and is often too technical and too abundant for consumers. At the many health sites designed for consumers, information is translated into more easily understood language, but these sites often pose other problems. Many have a financial stake in selling particular products or therapies, which may taint their objectivity and expose you to intrusive commercial messages. For example, when we typed "sleep disorders" into the search box at *www.CBSHealthWatch.com* an ad for zaleplon *(Sonata)*, a sleeping pill, popped up on the top of the screen, complete with information on insomnia provided by the pill's manufacturer.

It's also hard to know whether you can trust the accuracy of the information on some commercial web sites. Here, for example, is the essence of an online dialogue we had at *www.AmericasDoctor.com* where you can pose questions and receive immediate answers from a medical professional.

AmDoc50: Hi! Welcome to the America's Doctors chat rooms. You are in a one-to-one session with a medical provider.

Question: I have three children, aged 3 to 10. All have tested positive for Lyme at least once. Should they consider the vaccine?

AmDoc50: Certainly having Lyme disease and having been given treatment for it is no reason not to get vaccine since the vaccine may prevent [a] new onset of infection.

Question: So is it safe for kids, or is it only approved for adults?

AmDoc50: Well it is safe for kids.

If that answer means that the vaccine approved for kids, it's wrong. A search MEDLINE found one study that sugges that the vaccine may be safe in children. B as of July, 2000, the date of our search, t FDA had not yet approved the vaccine f those under 15 years of age.

STARTING RIGHT

Given the uneven quality of information o the Internet, a focused—rather than a ra dom—search is the best way to begin. "Th most important thing to know when you d go online is not to just type the name some condition into Yahoo! or some oth general search engine and see what com up," says Mary Joan Tooey, deputy direct of the Health Sciences and Human Servic Library at the University of Maryland.

For example, when we typed "Lyme dis ease vaccine" into the Yahoo! search engin the first ten references included links t "Cheryl's Lyme Disease Site," "Dawnie Lyme Site," and "Jean's Lyme Page." Thos sites contain individuals' personal experi ence with the disease. While such account may provide some useful insights, they' hardly authoritative sources.

Instead of using a general search engin the best place to start is usually MED LINE*plus*, the National Library of Medicine' consumer-health web site. (For other goo starting places, with links to reliable an current sites that have been selected by med ical professionals, see Information sites, o page 9.)

NAVIGATING MEDLINEPLUS

MEDLINE*plus* connects you to the 11 millio medical citations listed in MEDLINE and, fa more useful to the average person, numerou other helpful tools including a medica encyclopedia and several dictionaries; drug reference guide; general backgroun and more detailed reports on the diagnosis prognosis, and treatment of numerous med ical conditions; and links to hundreds o reputable health organizations.

But precisely because MEDLINE*plus* i so comprehensive, even it can be over whelming. "People often head straight into searching the medical journals through our link to MEDLINE, or head off into infor-

hTips

basic approaches will help you reach relevant sites and medical studies:

Web addresses

Many of the web addresses noted in this article take you directly to the relevant section of the web site. If you have trouble getting through, go to the main web address instead, and then look for the relevant section. For example:

Instead of: *www.nlm.nih.gov/medlineplus/druginformation.html*—

Enter: *www.nlm.nih.gov* or *www.nih.gov* and look for the button to connect you to MEDLINE*plus*. Once there, look for buttons to drug information, directories, dictionaries, and other resources.

Medical studies: basic search

At MEDLINE*plus*, use the search box to enter a topic (such as "back pain") to reach reference lists on hundreds of health topics prepared for consumers. The search there is automati- ··mited to English language, studies, clinical trials, review ·, and practice guidelines.

Medical studies: advanced search

- Go to PubMed, the National Library of Medicine's MEDLINE search engine (*www.ncbi.nlm.nih.gov/pubmed*) or Grateful Med (*igm.nlm.nih.gov*).
- In the Search box, enter the subject you're interested in. To clarify the search, use "AND," "OR," or "NOT" between two or more subjects. For example, "back pain AND kidney stones" will find studies about back pain caused by kidney stones. "Back pain NOT kidney stones" will find studies about back pain unrelated to kidney stones. "Back pain OR kidney stones" will find information about both.
- Before you hit "enter," or push the "Go" button, click on the word "Limits" below the search box.
- In the "Publication Types" box, select 'randomized clinical trials," "meta-analysis," "practice guidelines," or "reviews."
- In the "Language Box," select "··-h."
- ıe "Human or Animal" box, se- .man."
- In the "Publication Date Box," imit the search to a few recent years.

mation on clinical trials," says Lacroix, at the Library of Medicine. "That's usually a prescription for information overload."

When we typed in "back pain" in MEDLINE, for example, we got 458 references, the first of which was titled "Current management of calculi in horseshoe kidneys," published in the Scandinavian Journal of Urology and Nephrology. With practice, you can learn how to narrow your search (see "Search Tips" at left). Or you can simply access MEDLINE via MEDLINE*plus:* That site has predefined searches—limited to reviews, guidelines, or clinical trials recently published in readily available English language journals—for hundreds of diseases. When we searched for "back pain" that way we retrieved a manageable 57 citations. Included in the first 20 citations were reviews of the use of surgery, acupuncture, and chiropractic care for low-back pain.

Some of those citations have links to full-text online sources; most others have informative abstracts. You can have the full text of almost any article e-mailed, faxed, or mailed to you; but each retrieval can cost up to $25. Before you spend money for an article, see if a local public library has it or can retrieve it for you for free.

If you need help with the technical terms used in sources, MEDLINE*plus* offers several medical dictionaries. Among the resources that turn up when you search for "colon cancer" in MEDLINE*plus* are two specialized dictionaries, one from the National Digestive Diseases Information Clearinghouse, the other from the American College of Gastroenterology.

SECOND AND THIRD OPINIONS

"The single most common reason people come to us is that they have just received a diagnosis from their doctor and want a quick primer on the condition," says Michele Spatz, director of the Planetree Health Resource Center (*www.mcmc.net/phrc*), an Oregon health research group.

To get a background lesson on a medical condition, see "Reference books" and "Health organization listings" on page 9.

If you're interested in finding the treatment options for a specific condition, consult the sources described in "Guidelines and reviews."

Another way to decide if the treatment option recommended by your doctor is right for you is to get a second opinion, ideally from a leading expert in the field. You can find an expert by tracking down the author of a comprehensive review article you found through your MEDLINE search, then asking that person to recommend someone in your locale. (Many recent journal articles provide the author's e-mail address; otherwise, you can track down the author through his or her hospital or university affiliation.) The sites listed in "Locating an expert" can help you get started if you don't have a solid lead or are starting with a list of doctors who accept your insurance.

"The hardest research questions come from people who either aren't responding to standard therapy or have been told that there's not much medical science can offer," says Eileen Coan, resource director at The Gathering Place (*www.touchedbycancer.org*), an organization that helps cancer patients conduct medical research for free. "Those are the people who, for good reason, want to leave no stone unturned."

Getting second—and even third or fourth—opinions is especially important in such circumstances. A good strategy for finding new treatments is to look at the sources listed in "Clinical trials." Those sites provide information about ongoing studies that test new therapies against established ones. The sites generally describe the new therapy being tested and provide a phone number for the lead researcher. You can contact that researcher to see if you might be a candidate for enrolling in the trial. Even if you don't want to participate in the study, in some cases the researcher may be willing to consult with your local physician about the treatment. ■

For more information

- **A free, just-released 20-page booklet,** "How to Find Medical Information," offers additional tips on how to locate and interpret general medical information. For a copy, write to the National Institute of Arthritis and Musculoskeletal and Skin Diseases Information Clearing House, 1 AMS Circle, Bethesda, Md 20892-3675. Or call, toll-free, 877-226-4267, or e-mail: niamsinfo@mail.nih.gov.

Recommended health sites

HEALTH SITES	WEB SITE ADDRESS/PHONE	HOW TO USE
Medical libraries		
• The National Network of Libraries of Medicine	*www.nnlm.nlm.nih.gov/members;* 800-338-7657	Call or visit these sites for a comprehensive list of public libraries that have special health resources or medical libraries that are open to the public.
• The MEDLINE*plus* Library List	*www.nlm.nih.gov/medlineplus/libraries.html*	
• The Consumer and Patient Health Information Section of the Medical Library Association	*caphis.njc.org/directory*	
Reference books		
• The MEDLINE*plus* Medical Encyclopedia	*medlineplus.adam.com*	Print copies of some of these references as well as "Stedman's Concise Medical Dictionary" and "Dorland's Medical Dictionary" are available at many libraries.
• The Merck Manual of Medical Information, Home Edition	*www.merck.com/pubs/mmanual_home*	
• The World Book—Rush-Presbyterian-St. Luke's Medical Center–Medical Encyclopedia.	*www.rush.edu/worldbook*	
• Medical Library Association, "Deciphering Medspeak."	*www.mlanet.org/resources/medspeak*	
Health organization listings		
• The MEDLINE*plus* Organizations list	*www.nlm.nih.gov/medlineplus/organizations.html*	Sources for comprehensive lists of health and disease-related organizations.
• The Directory of Health Organizations	*dirline.nlm.nih.gov*	
• The National Institutes of Health's Office of Rare Diseases	*rarediseases.info.nih.gov/ord;* 301-402-4336	
• The National Organization of Rare Diseases	*www.rarediseases.org;* 800-999-6673	
Information sites		
• MEDLINE*plus*	*www.medlineplus.gov*	The best places to start health searches.
• Choices in Health Information	*www.nypl.org/branch/health/links.html*	
• New York Online Access to Health, at the City University of New York (NOAH)	*www.noah.cuny.edu*	Source for Spanish-language health information.
• Healthweb	*www.healthweb.org*	Reliable information selected by professionals.
• Oncolink	*www.oncolink.upenn.edu*	Cancer Information.
Guidelines and reviews		
• The Agency for Health Care Research and Quality	*www.ahcpr.gov;* 800-358-9295	Use these sites to check if there is general agreement among professionals on the best treatment for specific health problems.
• The Cochrane Collaboration	*www.cochrane.org*	
• The National Comprehensive Cancer Network Oncology Practice Guidelines	*www.cancernetwork.com/indexes/nccn.htm;* 888-909-6266	
• CancerNet	*cancernet.nci.nih.gov*	
Clinical trials		
• ClinicalTrials.gov	*www.clinicaltrials.gov*	List of ongoing trials funded by the NIH.
• CenterWatch Clinical Trials Listing Service	*www.centerwatch.com*	Lists mainly industry-funded clinical trials.
• CancerTrials	*cancertrials.nci.nih.gov*	Listing by the National Cancer Institute.
Locating an expert		
• The American Medical Association's On-Line Doctor Finder	*www.ama-assn.org/aps/amahg.htm*	Can provide the names of local specialists.
• The American Board of Medical Specialties	*www.abms.org;* 800-776-2378.	Can tell you if a doctor is board certified.
Drug questions		
• U.S. Food and Drug Administration	*www.fda.gov/cder/drug* or *www.fda.gov/cder/consumerinfo*	The FDA, Medwatch, and Medical Letter sites contain the latest information on new drugs and recently identified risks. The other sites have comprehensive information on older drugs.
• Medwatch	*www.fda.gov/medwatch/safety.htm*	
• The MEDLINE*plus* Drug Link	*www.nlm.nih.gov/medlineplus/druginformation.html*	
• The University of Miami's School of Medicine, Louis Calder Memorial Library	*calder.med.miami.edu/catalog/subject/pharmacology_and_toxicology.html*	
• The Medical Letter for Drugs and Therapeutics	*www.medical letter.com;* 800-211-2769	
Alternative medicine		
• National Center for Complementary and Alternative Medicine	*nccam.nih.gov/nccam; nccam.nih.gov/nccam/fcp/clearinghouse;* 888-644-6226	The first three sites provide comprehensive information. Quackwatch and NCRHI focus on identifying dubious alternative health-care claims. The last site and NOAH (see Information sites) provide lists of organizations that focus on specific alternative therapies.
• Nat'l Institutes of Health's Office of Dietary Supplements	*odp.od.nih.gov/ods*	
• National Cancer Institute's CancerNet Treatment Options: Complementary and Alternative Medicine	*cancernet.nci.nih.gov/treatment/cam.shtml*	
• Quackwatch	*www.quackwatch.com*	
• The National Council for Reliable Health Information	*www.ncrhi.org*	
• The University of Wisconsin-Madison, Health Resources Library	*www.medsch.wisc.edu/chslib/hw/altmed*	

For Health Consumers

"Top Ten" Most Useful Websites

The Medical Library Association finds the following web sites particularly useful (sites are listed in alphabetical, NOT ranked, order):

- **Centers for Disease Control and Prevention (CDC)**
- **healthfinder®**
- **HealthWeb**
- **HIV InSite**
- **Mayo Clinic Health Oasis**
- **MEDEM: an information partnership of medical societies**
- **MEDLINEplus**
- **National Women's Health Information Center (NWHIC)**
- **NOAH: New York Online Access to Health**
- **Oncolink: A University of Pennsylvania Cancer Center Resource**

The Consumer and Patient Health Information Section (CAPHIS) of MLA evaluates web sites based on the following criteria: credibility, sponsorship/authorship, content, audience, currency, disclosure, purpose, links, design, interactivity, and disclaimers.

Need more information? Try asking a medical librarian (note that not all medical libraries are open to the public). Call your local hospital, health care center, medical school, or contact MLA:

Medical Library Association
Suite 1900
65 East Wacker Place
Chicago, IL 60601-7298
312.419.9094
Fax, 312.419.8950

Diagnosing Websites

"Surf" your way to the information you need!

Use these tips to help decide if a Website is a reliable source of health care information.

- **Who sponsors the Web site?**
  Be sure the Web site hosts as well as their qualifications are clearly identified. Credible sources include medical associations, hospitals, medical centers, and medical schools. Remember, manufacturers of medical products, including drug manufacturers, often have good information but don't include information about competing products.
- **Is the site current?**
  Has it been updated recently?
- **Is the information factual or does it represent opinions?**
  If so, whose opinions are being presented? Are they qualified professionals?
- **Is the Web site intended for medical professionals or the general public?**

FOR HEALTH CONSUMERS

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Medical Library Association
312.419.9094 info@mlahq.org

Health Reporters Internet Seminar

Evaluation Criteria

(This is a mirror of the Greater Midwest Region NN/LM Tip Sheet)

Tips on Evaluating Web Resources

A recent Web search using the Lycos search engine's customized search function, which allows the searcher to use a Boolean "AND" to perform a combined search for the terms "fetal," "alcohol," and "syndrome," yielded seventy-nine hits. The same search performed with Alta Vista yielded many more. On the Web, you can talk to someone's cat, or read the latest version of the Centers for Disease Control's *Morbidity and Mortality Weekly Report*. It is usually easy to distinguish between possibly valuable information and entertainment.

Evaluation Criteria

With the number of health-related Websites growing daily, identifying Web resources that provide accurate, reliable medical information is more difficult. Although projects such as HealthWeb have begun to address this issue, librarians frequently encounter potentially useful sites that have not been evaluated by anyone. Here are some tips to help you develop your own evalutation criteria.

Content

What is the purpose of the Website? Is it stated? Is the site intended to educate or to sell? Is the information factual or opinion? Are there links to other sites? Are these links up to date? Have they been evaluated? Is it apparent why they were included? Is the information provided unique or can it be retrieved from other sources? If it can be found elsewhere, does the Web version complement the other version(s), or is it merely repetitive? Is the information accurate and verifiable? Is the resource detailed or more general in scope?

Audience

Is there an obvious intended audience for the Website (children, teenagers, consumers, health professionals,

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PUBLICATIONS
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Books, etc.
MLA News
Ordering Info
Standards, etc.
RESOURCES
Allied Groups
Buyer's Guide
Directory
Gov't Relations
Library Schools

etc.)? On what reading level is the information written?

Authority or Source
Is the author of the Website an individual, a university, a corporation, the government, or someone else? What expertise or authority does the author have to provide this information? Is there an obvious bias? Does the author list sources? Can the author be contacted with questions?

Date and Timeliness
When was the site first produced? When was it last revised? How often is it updated? Are these dates evident? Does the provided information tend to change frequently, or is it more retrospective in nature?

Structure/Access
Is the Website well designed? Is it user friendly? Does it contain images? If so, are they useful or merely decorative? Do they load quickly? Would the page be useful to someone with a text-only browser? Does it offer a local search engine?

- **Consumer Health Information Producers**
- **Types of Consumer Health Information**

Medical Library Association
312.419.9094 info@mlahq.org

Last updated: 16 February 2001
www.mlanet.org/resources/health_writer/evaluation_criteria.html

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Marketing & Advertising

Divider Title: _____

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Divider Title: Rusk

BIOGRAPHY OF MICHELLE RUSK

Michelle Rusk is a senior staff attorney in the Division of Advertising Practices, Bureau of Consumer Protection at the FTC. The Division is responsible for regulating national advertising matters, including claims about foods, OTC drugs, dietary supplements, cosmetics, alcohol, tobacco and environmental products. Ms. Rusk joined the FTC from private practice in 1990. Ms. Rusk was involved in the development of the FTC Guides for Environmental Marketing and co-authored a 1991 article entitled, "Commercial Speech and the FTC's Consumer Protection Program" for the Antitrust Law Journal. She has worked on a number of advertising issues that involve overlapping FDA jurisdiction including the development of the FTC's 1994 Enforcement Policy Statement on Food Advertising, the coordination of FTC enforcement activities for dietary supplement advertising, and Operation Cure.All, the FTC's ongoing project to combat health fraud on the Internet. Most recently, Ms. Rusk was responsible for developing the FTC's Advertising Guide for the Dietary Supplement industry.

FTC ADVERTISING LAW AND THE MARKETING OF COMPLEMENTARY AND ALTERNATIVE THERAPIES AND PRODUCTS

Statement of Michelle Rusk Before the
White House Commission on Complementary and Alternative Medicine Policy

March 26, 2001

Chairman Gordon and members of the Commission, I am Michelle Rusk, an Attorney in the Bureau of Consumer Protection's Division of Advertising Practices. I am pleased to have this opportunity to describe for you the Federal Trade Commission's role as it relates to the marketing and promotion of Complementary and Alternative Medicine (CAM).[1]

As a law enforcement agency, the FTC's mission is to ensure that consumers receive accurate information about the safety and efficacy of products, including CAM products and services, so that they can make informed decisions about their health care alternatives. The agency does this both by bringing actions against misleading and unsubstantiated claims in the marketplace, and by educating consumers so that they are better able to spot and avoid fraud.

In the short time available today I will do three things: first, very briefly

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[1]The views expressed here are my own and do not necessarily represent those of the Commission or any individual Commissioner.

outline the FTC's jurisdiction and general, long-standing principles of deception and ad substantiation; second, give a few examples of how we have applied these principles in the CAM area, both in terms of law enforcement and consumer education; and third, highlight the need for reliable sources of consumer information about CAM products and services. Although the FTC has challenged a number of unfounded claims and has engaged in extensive consumer education efforts in this area, there are still too many examples of deception in the marketplace. Consumers need to be especially skeptical of advertising claims and should exercise caution in their purchasing decisions.

There are two basic tenets of FTC advertising law: 1) that the ad must be truthful and not misleading; and 2) that any objective claims must be substantiated.[2] Advertisers are responsible for both express claims made in an advertisement and the reasonable implications conveyed to consumers from those claims. Claims about the safety or efficacy of a product that cannot be

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[2]The Commission enforces Section 5 of the Federal Trade Commission Act, which prohibits "unfair or deceptive acts or practices in or affecting commerce," 15 U.S.C. § 45, and Section 12, which prohibits the false advertisement of "food, drugs, devices, services, or cosmetics," 15 U.S.C. § 52. An advertisement is deceptive if it contains a representation or omission that is likely to mislead consumers acting reasonably under the circumstances, and the representation is material; that is, likely to affect consumers' conduct or decisions with respect to the product or service at issue. Advertising is false if it is misleading in any material respect.

substantiated if made directly should not be asserted indirectly, for example through testimonials that are not backed by supporting research. A consumer testimonial that states "My emphysema has improved 40% with product X," cannot be made in advertising unless there is supporting research to substantiate the underlying claim that product X is effective for the treatment of emphysema.

In the marketing of CAM products and services, there are some claims that are simply false and should be prohibited. There are other claims that may have some underlying support but greatly exaggerate the benefits of the product or service or the extent of support for the those benefits. The greatest challenge, however, concerns claims about products and services for which there is a sound body of emerging science, but which are not yet proven. The FTC Act's substantiation doctrine is sufficiently flexible to ensure that consumers have access to information about emerging areas of science. At the same time, it is sufficiently rigorous to ensure that consumers can have confidence in the accuracy of that information. The level of substantiation required will depend in large part on the specific claim being made and on how it is presented and qualified. For instance, ads claiming that "Scientists Now Agree" likely would be held to a scientific consensus standard. Where no specific level of support is stated, the FTC requires

"competent and reliable scientific" evidence to substantiate health-related advertising claims. This standard has been defined in numerous cases as:

> Tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted to yield accurate and reliable results.

There is no fixed formula for the number or type of studies required or for more specific parameters like sample size and study duration. In applying this standard, the Commission gives great weight to the generally accepted methods in the relevant fields of research and consults with experts in a wide variety of disciplines. In addition, the FTC evaluates the support for claims in light of all available evidence, including contrary evidence. In the health area, well-controlled, human clinical studies are generally considered the most reliable form of substantiation, although other forms of research may be acceptable substitutes in specific situations. It is important to note that, under the FTC Act, anecdotal evidence is not considered adequate substantiation and should not be used as a substitute for scientific support. These principles and their application in the health care area are explained in great detail in "Dietary Supplements: an Advertising

Guide for Industry," which is available on our web site at <www.ftc.gov/bcp/conline/pubs/buspubs/dietsupp.htm>, and which I have provided to this Commission.

I want to stress that our focus is on the advertising claims used to promote health care services and products. The FTC has traditionally refrained from actions involving communications between providers and their patients about treatment decisions and, as a matter of enforcement policy, has not addressed how health care professionals use or prescribe drugs, devices, or services in treating patients. Such quality of care issues are properly addressed under state law.

Here are a few examples of how the FTC has applied advertising law in the CAM field. One particular area of concern has been the rapid proliferation of claims for CAM products on the Internet. Consumers are increasingly using the Internet to obtain health information – 52 million U.S. Consumers have sought health and medical information online according to one recent estimate.[3] While use of the Internet to obtain health information appears to be expanding, 86% of

[3] *The online health care revolution: How the Web helps Americans take better care of themselves*; The Pew Internet & American Life Project; November 26, 2000.

users report that they are concerned about the reliability of information they obtain online.[4] An FTC health claims surf day in the fall of 1998, during which 80 organizations from 25 countries searched the Internet for treatment/cures for cancer, arthritis, heart disease, AIDS, diabetes, and multiple sclerosis, found an epidemic of health fraud on the Internet -- in one afternoon of surfing, searchers found 400 sites making apparently unfounded claims.

The Commission has an active law enforcement program to address these Internet promotions of treatments and cures for serious diseases, as part of its ongoing project "Operation Cure.All." For example, in two cases involving Internet sites marketing therapeutic magnet devices, the FTC challenged claims that the devices could treat and alleviate numerous medical problems and diseases, including cancer, liver disease, arthritis and high blood pressure. The consent orders prohibit unsubstantiated health claims and require the firms to notify their distributors of the settlement and to monitor distributors' ads. *Magnetic Therapeutic Technologies, Inc.* (C-3897) (Sept. 7, 1999) (consent) and *Pain Stops Here! Inc.,* (C-3898) (Sept. 7, 1999) (consent).

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[4] *Id.*

In another Internet case, the FTC challenged claims that Essiac Tea (a blend of four herbs: burdock root, sheep sorrel, rhubarb root and slippery elm bark), would cure cancer, diabetes, AIDS/HIV and feline leukemia. The consent order in that case prohibits unsubstantiated health claims and misrepresentation of the results of scientific studies. The company was also required to send notices to past purchasers advising them that Essiac Tea has not been demonstrated to be an effective remedy in fighting cancer or any other disease. *Michael D. Miller, d/b/a Natural Heritage Enterprises,* Dkt. No. C-3941 (April 5, 2000) (consent).

Finally, in *F.T.C. v. Lane Labs-USA, Inc.*, No. 00 CV 3171 WGB (D.N.J.) (June, 2000)(Stipulated Order), the FTC charged in federal district court that, among other things, defendants had falsely claimed that clinical studies proved that the shark cartilage supplement, Benefin, and its Skinanswer cream were effective in preventing, treating, and curing cancer and that the FDA had evaluated the effectiveness of Benefin. The stipulated injunction prohibits the firms from, among other things, making unsubstantiated health-related claims about any food, drug, or dietary supplement, and includes a million dollar judgment for consumer redress and disgorgement of profits, up to $450,000 of which defendants may use to supply product and placebo for a pending human clinical study of shark cartilage

capsules sponsored in part by the National Cancer Institute.

Our monitoring of the Internet reveals that there are still many instances where sick and vulnerable consumers are being misled about the efficacy and safety of alternative health care products and services. For this reason, the Commission has engaged in extensive consumer education activities.

Among the FTC's education efforts are the two brochures "Virtual Treatments" and "Fraudulent Health Claims" that are available in print and on our web site. These materials provide tips on spotting fraudulent promotions by identifying common red flags, including use of phrases like "scientific breakthrough" or "miracle cure" and claims that the product cures or treats a whole laundry lists of conditions. In addition, these pamphlets provide information and resources relating to specific diseases that are common subjects of health scams; and direct consumers to objective and reliable sources of health information, including several centers and databases of NIH and other government agencies. Finally, the FTC has also posted "Teaser" sites on the Web for products like "Arthriticure." These sites mimic commercial web sites, except that when a consumer attempts to purchase the product or service, instead of getting ordering

information, they are given tips on identifying and avoiding suspect claims. The goal of these sites is to catch consumers when they are at their most vulnerable, as they surf the web. One teaser site alone, claiming to have the cure for male impotence, has received more than 12,000 hits.

Our concerns about advertising in the complementary and alternative medicine area are not limited to the Internet. In *American College for Advancement in Medicine*, Dkt. No. C-3882 (1999), for example, the FTC challenged claims that: 1) chelation therapy is an effective treatment for atherosclerosis; and 2) every published study of chelation therapy for atherosclerosis described an improvement in blood flow and symptoms. Among other things, the order prohibits ACAM from representing that EDTA chelation therapy is an effective treatment for atherosclerosis without possessing and relying upon competent and reliable scientific evidence. The settlement addresses issues raised by claims ACAM made in brochures and other materials distributed to the public. It does not attempt to regulate how doctors use or prescribe drugs in the course of treating their patients or other choice of therapy issues.

And in *Cancer Treatment Centers of America*, 121 F.T.C. 692

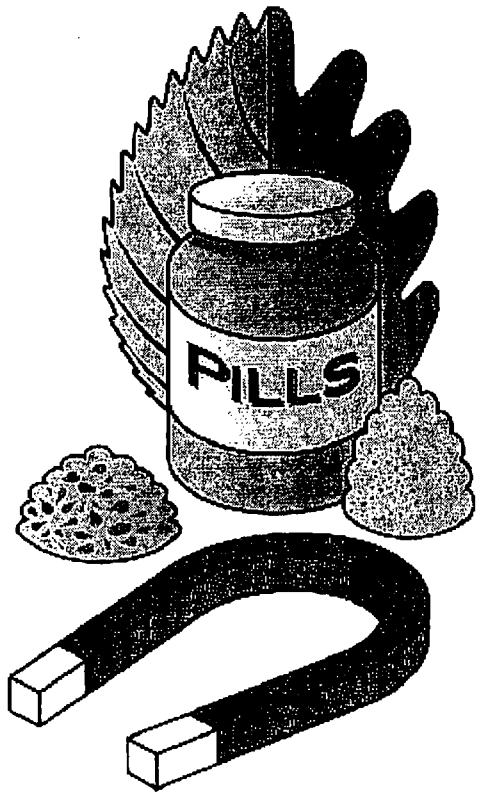
(1996)(consent), we challenged advertising claims by a hospital that: (1) "whole body hypothermia" was an independently-approved medical procedure that cured cancer previously untreatable by other treatment modalities; and (2) the clinic could improve the survivorship chances of many lung cancer patients through brachytherapy, a therapy only intended to alleviate symptomatic problems. The consent order in that case, among other things, requires the clinic to possess competent and reliable scientific evidence that substantiates any efficacy claim for any therapy that purports to treat or mitigate cancer or its attendant symptoms, and prohibits misrepresentations that any independent organization has approved any treatment regimen for cancer.

Despite all these efforts, however, deceptive promotions for complementary and alternative services and products are still widespread, and consumers do not have adequate means to make informed decisions about the plethora of services and products being promoted today, particularly on the Internet. The FTC shares one of the Commission's stated goals, to foster the dissemination of reliable information on complementary and alternative medicine to consumers. However, the FTC's law enforcement and consumer education efforts are clearly not enough to achieve this goal. Accordingly, we urge this Commission to explore ways to

provide consumers with independent and objective sources of reliable and up-to-date information about complementary and alternative services. Of course, the foundation for this effort is support for the research needed to give consumers the information they need. But better methods of dissemination of balanced information are needed also, and in this regard the Internet provides an incredible potential. For example, a system that would allow consumers to access third party reviews of an Internet web site is technologically possible. In our view, quality seal programs and portals such as healthfinder.gov also have a critical role to play in helping consumers find credible information. Continuing research, and improvements in the dissemination of reliable health information, will benefit both consumers and responsible complementary and alternative medicine providers. Thank you.

3rd Party Review of website Content

Alternative Medicines



"My brother has been diagnosed with cancer. He wants to find out about alternative medicine as a possible treatment. He has seen ads for a clinic that claims to have an amazing success rate using unconventional approaches to cure many forms of cancer and other serious ailments. Should he believe them?"

Many unconventional treatments for cancer and other diseases are on the market. A few have undergone rigorous scientific testing for their curative value. Many that have been tested don't show effectiveness. Still, some forms of alternative therapy are recognized as helpful in caring for patients and helping them cope with some illnesses.

Usually, a primary care physician is the best source of information about alternative medicine as a supplement to conventional treatments. If someone tries to sell you an alternative treatment by promising that it is effective, ask for a copy of the studies that prove it. Then ask your primary care physician or family doctor to review the studies to determine their credibility.

If you think you've been misled by advertisements for either alternative medicine or conventional treatments, be cautious and complain.

WHO CARES:

YOUR STATE ATTORNEY GENERAL
www.naag.org

FEDERAL TRADE COMMISSION
Consumer Response Center
Toll-free 1-877-FTC-HELP (382-4357)
www.ftc.gov

FOOD AND DRUG ADMINISTRATION
Toll-free 1-888-463-6332
www.fda.gov

NATIONAL CANCER INSTITUTE
Cancer Information Service

Toll-free 1-800-422-6237
www.nci.nih.gov

AMERICAN CANCER SOCIETY
Toll-free 1-800-227-2345
www.cancer.org

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DIETARY SUPPLEMENTS: AN ADVERTISING GUIDE FOR INDUSTRY

TABLE OF CONTENTS

I. INTRODUCTION

The dietary supplement industry is a dynamic one. Scientific research on the associations between supplements and health is accumulating rapidly. The number of products — and the variety of uses for which they are promoted — have increased significantly in the last few years. The role of the Federal Trade Commission, which enforces laws outlawing "unfair or deceptive acts or practices," is to ensure that consumers get accurate information about dietary supplements so that they can make informed decisions about these products.[1]

The Federal Trade Commission (FTC) and the Food and Drug Administration (FDA) work together under a long-standing liaison agreement governing the division of responsibilities between the two agencies. As applied to dietary supplements, the FDA has primary

responsibility for claims on product labeling, including packaging, inserts, and other promotional materials distributed at the point of sale. The FTC has primary responsibility for claims in advertising, including print and broadcast ads, infomercials, catalogs, and similar direct marketing materials. Marketing on the Internet is subject to regulation in the same fashion as promotions through any other media. Because of their shared jurisdiction, the two agencies work closely to ensure that their enforcement efforts are consistent to the fullest extent feasible.

In 1994, the Dietary Supplements Health and Education Act (DSHEA) significantly changed the FDA's role in regulating supplement labeling.[2] Although DSHEA does not directly apply to advertising, it has generated many questions about the FTC's approach to dietary supplement advertising. The answer to these questions is that advertising for any product — including dietary supplements — must be truthful, not misleading, and substantiated. Given the dramatic increase in the volume and variety of dietary supplement advertising in recent years, FTC staff is issuing this guide to clarify how long-standing FTC policies and enforcement practices relate to dietary supplement advertising.

The FTC's approach to supplement advertising is best illustrated by its Enforcement Policy Statement on Food Advertising (Food Policy Statement).[3] Although the Food Policy Statement does not specifically refer to supplements, the principles underlying the FTC's regulation of health claims in food advertising are relevant to the agency's approach to health claims in supplement advertising. In general, the FTC gives great deference to an FDA determination of whether there is adequate support for a health claim. Furthermore, the FTC and the FDA will generally arrive at the same conclusion when evaluating unqualified health claims. As the Food Policy Statement notes, however, there may be certain limited instances when a carefully qualified health claim in advertising may be permissible under FTC law, in circumstances where it has not been authorized for labeling. However, supplement marketers are cautioned that the FTC will require both strong scientific support and careful presentation for such claims.[4]

Supplement marketers should ensure that anyone involved in promoting products is familiar with basic FTC advertising principles. The FTC has taken action not just against supplement manufacturers, but also, in appropriate circumstances, against ad agencies, distributors, retailers, catalog companies, infomercial producers and others involved in deceptive promotions. *Therefore, all parties who participate directly or indirectly in the marketing of dietary supplements have an obligation to make sure that claims are presented truthfully and to check the adequacy of the support behind those claims.*

II. APPLICATION OF FTC LAW TO DIETARY SUPPLEMENT ADVERTISING

The FTC's truth-in-advertising law can be boiled down to two common-sense propositions: 1) advertising must be truthful and not misleading; and 2) before disseminating an ad, advertisers must have adequate substantiation for all objective product claims.[5] A deceptive ad is one that contains a misrepresentation or omission that is likely to mislead consumers acting reasonably under the circumstances to their detriment. The FTC's substantiation standard is a flexible one that depends on many factors. When evaluating claims about the efficacy and safety of foods, dietary supplements and drugs, the FTC has typically applied a substantiation standard of competent and reliable scientific evidence.

To determine whether an ad complies with FTC law, it is first necessary to identify all express and implied claims that the ad conveys to consumers. Once the claims are identified, the scientific evidence is assessed to determine whether there is adequate support for those claims. The following sections describe this two-step process with examples illustrating how principles of ad interpretation and substantiation apply in the context of dietary supplement advertising. The examples have been simplified to illustrate one or two specific points. Therefore, advertisers should use these examples as general guidance only.[6]

A. Identifying Claims and Interpreting Ad Meaning

1. Identifying Express and Implied Claims

The first step in evaluating the truthfulness and accuracy of advertising is to identify all express and implied claims an ad conveys to consumers. Advertisers must make sure that whatever they say expressly in an ad is accurate. Often, however, an ad conveys other claims beyond those expressly stated. Under FTC law, an advertiser is equally responsible for the accuracy of claims suggested or implied by the ad. Advertisers cannot suggest claims that they could not make directly.

When identifying claims, advertisers should not focus just on individual phrases or statements, but rather should consider the ad as a whole, assessing the "net impression" conveyed by all elements of the ad, including the text, product name, and depictions. When an ad lends itself to more than one reasonable interpretation, the advertiser is responsible for substantiating each interpretation. Copy tests, or other evidence of how consumers actually interpret an ad, can be valuable. In many cases, however, the implications of the ad are clear enough to determine the existence of the claim by examining the ad alone, without extrinsic evidence.

> ***Example 1:*** An advertisement claims that "university studies prove" that a mineral supplement can improve athletic performance. The advertiser has expressly stated the level of support for the claimed benefit and is therefore responsible for having "university studies" that document the advertised benefit. Furthermore, the implied reference to scientific evidence likely conveys to consumers the implied claim that the studies are methodologically sound.

> ***Example 2:*** An advertisement for a vitamin supplement claims that 90% of cardiologists regularly take the product. In addition to the literal claim about the percentage of cardiologists who use the product, the ad likely conveys an implied claim that the product offers some benefit for the heart. Therefore, the advertiser must have adequate support for both representations.

Depending on how it is phrased, or the context in which it is presented, a statement about a product's effect on a normal "structure or function" of the body may also convey to consumers an implied claim that the product is beneficial for the treatment of a disease. If elements of the ad imply that the product also provides a disease benefit, the advertiser must be able to substantiate the implied disease claim even if the ad contains no express reference to disease.

Example 3: An ad for an herbal supplement makes the claim that the product boosts the immune system to help maintain a healthy nose and throat during the winter season. The ad features the product name "Cold Away" and includes images of people sneezing and coughing. The various elements of the ad — the product name, the depictions of cold sufferers, and the reference to nose and throat health during the winter season — likely convey to consumers that the product helps prevent colds. Therefore, the advertiser must be able to substantiate that claim. Even without the product name and images, the reference to nose and throat health during the winter season may still convey a cold prevention claim.

Example 4: An ad for a dietary supplement called "Arthricure" claims that the product maintains joint health and mobility into old age. The "before" picture shows an elderly women using a walker. The "after" picture shows her dancing with her husband. The images and product name likely convey implied claims that the product is effective in the treatment of the symptoms of arthritis, and may also imply that the product can cure or mitigate the disease. The advertiser must be able to substantiate these implied claims.

2. When to Disclose Qualifying Information

An advertisement can also be deceptive because of what it fails to say. Section 15 of the FTC Act requires advertisers to disclose information if it is material in light of representations made or suggested by the ad, or material considering how consumers would customarily use the product. Thus, if an ad would be misleading without certain qualifying information, that information must be disclosed. For example, advertisers should disclose information relevant to the limited applicability of an advertised benefit. Similarly, advertising that makes either an express or implied safety representation should include information about any significant safety risks. Even in the absence of affirmative safety representations, advertisers may need to inform consumers of significant safety concerns relating to the use of their product.

Example 5: An advertisement for a multi-vitamin/mineral supplement claims that the product can eliminate a specific mineral deficiency that results in feelings of fatigue. In fact, less than 2% of the general population to which the ad is targeted suffers from this deficiency. The advertiser should disclose this fact so that consumers will understand that only the small percentage of people who suffer from the actual mineral deficiency are likely to experience any reduction in fatigue from using the product.

Example 6: An advertiser for a weight loss supplement cites a placebo-controlled, double-blind clinical study as demonstrating that the product resulted in an average weight loss of fifteen pounds over an eight-week period. The weight loss for the test group is, in fact, significantly greater than for the control subjects. However, both the control and test subjects engaged in regular exercise and followed a restricted-calorie diet as part of the study regimen. The advertisement should make clear that users of the supplement must follow the same diet and exercise regimen to achieve the claimed weight loss results.

Example 7: An advertiser claims that its herbal product is a natural pain reliever "without the side effects of over-the-counter pain relievers." However, there is substantial evidence that the product can cause nausea in some consumers when taken regularly. Because of the reference to the side effects of other pain relievers, consumers would likely understand this ad to mean that the herbal product posed no significant adverse effects. Therefore, the advertiser should disclose information about the adverse effects of the herbal product.

Example 8: An herbal weight loss product contains an ingredient which, when consumed daily over an extended period, can result in a significant increase in blood pressure. Even in the absence of any representation about the product's safety, the advertiser should disclose this potentially serious risk.

3. Clear and Prominent Disclosure

When the disclosure of qualifying information is necessary to prevent an ad from being deceptive, that information should be presented clearly and prominently so that it is actually noticed and understood by consumers. A fine-print disclosure at the bottom of a print ad, a disclaimer buried in a body of text, a brief video superscript in a television ad, or a disclaimer that is easily missed on an Internet web site, are not likely to be adequate. To ensure that disclosures are effective, marketers should use clear language, avoid small type, place any qualifying information close to the claim being qualified, and avoid making inconsistent statements or distracting elements that could undercut or contradict the disclosure. Because consumers are likely to be confused by ads that include inconsistent or contradictory information, disclosures need to be both direct and unambiguous to be effective.

Example 9: A marketer promotes a supplement as a weight loss aid. There is adequate substantiation to indicate that the product can contribute to weight loss when used in conjunction with a diet and exercise regimen. The banner headline claims "LOSE 5 POUNDS IN 10 DAYS," the ad copy discusses how easy it is to lose weight by simply taking the product 3 times a day, and the ad includes dramatic before-and-after pictures. A fine print disclosure at the bottom of the ad, "Restricted calorie diet and regular exercise required," would not be sufficiently prominent to qualify the banner headline and the overall impression that the product alone will cause weight loss. The ad should be revised to remove any implication that the weight loss can be achieved by use of the product alone. This revision, combined with a prominent indication of the need for diet and exercise, may be sufficient to qualify the claim. However, if the research does not show that the product contributes anything to the weight loss effect caused by diet and exercise, it would be deceptive, even with a disclosure, to promote the product for weight loss.

Qualifying information should be sufficiently simple and clear that consumers not only notice it, but also understand its significance. This can be a particular challenge when explaining complicated scientific concepts to a general audience, for example, if an advertiser wants to promote the effect of a supplement where there is an emerging body of science supporting that effect, but the evidence is insufficient to substantiate an unqualified claim. The advertiser should make sure consumers understand both the extent of scientific

support and the existence of any significant contrary evidence. Vague qualifying terms — for example, that the product "may" have the claimed benefit or "helps" achieve the claimed benefit -– are unlikely to be adequate. Furthermore, advertisers should not make qualified claims where the studies they rely on are contrary to a stronger body of evidence. In such instance, even a qualified claim could mislead consumers.

> ***Example 10:*** A company has results from two studies suggesting that the main ingredient in its supplement helps to maintain healthy cholesterol levels. There are, however, significant limitations to each of the studies and a better controlled study is necessary to confirm whether the effect is genuine. The company makes a claim in advertising that "scientific studies show that our product may be effective in reducing cholesterol." The use of the word "may" is not likely to be a sufficient disclaimer to convey the limitations of the science. A disclosure that clearly describes the limitations of the research, in language consumers can easily understand, and states directly and unambiguously that additional research is necessary to confirm the preliminary results is more likely to be effective. As discussed in the following section on substantiating claims, the extent to which studies support an unqualified claim will depend largely on what experts in the relevant field would consider to be adequate support.

B. Substantiating Claims

In addition to conveying product claims clearly and accurately, marketers need to verify that there is adequate support for their claims. Under FTC law, before disseminating an ad, advertisers must have a reasonable basis for all express and implied product claims. What constitutes a reasonable basis depends greatly on what claims are being made, how they are presented in the context of the entire ad, and how they are qualified. The FTC's standard for evaluating substantiation is sufficiently flexible to ensure that consumers have access to information about emerging areas of science. At the same time, it is sufficiently rigorous to ensure that consumers can have confidence in the accuracy of information presented in advertising. A number of factors determine the appropriate amount and type of substantiation, including:

- **The Type of Product.** Generally, products related to consumer health or safety require a relatively high level of substantiation.

- **The Type of Claim.** Claims that are difficult for consumers to assess on their own are held to a more exacting standard. Examples include health claims that may be subject to a placebo effect or technical claims that consumers cannot readily verify for themselves.

- **The Benefits of a Truthful Claim,** and

- **The Cost/Feasibility of Developing Substantiation for the Claim.** These factors are often weighed together to ensure that valuable product information is not withheld from consumers because the cost of developing substantiation is prohibitive. This does not mean, however, that an advertiser can make any claim it wishes without substantiation, simply because the cost of research is too high.

- **The Consequences of a False Claim.** This includes physical injury, for example, if a consumer relies on an unsubstantiated claim about the therapeutic benefit of a product and foregoes a proven treatment. Economic injury is also considered.

- **The Amount of Substantiation that Experts in the Field Believe is Reasonable.** In making this determination, the FTC gives great weight to accepted norms in the relevant fields of research and consults with experts from a wide variety of disciplines, including those with experience in botanicals and traditional medicines. Where there is an existing standard for substantiation developed by a government agency or other authoritative body, the FTC accords great deference to that standard.

The FTC typically requires claims about the efficacy or safety of dietary supplements to be supported with "competent and reliable scientific evidence," defined in FTC cases as "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results." This is the same standard the FTC applies to any industry making health-related claims. There is no fixed formula for the number or type of studies required or for more specific parameters like sample size and study duration. There are, however, a number of considerations to guide an advertiser in assessing the adequacy of the scientific support for a specific advertising claim.

1. Ads that Refer to a Specific Level of Support

If an advertiser asserts that it has a certain level of support for an advertised claim, it must be able to demonstrate that the assertion is accurate. Therefore, as a starting point, advertisers must have the level of support that they claim, expressly or by implication, to have.

> ***Example 11:*** An ad for a supplement includes the statement "Scientists Now Agree!" in discussing the product's benefit. This statement likely conveys to consumers that the state of science supporting the benefit has reached the level of scientific consensus. Unless the advertiser possesses this level of evidence, the claim is not substantiated.
>
> ***Example 12:*** An advertiser claims that its product has been "studied for years abroad" and is now the "subject of U.S. government-sponsored research." In addition to the explicit claim that the product has been studied, such phrases likely convey to consumers an implied claim that there exists a substantial body of competently-conducted scientific research supporting the efficacy of the product. The advertiser would be responsible for substantiating both claims.

2. The Amount and Type of Evidence

When no specific claim about the level of support is made, the evidence needed depends on the nature of the claim. A guiding principle for determining the amount and type of evidence that will be sufficient is what experts in the relevant area of study would generally consider to be adequate. The FTC will consider all forms of competent and reliable scientific research when evaluating substantiation. As a general rule, well-controlled human

clinical studies are the most reliable form of evidence. Results obtained in animal and *in vitro* studies will also be examined, particularly where they are widely considered to be acceptable substitutes for human research or where human research is infeasible. Although there is no requirement that a dietary supplement claim be supported by any specific number of studies, the replication of research results in an independently-conducted study adds to the weight of the evidence. In most situations, the quality of studies will be more important than quantity. When a clinical trial is not possible (e.g., in the case of a relationship between a nutrient and a condition that may take decades to develop), epidemiologic evidence may be an acceptable substitute for clinical data, especially when supported by other evidence, such as research explaining the biological mechanism underlying the claimed effect.

Anecdotal evidence about the individual experience of consumers is not sufficient to substantiate claims about the effects of a supplement. Even if those experiences are genuine, they may be attributable to a placebo effect or other factors unrelated to the supplement. Individual experiences are not a substitute for scientific research.[7]

Example 13: An advertiser relies on animal and in vitro studies to support a claim that its vitamin supplement is more easily absorbed into the bloodstream than other forms of the vitamin. However, the animal research uses a species of animal that, unlike humans, is able to synthesize the vitamin, and the in vitro study uses a different formulation with a higher concentration of the compound than the product being marketed. In addition, human research is feasible and relatively inexpensive to conduct in light of the potential sales of the product and is the type of research generally accepted in this particular field of study. The substantiation is likely to be inadequate in this case, both because there are significant methodological problems and because, in this particular instance, human research is both feasible and the accepted approach in the field.

Example 14: A company wants to advertise its supplement as helpful in maintaining good vision into old age. There have been two long-term, large-scale epidemiologic studies showing a strong association between life-long high consumption of the principal ingredient in the supplement and better vision in those over 70. Experts have also discovered a plausible biological mechanism that might explain the effect. A clinical intervention trial would be very difficult and costly to conduct. Assuming that experts in the field generally consider epidemiological evidence to be adequate to support the potential for a protective effect, and assuming the absence of any stronger body of contrary evidence, a claim that is qualified to accurately convey the nature and extent of the evidence would be permitted.

Example 15: An advertisement for a supplement claims that the product will cause dramatic improvements in memory and describes the experiences of 10 people who obtained these results. The descriptions of these anecdotal experiences are truthful, but the advertiser has no scientific substantiation for the effect of its product on memory and cannot explain why the product might produce such results. The individual experiences are not adequate to substantiate the claim without confirming scientific research.

3. The Quality of the Evidence

In addition to the amount and type of evidence, the FTC will also examine the internal validity of each piece of evidence. Where the claim is one that would require scientific support, the research should be conducted in a competent and reliable manner to yield meaningful results. The design, implementation, and results of each piece of research are important to assessing the adequacy of the substantiation.

There is no set protocol for how to conduct research that will be acceptable under the FTC substantiation doctrine. There are, however, some principles generally accepted in the scientific community to enhance the validity of test results. For example, a study that is carefully controlled, with blinding of subjects and researchers, is likely to yield more reliable results. A study of longer duration can provide better evidence that the claimed effect will persist and resolve potential safety questions. Other aspects of the research results — such as evidence of a dose-response relationship (*i.e.*, the larger the dose, the greater the effect) or a recognized biological or chemical mechanism to explain the effect — are examples of factors that add weight to the findings. Statistical significance of findings is also important. A study that fails to show a statistically significant difference between test and control group may indicate that the measured effects are merely the result of placebo effect or chance. The results should also translate into a meaningful benefit for consumers. Some results that are statistically significant may still be so small that they would mean only a trivial effect on consumer health.

The nature and quality of the written report of the research are also important. Research cannot be evaluated accurately on the basis of an abstract or an informal summary. In contrast, although the FTC does not require that studies be published and will consider unpublished, proprietary research, the publication of a peer-reviewed study in a reputable journal indicates that the research has received some measure of scrutiny. At the same time, advertisers should not rely simply on the fact that research is published as proof of the efficacy of a supplement. Research may yield results that are of sufficient interest to the scientific community to warrant publication, but publication does not necessarily mean that such research is conclusive evidence of a substance's effect. The FTC considers studies conducted in foreign countries as long as the design and implementation of the study are scientifically sound.[8]

> ***Example 16:*** An advertiser conducts a literature search and finds several abstracts summarizing research about the association between a nutrient and the ability to perform better on memory tests. The advertiser relies on these summaries to support a claim that its supplement, which contains the same nutrient, aids memory. However, without looking carefully at the specifics of the study design, implementation, and results, there is no way for an advertiser to ascertain whether the research substantiates the product claims. (For example, did the research use a comparable formulation of the ingredient? Was the study adequately controlled? Did the study yield results that are statistically significant?) The advertiser should carefully review the underlying science, with the assistance of an expert if necessary, before drafting advertising claims.

> ***Example 17:*** An advertiser makes an unqualified claim about the anti-clotting effect of a supplement that contains a compound extracted from fruit. There are three studies supporting the effect and no contrary evidence. One study consists of subjects tested over a one-week period, with no control group. The second

study is well-controlled, of longer duration, but shows only a slight effect that is not statistically significant. The third study administers the compound through injection and shows a significant anti-clotting effect, but there is some question whether the compound would be absorbed into the bloodstream if administered orally. Because the studies all have significant limitations, it would be difficult to draft even a carefully qualified claim that would adequately convey to consumers the limited nature of the evidence. The advertiser should not base a claim on these studies.

Example 18: The marketer of an herbal supplement claims that its product promotes healthy vision and is approved in Germany for this purpose. The product has been used extensively in Europe for years and has obtained approval by the German governmental authorities, through their monograph process, for use to improve vision in healthy people. The company has two abstracts of German trials that were the basis of the German monograph, showing that the ingredient significantly improved the vision of healthy individuals in the test group over the placebo group. Animal trials done by the company suggest a plausible mechanism to explain the effect. Although approval of the supplement under the German monograph suggests that the supplement is effective, advertisers should still examine the underlying research to confirm that it is relevant to the advertiser's product (for example, that the dosage and formulation are comparable) and to evaluate whether the studies are scientifically sound. Advertisers should also examine any other research that exists, either supporting or contradicting the monograph, especially if it is not possible to identify and review the research on which the monograph is based.

4. The Totality of the Evidence

Studies cannot be evaluated in isolation. The surrounding context of the scientific evidence is just as important as the internal validity of individual studies. Advertisers should consider all relevant research relating to the claimed benefit of their supplement and should not focus only on research that supports the effect, while discounting research that does not. Ideally, the studies relied on by an advertiser would be largely consistent with the surrounding body of evidence. Wide variation in outcomes of studies and inconsistent or conflicting results will raise serious questions about the adequacy of an advertiser's substantiation. Where there are inconsistencies in the evidence, it is important to examine whether there is a plausible explanation for those inconsistencies. In some instances, for example, the differences in results are attributable to differences in dosage, the form of administration (e.g., oral or intravenous), the population tested, or other aspects of study methodology. Advertisers should assess how relevant each piece of research is to the specific claim they wish to make, and also consider the relative strengths and weaknesses of each. If a number of studies of different quality have been conducted on a specific topic, advertisers should look first to the results of the studies with more reliable methodologies.

The surrounding body of evidence will have a significant impact both on what type, amount and quality of evidence is required to substantiate a claim and on how that claim is presented — that is, how carefully the claim is qualified to reflect accurately the strength of the evidence. If a stronger body of surrounding evidence runs contrary to a claimed effect, even a qualified claim is likely to be deceptive.

Example 19: An advertiser wishes to make the claim that a supplement product will substantially reduce body fat. The advertiser has two controlled, double-blind studies showing a modest but statistically significant loss of fat at the end of a six-week period. However, there is an equally well-controlled, blinded 12-week study showing no statistically significant difference between test and control groups. Assuming other aspects of methodology are similar, the studies taken together suggest that, if the product has any effect on body fat, it would be very small. Given the totality of the evidence on the subject, the claim is likely to be unsubstantiated.

Example 20: Advertisements for a fiber supplement make the claim that the product is "proven" to aid weight loss. Although the company has two published, peer-reviewed studies showing a relationship between fiber and weight loss, neither of these studies used the same proportions of soluble and insoluble fiber or the same total amount of fiber as the supplement product. There are numerous controlled, published human clinical studies, however, using the amount and type of fiber in the supplement product, that provide evidence that the product would not result in measurable weight loss. The totality of the evidence does not support the "proven" claim and, given the stronger body of contrary evidence, even a qualified claim is likely to be deceptive.

Example 21: An advertiser runs an ad in a magazine for retired people, claiming that its supplement product has been found effective in improving joint flexibility. The company sponsored a 6-week study of its supplement, involving 50 subjects over the age of 65, to test the product's effect on improving flexibility. The study was double-blinded and placebo-controlled and has been accepted for publication in a leading medical journal. The study showed dramatic, statistically significant increases in joint flexibility compared to placebo, based on objective measurements. In addition, several large trials have been conducted by European researchers using a similar formulation and dose of the active ingredient in the supplement. These trials also found statistically significant results. The advertiser reviewed the underlying European research and confirmed that it meets accepted research standards. The evidence as a whole likely substantiates the claim.

5. The Relevance of the Evidence to the Specific Claim

A common problem in substantiation of advertising claims is that an advertiser has valid studies, but the studies do not support the claim made in the ad. Advertisers should make sure that the research on which they rely is not just internally valid, but also relevant to the specific product being promoted and to the specific benefit being advertised. Therefore, advertisers should ask questions such as: How does the dosage and formulation of the advertised product compare to what was used in the study? Does the advertised product contain additional ingredients that might alter the effect of the ingredient in the study? Is the advertised product administered in the same manner as the ingredient used in the study? Does the study population reflect the characteristics and lifestyle of the population targeted by the ad? If there are significant discrepancies between the research conditions and the real life use being promoted, advertisers need to evaluate whether it is appropriate to extrapolate

from the research to the claimed effect.

In drafting ad copy, the advertiser should take care to make sure that the claims match the underlying support. Claims that do not match the science, no matter how sound that science is, are likely to be unsubstantiated. Advertising should not exaggerate the extent, nature, or permanence of the effects achieved in a study, and should not suggest greater scientific certainty than actually exists. Although emerging science can sometimes be the basis for a carefully qualified claim, advertisers must make consumers aware of any significant limitations or inconsistencies in the scientific literature.

Example 22: An ad for a supplement claims that a particular nutrient helps maintain healthy cholesterol levels. There is a substantial body of epidemiologic evidence suggesting that foods high in that nutrient are associated with lower cholesterol levels. There is no science, however, demonstrating a relationship between the specific nutrient and cholesterol, although it would be feasible to conduct such a study. If there is a basis for believing that the health effect may be attributable to other components of the food, or to a combination of various components, a claim about the cholesterol maintenance benefits of the supplement product is likely not substantiated by this evidence.

Example 23: A number of well-controlled clinical studies have been conducted to suggest that a mineral supplement can improve mental alertness and memory in subjects with significantly impaired blood circulation to the brain. A claim suggesting that the supplement will improve memory or mental alertness in healthy adults may not be adequately substantiated by this evidence. Advertisers should not rely on research based on a specific test population for claims targeted at the general population without first considering whether it is scientifically sound to make such extrapolations.

Example 24: An advertiser wants to make claims that its combination herbal product helps increase alertness and energy safely and naturally. The product contains two herbs known to have a central nervous system stimulant effect. The advertiser compiles competent and reliable scientific research demonstrating that each of the herbs, individually, is safe and causes no significant side effects in the recommended dose. This evidence may be inadequate to substantiate an unqualified safety claim. Where there is reason to suspect that the combination of multiple ingredients might result in interactions that would alter the effect or safety of the individual ingredients, studies showing the effect of the individual ingredients may be insufficient to substantiate the safety of the multiple ingredient product. In this example, the combination of two herbs with similar stimulant properties could produce a stronger cumulative stimulant effect that might present safety hazards. A better approach would be to investigate the safety of the specific combination of ingredients contained in the product.

Example 25: Several clinical trials have been done on a specific botanical extract showing consistently that the extract is effective for supporting the immune system. The studied extract is a complex combination of many constituents and the active constituents that may produce the benefit are still

unknown. An advertiser wishes to cite this research in its advertising, as proof that its product will support the immune system. The advertiser's product is made using a different extraction method of the same botanical. An analysis of the extract reveals that it has a significantly different chemical profile from the studied extract. The advertiser should not rely on these clinical trials alone as substantiation because the difference in extracts may result in significant differences in the two products' efficacy.

C. Other Issues Relating to Dietary Supplement Advertising

In addition to the basic principles of ad meaning and substantiation discussed above, a number of other issues commonly arise in the context of dietary supplement advertising. The following sections provide guidance on some of these issues including: the use of consumer or expert endorsements in ads; advertising claims based on traditional uses of supplements; use of the DSHEA disclaimer in advertising; and the application to advertising of the DSHEA exemption for certain categories of publications, commonly referred to as "third party literature."

1. Claims Based on Consumer Experiences or Expert Endorsements

An overall principle is that advertisers should not make claims either through consumer or expert endorsements that would be deceptive or could not be substantiated if made directly.[9] It is not enough that a testimonial represents the honest opinion of the endorser. Under FTC law, advertisers must also have appropriate scientific evidence to back up the underlying claim.

Consumer testimonials raise additional concerns about which advertisers need to be aware. Ads that include consumer testimonials about the efficacy or safety of a supplement product should be backed by adequate substantiation that the testimonial experience is representative of what consumers will generally achieve when using the product. As discussed earlier, anecdotal evidence of a product's effect, based solely on the experiences of individual consumers, is generally insufficient to substantiate a claim. Further, if the advertiser's substantiation does not demonstrate that the results are representative, then a clear and conspicuous disclaimer is necessary. The advertiser should either state what the generally expected results would be or indicate that the consumer should not expect to experience the attested results. Vague disclaimers like "results may vary" are likely to be insufficient.

> ***Example 26:*** An advertisement for a weight loss supplement features a before-and-after photograph of a woman and quotes her as saying that she lost 20 pounds in 8 weeks while using the supplement. An asterisk next to the quotation references a disclaimer in fine print at the bottom of the ad that reads, "Results may vary." The experience of the woman is accurately represented, but the separate, competent research demonstrating the efficacy of the supplement showed an average weight loss of only 6 pounds in 8 weeks. Therefore, the disclosure does not adequately convey to consumers that they would likely see much less dramatic results. The placement and size of the disclaimer is also insufficiently prominent to qualify the claim effectively. One approach to adequate qualification of this testimonial would be to include a disclaimer

immediately adjacent to the quote, in equal print size that says, "These results are not typical. Average weight loss achieved in clinical study was 6 pounds."

When an advertiser uses an expert endorser, it should make sure that the endorser has appropriate qualifications to be represented as an expert and has conducted an examination or testing of the product that would be generally recognized in the field as sufficient to support the endorsement. In addition, whenever an expert or consumer endorser is used, the advertiser should disclose any material connection between the endorser and the advertiser of the product. A material connection is one that would affect the weight or credibility of the endorsement, or put another way, a personal, financial, or similar connection that consumers would not reasonably expect.

Example 27: An infomercial for a dietary supplement features an expert referred to as a "Doctor" and a "leading clinician in joint health" discussing the effect of a supplement product on the maintenance of healthy joints. The expert is not licensed to practice medicine, but has a graduate degree and is a trained physical therapist, running a sports clinic. The expert has not conducted any review of the scientific literature on the active component of the supplement. In return for appearing in the infomercial, she is given a paid position as an officer the company. The ad is likely to be deceptive for several reasons. First, her qualifications as an expert have been overstated and she has not conducted sufficient examination of the product to support the endorsement. In addition, her connection to the company is one that consumers might not expect and may affect the weight and credibility of her endorsement. Even if she is adequately qualified and has conducted an adequate review of the product, her position as an officer of the company should be clearly disclosed.

Example 28: A best-selling book about the benefits of a supplement product includes a footnote mentioning the most effective brand of the supplement, by name. The manufacturer of the brand cited in the book has an exclusive promotional agreement with the author and has paid him to reference the product by name. The manufacturer's ad touts the fact that its product is the only brand recommended in this best-selling book. The ad is deceptive since it suggests a neutral endorsement when, in fact, the author has been paid by the manufacturer to promote the product.

2. Claims Based on Traditional Uses

Claims based on historical or traditional use should be substantiated by confirming scientific evidence, or should be presented in such a way that consumers understand that the sole basis for the claim is a history of use of the product for a particular purpose. A number of supplements, particularly botanical products, have a long history of use as traditional medicines in the United States or in other countries to treat certain conditions or symptoms. Several European countries have a separate regulatory approach to these traditional medicines, allowing manufacturers to make certain limited claims about their traditional use for treating certain health conditions. Some countries also require accompanying disclosures about the fact that the product has not been scientifically established to be effective, as well as disclosures about potential adverse effects. At this time there is no separate regulatory process for approval of claims for these traditional medicine products under DSHEA and FDA labeling rules.

In assessing claims based on traditional use, the FTC will look closely at consumer perceptions and specifically at whether consumers expect such claims to be backed by supporting scientific evidence. Advertising claims based solely on traditional use should be presented carefully to avoid the implication that the product has been scientifically evaluated for efficacy. The degree of qualification necessary to communicate the absence of scientific substantiation for a traditional use claim will depend in large part on consumer understanding of this category of products. As consumer awareness of and experience with "traditional use" supplements evolve, the extent and type of qualification necessary is also likely to change.

There are some situations, however, where traditional use evidence alone will be inadequate to substantiate a claim, even if that claim is carefully qualified to convey the limited nature of the support. In determining the level of substantiation necessary to substantiate a claim, the FTC assesses, among other things, the consequences of a false claim. Claims that, if unfounded, could present a substantial risk of injury to consumer health or safety will be held to a higher level of scientific proof. For that reason, an advertiser should not suggest, either directly or indirectly, that a supplement product will provide a disease benefit unless there is competent and reliable scientific evidence to substantiate that benefit. The FTC will closely scrutinize the scientific support for such claims, particularly where the claim could lead consumers to forego other treatments that have been validated by scientific evidence, or to self-medicate for potentially serious conditions without medical supervision.

The advertiser should also make sure that it can document the extent and manner of historical use and be careful not to overstate such use. As part of this inquiry, the advertiser should make sure that the product it is marketing is consistent with the product as traditionally administered. If there are significant differences between the traditional use product and the marketed product, in the form of administration, the formulation of ingredients, or the dose, a "traditional use" claim may not be appropriate.

> ***Example 29:*** The advertiser of an herbal supplement makes the claim, "Ancient folklore remedy used for centuries by Native Americans to aid digestion." The statement about traditional use is accurate and the supplement product is consistent with the formulation of the product as traditionally used. However, if, in the context of the ad, this statement suggests that there is scientific evidence demonstrating that the product is effective for aiding digestion, the advertiser would need to include a clear and prominent disclaimer about the absence of such evidence.
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> ***Example 30:*** A supplement manufacturer wants to market an herbal product that has been used in the same formulation in China as a tonic for improving mental functions. The manufacturer prepares the product in a manner consistent with Chinese preparation methods. The ad claims, "Traditional Chinese Medicine — Used for Thousands of Years to Bring Mental Clarity and Improve Memory." The ad also contains language that clearly conveys that the efficacy of the product has not been confirmed by research, and that traditional use does not establish that the product will achieve the claimed results. The ad is likely to adequately convey the limited nature of support for the claim.
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> ***Example 31:*** A supplement manufacturer markets a capsule containing a

concentrated extract of a botanical product that has been used in its raw form in China to brew teas for increasing energy. The advertisement clearly conveys that the energy benefit is based on traditional use and has not been confirmed by scientific research. The ad may still be deceptive, however, because the concentrated extract is not consistent with the traditional use of the botanical in raw form to brew teas and may produce a significantly different effect.

Example 32: A supplement ad claims that a supplement liquid mineral solution has been a popular American folk remedy since early pioneer days for shrinking tumors. The ad is likely to convey to consumers that the product is an effective treatment for cancer. There is no scientific support for this disease benefit. Because of the potential risks to consumers of taking a product that may or may not be effective to treat such a serious health condition, possibly without medical supervision, the advertiser should not make the claim.

3. Use of the DSHEA Disclaimer in Advertising

Under DSHEA, all statements of nutritional support for dietary supplements must be accompanied by a two-part disclaimer on the product label: that the statement has not been evaluated by FDA and that the product is not intended to "diagnose, treat, cure or prevent any disease." Although DSHEA does not apply to advertising, there are situations where such a disclosure is desirable in advertising as well as in labeling to prevent consumers from being misled about the nature of the product and the extent to which its efficacy and safety have been reviewed by regulatory authorities. For example, a disclosure may be necessary if the text or images in the ad lead consumers to believe that the product has undergone the kind of review for safety and efficacy that the FDA conducts on new drugs and has been found to be beneficial for the treatment of disease. Failure to correct those misperceptions may render the advertising deceptive.

At the same time, the inclusion of a DSHEA disclaimer or similar disclosure will not cure an otherwise deceptive ad, particularly where the deception concerns claims about the disease benefits of a product. In making references to DSHEA and FDA review, advertisers should also be careful not to mischaracterize the extent to which a product or claim has been reviewed or approved by the FDA. Compliance with the notification and disclaimer provisions of DSHEA does not constitute authorization of a claim by FDA and advertisers should not imply that FDA has specifically approved any claim on that basis.

Example 33: A company markets a supplement for "maintaining joint flexibility." The product packaging is similar in color and design to a nonprescription drug used to treat joint pain associated with arthritis and the product name is similar to the drug counterpart. The ad includes statements urging consumers to "ask their pharmacist" and "accept no generic substitute." The various elements of the ad may lead consumers to believe that the supplement is, in fact, an approved drug, or may give consumers more general expectations that the product has been subjected to similar government review for safety and efficacy. A clear and prominent disclaimer may be necessary to indicate that the product has not been evaluated by FDA and is not an approved drug product.

Example 34: An advertisement for an herbal supplement includes strong,

unqualified claims that the product will effectively treat or prevent diabetes, heart disease, and various circulatory ailments. The advertiser does not have adequate substantiation for this claim, but includes the DSHEA disclaimer prominently in the ad. In face of the strong contradictory message in the ad, the inclusion of the DSHEA disclaimer is not likely to negate the explicit disease claims made in the ad, and will not cure the fact that the claims are not substantiated.

Example 35: A dietary supplement advertisement makes a number of claims about the benefits of its product for supporting various body functions. The ad also includes the statement, "Complies with FDA notification procedures of the Dietary Supplement Health and Education Act." This statement may suggest to consumers that FDA has authorized the claims made in the ad or that it has reviewed the support for the claims and found the product to be effective. Because there is no review and authorization process for such claims under DSHEA, this would be deceptive.

4. Third Party Literature

Dietary supplement advertisers should be aware that the use of newspaper articles, abstracts of scientific studies, or other "third party literature" to promote a particular brand or product can have an impact on how consumers interpret an advertisement and on what claims the advertiser will be responsible for substantiating. For purposes of dietary supplement labeling, Section 5 of DSHEA provides an exemption from labeling requirements for scientific journal articles, books and other publications used in the sale of dietary supplements, provided these materials are reprinted in their entirety, are not false or misleading, do not promote a specific brand or manufacturer, are presented with other materials to create a balanced view of the scientific information, and are physically separate from the supplements being sold.

The FTC will generally follow an approach consistent with the labeling approach when evaluating the use of such publications in other contexts, such as advertising. Although the FTC does not regulate the content or accuracy of statements made in independently written and published books, articles, or other non-commercial literature, FTC law does prohibit the deceptive use of such materials in marketing products. The determination of whether the materials will be subject to FTC jurisdiction turns largely on whether the materials have been created or are being used by an advertiser specifically for the purpose of promoting its product. As a practical matter, publications and other materials that comply with the elements of the DSHEA provision, particularly with the requirement that such materials be truthful, not misleading and balanced, are also likely to comply with FTC advertising law.

Example 36: An author publishes a book on the curative properties of an herb. The book title is "The Miracle Cancer Cure." The book does not endorse or otherwise mention any particular supplement brand. The author/publisher does not sell the herbal supplement and does not have any material connection to any marketers of the herb. As non-commercial speech, the book itself would not be subject to the FTC's jurisdiction over advertising. However, if a marketer of the herb referred to the book in advertising materials (for instance, by quoting the title and using excerpts to describe the anti-cancer benefits of its product), such references would likely be considered advertising. The advertiser would be

responsible for substantiating any claims about the advertiser's product that are conveyed by these references.

III. CONCLUSION

Marketers of dietary supplements should be familiar with the requirements under both DSHEA and the FTC Act that labeling and advertising claims be truthful, not misleading and substantiated. The FTC approach generally requires that claims be backed by sound, scientific evidence, but also provides flexibility in the precise amount and type of support necessary. This flexibility allows advertisers to provide truthful information to consumers about the benefits of supplement products, and at the same time, preserves consumer confidence by curbing unsubstantiated, false, and misleading claims. To ensure compliance with FTC law, supplement advertisers should follow two important steps: 1) careful drafting of advertising claims with particular attention to how claims are qualified and what express and implied messages are actually conveyed to consumers; and 2) careful review of the support for a claim to make sure it is scientifically sound, adequate in the context of the surrounding body of evidence, and relevant to the specific product and claim advertised.

The FTC works for the consumer to prevent fraudulent, deceptive and unfair business practices in the marketplace and to provide information to help consumers spot, stop and avoid them. To file a complaint, or to get free information on any of 150 consumer topics, call toll-free, **1-877-FTC-HELP** (1-877-382-4357), or use the online complaint form. The FTC enters Internet, telemarketing, and other fraud-related complaints into **Consumer Sentinel**, a secure, online database available to hundreds of civil and criminal law enforcement agencies worldwide.

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1-877-FTC-HELP	www.ftc.gov

ENDNOTES

1. The FTC's authority derives from Section 5 of the FTC Act. In addition, supplements have traditionally been regulated under Sections 12 and 15, which prohibit false advertisements, defined as those that are "misleading in a material respect," for foods, drugs, devices or cosmetics.

2. Under DSHEA, supplement marketers are allowed to make two kinds of claims on labeling: 1) health claims specifically authorized by the FDA; and 2) statements of nutritional support. Health claims — representations about the relationship between a nutrient and a disease or health-related condition — are permitted only if they have been authorized by an FDA finding that there is "significant scientific agreement" to support the claim. The Food and Drug Administration Modernization Act of 1997 (FDAMA) also now allows health claims that are based on "authoritative statements" from certain federal scientific bodies, such as NIH and the National Academy of Sciences. Aside from these authorized claims, supplement marketers are prohibited from making any labeling claim about the diagnosis, mitigation, treatment or cure of a disease. In contrast to health claims, "structure/function" claims, within the broader category of "statements of nutritional support," refer to representations about a dietary supplement's effect on the structure or function of the body for maintenance of good health and nutrition. Structure/function claims are not subject to FDA pre-authorization. A marketer may make these claims in labeling if it

notifies FDA and includes a disclaimer that the claim has not been evaluated by FDA and that the product is not intended to diagnose, mitigate, treat, cure, or prevent disease. DSHEA also requires that structure/function claims in labeling be substantiated and be truthful and not misleading. This requirement is fully consistent with the FTC's standard that advertising claims be truthful, not misleading and substantiated.

3. FTC policy statements and other information for businesses and consumers are available on the FTC's Internet home page.

4. As indicated in the Food Policy Statement, the FTC will be "especially vigilant in examining whether qualified claims are presented in a manner that ensures that consumers understand both the extent of the support for the claim and the existence of any significant contrary view within the scientific community. In the absence of adequate qualification the Commission will find such claims deceptive."

5. These principles are articulated in theFTC's Deception Policy Statement and Advertising Substantiation Policy Statement. The FTC also has authority to challenge unfair trade practices. An unfair practice is one that causes or is likely to cause substantial injury to consumers which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or competition. The majority of advertising cases are brought pursuant to the FTC's deception authority.

6. Throughout these examples the terms "advertiser," "marketer," "supplement manufacturer" and "company" are used interchangeably.

7. Additional guidance on the use consumer testimonials is provided in Part C.1. below.

8. Any foreign research submitted to the FTC in the course of an investigation should be presented in English translation and with sufficient detail to allow the agency to evaluate the study.

9. The FTC has provided detailed guidance on this subject in its Guides Concerning Use of Endorsements and Testimonials in Advertising.

ftc consumer feature

Bureau of Consumer Protection | May 2000 | Federal Trade Commission

Contact: Paula Kurtzweil Walter, 202-326-2583

Promotions for Kids' Dietary Supplements Leave Sour Taste

Used to be that you couldn't expect a kid to stomach much more than a daily dose of cod liver oil or a multivitamin supplement. But lately, with the trend toward marketing herbs and other non-traditional dietary supplements for children's use, it's the Federal Trade Commission that's raising objections. The products are being advertised for maintaining kids' health as well as for treating their ailments.

"We're very concerned about how some of these products are being portrayed in advertisements," says Jodie Bernstein, director of the FTC's Bureau of Consumer Protection. "There are many worrisome unfounded claims. A lot of these products have not been proven to provide any benefit and in some cases, may even present safety risks."

The FTC has noted an increase in dietary supplement advertising that promotes products as preventives or cures for a variety of childhood ailments, ranging from colds and ear infections to serious conditions like asthma and chronic bronchitis. In the past two years, the Commission has taken action against several marketers of kids' supplements for making unsubstantiated advertising claims. The marketers touted their products as safe, effective treatments for colds in children and attention deficit/hyperactivity disorder (AD/HD), which affects as many as 2.5 million school-aged kids in the United States.

"Our concern with these claims is that parents fall for the products and ignore proven, perhaps essential, treatments for their child's disorder," Bernstein says.

Though the marketers charged in these cases agreed to stop making the fraudulent claims, there's no guarantee that similarly egregious claims about certain supplements for kids will not surface in the marketplace. Says Bernstein, "The bottom line for parents is to exercise caution in giving supplements to kids."

Supplements for Kids

Traditionally, the term dietary supplement referred to vitamins and minerals. But in the wake of a rapidly expanding market, it has come to mean herbs and other botanical products, enzymes, animal extracts and more.

The need for vitamins and minerals is well-established. These nutrients are necessary for life and are widely available in food. Sometimes, though, nutrients must be consumed as supplements to treat or prevent nutritional deficiencies. Other supplements, such as some herbs, may offer health benefits, too, but the science on that issue is still developing.

For most healthy children who eat a variety of foods, experts generally agree that dietary supplements beyond a daily multivitamin and mineral supplement are not necessary, let alone safe or effective. "I don't recommend dietary supplements for children under 12," says Varro Tyler, professor emeritus at Purdue University and a leading authority on herbal medicines. Many of the products being marketed for kids have not been adequately tested in children to determine their safety and value.

"We have no systematic scientific data," says Dennis Bier, a pediatrician and researcher at the Children's Nutrition Research Center in Houston. "Yes, some of these products may have been used for millions of years, but no one has ever systematically collected data on their use in children. We don't know if these products are safe."

Experts also advise against giving children dietary supplements because unlike medicines in this country, their manufacture is not currently held to any set of federal standards to ensure purity and quality.

"It's a crapshoot," says Susan Baker, a professor of pediatrics at the Medical University of South Carolina. "You have no idea what these products contain."

Professor Tyler believes that the risk of consuming substances not made according to any national standards is one that adults can weigh for themselves. "But," he says, "they shouldn't push that risk off on children."

Taking Aim at Disease Prevention Claims

Parents whose children suffer from chronic disorders may find it especially hard to resist dietary supplements promoted as effective treatments for their children's disease. Ads for these products promote them as safe, natural alternatives to prescription drugs, which some may view as having harsh side effects. But as the FTC has found, these claims often are unfounded.

"False claims exploit parents' fears about giving their children prescription drugs, " the FTC's Jodie Bernstein says. "But these alternative therapies may actually do the children more harm than good."

Often, the deceptive ads describe the supplement products as "natural," a term that consumers generally take to mean as "safe," especially when compared with prescription medicines. But according to Michelle Rusk, an attorney in the FTC's Division of Advertising Practices, natural is not necessarily safe. "Botanical products, like drugs, can have potent pharmacological effects," she says.

In the FTC's experience, many deceptive ads have focused on AD/HD, a disorder whose diagnosis and treatment arouse controversy among parents and health care providers alike.

Kids with AD/HD usually display inappropriate activity for their age, are easily distracted and act impulsively. They often cannot sit still or pay attention in class, and their behavior often can lead to academic and social problems. The recommended treatment combines medicine, usually a stimulant such as Ritalin, with behavior management and parent training. Studies have found this regimen to be safe and effective.

"AD/HD is a difficult, frustrating problem," pediatrician Bier says. "It interferes with a child's growth...and with family lives. Parents want to find something that will work. They're looking for a magic bullet."

The traditional treatment is viewed as time-consuming and inconvenient, and many parents, concerned about long-term effects, balk at giving their children stimulants.

In one of the cases brought by the FTC, the marketers were promoting dietary supplements as safe and effective treatments for AD/HD. Ads for the product, called God's Recipe, claimed it was a safe alternative to the prescription drug Ritalin. God's Recipe was widely advertised on the Internet.

Additional Concerns

The FTC also has objected to ads making unfounded safety claims. The Commission sought and received an injunction against the makers of so-called body-building supplements used by teenagers and athletes. The manufacturers, MET-Rx USA Inc. and AST Nutritional Concepts, were unable to substantiate their claims that the products could increase strength and muscle mass "safely and with minimal or no negative side effects." The products contain androgen and other steroid hormones known to have harmful effects, including unwanted changes to male and female sexual features.

"Children may take steroid hormone supplements to emulate popular athletes," the FTC's Rusk says. "But there's a potential for harm, especially considering that, as children, they're still growing and developing."

Some products that contain gamma butyrolactone (GBL) — like Renewtrient, Revivarant, Blue Nitro and Gamma G — are touted as performance enhancers. Taken orally, GBL is converted in the body to gamma hydroxybutyrate (GHB), an illegal drug that can cause unconsciousness, coma and even death.

Giving children dietary supplements raises still another concern: that products recommended for adults will be given to children. "Parents shouldn't assume that supplements work the same way in children as they do in adults," Rusk says. "What's safe for an adult may be risky for children."

Some dietary supplements are not deemed safe even for adults. According to the Food and Drug Administration, the following supplements are potentially dangerous: chaparral, comfrey, lobelia, germander, willow bark, ephedra (ma huang), L-tryptophan, germanium, magnolia-stephania preparations, dieter's teas, and excess amounts of some vitamins and minerals.

Because these substances are sold in products for kids, parents should always read the ingredient list on the labels of dietary supplements and avoid giving their children any that contain these potentially dangerous substances. But what about other dietary supplements? How can parents determine whether they are safe to give to their children?

Ask an expert - for example, a pediatrician or other health care practitioner who is knowledgeable about herbal medicine and the disorder or condition for which the product might be used.

"Parents need to be careful," says New York City dietitian Wahida Karmally. "There are so many kinds of supplement products on the shelf, and none of them may be necessary or safe for their child."

Pointers for Parents

Before you give your child a dietary supplement, be aware that:

- Many dietary supplements, especially herbal products, have not been tested in kids to determine their safety or effectiveness.
- Dietary supplements in this country are not held to any set of federal standards for quality or purity.
- Your best advisor is your child's pediatrician or another health care provider. Be sure to check with them before starting your child on a supplement. And keep them informed of your child's continuing use of the product.
- Supplements advertised as "natural" are not necessarily safe. In fact, herbs, like other so-called natural products, can have powerful drug-like effects. Some of these effects can be especially risky for people who take other medicines or have certain medical conditions.
- Fraudulent promoters often fall back on the same claims to trick consumers into buying their products. Tip-offs that they're trying to fool you are:
  - Claims that the product is a "scientific breakthrough," "miraculous cure," "exclusive product," "secret ingredient," or "ancient remedy." Says Jodie Bernstein, director of the FTC's Bureau of Consumer Protection: "Ask yourself, 'If a product is so amazing, why would I be reading about it for the first time in an ad?'"
  - Claims that the product is a quick and effective cure for a wide range of ailments.
  - Claims that use medical terms that sound impressive. This ploy is an attempt to cover up a lack of good science.
  - Claims that the government, medical profession and health care industry are in a conspiracy to suppress the advertised product.
  - Undocumented case histories of people who've had supposedly amazing results.
  - Claims that the product is available from only one source, and payment is required in advance.
  - Claims of a "money-back guarantee."

FTC Staff Comment on Draft Report of the Commission on Dietary Supplement Labels

Bureau of Consumer Protection

August 14, 1997

Kenneth D. Fisher, Ph.D.
Executive Director
Commission on Dietary Supplement Labels
Office of Disease Prevention and Health Promotion
Room 738G, Hubert H. Humphrey Building
200 Independence Ave., S.W.
Washington, D.C. 20201

RE: FTC Staff Comment on Draft Report of the Commission on Dietary Supplement Labels[1]

Dear Mr. Fisher:

Thank you for the opportunity to comment on the June 1997 draft Report of the Commission on Dietary Supplement Labels ("Report"). As you know, the Federal Trade Commission ("FTC") has responsibility, pursuant to Section 5 of the Federal Trade Commission Act ("FTC Act"), 5 U.S.C. § 45, for the regulation of claims made in advertising about dietary supplements.

The staff of the FTC has followed closely the work of the Commission. We appreciated the opportunity to participate in the September 1996 Commission meeting to discuss the FTC's approach to evaluating substantiation for advertising claims. As we indicated at the September meeting, we believe that consumers benefit from accurate, nonmisleading information about the potential benefits of dietary supplements. The recommendations outlined in the Report will help ensure that consumers are given balanced information about the benefits of supplements, that discussions of the evidence supporting those benefits and any limitations of the evidence are fairly presented, and that consumers are adequately protected from any potential safety risks. These goals are consistent with the FTC's approach to supplement advertising.

Staff would like to offer our comment on a few specific issues. For reference, staff has organized these comments to follow the subject categories of the Report.

Statements of Nutritional Support

Use of Specific Terms in Statements of Nutritional Support

The Report includes several recommendations relating to statements of nutritional support in dietary supplement labeling. First, the Report seeks to provide industry with clearer boundaries between permissible statements of nutritional support and unauthorized health or drug claims. Among other recommendations, the Report identifies

specific terms that may be used in labeling, such as "stimulate," "maintain," "support," "regulate," or "promote," as long as they do not suggest disease prevention or treatment. The Report also identifies terms that should not be used, such as "diagnose," "treat," "prevent," "cure," or "mitigate." Staff supports the goal of providing guidance to industry about how to frame permissible claims under DSHEA. As the Report suggests, however, terms used to describe healthy body structure and function may well suggest disease prevention or treatment, depending on context.[2]

Recognizing that many other elements of a product label or ad can influence how consumers interpret claims, our approach is to examine all express and implied messages conveyed by the entire context of the label or advertisement. Thus, additional consumer research may be needed before finalizing a list of approved or unapproved terms. Such consumer research could provide valuable insights about how consumers make distinctions, if any, between health claims, drug claims, and statements of nutritional support. In any event, we believe that it will be important to emphasize that the propriety of using any "approved" term will necessarily depend on the context in which it is used.

Content of Substantiation Files and Use of Consumer Summaries

The Report also provides detailed suggestions about what information should be included in the notification letters that must be filed with FDA, and in the company's own substantiation files for such claims. Among other things, the Report recommends that companies making statements of nutritional support include, both in their substantiation file and in their FDA notification letter, an interpretive summary, prepared by a qualified expert, of the evidence supporting the claim. The Report also recommends that companies prepare a consumer version of the summary to be included in the notification letter and to be made publicly available.

Staff supports the recommendation that appropriate experts prepare a summary of the scientific evidence substantiating a claim. In fact, the first step that FTC staff often takes in evaluating substantiation for a claim is to obtain an evaluation of the supporting evidence by an independent expert. Staff believes that such a summary requirement could assist companies in framing claims that accurately reflect the supporting evidence. It could also be a valuable starting point for both FDA and the FTC in assessing claims for dietary supplements.

Consumers should, as well, be given accurate and understandable information so that they can assess the benefits and safety of a particular supplement. Yet we share the concern noted in the Report that consumer summaries, if not objectively prepared and carefully qualified, could themselves be misleading or be misunderstood.[3][4]

In order to reasonably inform consumers about the implications of the scientific evidence, consumer summaries would need to fairly present the state of the evidence available to support the claim. Where the supporting evidence is consistent, clear and compelling, a summary would be unlikely to deceive. But where the evidence is mixed, conflicting or preliminary, summaries would need to be carefully crafted and qualified. Consumer research indicates that caveats about the limitations of supporting scientific evidence are often ineffective to prevent a significant number of consumers from taking an absolute message that science has proven the claimed effect.

It is also important to ensure that any consumer summary included in any FDA filing not be understood by consumers as government approved. For example, if a manufacturer claims that the scientific support for the benefits of its supplement are "on file with the United States Food and Drug Administration," consumers may expect that the FDA has reviewed and endorsed that summary. In the absence of some process for government review and approval of the consumer summary before it is made publicly available, staff would recommend inclusion of a clear and prominent disclaimer advising consumers that the summary was prepared by the manufacturer and that the FDA has not made any determination about its accuracy. To help ensure that these summaries are accurate and informative, staff believes that it may also be worthwhile to consider including in any implementing regulations guidelines on how to prepare such summaries, *e.g.*, that the consumer summary be prepared by an objective and independent party, that it be balanced and accurate, that it include a discussion of any conflicting evidence of which the company is or should be aware, and that the submitter certify that the information provided is accurate and complete.

In considering how to implement the Report's recommendations on substantiation statements and the consumer summaries of those statements, it may also be helpful to examine regulatory models of other agencies that require filing of detailed information summaries for possible guidance.[5]

Standard for Substantiating Statements of Nutritional Support

The Report also outlines some general principles on the evidence needed to substantiate statements of nutritional support. The principles correspond, in many ways, to the FTC's approach to substantiation of claims in advertising. For example, the Report indicates that the evidence needed to substantiate a statement of nutritional support will vary depending on a number of factors including the nature of the statement made; that it is appropriate to consider various types of evidence, including epidemiologic studies, human clinical studies, animal studies and *in vitro* studies; that all relevant evidence, including contrary evidence, must be considered; and that the weight of the evidence should substantiate the claim.[6] Staff supports the Report's proposed flexible approach to evaluating substantiation.

Therapeutic Claims for Botanical Products

The Report calls for a comprehensive evaluation of the regulatory systems of other countries for botanical products, including the current efforts to develop World Health Organization ("WHO") model monographs for botanicals. The Report recommends study of whether an alternative regulatory approach, perhaps modeled after one of these systems, could be implemented to permit certain therapeutic claims for botanical products, in cases where the scientific data would not support approval of the claim under the current standard for OTC drug review. As part of this study, the Report recommends examining what disclaimers might be effective in conveying the distinction between a claim approved under the OTC drug standard and a claim approved under an alternative process for botanicals.

Staff believes the proposal for review of other countries' regulatory approaches to

botanical products has merit. Given a growing body of literature suggesting the difficulty of fashioning meaningful disclosures, research may be needed testing disclaimers in the context of actual labeling and advertising to see if consumers understand the basis for the claimed effect. Disclaimers used in other countries are an important starting point, but may not be effective in the United States if consumers here have less familiarity with the therapeutic use of botanical products. Would U.S. consumers, for instance, understand that the disclaimer, "traditional medicine," used for botanical products in Canada, is an indication that the medicinal effects of the product have not been evaluated under the same criteria used for drug products?

The Commission on Dietary Supplement Labels and FDA should also consider how any disclaimer would be communicated. Our anecdotal observations about those instances where the DSHEA disclaimer has been included in advertising suggest that it is often presented in a format that may have little, if any, communicative value. For example, the DSHEA disclaimer has often appeared in fine print at the bottom of the ad where it is unlikely to be noticed by most consumers.

Finally, it is staff's understanding that some botanical products can have powerful pharmacological effects, which may raise safety concerns. Consumers may make incorrect assumptions that these products are inherently safe or safer than synthetic drug products because they are "natural." Staff believes that it may be appropriate in certain circumstances to require warnings about significant safety risks associated with use of these products and particularly about the safety implications of exceeding recommended doses.[7] Staff therefore strongly supports the Report's recommendation that supplement manufacturers include appropriate warnings in product information where necessary.

We look forward to the publication of this valuable Report and will continue to work with FDA staff to ensure consistent approaches to enforcement for dietary supplement labeling and advertising claims.

Sincerely,

C. Lee Peeler
Associate Director
Division of Advertising Practices

Endnotes:

1. The views expressed in this letter are those of the staff of the Division of Advertising Practices of the FTC's Bureau of Consumer Protection and do not necessarily represent the views of the Federal Trade Commission or any individual Commissioner.

2. A recent study cited by the Report, of how consumers perceive health claims and nutrient content claims in food labeling, stated that 90% of consumers interpreted a nutrient content claim as a claim about the food's health benefits. A. Levy et al., "Consumer Impacts of Health Claims: An Experimental Study," Division of Market Studies, Center for Food Safety and Applied Nutrition, FDA (1997).

3.

4. Consumers, for example, may not be able to make accurate assessments about the relative weight of *in vitro*, animal and controlled human clinical studies, or to understand certain basic principles of scientific

research that may have a significant impact on the strength of support for a claim -- such as whether a study has a control, whether it is double-blinded, or whether it uses the same form and strength of active ingredient as that contained in the supplement. Several recent FTC cases challenged misleading ads that referred to scientific studies as proving the product's efficacy, when in fact for various methodological reasons the studies were not supportive of the specific claims made in the advertising.

5. For instance, one model to consider for preparing summaries of the evidence supporting the safety of a supplement would be the regulations of Department of Labor's Occupational Safety and Health Administration (OSHA) for Material Safety Data Sheets that summarize the science relating to a chemical's health hazards. The material safety data sheets (MSDSs), which are completed by chemical manufacturers, include comprehensive technical information on the physical and health hazards of specific chemicals and serve as a reference document for workers that may come in contact with the chemicals. One pertinent provision of the regulations specifies that if there is any study that reports a statistically significant conclusion regarding the health effects of a chemical it must be reported in the MSDS. The manufacturer may also report results of other scientifically valid studies that tend to refute the findings of a health hazard. See 29 C.F.R. § 1910.1200 Appendix B. In addition, a compliance directive issued by OSHA indicates that the MSDS may not claim that OSHA has made a finding as to whether a particular chemical is hazardous, since the agency does not make case-by-case determinations. See OSHA Instruction CPL 2-2.38C, "Inspection Procedures for the Hazard Communication Standard," Oct. 22, 1990.

6. This last principle is similar to that articulated in the FTC's Food Policy Statement that, where a claim is based on science that is inconsistent with the larger body of evidence, it is likely to be misleading, even if qualified. 59 Fed. Reg. at 28,393-94.

7. The FTC's recently announced consent agreement in Global World Media Corporation provides an example of circumstances where such a safety warning is necessary to alert consumers to the potentially serious health risks of a product. Global World Media Corporation, File No. 9623210 (July 22, 1997) (consent agreement accepted for public comment). The Global World case involved the marketing of an ephedra supplement, Herbal Ecstacy, as a street drug alternative being promoted in large doses, as a safe and natural high. The proposed consent order requires respondents to include a warning in all advertising and labeling for such products about the safety risks of consuming ephedra.

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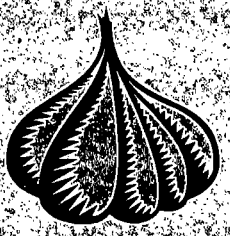

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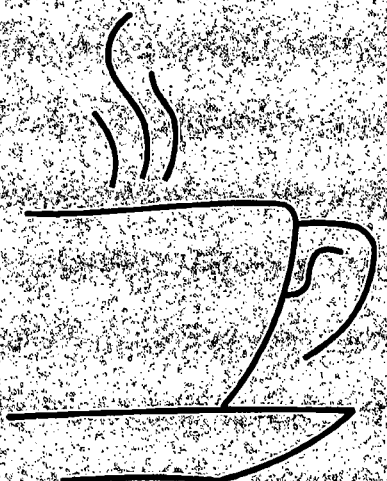

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