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Detwiller

Divider Title: \_\_\_\_\_

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## ABOUT SUSAN M. DETWILER

An expert in assessing and identifying quality healthcare information, Susan Detwiler has over 24 years of market research and analysis experience in the healthcare and information industries. Detwiler's most recent report on the accuracy and timeliness of information on health and medical Web sites, issued in January 2001, was titled *The Medium Doesn't Get the Message*.

In addition to being a researcher, Detwiler is also a book author and frequently writes for magazines and newsletters on medical and healthcare information. In 2000 her book, *The Super Searchers on Health & Medicine: The Online Secrets of Top Medical Researchers*, was published by CyberAge Books. Detwiler is a frequent speaker at national industry groups such as Online World, the Medical-Surgical Marketing Research Group and the American Library Association. At last May's eHealthcare conference, she moderated a panel on Web content quality. Detwiler also teaches small groups at companies and organizations on improving the accuracy and quality of their business and healthcare research.

Detwiler was recently named to the Dorland Healthcare Information editorial advisory board. She contributes to the Medical and Healthcare Marketplace Guide, and Medical Industry Information Report, and participates in the industry as a member of the Medical-Surgical Marketing Research Group, of which she is past-president. Detwiler is also a member of the Association of Independent Information Professionals, the Midwest Healthcare Marketers Association and the Special Libraries Association.

In 1992 she began producing *Detwiler's Directory of Health and Medical Resources*, an annual volume which profiles and cross-references organizations providing information of use to the healthcare industry. The Directory was awarded one of the Top 100 Sources of Marketing Information by *American Demographics* magazine, and named an "invaluable" resource by American Reference Book Annual. In February 2001, Information Today, Inc. acquired the directory and will be responsible for the production of all future editions of this annual directory.

Prior to founding The Detwiler Group, Detwiler was Market Research Manager for Zimmer, Inc., division of Bristol Myers, and Market Analyst for American V. Mueller, of American Hospital Supply Corporation (now Allegiance Corp.)

Detwiler has an MBA from University of Michigan and a BS in Business Administration from the State University of New York at Albany. She is profiled in the Millennium edition of Marquis Who's Who.

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## **Testimony to the White House Commission on Complementary and Alternative Health Policy**

**By Susan Detwiler**

**President, The Detwiler Group**

**March 26, 2001**

Ladies & Gentlemen, I am honored to have the opportunity to testify before the White House Commission on Complementary and Alternative Medicine Policy. My name is Susan Detwiler, and I am President of The Detwiler Group, an independent information consulting firm, which specializes in the information needed by the health and medical industry. One of our goals is to not only stay aware of the quality of information available to these businesses, but also to evaluate the quality of health information available to the American public. To that end, we recently conducted a study of the timeliness of drug data on the Internet, which we released under the title, *The Medium Doesn't Get the Message* in January of this year. In addition, we conducted research on medical misinformation on the Web, much of which was published under the title, *Charlatans, Leeches and Old Wives*, in the March 2001 issue of *Searcher* magazine. I've submitted both of these reports to the commission for the record.

Although our specialty is health and medical information, our emphasis is on the information end of this phrase, rather than the health or medicine side. No one in The Detwiler Group is a physician, or a licensed health professional. However, we are experienced in finding health related information, as well as in evaluating how well different sources do at providing that information. Therefore this is where I will direct my remarks.

Studies at the Pew Internet and American Life Project have shown that more than half of all Americans with access to the Internet have used it to find information about health. While 70% search for specific illness related information, only 13% search for health or wellness related information. Instead of heading towards sites which had been recommended to them, 81% of the health seekers said they did a general search for the information they wanted. More than 60% said they had never heard of the sites they ultimately reached, and 30% checked four or more sites during their most recent search.

In other words, with all due respect to the information providers with high ethics and quality editorial standards, this Commission would be remiss if it ignored the reality of how the public seeks and finds its health information. We cannot focus on just the quality of top sites, or those with brand names. The Commission must be concerned with the broad spectrum of conflicting information which the public confronts when it conducts general searches for health advice. Therefore, in addition to a look at the CAM information presented by popular health sites like WebMD and drKoop, The Detwiler Group also reviewed the results of general searches on AltaVista, Google, and MSN, and sampled the message boards of AOL.

We emerged with three main findings:

- ◆ First, unlike information about mainstream or Western medicine, information about complementary and alternative medicine is frequently contradictory, often within the same website.
- ◆ Second, many general search engines are more likely to turn up spurious sites than they are to find balanced information, and the most popular results are not necessarily the most valid.
- ◆ Third, much of the information about CAM modalities is spread through chats and message boards, both on mainstream websites and in person-to-person systems.

Let's take these one at a time. First conflicting information on the same site. When it comes to acupuncture and homeopathy, much of the information on mainstream health websites, such as DrKoop.com and WebMD present balanced perspectives. They tend to be Western medicine based, but do indicate when there have been clinical studies indicating their effectiveness for particular indications. However, even within these balanced perspectives, they offer conflicting information. The public can easily become confused when a single health site offers information that is both positive and negative regarding a particular modality. For example, on DrKoop, the initial search for acupuncture turned up 50 results. At the top of the list was a news item from Reuters Health which talked about how useful acupuncture is as a treatment for tennis elbow. However, the following two items on that same list were two parts of a three-part story titled *Acupuncture Perspectives*, which calmly and precisely rips apart the science behind acupuncture, stating that "researchers have concluded...that acupuncture is no more effective than a placebo for weight loss, for smoking cessation, against pain (e.g., back pain), and against osteoarthritis."

A similar dichotomy of results emerged when we looked up homeopathy. The results on DrKoop.com include a number of Western based medicine perspectives on whether homeopathy is valid. The results also include an article which offers encouragement to try traditional Chinese medicine such as homeopathy, herbal medicine and DHEA for chronic fatigue syndrome.

Taking a look at WebMD, the first result for homeopathy is the balanced NIH overview of homeopathic medicine. Meanwhile, on the message boards, we see a diatribe against homeopathic remedies lifted directly from Dr. Stephen Barrett's Quackwatch site, followed by a WebMD sponsored chat with a practicing naturopathic physician and chiropractor who has specialized in homeopathic medicine for over 25 years. Other messages on the board are primarily touting the benefits of homeopathy for endometriosis, allergy, irritable bowel syndrome, asthma, learning disabilities and other chronic conditions. Several messages were commercial in nature, directing individuals websites for more information.

We now turn to the mixed results of general search engines. Since 70% of Americans search for a specific disease, we looked at the results they would get when searching for a cure. Using the words “cancer” and “cure,” we tested Google, AltaVista, and MSN, three of the most popular search engines.

The first result in a Google search was the site of The Cancer Cure Foundation This Foundation is dedicated to the promotion of alternative therapies for cancer, including electrotherapy, hydrogen peroxide therapy, laetrile, herbal extracts and detoxification through homeopathic, chelation or other therapies. The reference to zipper and anti-parasitic herbals leads to a site promoting a Mexican based clinic to cure cancer. Doing a backwards link search, it appears that more than a hundred other sites link to the Cancer Cure Foundation.

Conducting the same very simple “cancer” “cure” search on AltaVista led to a similar result. The first site listed is a personal page covered with links to informative treatises with titles like “Mammography – Radiation Induced Breast Cancer!” At the top of the page is a link to “Cancer Therapies FAQ”. This is a listing of alternative therapies ranging from parasite cleansing, to laetrile, to hydrogen peroxide therapy and scores of other alternative therapies.

Doing an MSN search, which is the default if you just put your search terms into the Internet Explorer URL locator, results in a similar set of sites. Here, the very first link is to The Gerson Institute, which describes itself as a non-profit organization dedicated to the holistic treatment of degenerative disease. MSN also gives you the opportunity to see the 10 most popular sites that match your words. Here we find “Alternative Cancer Cures and AIDS Cover-ups by Lorraine Day, MD”. On this site, the health seeker finds sales literature for a video on “Sorting Through the MAZE of Alternative Medicines,” as well as treatises on “The Government Cover-up of AIDS,” “Why Condoms Don’t Work” and similar topics. According to the counter on the site, I was visitor number 733332.

Finally, we looked at the information conveyed on person-to-person networks. Since so many people use AOL for its message boards, we tested the forums on its Alternative Medicine channel. AOL, with almost 88 million unique visitors in February, has an Alternative Medicine channel with several active message boards. In 4 weeks, the Herbal Remedies board picked up 136 subjects, each beginning with a plea from some individual for information about an herb or for herbal help with a disorder or disease. Most had several responses. In one case a respondent who suggested a Western medicine solution to a problem was chastised for posting on the Alternative Medicine Board.

All we know about the respondents are their email handles and the credentials which they list. Many state they are physicians or trained herbalists, but there is no way to check these credentials. Frequently, the advice of those who identified themselves as experts were contradictory, and in several cases the posted messages descended into an argument.

Based on this study of the Internet as a source for CAM information, I have to reiterate that the Commission cannot rely on the mainstream press and mainstream Web presences to convey accurate, balanced information about complementary and alternative medicine. In effect, what has developed is the Internet as an overgrown version of the village well. Any individual can state any item as fact, and there will be someone around to believe it.

Therefore, I have three recommendations to the Commission.

1) Acknowledge that mainstream health websites make up a small part of how complementary and alternative medicine information is spread on the Web, and plan accordingly. Turning a blind eye to the invisible networking that occurs among people on the Internet will undercut the effectiveness of any policy you put in place. Recognize that most people are NOT aware of the quality health sites. WebMD, the top ranked health website with 4.7 million unique visitors in December, still had less than 6% of the Web visitors. drKoop.com, with 981,000 unique visitors had 1.2%. Meanwhile, AOL Time Warner Network had more than 69 million unique visitors in February, almost 15 times as many as WebMD.

2) Once you have a policy in place, don't hide it. Create a public education campaign about how to benefit from this policy. Right now, much of the complementary and alternative medicine using public believes the government is deliberately fighting its use. There are whole websites devoted to conspiracy theories linking the pharmaceutical companies with the FDA in schemes to keep herbal remedies from the public. Create a website for CAM information, or build onto the NCCAM site, and invite conventional, integrative and alternative practitioners to link to it.

3) Create an educational campaign for use in the schools, probably at the middle school level, to teach critical thinking. The focus should be on how to evaluate information you get from your friends, strangers, people you 'meet' in Internet chat rooms and on message boards, and on various websites. This recommendation extends beyond the subject of complementary and alternative medicine, and perhaps should involve other entities in the Government. Students are taught how to use computers and how to find information on the Internet, but they are not taught how to evaluate that information. If they are fortunate to have instructors who teach about evaluating content, it is very unlikely that this lesson is extended to evaluating information received through emails and message boards. Students should be taught that anyone can claim to be a doctor or specialist and how to check out the "facts" they are told.



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***The Medium Doesn't Get the Message:***

***When does breaking health news become permanent information?***

A report on the currency of drug databases associated with health and  
medical websites

Report #200101

January 15, 2001

***The Medium Doesn't Get the Message:  
When does breaking health news become permanent information?***

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## Executive Summary

In order to evaluate the speed with which new information is placed on medical websites, The Detwiler Group undertook to test selected sites for information about a newly approved drug and an FDA warning about an existing pharmaceutical. Initial tests began October 2, 2000 and concluded January 3, 2001. Over the course of three months, a total of eleven sites were periodically searched for mentions of either the new drug or the FDA warning.

The results were disheartening. On April 24, 2000, the Novartis drug Exelon (rivastigmine tartrate) was approved by the Food and Drug Administration for use in mild to moderate cases of Alzheimer's disease or dementia. On June 21, 2000, Novartis announced the drug was on pharmacy shelves. As of January 3, 2001, almost nine months later, *LaurusHealth*, *HealthAnswers*, and *WebMD* did not have the drug listed in their drug databases, although *HealthAnswers* did mention it in a patient education article on Alzheimer's. The *Alzheimer's Disease Education and Referral Center* fact sheet on Alzheimer's disease was dated 1995, and a search of the site noted Exelon as pending approval. None of the sites which listed Exelon in their databases had patient education articles which included the drug.

On November 6, 2000, the Food and Drug Administration issued a warning about phenylpropanolamine (PPA), a drug commonly used as a decongestant and diet aid in over-the-counter pharmaceuticals. The administration had determined that users of medications containing this drug had a higher risk of hemorrhagic stroke than those who did not use PPA. The FDA requested that manufacturers stop marketing drugs using PPA as an ingredient. On November 7, 2000, several drug stores voluntarily removed from their shelves OTC drugs which contained PPA. Of six websites tested on January 3, 2001, only *Medscape* linked its phenylpropanolamine monograph to the FDA warning. Only *Intelihealth* maintained a prominent warning on its website.

An estimated 100 million Americans use the Internet to get information about diseases and therapies, yet even the best known sites aren't fulfilling their promise. The implications are significant. Pharmaceutical manufacturers spend billions of dollars to promote their drugs direct-to-consumer, but a key avenue for finding more information is

closed. Health information consumers rely on prominent health websites for up-to-date information on diseases and drugs, but the sites are not upholding their side of the bargain. Unless news items are incorporated into reference materials, they quickly become invisible. Relying on outsourced drug databases is an acceptable alternative, but only if the uploads are frequent and the database producers actively maintain their information.

In the following report, we examine eleven health information websites for timely introduction and maintenance of important drug news.

## **Introduction**

Many of the most popular medical websites, whether targeted to professionals or consumers, do an excellent job of reporting breaking health news. News releases are updated at least daily, and most keep searchable news archives. The question then becomes, how long is it before this breaking news becomes incorporated into the site's permanent reference materials? When a drug is newly approved, or a warning is issued by the Food and Drug Administration, how quickly is this news transferred into the site's reference materials? When does it become readily available to prescribing physicians or health consumers?

The importance of these questions cannot be overstated. In 1999, pharmaceutical companies spent approximately \$2 billion on TV, print, radio and outdoor direct-to-consumer advertising<sup>1</sup>. However, many of these ads lead to confused consumers. The statement "ask your doctor about....." is nice in concept, but most consumers do not spend their money to visit the doctor based on a television advertisement. With 69% of those with access to the Internet using it to seek information about healthcare, this venue becomes an important source of information about drugs and medical conditions. Indeed, 97% of the public believes it is important that online information about healthcare should be timely, and the date of publication should be evident.<sup>2</sup>

For reference information about pharmaceuticals, most health websites rely on drug database producers for content. This is not usually a problem for long-standing pharmaceuticals. But while this is standard and acceptable practice for reference information, the very nature of drug information makes it imperative to update the databases on a frequent basis. Not only must database producers be vigilant, but host sites must have a policy of timely reloads for licensed information.

In particular, newly approved drugs, changes in drug indications, and FDA warnings should be quickly added to the drug databases. Further, information about a drug should be incorporated into any professional or patient education information about the disease which it treats.

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<sup>1</sup> *A prescription for direct drug marketing*. The McKinsey Quarterly. March 22, 2000.

<sup>2</sup> *Ethics and the Internet: Consumers vs. Webmasters*. Conducted for: Internet Healthcare Coalition and National Mental Health Association by Harris Interactive, Inc. October 5, 2000.

#200101: *The Medium Doesn't Get the Message: When does breaking health news become permanent?*

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In order to evaluate the speed with which new information is placed on medical websites, The Detwiler Group undertook to test selected sites for both a newly approved drug and an FDA warning about an existing pharmaceutical. Initial tests began October 2, 2000 and concluded January 3, 2001. Over the course of three months, a total of eleven sites (See Appendix A for complete list and URLs) were periodically searched for mentions of either the new drug or the FDA warning.

Research was hampered by the lack of uniformity among the sites. The default breadth of search differs from one site to the other. For example, a search on *Medscape* defaults to clinical content. A separate search must be done to cover news items or drug information. However, a search on *Intelihealth* defaults to reference materials (including drug information), and a second search must be done for news. The default for *drkoop.com* is presumably to the entire site, but the entire site search does not include drug information. *MD Consult* can do a complete site search, or just selected parts.

There was also a lack of uniformity in whether the sites dated their reference materials. Despite the efforts of several health information quality initiatives, most of the drug information we retrieved did not identify the most recent date of review. Sites which license their data from outside sources do not make the update frequency evident. In addition, news items were not always identified with the year of the information, although month and day might be prominently displayed. Update policies vary considerably, are not always forthcoming, and do not appear to relate to whether or not the website indicates agreement with any of the health information quality initiatives.

## **New Drug Approval**

### **Testing the Drug Databases**

On April 24, 2000, the Food & Drug Administration approved the Novartis drug Exelon (rivastigmine tartrate) for use in mild to moderate Alzheimer's cases. On June 21, 2000, Novartis announced the drug was on pharmacy shelves. The initial searches were performed almost six months later, on seven general health sites (*Medscape*, *MD Consult*, *WebMD*, *LaurusHealth*, *drkoop.com*, *Clinical Pharmacology 2000*, *HealthAnswers.com*), one person-to-person network (*About.com*), plus one disease specific site (*Alzheimer's Disease Education and Referral Center ADEAR*). The primary goal was to determine when the drug was incorporated into the general medical site's drug database. In the process, we also gleaned information about whether the drug was mentioned in other venues on the site

### **October 2000**

By October 17, only three of the seven general health information sites included rivastigmine in their drug databases. These were *Medscape*, *MD Consult*, and *Clinical Pharmacology 2000*. While *pharmacology.about.com* does not have a drug database, the site's general search engine turned up pointers to complete information about the drug. At *Alzheimer.about.com*, the drug was already documented.

At *HealthAnswers.com*, rivastigmine was included in the site's article on Alzheimer's, with the notation "new drug called rivastigmine." However, while the other drugs mentioned in the article had links to additional information, rivastigmine did not. At *WebMD*, rivastigmine was listed in a general article on Alzheimer's, but did not turn up in the drug database.

Neither *ADEAR* nor *LaurusHealth.com* had rivastigmine as approved.

## November 2000

By November, some changes were seen in the sites which had already carried rivastigmine in their databases.

On November 2, 2000, the *Alzheimer.about.com* site had a comparison of the three main drugs approved for amelioration of Alzheimer's disease, including rivastigmine. *MD Consult* now had full dosing information in its drug database.

By November 30, the *Medscape* drug database still listed rivastigmine as approved, but there was no dosing information as yet. *HealthAnswers.com* still had no link to further information about the drug.

*LaurusHealth* only mentioned rivastigmine in passing, as approved in Europe but not in the US. There was no mention of the drug on *drkoop.com*<sup>3</sup>. The *ADEAR* site still had no mention of the drug as approved and there appeared to have been no updates to the information on the site. *WebMD* consumer version had no rivastigmine in its drug database.

## Final Outcome: January 2001

Our final check was on January 3, 2001.

By this time, *Medscape* had complete information about rivastigmine in its database. *Medscape's* Alzheimer Disease Resource Center, geared toward medical professionals, had been most recently updated on December 19, 2000. This Resource Center included a combination of News, Articles, Journal Scans, Conference Summaries, Treatment Updates, and similar items, many of which included information about the use of rivastigmine. However, the patient information database had no data on the drug.

*MD Consult* had full prescribing information on rivastigmine. However, it only emerges when "rivastigmine" is the word being searched. "Alzheimer," "Alzheimers," and "Alzheimer's" only turned up the two other approved drugs. *MD Consult's* patient education handout on Alzheimer's Disease includes rivastigmine as showing promise in

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<sup>3</sup> It is possible the drug was in the drug interaction segment of Drkoop.com. However, using the ENTIRE SITE search option did not produce any listing. See January 2001 for more details.

trials. As the website relies on practice guidelines from other sources, there were no current guidelines which include rivastigmine in the approved treatment options.

*Pharmacology.about.com* had links to several sources of information about rivastigmine, including FDA approvals. In addition, the search turned up links to the information about rivastigmine on *Alzheimer.about.com*.

*WebMD* remained completely devoid of any information about rivastigmine in its database. A search turned up two articles in the reference section which mentioned the drug. One had a March 1999 copyright date; the other was undated. To find news about rivastigmine, the consumer must select “news” to search. Only two articles result, one dated October 1999, the other mentioning rivastigmine in passing.

The *Alzheimer Disease Education and Referral Center (ADEAR)* site had a total of five hits in a search for rivastigmine. Of these, four were slides from presentations on Alzheimer’s treatment. Oddly, one of the slides was modified to include rivastigmine among the cholinesterase inhibitors which were approved, yet the other slides continued to call rivastigmine ‘approvable as of 1999’. The slides had been modified April 30, 2000.

In a full site search on *LaurusHealth*, rivastigmine showed up in the news category. Only one of the news articles mentioned rivastigmine as approved, and then as part of an additional study on dementia. *LaurusHealth* had a page of available clinical trials for Alzheimer’s Disease. Included was the now completed Phase III clinical for rivastigmine; the clinical trial page was last updated on December 1, 1999. A topic study of rivastigmine in the Illnesses and Conditions library described it as a new drug like the previously approved tacrine and donepezil, but that it had not yet been approved in the United States.

*drkoop.com* permitted a search of the entire site, which returned only one article mentioning rivastigmine. In large print, the screen notes that “*You have searched ENTIRE SITE @ drkoop.com.*” Following a search like this, one would presume that no other information about rivastigmine is available. In truth, selecting a search of the *drkoop.com Drug Checker*, we found a complete patient information fact sheet about



rivastigmine.<sup>4</sup> It appears that this is a link to a branded page on the Multum Drug Checker site. While it is technically true that the drug information comes from a non drkoop.com source, there are cross-implications here. First, the site implies that the Drug Checker is on the drkoop.com site, then, when a full site search is conducted, it leaves out the Drug Checker information. The drkoop.com article on Alzheimer's Disease, listed under Conditions and Concerns, did not mention any pharmaceuticals by name.

*Clinical Pharmacology 2000* continued to have a complete pharmacological monograph on rivastigmine, as well as a consumer level information sheet. Both of these were revised as of April 27, 2000, that is, within 3 days of approval. As strictly a drug database, there were no articles on Alzheimer's Disease to test.

An advanced search across all of *HealthAnswers.com* resulted in two articles which mention rivastigmine. These included a December 2000 article on dementia treated with rivastigmine, and the originally uncovered patient article on Alzheimer's Disease, which mentions rivastigmine as a medication to treat the disorder. There was still no link to further information about the drug, although links to tacrine and donepezil were still functioning.

While not included in the previous tests, on January 3, 2001 we also checked *InteliHealth*. Complete prescribing information was available for rivastigmine, as was a patient information sheet. However, the patient information handout on Alzheimer's Disease did not include rivastigmine among approved drug treatments. The last update for this patient information sheet was June 13, 2000, eight weeks post approval, but prior to market introduction.

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<sup>4</sup> It is possible that this information was available earlier in the year. Using the ENTIRE SITE search option in earlier months, The Detwiler Group presumed that the information was not on the site.

Table 1: When Sites Reflected ‘Approved’ Status of Exelon

| Site                  | In Drug Database | Full Information in Database | Mentioned in Alzheimer monograph | Noted as “Approved” in monograph | “Any” mention implying drug as approved |
|-----------------------|------------------|------------------------------|----------------------------------|----------------------------------|-----------------------------------------|
| About**               | October          | October                      | October                          | October                          | October                                 |
| ADEAR*                |                  |                              |                                  |                                  | January                                 |
| Clinical Pharmacology | October          | October                      | NA                               | NA                               | October                                 |
| Drkoop                | January          | January                      |                                  |                                  | January                                 |
| HealthAnswers         |                  |                              | October                          | October                          | October                                 |
| LaurusHealth          |                  |                              |                                  |                                  | January                                 |
| MD Consult            | October          | November                     |                                  |                                  | October                                 |
| Medscape              | October          | January                      |                                  |                                  | October                                 |
| WebMD                 |                  |                              |                                  |                                  | October                                 |

\*Alzheimer’s Disease Education and Referral Center

\*\* Pharmacology.about.com and Alzheimer.about.com. Complete drug information not on the site, but links to full drug information are there.

## **Food and Drug Administration Warning**

### **Testing the Drug Databases**

On November 6, 2000, the Food and Drug Administration announced a safety warning regarding phenylpropanolamine (PPA). The administration had determined that users of medications containing this drug had a higher risk of hemorrhagic stroke than those who did not use PPA. Although the risk remained very low, the FDA believed that the medical conditions for which PPA was being administered were not serious enough to warrant exposure to an increased risk of stroke. PPA is a decongestant, and is commonly found in cough and cold remedies and in diet formulations. While primarily used in over-the-counter medications, PPA is also an ingredient in some prescription drugs.

Although a formal ban on the drug was anticipated, the FDA issued this warning to ask drug stores to remove offending medications from their shelves, and to request that manufacturers stop marketing preparations containing PPA. The next day, regional and national drug store chains announced that they were removing all preparations containing PPA from their shelves.

As almost 100 million Americans use the Internet as their source of health information, The Detwiler Group decided to test how quickly medical websites incorporated this warning into their information about drugs containing phenylpropanolamine. The initial search was conducted the day following the warning, November 7, 2000. Six sites (*Medscape*, *MD Consult*, *Clinical Pharmacology*, *WebMD*, *MedlinePlus*, *Intelihealth*) were tested.

### **November 7, 2000**

By 4:00 PM EST, November 7, 2000, one day following the announcement, several of the tested sites had the warning in their news briefs. Only *Medscape* had a link in its drug database to the FDA warning. This link was shown at the top of the page, immediately upon retrieving the drug monograph for phenylpropanolamine. However, this was the only link. No multiple ingredient drugs which contained PPA had this warning.

November 13, 2000

On November 13, 2000, one week after the FDA warning, *Medscape* continued to be the only site with a warning linked directly to the drug information.

*MedlinePlus* did not have any revisions or warnings re:phenylpropanolamine in its drug monograph. *Clinical Pharmacology 2000* did not include the information in its monographs. *MD Consult* did not have any warning information in the drug monographs.

*WebMD* did not have any warnings connected to its monographs; the monographs were dated December 1999. At the bottom of each monograph was the following statement: “Every effort has been made to ensure that the information provided by Multum Information Services, Inc. is accurate, up-to-date, and complete, but no guarantee is made to that effect. In addition, the drug information contained here in may be time sensitive and should not be utilized as a reference resource beyond the date hereof.”

*Intelihealth* had the drug warning on its opening page. A search for the drug brought up several results, however the links were not operating at that time.

Final Outcome: January 3, 2001

To determine whether any changes had been made in the databases over the course of the two months which followed the initial warning, a final test was conducted on January 3, 2001.

*Medscape* continued to be the only drug database with a notification of the FDA warning tied to the drug monograph. Again, at the top of the phenylpropanolamine monograph, there was a direct link to “11/6/2000 – FDA MedWatch Alert.” However, as before, none of the compound drugs which include PPA had the alert.

There was no change to the drug monograph on *MD Consult*. The copyright date on the drug information was © 2000, Mosby’s GenRx®, 10<sup>th</sup> ed. There was no indication of the date of update.

*Clinical Pharmacology* had no discernable information about the FDA warning concerning phenylpropanolamine. Complete prescribing information for the single ingredient drug was dated July 16, 2000, Clinical Pharmacology 2000 © 2000.

The patient information drug monographs on *WebMD* made no mention of the FDA warning for phenylpropanolamine. No date was given for when the monograph was written or updated. Both PPA as a cough and cold medication and as an ingredient in diet pills were checked. The only date on the cough/cold monograph was Copyright 2000. Micromedex Thomson Healthcare. The date on the Acutrim (diet pill) monograph was ©2001-1996 WebMD Corporation. However, the FDA Warning was third in the WebMD listing of top medical news of the year.

*MedlinePlus* had no change to its drug monograph for phenylpropanolamine, and no link to any warnings. The date on the monograph was December 9, 1998, Copyright ©2000 Micromedex, Inc.

A search of drug information on *Intelihealth* turned up several references to phenylpropanolamine, including the FDA warning. However, there continued to be no link from any of the patient education articles to a warning about PPA. The patient education article for phenylpropanolamine was dated Copyright © 1999 Micromedex, Inc. The item for a combination drug including phenylpropanolamine was dated ©1996-2001 InteliHealth. In the *Intelihealth* Drug Resource Center, one of the featured articles was the about the FDA warning, titled “Phenylpropanolamine”

Table 2: Whether FDA Warnings are Incorporated into Website

| Site                       | Warning linked to drug monograph? | Warning prominent on site? | Warning in search results? |
|----------------------------|-----------------------------------|----------------------------|----------------------------|
| Medscape                   | Yes                               | No                         | Yes                        |
| MD Consult                 | No                                | No                         | Yes                        |
| WebMD                      | No                                | No                         | Yes                        |
| Clinical Pharmacology 2000 | No                                | No                         | No                         |
| MedlinePlus                | No                                | No                         | No                         |
| Intelihealth               | No                                | Yes                        | Yes                        |

## **Health Quality Initiatives and Timeliness**

### **Industry Interest**

The health and medical dot-com industry has noted that timeliness is an important issue. At least in theory, site publishers are aware that along with having quality information, the public should have access to background about the source and date of this information. In recognition of this and other issues regarding quality and privacy of healthcare sites, a number of initiatives have begun.

Health on the Net (HON), Internet Healthcare Coalition (IHC), and Health Internet Ethics (Hi-Ethics), are the three most prominent initiatives. While they cover far more than timeliness in their codes of ethics and/or quality, each of the three have made timeliness, sourcing, and dating of information an integral part of these codes.

### **Health on the Net**

Health on the Net is a Swiss, non-profit foundation, begun through the workings of a 1995 consortium on telemedicine. The oldest of the systems for validating healthcare websites, HON Code of Conduct<sup>5</sup> is a list of eight principles of basic ethical standards in presenting information. Principle number 4, Attribution, states:

*“Where appropriate, information contained on this site will be supported by clear references to source data and, where possible, have specific HTML links to that data. The date when a clinical page was last modified will be clearly displayed (e.g. at the bottom of the page).”*

### **Internet Healthcare Coalition**

The Internet Healthcare Coalition, formed in 1997, is dedicated to the promotion of high quality healthcare information on the Internet. Several well-known commercial and non-profit healthcare information providers are members. IHC's Code of Ethics<sup>6</sup> is

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<sup>5</sup> Health on the Net Code of Conduct <http://www.hon.ch/HONcode/Conduct.html>

<sup>6</sup> Internet Healthcare Coalition Code of Ethics <http://www.ihealthcoalition.org/ethics/code0524.pdf>

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much more detailed than that of HON. Within the third principle, “Provide information that is accurate, easy to understand, and up-to-date,” are the further admonishments that:

*“Consumers have the right to expect that the information they receive is up to date. Sites should clearly indicate:*

- ◆ *When the site published the information it provides (and what version of the information users are seeing if it has been revised since it was first published)*
- ◆ *When the site most recently reviewed the information*
- ◆ *Whether the site has made substantive changes in the information and if so, when the information was most recently updated .”*

### Health Internet Ethics (Hi-Ethics)

In November 1999, the Health Internet Ethics (Hi-Ethics) organization was formed by some of the largest, most widely used health resources on the Internet. In May, 2000, Hi-Ethics released a set of 14 ethical principles<sup>7</sup> for the health internet. Within principle number eight, Authorship and Accountability, are these two explicit statements:

*“B. Where we reproduce health information content created by third parties, we will clearly disclose the author and/or source of the material and the date of the material or its last update.”*

*“E. Where we create health information content, we will clearly disclose the date it was created or last updated.”*

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<sup>7</sup> Hi-Ethics. <http://www.hiethics.com/Principles/index.asp>

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Table 3: Tested Websites' Stated Adherence to Code of Ethics or Accountability

| Site                  | HON | HI-<br>Ethics | IHC* |
|-----------------------|-----|---------------|------|
| About.com             |     |               |      |
| ADEAR**               |     |               |      |
| Clinical pharmacology |     |               |      |
| Drkoop.com            | X   | X             | X    |
| HealthAnswers         | X   |               |      |
| Intelihealth          | X   | X             |      |
| LaurusHealth          | X   | X             |      |
| MD Consult            |     |               |      |
| MedlinePlus           | X   |               |      |
| Medscape              |     | X             | X    |
| WebMD                 | X   | X             |      |

\* As of May 26, 2000.

\*\* Alzheimer's Disease Education and Referral Center



## **APPENDIX A: Tested Websites and URLs**

| <b>Site</b>           | <b>URL</b>                                                                     | <b>Test for<br/>rivastigmine</b> | <b>Test for PPA</b> |
|-----------------------|--------------------------------------------------------------------------------|----------------------------------|---------------------|
| About.com             | <a href="http://Pharmacology.about.com">Pharmacology.about.com</a>             | Yes                              | No                  |
| ADEAR                 | <a href="http://www.alzheimers.org">www.alzheimers.org</a>                     | Yes                              | No                  |
| Clinical pharmacology | <a href="http://www.clinicalpharmacology.com">www.clinicalpharmacology.com</a> | Yes                              | Yes                 |
| Drkoop.com            | <a href="http://www.drkoop.com">www.drkoop.com</a>                             | Yes                              | No                  |
| HealthAnswers         | <a href="http://www.healthanswers.com">www.healthanswers.com</a>               | Yes                              | No                  |
| Intelihealth          | <a href="http://www.intelihealth.com">www.intelihealth.com</a>                 | No                               | Yes                 |
| LaurusHealth          | <a href="http://www.laurushealth.com">www.laurushealth.com</a>                 | Yes                              | No                  |
| MD Consult            | <a href="http://www.mdconsult.com">www.mdconsult.com</a>                       | Yes                              | Yes                 |
| MedlinePlus           | <a href="http://www.medlineplus.gov">www.medlineplus.gov</a>                   | No                               | Yes                 |
| Medscape              | <a href="http://www.medscape.com">www.medscape.com</a>                         | Yes                              | Yes                 |
| WebMD                 | <a href="http://www.webmd.com">www.webmd.com</a>                               | Yes                              | Yes                 |

## **APPENDIX B: Update Policies for Drug Databases**

*Tested websites were asked for their update policies for drug information. Here are the responses we received.*

ADEAR (Alzheimer's Disease and Education Referral Center)

<http://www.alzheimers.org>

In e-mail:

"The Clinical Trials database on CHIDS is updated 3 times a day.... Reloads are done as often as needed, which is usually monthly."

Kathryn Smith  
ADEAR

*Author's Note: Respondent did not answer the question about drug information. Response is about the Clinical Trials database, and about the CHIDS database, of which ADEAR is a part.*

From the website:

*Author's note: There was no notification of sources on the ADEAR site.*

Clinical Pharmacology <http://www.clinicalpharmacology2000.com>

In E-mail:

"Currently, we update our web site on a quarterly basis (Jan, Apr, Jul, Oct), but we are hoping to move towards monthly. Internally, we are constantly adding to our content and revising existing content."

Stan Reents, PharmD  
Editor In Chief, Clinical Pharmacology  
Gold Standard Multimedia, Inc.

From the website:

Clinical Pharmacology 2000® monographs are developed through an independent, peer-reviewed process and represent an objective analysis of the most clinically-relevant drug information.

*Author's note: The journals which Clinical Pharmacology uses to develop the monographs are listed on the site.*

DrKoop.com <http://www.drkoop.com>

In e-mail:

*[How often is the drug database updated] "Quarterly"*

"We don't have a lot of database information. Instead, we get our basic disease information from ADAM.com, and it is updated quarterly. Most of our other content is provided by doctors, experts and medical writers and is updated as needed and when specified by our Medical Advisory Board."

Stephanie H. Elsea  
Communications Director, drkoop.com

From the website:

To improve the depth and breadth of its content offering, drkoop.com may enter into relationships with third parties that entail featuring their content on the drkoop.com Web site. These third parties may also be advertisers on the site, however the drkoop.com staff maintains complete editorial control over the content, regardless of the materials' origin.

To improve the user's experience, drkoop.com may include links to external sites within its content. However, external sites are not part of, or recommended by, drkoop.com, and drkoop.com has no control over the content and availability of these sites. So that users will be able to distinguish internal and external site links, the following disclaimer will be posted next to said links: "NOTE: External sites are not part of, or recommended by, drkoop.com, and drkoop.com has no control over the content and availability of these sites."

*Author's Note: Drug Checker is not specifically mentioned in the Editorial Content Policy, and no note is made that Drug Checker is an external link.*

HealthAnswers.com <http://www.healthanswers.com>

In e-mail:

*Author's note: Over the course of two weeks, there was no email or telephone response from HealthAnswers.com.*

From the website:

Gold Standard Multimedia

Gold Standard Multimedia is a leading supplier of healthcare knowledge bases in the U.S.

*Author's note: GSM is the parent of Clinical Pharmacology 2000, and is listed as the source for drug information at the bottom of HealthAnswers.com drug monographs.*

Intelihealth <http://www.intelihealth.com>

In e-mail:

"Our drug databases are updated quarterly. All of the information on our site is reviewed every 18 months for medical accuracy. In addition, information is updated on an ongoing, daily basis."

Margoleath Berman  
Intelihealth.com

From the website:

We also use materials, including information and databases, licensed to us from third parties. These materials include, among others, the Merriam Webster Medical Dictionary and a drug database containing information from USPDI (United States Pharmacopoeia Drug Information, used with permission of Micromedex, Inc.) and the Johns Hopkins Drug Encyclopedia.

LaurusHealth <http://www.laurushealth.com>

In e-mail:

"The health information content is provided by Healthwise. Health News is provided by Reuters and updated each business day. Other information is updated at various intervals on an on-going basis."

*Author's Note: Respondent did not say that Multum was the source for drug information, nor did respondent give the frequency of update for drug information.*

From the website:

Healthwise is a not-for-profit educational, charitable, and scientific organization founded in 1975 to help people do a better job of staying healthy and taking care of their health problems.

All information published by Healthwise undergoes rigorous scrutiny before it is made available to the public. Each topic is initially reviewed by the Healthwise Medical Director or one of three Associate Medical Directors, who are board-certified in family practice, emergency medicine, internal medicine, and pediatrics. The text is then submitted for further review by a member of the Healthwise Medical Review Board. Review Board members are board-certified in their specialty areas.

Also from the website, at bottom of drug search results:

Every effort has been made to ensure that the information provided by Multum is accurate, up-to-date, and complete, but no guarantee is made to that effect. In addition, the drug information contained herein may be time sensitive.

MD Consult <http://www.mdconsult.com>

In e-mail:

“Our drug database is fully updated quarterly, with interim daily updates highlighted in our Drug Updates area.”

W. William Haines  
MD CONSULT L.L.C.

From the website:

Drug Information:  
Mosby's GenRx, the leading independent drug reference, featuring information on over 30,000 medications.

Medscape <http://www.medscape.com>

In e-mail:

“The main portion of the database is reloaded once a month. Alerts from the FDA are updated continually (usually within an hour or so of being released)... it is reloaded monthly but is maintained continually by Medscape to adjust for label changes, new warnings and market withdrawals.”

Nick Altebrando  
User Experience Architect  
Medscape.com

From the website:

Drug Search 2000 is a market-leading drug information search tool based on our integrated database. This database was developed as a joint effort of First DataBank, the American Society of Health-System Pharmacists and Medscape. The database combines information from the National Drug Data File with information from the American Hospital Formulary Service Drug Information.

Pharmacology <http://Pharmacology.About.com>

In e-mail:

“I do not personally maintain a drug database, but rather I link to those maintained by others. The better ones are updated at least quarterly.

All articles which appear on the About Pharmacology site include a date prominently located near the title of the article. This is the date on which the information was current. It's not possible to keep everything current and updated, since the production and maintenance of the site is not a full-time effort. All articles carry the statement that the date near the title was the date on which the material was current. If the article or information is substantially changed, that date is changed.

The sources of information vary, but they are usually listed near the end of each article or on a separate links/references page. I rely heavily on the FDA, the NIH, and other U.S. Government web sites, as well as on professional journals, offline professional textbooks, and a few drug databases listed on the Pharmacology site at [http://pharmacology.about.com/health/pharmacology/bl\\_drugs\\_databases.hm](http://pharmacology.about.com/health/pharmacology/bl_drugs_databases.hm)”

Mary Ann E  
Mary Ann Elchisak, Ph.D.  
Pharmacology Guide at About

From the website:

*Author's Note: Website does not maintain its own drug database.*

WebMD <http://my.webmd.com>

In e-mail:

“We update our site a few times a day with breaking stories. This is true for both the physician and consumer sites. And to use your example ... if a new drug is approved for Alzheimer's, the story will be put up as quickly as our FDA writer in DC can write a story. We usually have a story up within a couple of hours of the announcement.”

Sales@webmd.com

*Author's Note: Respondent did not answer how frequently the drug database is updated.*

From the website:

*Author's note: Website does not specifically have a list of information providers. At bottom of drug search page is this copyright notice:*

Copyright 2000. MICROMEDEX THOMSON HEALTHCARE. All rights reserved. USP DI® and Advice for the Patient® are registered trademarks used under license to Micromedex Inc. Information is for the use of End Users only and may not be sold, redistributed, or otherwise used for commercial purposes.

## **About The Detwiler Group**

Founded in 1985, The Detwiler Group consults with information providers on health and business information content, and conducts market and business research for the health and medical industries.

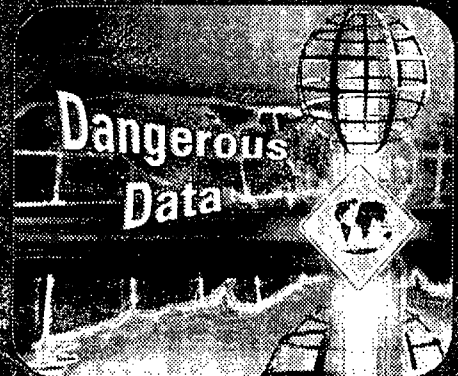
President Susan M. Detwiler has 25 years experience at the intersection of the health and information industries, and frequently evaluates healthcare content on the Internet for traditional and dot-com companies. In addition to speaking at medical industry information seminars and conferences, she writes regularly for the *Medical and Healthcare Marketplace Guide*, *Medical Industry Information Report*, and several information industry journals. Her recently published book, *Super Searchers on Health & Medicine: The Online Secrets of Top Health and Medical Researchers* (CyberAge Books, ©2000), is a collection of interviews with expert users of health and medical information.

Since 1992, The Detwiler Group has produced the annual *Detwiler's Directory of Health and Medical Resources*. The directory was purchased in February 2001 by Information Today, Inc., retaining Susan Detwiler as Editor.

For more information about The Detwiler Group and its services, e-mail [info@detwiler.com](mailto:info@detwiler.com), visit our website at [www.detwiler.com](http://www.detwiler.com), or telephone (219) 749-6534.



# Charlatans, Leeches, and Old Wives: Medical Misinformation



Vaccinations cause the diseases they're supposed to prevent! Drinking hydrogen peroxide will flush out your system! Milk is the best source of calcium! A 5-year-old boy suffering from low libido should take Viagra! Deep coughing at the onset of a heart attack can save your life!

Which of the above is true? Well, that depends on which direct e-mail you believe, which Web site you go to, whether you can trust the person who said it, or if you can even *figure out* who said it!

Back in a 16th century village, you had barbers who acted as surgeons and trained physicians ("leeches") who kept up on the latest advances in medicine, such as new "cupping" or bleeding techniques. Apothecaries compounded and sold medicines, mainly herbal concoctions. Next-door neighbors supported you in your troubles by recommending meddling "old wives" who told you why the physician was a fraud. Charlatans came to town with noxious nostrums to cure what ailed you. As recently as the 19th century American West, the latter still circulated, earning the name of "snake oil salesmen."

They're all still here. Except instead of a few hundred people, the Internet's global village now numbers almost 200 million! Each classic village resident still exists, but reach and resources are wider. Truth and good news move at the speed of electrons, but so do misinformation and tales of misfortune. Medical horror stories spread like viruses. Where once in the village bribery could be spied out through a hole in the wall, we now have to track down layers of who contributes to whom. And the potential for harm is multiplied by the very speed and reach that promises so much good.

This is especially true as more people connect to the Internet precisely because they seek health information. According to the Pew Internet & American

Life Project<sup>2</sup>, 52 million American adults have used the Web to get health information. Ninety-one percent of these have looked for material relating to a specific physical illness. We gather everything we can get our hands on, and we're particularly vulnerable to misinformation. When we're sick, we often become like children, grasping at anything that will make the hurt go away.

Consider the notion that a sustained, rhythmic coughing can keep you alive during a heart attack, presuming you can make it to the hospital fairly soon. This marvelous news comes to you by way of Rochester General Hospital and Mended Hearts, a heart attack victims' support group. Or so the e-mail in your inbox says. This is great news! Uncle Larry should hear of it. And Mrs. Jones, your old teacher. And all your friends on the electronic list. After all, this could save someone's life. Not really. The truth is, Rochester General Hospital never said it; Mended Hearts, which published the item in a newsletter, has retracted it; and the procedure, which is occasionally used for specific types of heart attacks in emergency situations, is only done under professional supervision. In fact, the *Washington Post* of February 15, 2000, carried an article in which a physician at Brigham and Women's Hospital in Boston said the best thing to do in the event of a heart attack is to take an aspirin (to dissolve blood clots) and call 911.

Something like this is fairly easy to check at one of the many urban legends sites. If it were merely a harmless urban legend circulating through e-mail, one could laugh it away. But it doesn't stop there. This miraculous life-saving news is still circulating, still being posted in innumerable list archives and on hundreds of ostensible healthcare sites—all the way from the International Medical and Dental Therapy Hypnosis Association [<http://www.infinityinst.com>] to MedicsIndex [<http://www.medicsindex.org>], a service of the Middle East

Health Network. Registered in the United Kingdom and Jordan, MedicsIndex aims to create a single electronic database of health practitioners in the Middle East and Gulf Region. MedicsIndex still cites Rochester General Hospital and Mended Hearts as the authority for this mis-advice. The error even appears on the PaulingTherapy site [<http://www.paulingtherapy.com>], created by distributors of Linus Pauling's Heart Disease video. The version on the PaulingTherapy site ends with the line: "Note: Aspirin has also been touted as a life saver during a heart attack. Who are we to question national advertising and the findings of the United States government? We will point out that bleeding during and after cardiovascular surgery is a serious problem that is exacerbated [sic] by taking aspirin." Does it seem to you that the note implies skepticism over the aspirin advice while approving the coughing?

## Who Says and Why?

This is innocence run amok. The good people of our village genuinely want to believe they're helping others, and so they forward any e-mail that looks harmless and might help. Less innocent are one-sided facts and figures circulated by well-respected institutions.

Hospitals and educational institutions freely give health advice, and rightly so. But where does this advice come from? And who's behind the facts? It's not always easy to tell. Even legitimate organizations, sometimes fall short of full disclosure. A large, well-respected hospital in Indiana posts on its welcome page an internal link to the "got milk" quiz. Presumably, this fun little nutrition quiz has been checked for factual information by the Webmaster. Nowhere on the site does it offer the source for the quiz or its answers. But one tip-off: The phrase "Got Milk?" might indicate it came from a promotional dairy campaign. Links to

photos of adults and children with "milk mustaches" — a well-known marketing image of the dairy industry — provides more evidence.

A search using the questions from the quiz yielded identical quizzes on at least three other sites: a community healthcare consortium in New York, a commercial dairy, and the Texas Agricultural Extension Service Urban Extension Program. None of them gave a source for the quiz nor its answers, but the extension service had a link for more information to <http://www.whymilk.com>. From Whymilk.com, it's a quick link to the <http://www.familyfoodzone.com> and <http://www.nutrition-explorations.com> Web sites. Here, the National Dairy Council proudly proclaims, "This Web site is developed by the National Dairy Council as a public service to nutrition educators, parents, and children."

Whymilk.com doesn't list its sponsor on the Web site, but a "whois" lookup at Network Solutions shows that this is one of the domains managed by the same public relations firm handling the official Web site of Dairy Management, Inc. Dairy Management is a joint effort of the Dairy Board and the United Dairy Industry Association and manages the programs of the Dairy Board, the National Dairy Council, and the American Dairy Association<sup>3</sup>. Dairy Management and its counterparts make good use of the Internet in getting out their point of view. Dairy Management owns a number of Web sites, all geared to promoting dairy products: [butterisbest.com](http://butterisbest.com), [cheeseforcalcium.com](http://cheeseforcalcium.com), [chefcombo.com](http://chefcombo.com), [dairyinfo.com](http://dairyinfo.com), [dairyinfo.net](http://dairyinfo.net), [dairyinfo.org](http://dairyinfo.org), [dairynutrition.com](http://dairynutrition.com), [dairyutrition.org](http://dairyutrition.org), [extraordinarydairy.com](http://extraordinarydairy.com), [ilovecheese.com](http://ilovecheese.com), [kidsfoodzone.com](http://kidsfoodzone.com), [milkinfo.com](http://milkinfo.com), [nationaldairyboard.com](http://nationaldairyboard.com), and [nationaldairycouncil.org](http://nationaldairycouncil.org).

Who funds the programs of Dairy Management, Inc.? Well, through the Dairy Production Stabilization Act of 1983, Congress mandated a 15-cent-per-hundredweight assessment on all milk produced in the contiguous 48 states and marketed commercially by dairy farmers. The purpose was "to in-

crease human consumption of milk and dairy products and reduce milk surpluses."<sup>4</sup> So the general population's absolute conviction that milk is good for you is partly the product of a business decision on the part of Congress. It was bailing out the dairy industry by creating a marketing board to reduce surpluses.

How extensive is the influence of Dairy Management, Inc. and its counterparts? Going to the American Dietetic Association Web site, we find that DMI and the National Dairy Council each contributed more than \$10,000 to the Association in fiscal year 2000, and the NDC Vice President for Nutrition and Health has been on the American Dietetic Association Foundation's Board of Directors for at least 2 years. A journal article found on the American Dietetic Association Web site entitled "Effects of Increased Consumption of Fluid Milk on Energy and Nutrient Intake, Body Weight, and Cardiovascular Risk Factors in Healthy Older Adults"<sup>5</sup> was supported by a grant from the International Dairy Foods Association.

Now let's make one thing clear. We are not against milk! Is milk, in and of itself, evil? Of course not. Is a trade association promoting its members' products evil? Again, of course not. But it behooves the public to know the source and any potential biases of any medical information or health advice. The Indiana hospital and the New York healthcare consortium do no one a service by promoting a trade association's point of view without disclosing the source.

In fact, looking at the answers to the quiz, the health-minded Web surfer might easily be misled. One True-False question posits "Lots of different foods contain calcium." The answer on the quiz is "FALSE. About 75 percent of the calcium in the food supply comes from milk and milk products...." Well, that still means that 25 percent of the calcium in the food supply comes from other sources. In fact, the USDA Food Pyramid says the average person only needs 2-3 servings of dairy a day,

should opt for low-fat or fat-free versions, and can substitute soy-based beverages with added calcium as an option<sup>6</sup>. Worse yet, the final True-False question is, "I can get the calcium I need from a supplement." Astonishingly, the quiz answers FALSE, not based on the argument that you can't get the calcium, but because calcium supplements don't provide vitamin D. Since there are several calcium supplements which *do* provide vitamin D, and because there are other ways of getting vitamin D (including sunlight and full-spectrum vitamins), this seems extremely misleading.

Is the American Dietetic Association tainted by its association with the dairy industry? Probably not. In fact, the Association does a nice job of relating information on vegetarian and vegan diets. But users should always ask for full public disclosure. Give us the tools to be informed consumers and we salute you, but when we don't know where information comes from, or when it seems to come from someone other than the true provider, that ignorance can blind us to the possibility of bias.

Medem, a network of seven medical societies led by the American Medical Association, does a nice job of disclosing its supporters. Each page carries a list of sponsoring organizations. While pediatricians may not be thrilled that the infant formula producer, Nestle, sponsors the pages about breastfeeding and infant nutrition, at least the sponsorship is not hidden. The link to Nestle stops at a page which declares that the browser is leaving the Medem site and offers the option of deciding not to follow the link to Nestle<sup>7</sup>. In terms of our global village, we like to know who's paying whom, so we can decide if we want to buy whatever product sponsors push our way. Kudos to those who don't hide their sources of income.

### Ouch!

Which brings us to the next problem with healthcare information via elec-

tronic media. "On the Internet, no one knows you're a dog." That's how *The New Yorker* cartoon caption summed up the comments of a high-tech dog explaining Net anonymity to his offline colleague, while corresponding online. When you go to your village physician, you know who you're dealing with. You can see the diploma on the wall. You know people who this person has treated. You can see if the place looks clean and if the doctor seems intelligent. You may be misled, but there are at least clues. Not so on the Internet. Anyone can claim to be anything. And even if you're dealing with a legitimate degreed doctor, how do you know if they're licensed in your state?

At least one Web site purports to diagnose an illness based on the answers to a series of questions. At the innocuously named Library of The National Medical Society (which on some pages also calls itself the American Medical Society), you lay down a \$9.95 fee for access to its so-called library. Much of the information in this library is a set of links to sites full of free medical information, no-cost Web sites that you could seek out on your own. For example, you can link to the National Library of Medicine, The Merck Manual Home Edition (listed here as a *Manual of Medicine*), University of Iowa Family Practice Handbook, or RxList (listed as *Drug Index*). Other links connect to individual online textbooks published by other companies, such as eMedicine and the Internet Dermatology Society. Note that with the exception of the National Library of Medicine and the Iowa Handbook, none of these links are identified as not being part of the National Medical Society's "Library."

Mixed in with this potentially good set of links are one- or two-word links to treatises of dubious quality published by the "Library's" parent, CCS Publishing. By way of background, CCS Publishing is located in Laguna Hills, California, and publishes inexpensive, pocket-sized books that practitioners can use for quick look-ups.

## Avoiding the Charlatans

There are many ways to protect yourself from both the unscrupulous and the well-meaning but misguided folks in the village. The Food and Drug Administration takes an active role, particularly in the areas of unlawful drug sales. As of October 2000, the FDA had issued 80 warning letters, 18 seizures, and 11 recall actions, as well as setting in motion seven arrests on criminal charges related to the Internet and two pharmacy convictions<sup>8</sup>.

The oldest system for validating healthcare Web sites, Health on the Net (HON), went live in 1996 with a system for identifying healthcare sites adhering to specific standards. HON is a Swiss non-profit foundation, begun through the workings of a 1995 consortium on telemedicine. While a HON certificate does not guarantee high-quality information, a site with a HON certificate must adhere to certain basic ethical standards in presenting information. There are eight principles (<http://www.hon.ch/HON-code/Conduct.html>, accessed December 31, 2000), which cover such items as sourcing the information, ensuring that readers know the information is only an adjunct to a doctor/patient relationship, providing clear disclosure of sponsorship or funding, and availability of direct contact with the Web providers. If a site has received a HON certificate, it may display that symbol on its Web site. Each certificate is assigned a number and linked back to the HON site. If you run your cursor over the certificate, you see a HON certificate number associated with the link, evidence that the certificate is still valid. Since a site must apply to receive the HON certificate, lack of a certificate is not an automatic disqualification. However, a valid certificate is a good indication of a site which adheres to at least certain minimal standards.

In 1997, the Internet Healthcare Coalition (IHC) was formed, dedicated to the promotion of high-quality healthcare information on the Internet. The coalition includes organizations such as the Association of Cancer Online Resources, PharmInfo, PanAmerican Health Organization, Medscape, Intellihealth, and other publishers and providers of health information. Much of IHC's efforts are directed towards creating a common code of ethics for health information on the Internet, and in May 2000, IHC released a nine-page International Code of Ethics for healthcare sites and services on the Internet (<http://www.ihealthcoalition.org/ethics/code0524.pdf>, accessed December 31, 2000). This code is much more detailed than the HON code, but doesn't provide a certificate or indication of a site's adherence to it. Unfortunately, it leaves the researcher out in the cold, relying on his or her own efforts to determine if a site lives up to a high ethical standard.

In November 1999, the Health Internet Ethics (Hi-Ethics) organization was formed, from some of the largest, most widely used health resources on the Internet. Founding members include drKoop.com, IntelliHealth, LaurusHealth.com, and America Online. In May 2000, Hi-Ethics released a set of 14 ethical principles (<http://www.hiethics.com/Principles/index.asp>, accessed December 31, 2000) for the health Internet, which cover many of the same principles as IHC and HON, but focus more on issues relating to commercial sites. Privacy figures prominently in its concerns, as does full disclosure of sources of funding and sources of data. Hi-Ethics members gave themselves until November 2000 to comply with the code; as of December 2000, Hi-Ethics had signed an agreement with TRUSTe, the leading online privacy seal program, to develop a E-Health Seal for sites which adhere to the Hi-Ethics principles.

With three somewhat competing organizations developing similar codes of ethics, the Internet Health Coalition spearheaded a joint commission among them. In October 2000,

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## Medical Misinformation

These pocket books have been put online in PDF format. Checking through one of them, *Pediatrics*, we find the author is Paul D Chan, MD. Dr. Chan also authored other books in the series — *Internal Medicine*, *Gynecology & Obstetrics (2002 edition!)*, *Outpatient and Primary Care Medicine*. None of these give references for the information in them; if you want references, you're directed to contact the publisher. The books are generally around 200 pages.

What about its journals? Yes, the Library of the National Medical Society also publishes journals. The Web site proclaims the current edition to be the current month. Under the heading *Continuing Medical Education*, the "December edition" of the "Osteoporosis" article was identical to the October edition.

Keep in mind that the following is supposed to come from a reputable medical journal, as you read this first paragraph of the "Osteoporosis" article in *Continuing Medical Education*:

If you were to take a biopsy of normal vertebral bone, you'll notice that there are a lot of trabeculae in all directions. Bone is very nicely designed to withstand the biomechanical forces that we subject it to....

And a later paragraph:

In order to understand how we get to this point, pathophysiologically, and how the interventions that we have in hand, that we can write prescriptions for that work, I need to remind you of the basic bone biology. I think the real take-home message is that bone is not static. That we don't grown to our adult height and then that's it for bone; it's an inert scaffold that we carry around with us....[sic]

A look at the references for this article shows none dated later than 1995. Authored by Barbara Wood, MD, there is no information about Dr. Wood's credentials. Searching through all 50 states at SearchPointe.com [<http://www.searchpointe.com>], we found a single

Barbara Wood with an active license. This is likely not the author, as her specialty is Psychiatry. Truly, this is continuing medical education at its best.

And yet, the worst is yet to come. Remember that 5-year-old boy mentioned in the very first paragraph of this article? The one suffering from low libido and told to take Viagra? This is the place that gave the advice. One of the links provided by the Library of The National Medical Society is to Online Diagnosis, "Accurate online medical diagnosis of symptoms, illnesses, diseases, and psychiatric disorders." Linking here brings you to a list of more than 500 symptoms. The instructions say, "Click on your symptom, then enter additional symptoms to receive diagnosis." The possibilities start with Abdominal Fluid and end with Yellow Skin. In between is offered Anal Bleeding, Jaw Pain, Halitosis, Obsessive Thoughts, Vasculitis, Hypotension, and, of course, Sexual Dysfunction.

The Sexual Dysfunction page, which takes patient history, has a box for "Describe symptoms," followed by "How many days have the symptoms been present?," "How old is the patient?," a few additional queries, and "Male Patient" — Yes/No, or "Female Patient" — Yes/No.

When tested, it didn't seem to matter what you entered under symptoms, days present, or age. You could say you're a 2-year-old with an itchy nose. According to the source code for the page, only the last question has any bearing on where you're linked next. If you click Female Patient — Yes, you're offered four options: "Low sexual desire," "Inability to achieve orgasm," "Painful intercourse," or "Vaginal muscle spasm during intercourse." If you click Male Patient — Yes, you're offered three options: "Decreased desire for sex — low libido," "Difficulty maintaining erection — erectile dysfunction," or "Difficulty with ejaculation — ejaculatory dysfunction." Click on that second option, and you read: "Morning erections present" or "Morning erections absent." Clicking on that first option (still remembering that we've

identified ourselves as 2 years old), we're told to test with a Nocturnal Tumescence Ring. If no Nocturnal Erections are detected, treatment is recommended — oral Viagra, surgically implanted prosthesis, or a vacuum tumescence device.

But what about a less-ridiculous test? After all, how many 2-year-olds suffer from erectile dysfunction? So we tried for another online diagnosis. This time, bleeding gums. Once again, it made no difference what we answered, until the question, "Does the patient take aspirin?" Once the answer is "No," it asks about splenomegaly or systemic rash. If the answer is again "No," the system queries for an abnormal dental exam or normal dental exam. With a normal dental exam, it says to check vitamin C levels. Diagnoses are "Injury with toothbrush, early scurvy, or phenytoin use." Hmm...those latter two are pretty serious. Maybe the diagnostics should have considered our answer to the question of symptom duration — 2 days.

Who are the doctors diagnosing online? We're not sure. The four names followed by MDs have no credentials attached. One name is fairly common and shows up on the American Board of Medical Specialties Web site and CD-ROM. Whether any of those listings identify this author, we don't know. None of the other three show, and none have a match in California, where CCS originates.

Legality is another question. Even if they are certified physicians, they most certainly are not licensed to practice medicine in every state of the union. There are no disclaimers on the site, saying that this is just a tool to assist other physicians. There are no statements telling consumers to check with their own physicians.

Even scarier is the number of links to the Library, the number of other sites citing this one. According to a link search on Google, about 540 pages link to <http://www.ccspublishing.com>. More than 630 link specifically to <http://www.medical-library.org>, including even misguided libraries pub-

lishing lists of "notable sites for medical research."

Before you pay the \$9.95 for your very own subscription, here's a gift. Just use "member" as the userid, and "1881" as your password. That's the instruction to those who forget their logon id and password. It's also the one given to me when I shelled out the subscription fee. Apparently, there is no such thing as a password protect, and anyone who knows the secret word can get in, \$9.95 or not.

Are these folks charlatans? Well, maybe. Classically, charlatans are voluble, making loud claims about their own skill or knowledge. Here, the claims to skill and knowledge are implied, rather than touted, in the mere fact that the site purports to diagnose every manner of illness. Quack, perhaps? Well, again, we don't know the actual credentials behind the site. But the site definitely related to one of those classic village personages. The site is certainly treading a fine line and may be practicing medicine without a license by diagnosing across state lines.

The best thing to do when confronted with something like this is to run the other way. Find other sources that do give you the appropriate disclaimers and direct you to your own physician for accurate diagnoses. If you can't track down the source of the information, you have no idea of its quality. Dr. Wood and Dr. Chan may be excellent physicians, but you are given no way to check. The information is outdated, with an outright lie as to the date of the *Continuing Medical Education* journal articles. Sources are withheld or so old as to be laughable. The grammar is pitiful. Run away. Fast.

## For One Thin Dime, One Tenth of a Dollar

Next in our village gallery are the true mountebanks — folks who sell their own nostrums to cure what ails you. There are many false cures out there. Often, they're tied into promotions for books and videos about con-

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the three organizations announced that they will work together to ensure that the e-health codes share a common terminology that the public can understand.

Meanwhile, however, barring the HON seal, there isn't a lot that can tell users at a glance whether a site is good or not. So what should an Internet health information seeker do? The answer isn't much different from what you should do if confronted with information in some other medium<sup>9</sup>. THINK!

**First: Know what you're looking for.** Even though it's difficult to stay calm and focused when you're considering the health of yourself or a loved one, remember that you can't find what you're looking for unless you know what it is. The old cliché, "If you don't know where you're going, any road will get you there," is as true here as when behind the wheel. Before sitting down at the computer, consider what it is you seek. Background information on a disease? Accepted therapies? Clinical trials of potential cures? Physicians or hospitals treating the disorder? If you know what you want, you're less likely to follow link after link, wasting time and getting nowhere. If the link you find doesn't focus on what you seek, go back to the search results and start again.

**Second: Start in the right place.** Starting in the right place may mean using a good search engine or starting with a known, high-quality, medical Web site. If you use a general search engine, be aware of how they rank the results. HotBot (<http://www.hotbot.com>) is a popularity contest. Top links are those receiving the most hits. Probably good for finding information about Britney Spears; not so good for medical information. Google (<http://www.google.com>) is much better. By ranking sites according to how many other sites link to them, the top sites are generally those with a higher credibility. It's not foolproof, but for diseases or disorders that are not extremely rare, the top sites returned by Google are usually good places to start. For more obscure items, AltaVista (<http://www.altavista.com>) may be useful, as it has an extremely broad base of sites in its inventory. However, AltaVista changes its ranking method periodically, so it becomes very important to scrupulously follow the remaining guidelines for evaluating results.

Professional associations of medical professionals who research or treat the specific disorder are excellent places to begin. Most of these associations maintain public resources on their sites, including actual information about the disease or links to organizations which will have more information. To find these associations, you can use a general search engine, but make sure you put in just the disorder and/or the treating physician type, and the word "association." Don't put in "cure," "treatment," or "therapy," or you leave yourself open to the charlatans who baste their sites liberally with the word cure.

Starting with a known quality, medical Web site is also a good idea, but the public generally isn't aware of them. You can start with the Health on the Net, Internet Healthcare Coalition, or HI-Ethics sites to find links to their members. However, many, many other excellent sites have not bothered to register with any of these, despite their essential agreement with the principles of ethics. To find sites reviewed by professionals, you might start with Healthfinder (<http://www.healthfinder.gov>), from the U.S. Department of Health & Human Services; Healthweb (<http://healthweb.org>), a set of pages which include links to sites reviewed by medical librarians and professionals, arranged by topic; and the Hardin metadirectory (<http://www.lib.uiowa.edu/hardin/md/>), which maintains lists of places to find more lists of topic-specific resources.

Sites designed for medical professionals are also good places to start, as many of them maintain consumer-level information, as well. A few of the many good professional sites that allow non-professionals to get good information include Medem, Med-

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spiracies among the medical establishment, who, of course, strive to keep these cures from the general public. Titles of these videos are designed to shock: *Emerging AIDS & Ebola; Nature, Accident, or Intentional?* and *The Nazi-American Biomedical/Biowarfare Connection*<sup>10</sup> are just two examples. The site which carried these boasted more than 107,000 visitors from October 19, 1999, to October 18, 2000. Whether most of the 107,000 believed the tales is questionable, but it's likely that many followed links from similar sites, in an effort to find out "THE TRUTH."

While most people will see through these rants, there is a subtle insidiousness to cures using everyday household items. Take, for instance, the seemingly harmless hydrogen peroxide.  $H_2O_2$  is ubiquitous. Most households have a bottle of a 3 percent solution of  $H_2O_2$  tucked away somewhere. It's the substance that made "bleached blondes" a household phrase and is well known for its use in cleaning cuts and abrasions. But despite its innocuous place in our homes, the Occupational Safety & Health Administration has a health guideline for hydrogen peroxide that warns how it can irritate the eyes, mucous membranes, and skin, and that inhalation may cause extreme respiratory irritation. In large enough doses, systemic poisoning may occur, resulting in vomiting, diarrhea, tremors, convulsions, pulmonary edema, or shock. During in vitro human tests, hydrogen peroxide has caused DNA damage. Acute exposure may cause mild bronchitis or pulmonary edema and corneal ulceration<sup>11</sup>.

Clearly, anything more than a 3-5 percent solution of this substance is a chemical to be reckoned with; even at low levels, one should think twice about ingesting it, much less contemplating an intravenous solution. Yet intravenous hydrogen peroxide therapy is precisely what is recommended by a number of Web sites. At Ozone Services [http://www.o3zone.com, accessed October 26, 2000],  $H_2O_2$  therapy is described:

Hydrogen peroxide is infused into the circulatory system through a vein in the arm...in the blood it encounters two enzymes: catalase and cytochrome-C.... In this way the benefits of hydrogen peroxide are made available to all cells...the effect of singlet oxygen in the human body is two-fold. It kills, or severely inhibits the growth of, anaerobic organisms (bacteria and viruses which use carbon dioxide for fuel and leave oxygen as a by-product).... anaerobic bacteria are pathogens, the organisms which cause disease. All viruses are anaerobic.

These identical words appear in a paper by Ron Kennedy, MD, at Medical Library.net<sup>12</sup>. Both sites offer lists of physicians who conduct this therapy. True to form, another site claims there is a conspiracy to keep knowledge of  $H_2O_2$  therapy out of the hands of the public, so the pharmaceutical companies and physicians can reap the benefit of trillions of dollars of drug sales<sup>13</sup>. Most disturbing is that these sites promoting oxygenation therapy make it sound as if the nasty adverse effects are merely proof that the therapy is working.

One woman experienced sudden severe nose bleeding with the elimination of two large blood clots from her right nostril. She can now breath through the nostril for the first time in years! Another person had bleeding from the mouth when he spit up huge amounts of mucous. Another had rectal bleeding as his hemorrhoids reduced. These are natural cleansing processes, and they will be of short duration as you continue the program.... There are hundreds of published articles against the use of hydrogen peroxide as a therapeutic agent because this cleansing process was misinterpreted as being "BAD." It is the necessary price for recovery of your precious health. Don't be

misled by a "Healing Crisis!!"

Rather, be GRATEFUL FOR IT!<sup>14</sup>

Yet if you look more closely on the Web, you can find the facts about  $H_2O_2$  therapy.

One of the main proponents of  $H_2O_2$  IV therapy is Kurt Donsbach, a chiropractor originally licensed in Montana, who then used a forged document to obtain a license to practice naturopathy in Oregon. Donsbach is now in Rosarita Beach, Baja Mexico, using "Bio-Oxidative Therapy" with a claimed remission rate of 70 percent in more than 300 patients who have "tried everything else" and been told their cases were hopeless<sup>15</sup>. What the proponents of bio-oxidative therapy don't tell you is that Donsbach is not a doctor. At one time he pleaded guilty to practicing medicine without a license in California, and since then has left a trail of misrepresentations and illegal medicinal claims. His Hospital Santa Monica uses hydrogen peroxide intravenously, orally, in ear drops, a nasal spray, a tooth gel, a pain gel, breath drops, and enemas for the purpose of "aging rejuvenation, allergies, arthritis, cancer, cardiovascular, cataracts, immune stimulation, and multiple sclerosis."<sup>16</sup> In 1988, the U.S. Postal Service issued a cease and desist order to Donsbach, to stop him from claiming that hydrogen peroxide is fit for human consumption.<sup>17</sup>

In 1989, the Food and Drug Administration issued a press release that industrial strength hydrogen peroxide, illegally promoted to treat AIDS and cancer, had caused at least one death in Texas and several more serious injuries. Although the 35 percent solutions were sold to be diluted and used in "Hyper-Oxygenation Therapy," there was no proof that either the product or the therapy had any medicinal value. To quote the FDA press release, "Buyers are being cheated and subjected to significant risks and family members are being injured."<sup>18</sup>

These sites get an impressively high number of hits. Unlike our little village of olden days, where the mountebank gets run out of town once he's unmasked, in our global village the sites

keep springing up. Anyone with a computer and a telephone line can create a professional-looking Web site, and anyone who questions the validity of the information can hear from proponents all over the world. From January 1999 to October 2000, the site carrying the Kennedy paper received over 3 million hits. And on America Online, the subject of H<sub>2</sub>O<sub>2</sub> infusion therapy has been a topic of discussion on message boards, with only those who confirm its positive effects answering queries<sup>19</sup>. Even Dr. Weil at Dr-Weil.com has been questioned about its efficacy. Fortunately, Dr Weil's measured response is a good antidote to the hype. As he put it,

One of the reasons people take antioxidant vitamins and minerals is to prevent the oxidative damage caused by chemicals such as hydrogen peroxide and ozone. You can't have it both ways here — hydrogen peroxide and ozone can't both promote healing and be so toxic...save it for the next time you have a yen to go blond<sup>20</sup>.

## Doctor? Who Needs a Doctor?

Speaking of message boards, it's time to make a stop at the village well, as townsfolk stop and chat about their concerns. Today, our village well consists of the communities, message boards, and chat rooms on several highly frequented networks. In a 1-month period, America Online garners almost 80 million unique visitors; About: The Human Internet has more than 20 million, and iVillage.com almost 8 million<sup>21</sup>. What these three networks offer are communities wherein people chat about their lives and concerns. Just like at the well, bad information can be as prevalent as good.

According to a study at Johns Hopkins School of Public Health, vaccines are one of the reasons behind the dramatic 50 percent increase in Americans' life expectancies over the course of the 20th century<sup>22</sup>. You wouldn't

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scape [<http://www.medscape.com>], Healthgate [<http://www.healthgate.com>], Virtual Hospital [University of Iowa, <http://www.vh.org>]. For cancer-specific questions, two excellent places to start are the University of Texas MD Anderson Cancer Care Center [<http://www.mdanderson.org>] and Oncolink [<http://cancer.med.upenn.edu/>] from University of Pennsylvania Cancer Center.

**Third: Maintain a healthy skepticism.** In beginning journalism, students are taught that the lead paragraph of an article should cover *Who, What, When, Where, Why* and *How*. Evaluating information on the Web requires the same 5W's and H. *Who* wrote the piece? That is, is this a medical professional? Does the site give you credentials? Are those credentials valid? Look them up! *What* is the source of the data? If there are no footnotes or references, be skeptical. Even if there are references, subject them to the same scrutiny. *When* was this piece written? *When* was it last updated? If there's no date on the piece, how do you know it's still current? No matter how good the credentials of the site, outdated information is still outdated information. The Alzheimer's Disease Education and Referral Center (ADEAR) [<http://www.adear.org>] does very good work. However, its fact sheet on Alzheimer's is dated 1995. Several new advances in Alzheimer research have been made since then.

*Where* did the site get its funding? If the site seems bent on selling you the latest cure for the disorder, it's a fairly good bet that the sole purpose of the site is to sell products. Run the other way. If the site just happens to have advertising or prominently displays sponsorship by a commercial entity, it's probably a better choice. The key is to read the advertising or funding policy if the site makes it available.

*Why* was the piece written? The best bet is if the piece is solely intended to be informative, as part of a professional medical site (commercial or association). If the piece is written for the purpose of selling a product, again, run away. More subtle agendas may try to push certain point of view — for example, the People for the Ethical Treatment of Animals site might only publish information about the negative findings about milk, rather than a balanced view. If that's the case, it's important to learn about the site's agenda and balance it with alternative views — maybe by touching on the National Dairy Council site, as well.

*How* did you find the information? This is a point many overlook. If you find this site through a series of links from other sites, remember that it retains the bias of every site prior to the one you're on. Just like in AIDS, where the professionals warn that you don't sleep with just one person, but with every person that one has slept with before, the site you're on is a product of the biases of every site which led you here. To get a different point of view, you have to go back to your original search results and start another trail.

**Fourth: Give it the smell test.** If the site promises miraculous cures or claims to cure different diseases with the same substance, it's probably a hoax. If it sells drugs without a doctor's visit, it's probably skirting the law. If it doesn't give you a way to verify the information, or if the most recent references are more than 5 years old, be wary. If it's a personal Web site, it's likely to have a personal agenda. If you found it through an e-mail, check one of the urban legends Web sites, such as [urbanlegends.about.com](http://urbanlegends.about.com) [<http://urbanlegends.about.com>] or Urban Legends Reference Page [<http://www.snopes.com>]. In other words, if it smells fishy, it probably is.

**Fifth: When in doubt — ask a professional.** Most medical librarians and professionals find out about new sites through networking with each other or reading their professional journals. It is their job to keep up with the best resources out there and they immerse themselves in the subjects. Many hospital libraries have consumer help desks; if not, librarians are happy to point you in the right direction to conduct your own research. If you're not sure about the information you've found, ask your doctor.

There are many ways to protect yourself from the charlatans, but it all comes down to the same guidelines as for everything else. Be smart. Don't turn off your brain. THINK!



know it if you relied on Internet chat rooms for your information. An AOL message board search for "vaccination OR immunization OR vaccines" resulted in 1,158 hits in just 1 month. Here's a sampling of the messages: "the unofficial policy of the World Health Organization and... Save the Children's Fund and... [other vaccine-promoting] organizations is one of murder and genocide..." "just get in touch with a certified homeopath and stop going to doctors," "I guess the drug companies wanted a big increase in U.S. sales of the hepatitis B vaccine, because all of a sudden the CDC started hyping the disease as a huge health threat." The messages on iVillage ran in a similar vein, with messages which link to sites like Biological Manipulation of Human Populations, using quotes from the 1955 Surgeon General that "No batch of vaccine can be proved safe before it is given to children,"<sup>23</sup> and to the personal homepage of a D. K. Yuryev, proudly proclaiming that his paper was rejected by *Nature*, *Lancet*, *International Immunology*, and the *New York Academy of Science*, and therefore he is publishing it on the Web. In the introduction he states that "I'm afraid, this article too obviously implies an idea that vaccinology and AIDS campaign are governed by idiots..."<sup>24</sup> The sites promoted and quoted by the anti-vaccine crowd are highly inbred, with each having lists of links to similar sites which link to each other.

Following the trails begun with these messages, the health searcher is led to articles like "Vaccines: The Truth Revealed" [<http://www.odomnet.com/vaccines/introduc.htm>, accessed October 17, 2000]. Here, we are told that the government has a computer database containing several thousand names of disabled and dead babies who were alive just prior to receiving vaccines. In actuality, there is a Vaccine Adverse Event Reporting System (VAERS), operated by the Centers for Disease Control and Prevention (CDC) in conjunction with the Food & Drug Administration (FDA) [<http://www.fda.gov/cber/vaers/what.htm>, accessed December 29, 2000]. Approximately 10,000-12,000 VAERS reports are filed annually, with about 15 percent classified as serious, i.e., seizure, high fever, life-threatening illness, or death. Any adverse event which occurs after a vaccination may be reportable, whether or not the event is related to the actual vaccine. More than 10 million vaccinations are given each year. Doing the math, this means that less than 0.1 percent (that's *point one percent*) of all vaccinations result in a VAERS report, and less than 0.02 percent (*point oh two percent*) are classified as serious.

One of the sadder aspects of these popular message boards is that the very same systems that allow bad information to go unchallenged in their communities also make available excellent, mediated information. On the About.com system, a retired pharmacologist is the "Guide" to Pharmacology. At [Pharmacology.about.com](http://Pharmacology.about.com), an 11-page, well-written, balanced view of vaccine safety is available [<http://pharmacology.about.com/health/pharmacology/library/weekly/bl000217.htm>, accessed October 25, 2000]. The article ends with links to resources like the parent pamphlets required to be given to vaccine recipients, the VAERS system, the FDA, and the World Health Organization. All the information in the article is sourced. It's just like in our representative village. The people at the well turn to each other for support, with the highly vocal anti-establishment responding. Meanwhile, those in a position to offer facts are ignored.

### You'll Need a Prescription for That

Stepping away from the village, for a moment, we ride into the city of London. Early in the history of the British Royal College of Physicians, its members asked Her Majesty Queen Elizabeth to command that "arsenic, sublimate, and opium should be sold to only those persons willing to give their names, and that no apothecary should

sell or prescribe medicine without a physician's prescription."<sup>25</sup> This battle is still being fought, only now the scale is multiplied a thousandfold. Most of us with any kind of activity on the Web have become used to receiving e-mails promising anonymous prescriptions to lifestyle drugs. Maybe Viagra for erectile dysfunction; perhaps Propecia for hair loss.

Ostensibly, these sites have physicians just waiting to "approve" you for purchase of the drug. Of course, every one which I've checked requires you to acknowledge that you're not taking any medications that might react with the drug in question and promise to have a physical examination prior to consuming the pharmaceutical<sup>26</sup>. In fact, the agreement in at least one of these has the prospective buyer agreeing, "I further certify and affirm that I am aware of and know of the potentially lethal side effects of Propecia, if I have ingested or taken other medications that are contraindicated with use of Propecia. I certify truthfully that I have not been taking any such medications." Nowhere on the site, however, are these contraindicated medications listed! In the Frequently Asked Questions, the only contraindications are women and children, and anyone allergic to any of the ingredients. Again, nowhere on the site are the ingredients listed. What about the question of whether the "prescribing physician" is properly licensed? To get around that question, the buyer must certify, "I agree that all on-line medical consultations, diagnoses, and treatments (including prescriptions for the treatment of hair loss) will be deemed to have occurred in the state where the physician is physically located and licensed to practice medicine."<sup>27</sup>

There is some hope that these sites will feel the brush of the law. While buyer agreements may work in most states, Pennsylvania has barred two of these companies from selling any prescriptions at all to citizens of Pennsylvania. As of November 2, 2000, both sites must prominently post that these services are not available to residents

of Pennsylvania, and if you've previously purchased from them, the consultation fee may be refunded until March 2001<sup>28</sup>. These kinds of sites are under constant investigation by the Food and Drug Administration. Unfortunately, there is no reason to believe that they will stop, or even slow down. A month after receiving an e-mail invitation to purchase Viagra, I checked and found the site no longer there, but in the interim I received several additional invitations. As long as there are townspeople vain enough to circumvent the law in order to grow hair, or unsure enough of their own virility to bypass a physical in favor of quick access to miracle cures, the unscrupulous apothecaries will continue to have their way.

If you think you're immune by virtue of never, ever going to a Web site under your own name, you're not. Published hard copy alumni directories have become fodder for scam mill. Shortly after my alma mater published a directory, I received an e-mail with the subject line: Albany Alumni. It was spam, selling something called "Crystal Vision," with the "most powerful antioxidants for macular health as well as nutrients that promote healthy functioning eyes." There was an illegible signature, over the tagline "Your Alumni Friend." Of course the return address was a nonsense word. Oh yes...if I ordered immediately, I would receive a free bottle of Echinacea.

## One Last Villager

So all the village members are still here: the charlatans who sell their own nostrums, the physicians ("leeches") who provide the truth, the apothecaries who fill prescriptions (both legitimate ones and those who are not) and the "old wives" who sit at the well and mind your business for you. And, there's one more role to be played. Frankly, there are also village idiots in enough numbers to make the scams worthwhile. \*

## Footnotes

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Srinivasan

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**V. Srini Srinivasan, Ph.D.**

## **Criteria for Levels of Evidence for evaluation of botanical preparations –An approach**

**V.Srini Srinivasan Ph.D.**

Good afternoon. I would like to thank the White House Commission on Complimentary and Alternative Medicines for inviting me as representative of the United States Pharmacopeia to participate in this panel discussion.

USP was established in 1820 and we are in our third century. The first edition of the United States Pharmacopeia published in 1820, described standards for 217 botanical preparations. In the beginning all drugs were natural-animal, botanical and mineral. Over the next 100 years or so, USP added standards for nearly 700 botanical preparations. At the turn of the 20<sup>th</sup> century, with the availability of pure active constituents from plants drugs coupled with the synthetic organic medicinal compounds began to appear on the market, and prescribing habits of physicians began to change. As a result of this change, USP started establishing standards for modern drugs that were widely prescribed. This inevitably resulted in the removal of most of the botanical monographs from the pharmacopeia. However with the recent resurgence of interest in natural medicines of plant origin and with the passage of the DSHEA in 1994, which classified botanical preparations as dietary supplements, the USP Convention adopted a resolution in 1995 encouraging the USP to establish standards and authoritative information for botanicals and other ingredients labeled and marketed as dietary supplements. Thus USP is engaged in the development of public standards for botanicals marketed as dietary supplements.

It is important to keep in mind that under the current USP and NF admission policies, the USP Information Experts Committees must first determine whether or not a botanical poses a safety concern. If none are found, the standards setting process is set in motion. The next critical role of these Committees as defined by the policy, is to determine whether or not there is an FDA or USP identified or accepted use. If the answer is "Yes", the compendial standards will be published in the USP. If the answer is "No", the standards will be published in the National Formulary. The underlying rationale for this differentiation is 1) to maintain and protect the credibility of the USP and 2) to help dietary supplement purchasers make more informed decisions. During the period 1995-1997, prototype information monographs for four botanicals Ginger, Valerian, Feverfew and St. John's wort were published. They were not received well primarily because practitioners and manufacturers viewed USP's approach to developing information as being too "drug like". To respond to that expressed concern, in 1998 USP constituted an *ad hoc* Advisory panel on botanicals. The Panel was charged with the task of developing criteria for evaluation of evidence that could be used as the basis for determining safety and USP acceptance or non-acceptance of specific indications being claimed for botanicals. The Panel rigorously reviewed the information and various evaluative criteria and developed a Criteria of Levels of Evidence (see accompanying Table). These Criteria provide us with a more objective measure to determine whether or to admit botanicals in the USP-NF.

|     | A                                                                                                                                                                                                                                                            | B                                                                                                                                                                                                                                                                                                                    | C                                                                                                                                                                                                                                                                                                                                                |
|-----|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| I   | <b>RCT</b> <ul style="list-style-type: none"> <li>➤ Highest quality</li> <li>➤ Adequately powered</li> <li>➤ Comprehensively reported</li> <li>➤ Well-designed and executed in all respects</li> </ul>                                                       | <b>Meta-Analysis</b> <ul style="list-style-type: none"> <li>➤ A representative universe of RCT's that meet inclusion/exclusion criteria</li> <li>➤ Results are based mostly on Level IA quality trials</li> <li>➤ Comprehensively reported – pooling methods/statistical analysis well described</li> </ul>          | <b>Epidemiological Studies</b> <ul style="list-style-type: none"> <li>➤ For safety and drug adverse event associations of high scientific credibility</li> <li>➤ Case-control, cohort or other appropriate design</li> <li>➤ Case selection minimizes and controls for confounding factors</li> <li>➤ No serious methodological flaws</li> </ul> |
| II* | <b>RCT</b> <ul style="list-style-type: none"> <li>➤ Methodological flaws, if present, may not be serious enough to undermine the conclusions</li> <li>➤ Methods of analysis or reporting may be less completely described</li> </ul>                         | <b>Meta-Analysis</b> <ul style="list-style-type: none"> <li>➤ Universe of RCTs that met inclusion/exclusion criteria may be less representative</li> <li>➤ Results are based mostly on Level IIA quality trials</li> <li>➤ Comprehensively reported – pooling methods/statistical analysis well-described</li> </ul> | <b>Epidemiologic studies</b> <ul style="list-style-type: none"> <li>➤ For safety and drug adverse event associations</li> <li>➤ Uncontrolled long-term post-marketing surveillance studies</li> </ul>                                                                                                                                            |
| III | <b>Inconclusive Studies</b> <ul style="list-style-type: none"> <li>Non-randomized trial</li> <li>Serious methodological flaws</li> <li>Efficacy studies lacking an appropriate control</li> <li>Inappropriate size or duration to be of any value</li> </ul> |                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                  |
| IV  | <b>Anecdotal Evidence</b> <ul style="list-style-type: none"> <li>Case reports</li> <li>Descriptive rather than experimental studies</li> <li>Considered useful for hypothesis generation</li> </ul>                                                          |                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                  |

## CRITERIA FOR LEVELS OF EVIDENCE

### Level I: Randomized Controlled Trials, Meta-Analyses and Epidemiological Studies of Highest Quality

#### A. Randomized Controlled Trial (RCT)

The study is a randomized controlled trial that is adequately powered to show a treatment effect vs. placebo or an appropriate active or historical control. The report of the study must describe the objectives and design of the study, the endpoints measured, the method of randomization, the method of blinding, the assessment of outcome, and the statistical analysis employed, including the handling of dropouts and withdrawals (e.g., intention-to-treat vs. per protocol analyses). The results must be presented comprehensively, not selectively. Sponsorship of the study and the measures taken to assure the validity and integrity of the data (e.g., monitoring) should be noted. The study may not have a methodological flaw, or a potentially biased statistical analysis that is serious enough to undermine the conclusions of the study.

#### B. Meta-Analysis

The study contains a representative universe of RCTs in the worldwide medical literature that meet the pre-specified inclusion and exclusion criteria of the meta-analysis, at least some of which are Level IA in quality. The report of the meta-analysis must describe in detail the inclusion/exclusion criteria, the methods used to minimize selection bias, the method of pooling data, and the statistical analysis used. The study may not have methodological flaws sufficient to undermine the conclusions of the study.

#### C. Epidemiological Study

For the demonstration of drug-adverse event (AE) associations (but not drug efficacy), the study is a case-control study (or other epidemiological study of appropriate design) that demonstrates a drug-AE association of high scientific credibility, i.e., an association that is biologically plausible, has a non-marginal relative risk and a low probability of error. The report must describe in detail the method of selecting cases and controls and the measures taken to minimize selection bias and to control for confounding variables. The study may not have methodological flaws sufficient to undermine the conclusions of the study.

### Level II: Randomized Controlled Trials, Meta-Analyses and

## Epidemiological Studies of Moderate Quality

### A. Randomized Controlled Trial

The study is a randomized controlled trial that is designed to show a treatment effect vs. placebo, an active control, or a historical control. However, the report lacks a sufficient description of the methods or analyses, particularly with respect to specified endpoints, randomization, blinding and/or the statistical analysis, to meet a IA level of quality. Evidence of quality control of the data though independent monitoring is usually lacking. The study may have significant methodological flaws, or uncertainties in the statistical analysis, but none that is overt and serious enough to undermine the conclusions of the study. Many clinical studies reported in the older medical literature or in non-peer-reviewed journals may meet this description.

### B. Meta-Analysis

The study is a meta-analysis of a sample of trials that is less than the full universe of published trials meeting the pre-specified inclusion or exclusion criteria or is composed only of studies that are Level IIA in quality, but in other respects is appropriately conducted and reported.

### C. Epidemiological Study

For the demonstration of a drug-AE association, the study is a case control study (or other epidemiological study of appropriate design) that would meet the standards of a Level IA study except that the relative risk and/or the P value marginal. Serious drug-related AE's identified in large, uncontrolled, long-term studies or in post-marketing surveillance belong in this category.

## Level III: Inconclusive Studies

This level includes non-randomized trials, efficacy studies lacking an appropriate control group, studies with methodological flaws serious enough to render them uninterpretable, and studies that are too small or of insufficient duration to be of value. The conclusions of Level III studies are not necessarily incorrect, but they cannot be shown by scientific methods to be correct. Level III studies can be useful as hypothesis-generating studies but are ordinarily considered inconclusive in supporting the overall efficacy assessment of a drug.

## Level IV: Anecdotal Evidence

This level includes case reports and/or papers reporting a series of cases. Such reports are not necessarily incorrect, but are generally considered as descriptive rather than experimental, and hypothesis-generating at best.



## V.Srini Srinivasan Ph.D.

Dr.Srinivasan serves as the Director of the Dietary Supplements program at the United States Pharmacopeia(USP). In this capacity he is responsible for assisting the USP Council of Experts in the development and establishment of public standards for dietary supplements that include vitamins, minerals, amino acids , botanicals and their preparations.

Dr.Srinivasan graduated from the University of Western Ontario, London, Canada with a Ph.D. degree in Natural products - Medicinal Chemistry.

He has numerous publications in leading national and international scientific research journals covering various aspects of medicinal chemistry, natural products, aerosol preparations, nutritional supplement preparations, etc. He served on the ad-hoc Advisory Panel to the Office of Dietary Supplements in the Strategic Planning for Dietary Supplements Research, ad-hoc Advisory Panel to the National Institutes of Mental Health in the identification of Hypericum products for clinical trials for mental depression, and on the Panel of Peer Reviewers for Evidence Reports/Technology Assessment, prepared by the San Antonio Evidence –based Practice Center of the University of Texas for Agency for Healthcare Research and Quality, on Botanicals Garlic and Milk Thistle . Dr.Srinivasan is a frequently invited speaker at national and international scientific meetings covering the above subjects.

His most recent interest is in the area of bioavailability of nutrients and botanical dosage forms.

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Maine

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**Lucinda Maine, Ph.D.**

**Statement to the President's Commission on Complementary and Alternative  
Medicine Policy – Evaluation of CAM Information**

**Lucinda L. Maine, PhD, RPh**

**Senior Vice President, American Pharmaceutical Association**

I am pleased to represent APhA, the national professional society of pharmacists, at today's hearing and to have this opportunity to address key issues regarding information available to professionals and consumers to guide their selection and use of complementary and alternative medicine products. Pharmacists largely deal with patient or consumer use of dietary supplements, including vitamins and herbal products, and my comments will in large measure relate specifically to these components of CAM products and services. It is APhA's position that pharmacists have a responsibility to assist consumers with decisions about effectiveness, proper use, indications, safety and potential interactions between alternative medicines and traditional therapy. Their ability to carry out this responsibility depends on the availability of credible, evidence-based information to supplement their professional education and experience.

I will draw upon several sources in framing my remarks, including a publication issued as a joint effort of APhA and the American Dietetic Association last year, which has previously been shared with the Commission. In addition, I have gleaned the highlights from focus groups held just one week ago during the APhA Annual Meeting. These were convened by staff members from the Office of the Inspector General of HHS in the Boston office. They are embarking upon a study of the sufficiency of dietary supplement labeling and the impact of these products and available information on the elderly population specifically. Finally, research results from colleagues at the University of Minnesota College of Pharmacy who addressed the Commission at your open hearing in Minneapolis have been helpful in guiding development of my brief comments.

For perspective, I believe it is important to note several things about pharmacists and dietary supplements. Pharmacists, and especially those practicing in community pharmacy settings, are a highly accessible resource for the public for guidance about selection and use of alternative medicines. The Minnesota survey I just referenced indicated that pharmacists are approached on average approximately 7 times per week by consumers with questions about herbals and/or other natural products. This is a striking increase when compared to a national survey conducted in 1996 which found a rate of only 10 queries a month. In addition, the MN pharmacists surveyed reported receiving questions from other health care practitioners about use of these products.

How comfortable are pharmacists with their knowledge base and their access to scientifically grounded information on these products and their use? By observation and focus group results I would say far less comfortable when compared to other categories of products commonly purchased in pharmacies. Almost 40 percent of the MN pharmacists responded that available clinical and technical information used in making decisions about herbal/natural products was not adequate and another 57 percent indicated information was only somewhat adequate. For the past several years, standing

room only crowds of practitioners have attended educational sessions held at ours and other association meetings. We feel this reveals an unsatisfied demand for credible information from pharmacists.

In the recent focus group discussions, pharmacists indicated that both they and their patients found dietary supplement labeling confusing and inadequate to guide point of purchase decision-making. Confusion also stems from disclaimers which are too small and suggests something about product review by the FDA but leave many questions in the minds of consumers and pharmacists. Further, while pharmacists find that references on labels to USP is important in judging product quality, references to other "quality reviews" that may also appear on labels is confusing and potentially misleading. Concerns about product quality and purity, in addition to other concerns about combining these products with traditional therapy are prevalent in the thinking of pharmacy practitioners.

There are two important points about the interface of pharmacists and consumers in the CAM arena. First, while many consumers appear to reach for these products in the context of health-seeking and wellness, those who access such products in pharmacies, we believe, are more likely to be individuals who are familiar with the pharmacy setting because they may also have acute or chronic conditions that prompt prescription or nonprescription medication use. Fortunately, when they ask pharmacists for guidance they may be thinking of their need to assure that whatever self-care activities they engage in won't interact with or complicate their other health conditions. But there are limits to what is known about such combinations of therapy and pharmacists do not feel that existing literature, whether primary, secondary or commercial, meets either their needs as professionals or the needs of consumers for safe use.

The second point about sale and labeling of CAM products in the pharmacy environment is that often herbal/natural products are sold very near or integrated with traditional over the counter medicines. Pharmacists are split in their opinion about whether labeling should be modeled more like OTC products or food. Proponents of OTC-like labeling believe consumers are used to that format and would benefit from similar labeling for CAM products. Others feel that it is inappropriate to infer that CAM products are like OTC medications. A third group told the OIG staff that it really didn't matter how products were labeled because consumers ignored product labels anyway.

There was a feeling that labels should encourage consumers to share information about their use of dietary supplements with their physicians and pharmacists. Further, a warning regarding seeking health care provider input if the symptoms, if any, for which consumers are using the CAM products don't resolve is highly recommended.

My final point is about surveillance of experience with CAM. Pharmacists are perhaps most uncomfortable with what we don't know about actual consumer experience with CAM products. APhA believes it is time for a much more robust system of experience reporting by consumers and health care providers. Ideally such a system could be voluntary and be embraced by manufacturers of CAM products as a key tool for

collecting and analyzing actual use information about their products. A program could be modeled, we believe, after reporting systems used by chemical and related products industries. APhA would support and cooperate in the development of an accessible reporting system that would meet the needs of manufacturers, regulators and providers for information about product quality and consumer experience with dietary supplements and other CAM products.

Thank you for seeking the input of America's pharmacists on these issues before the Commission. I would be happy to provide additional information as time permits.

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DAVID G. SCHARDT  
Associate Nutritionist  
Center for Science in the Public Interest

David Schardt is Associate Nutritionist with the Center for Science in the Public Interest (CSPI), a non-profit consumer advocacy group specializing in food, nutrition, and dietary supplement issues. Founded thirty years ago, CSPI is supported primarily by its 850,000 members and subscribers.

David has been writing about nutrition for the general public and for professionals for 20 years. His articles covering most aspects of food, nutrition, and dietary supplements have appeared in numerous magazines, newspapers, newsletters, college textbooks, and Web sites. His reports on nutrition and dietary supplements are featured each month in the Nutrition Action Healthletter, the nation's most popular nutrition newsletter.

In 1988, he helped to write and edit the landmark Surgeon General's Report on Nutrition and Health. His book *Eating Leaner and Lighter*, published by Warner Books in 1994, was recommended for sensible nutrition by the United States Department of Agriculture's Food and Nutrition Information Center. He recently served on a national advisory panel evaluating the potential health benefits of the herbal supplements garlic and milk thistle, convened by the U.S. Department of Health and Human Services' Agency for Healthcare Research and Quality.

David has been featured on numerous television and radio programs, including ABC's *World News Tonight*; NBC's *Nightly News*; ABC's *20/20*; NBC's *Dateline*; *Good Morning, America*; the *Today Show*; CBS *This Morning*; CNN; CNBC's *Business Report*; *Hard Copy*; The Food Channel; PBS's *Healthweek*; *America's Talking*; more than 50 appearances on CNBC's *Steals and Deals*; The Donohue Show; National Public Radio's *All Things Considered*, and many other television and radio programs. He is widely quoted in the print media, especially on the subject of dietary supplements.

David has graduate degrees in nutrition and biochemistry from Oregon State University and graduate study and research experience with Cornell University's Division of Nutritional Sciences.



White House Commission on Complementary and Alternative Medicine Policy  
March 26, 2001

David Schardt  
Center for Science in the Public Interest

Most of the traditional media, such as television, radio, newspapers, magazines, and newsletters, are valuable for acquainting people with Complementary and Alternative Medicine (CAM) and for notifying them of new developments. However, these media have been less valuable for providing the kind of extensive, in-depth, objective, and practical information people and health professionals need to make informed decisions about whether to try CAM and, if so, which ones.

Many of the traditional media are constrained by:

- \* limitations of air time and column space
- \* need for newsworthiness
- \* need for visual images and human emotion
- \* need for conflict
- \* short shelf life
- \* lack of beat reporters

If the CAM community wants to foster better coverage in the traditional media, given these constraints, it should recognize that it is harder to produce good CAM stories than conventional medicine stories. The scientific literature is scattered and not easy to assemble, credible authorities and institutions are not as easy to identify and reach, and the latest news is not as easy to obtain.

The CAM community should establish a top-notch press office to make it as easy as possible for reporters to research, write, and record CAM stories. The office should be staffed by well-informed people who can promptly refer journalists to reliable background material and credible people to interview, who can answer simple questions, and who can help suggest stories.

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Divider Title: Hendel

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03/18/01

Chris Hendel has been the senior researcher for Consumer Reports on Health, a 12-page monthly newsletter that offers consumers advice on diverse health-related matters, since its launch in 1989. He is also the health research manager for Consumer Reports magazine. Both are publications of the Consumers Union of the U.S., Inc., and when combined, their health coverage reaches 5 million paid subscribers. The information is also disseminated through Consumer Reports Online, Consumer Reports Television, and Consumer Reports Radio, as well as through press releases from CU's Office of Public Information.

Along with his work for CU, he is an advisor to the United States Pharmacopeia (USP) on dietary supplement issues (specifically botanicals) and is also CU's official representative to the USP. In addition, he has been the primary researcher for several books on medical and health care issues published by CU, as well as *The Complete Guide to Women's Health* by Random House. Some of his other research work includes two Internet health information guides: *Online Medical Resources* and *Online Health and Fitness*, published by Macmillan. He was also a researcher for the Emmy-Award-nominated production "Smoke Alarm: The Unfiltered Truth About Cigarettes," a joint collaboration of Consumer Reports Television and HBO.

Before joining CU in 1989, he worked with the Vermont Department of Health in Burlington, analyzing physician practice patterns and hospital cost containment. Prior to that, he was a researcher for a health care consulting firm in Atlanta, Georgia. He received a bachelor's degree in anthropology/sociology and psychology from Springfield College in Massachusetts and his master's degree in anthropology from Southern Illinois University in Carbondale. As part of his graduate work, he spent the better part of 1982 and 1983 in India and Nepal, performing an epidemiological study of vision disorders in northern India, and also a cultural and economic impact study of tourism and mountaineering expeditions on the indigenous Sherpa of northeastern Nepal.

Christopher Hendel  
Senior Researcher and Health Research Manager  
Consumers Union of the U.S., Inc.

March 26, 2001

I would like to begin with a brief history and philosophy of our organization.

Dating back to our premier issue of Consumer Reports magazine, published in May of 1936, Consumers Union has provided the U.S. consumer with unbiased, accurate information about products and services in the marketplace, whether it be a new or used car, a toaster, specific medications, medical treatments, or even a new health plan for their family. As the largest non-profit, independent testing and information organization in the world, Consumers Union's fundamental mission has always been to test products, inform the public, and protect the consumer. Our income is derived solely from the sale of our publications and services, and from nonrestrictive, noncommercial contributions, grants, and fees. We buy all the products we test, and accept no free samples. We take no advertising from outside entities and do not let any company use our reports or ratings for any commercial purpose.

In preparing reports for consumers about products and services in areas of medicine and health, in addition to our own tests, exhaustive search and analysis of the literature, discussions with researchers and clinicians, etc., we often have the luxury of turning to our own readers to learn about their specific real-life experiences. In 1999, as part of our Annual Questionnaire which we send out to subscribers of Consumer Reports in the U.S. and Canada in the spring, we included a section of the survey entitled "Health Care" inquiring about specific treatments our readers used most often for the two most serious or bothersome medical conditions they encountered during the previous two years. Since the survey was not presented to the reader as "alternative health care", we are confident our sample is not comprised solely of people with strong predisposed notions regarding the topic. Respondents informed us about their experiences with such conventional treatments as prescription and OTC medications, physical therapy, and surgery, and lifestyle changes (diet and exercise), as well as their experiences with complementary treatments. We received well over 46,000 responses. A separate validation survey was performed by our survey department to demonstrate that the respondents were representative of our universe of readers. At final analysis, our survey appears to be the largest and most detailed snapshot of alternative-medicine use in North America. Before I discuss some of the key points from that survey further, it's very important to note some caveats: Seventy percent of the respondents were male and both the men and women in our survey tended to have higher education and income levels than the national norms. Because of this, our findings may not be directly comparable with other studies. However, we feel the findings do provide some very interesting answers to questions about the use of alternative and complementary medical practices in our present medical care system.

Without going into every specific detail of our analysis of the 46,000-plus individuals, I'd like to share some very intriguing findings about our readers' use of treatments and the efficacy of those treatments. More details can be found in the published results of the survey which appeared in the May 2000 issue of Consumer Reports. When you look back at earlier published surveys by Drs. Eisenberg (1993 and 1998), Astin (1998) and Druss (1999), we see some similarities, but also several new and interesting developments regarding the use of alternative medicine.

- More than one-third (35 percent) of the survey respondents tried alternative treatments. Most respondents (79 percent) who used alternative treatments also tried conventional treatments, mainly for relief from troublesome symptoms that had not yielded to conventional treatments. Those individuals who said that they were in severe pain or stress were more likely to try alternatives.
- For most medical conditions, the majority who tried alternatives found them very helpful or somewhat helpful. However, some medical conditions, including an enlarged prostate, scored rather poorly, even though the clinical trial evidence published to date suggests that the use of the botanical supplement saw palmetto may benefit some men with mild symptoms--at least in the short term.
- When we first began reporting about the rise in the use of alternative medical practices in this country in the early 1990s, we noted that a majority of Americans who were experimenting with alternative medicine were doing so without the knowledge--and consent--of a health-care professional. At least among our readers, this appears to have changed. When readers felt comfortable enough to tell their doctors about their use of alternative treatments for their condition--and 60 percent did--most doctors expressed approval (55 percent) or at least neutrality (40 percent). Only 5 percent of the group said that their doctor disapproved.
- And, nearly one in four readers who tried an alternative treatment did so on the recommendation of a doctor or a nurse. More than half of those recommendations were for botanicals and other supplements, most typically for arthritis and prostate problems. A smaller number of professionals recommended hands-on therapies.

What persuaded our readers to try--or not to try--complementary and alternative treatments for their medical condition? Although not noted in the final published results, I'd like to share some information about that specifically:

- Forty-seven percent said that they were persuaded to try a specific treatment because of their own reading or research.
- Only 9 percent were persuaded by advertisements they saw (almost all for botanicals and supplements).

Among those who did not try complementary and alternative treatments, the reasons why they did not were:

- Forty percent replied that they did not know enough about the treatments.
- Twenty-eight percent did not trust treatments not provided by their doctors.
- Eleven percent specifically replied that they thought complementary and alternative treatments were “too risky.”

As noted earlier, the increase in discussion between our readers and the health care professionals they visit is a very welcome sign. Because as the medical and research community digs deeper into the safety and efficacy of complementary and alternative treatments in a broader range of individuals, we are learning more and more concrete information which will benefit everyone, especially in the light of much inadequate, nonscientific-based information circulating the media, not to mention the lack of significant regulation of the dietary supplement industry. There is still so much we don't know with respect to long-term use and how many dietary supplements work and how those mechanisms may effect other active medications individuals may be taking.

I mentioned the first issue of Consumer Reports magazine earlier. Back in 1936, “Alka-Seltzer” was all the rage, in no small part due to the manufacturer's promotion of the simple white tablet's ability to relieve or cure the common cold, headache, neuralgia, muscular pain, rheumatic fever, dissipation, over-indulgence, sour stomach, heartburn, fatigue, nervousness, sleeplessness, alcoholic excess, and minor throat irritations. CU reported to the public about the truth behind those claims, and informed them of the products' ingredients--ordinary aspirin, citric acid and baking soda. Some things never change.

Today, we know by virtue of extensive biochemical analysis and the randomized controlled clinical trial evidence that aspirin--even in doses less than 100 milligrams, roughly a third of a standard 325 milligram tablet--has a potent inhibitory impact on prostaglandins, substances in the body that produce a wide range of effects, such as pain and inflammation, as well as clotting of the blood. We've also learned that aspirin's impact on prostaglandins also effects a protective role of the substance--that of protecting the stomach and duodenum against ulceration. That's why the long-term use of aspirin has been found not only to reduce the risk of heart attack and stroke, but also to increase the risk of gastrointestinal bleeding and ulcer formation. Aspirin falls under the FDA regulatory rubric as an “OTC drug and must meet specific chemistry, compendial, and labeling requirements of the FDA. However, you won't find aspirin sprinkled over potato or corn chips, in a pint of ice cream or a can of soda. I wish we could say the same for a lot of botanical ingredients which do appear to have

documented drug-like effects on the body. And unfortunately, no one really knows how much these “functional” snack foods and beverages contain. There’s no standard, validated testing method to analyze foods and beverages for the presence and concentration of these botanicals. We feel that the FDA should vigorously enforce existing laws and develop regulations on the evidence needed to document the safety of botanical ingredients in foods and require safety information on food labels.

Regarding dietary supplements, consumers also have virtually no protection against inaccurate labeling or substandard preparation, because of a lack of meaningful government regulation. For this reason, since 1995, CU has been testing supplement products to evaluate their content and how that content conforms to information on the label. We started with ginseng back then and found substantial brand-to-brand variation in the amount of ginseng in the pills (other more recent analyses have found variation in content and also pesticide residues). Thus far, we have evaluated echinacea, ginkgo biloba, saw palmetto, St. John’s wort, kava, and SAM-e, and we will continue to evaluate products in the market, working with outside laboratories that specialize in testing botanical products and focusing on those that have performed 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 multiple samples of each brand, obtained from different parts of the country.

We are learning too much after the fact for a lot of these substances, many of which have very clear effects on the body which accounts for some of their efficacy in the controlled trials. We are also just now learning how many of these active compounds are metabolized. For example, we’ve only recently learned about the effect St. John’s wort has on enzymes in the liver and how this alters the therapeutic effectiveness of many prescription medications.

But how do consumers hear about this information? While the Internet has created an incredible opportunity to the consumer for obtaining information about dietary supplements specifically, and complementary and alternative medicine in general, much of that information is of questionable credibility and accuracy.

When we begin to develop our articles on specific medical treatments or preventive measures to reduce risk of developing various medical conditions irregardless of whether the option being researched is “conventional” or “complementary/alternative,” we often choose the same approach. This typically begins with a collection of the pertinent clinical trials and/or epidemiological data that exists. While the National Library of Medicine’s MEDLINE database is a good place to start, not all the information that we need to develop thorough coverage exists there. And actually, an article in this month’s issue of the American Journal of Clinical Nutrition bears this out, noting that a limited search plan focused on MEDLINE failed to locate nearly one-half of the relevant studies for a specific alternative treatment. If we limit ourselves to MEDLINE for specifics about an alternative or complementary

treatment, we may miss out on much critical data we would need to comprehensively evaluate the treatment. However, with more and more medical and science journals indexed by MEDLINE making their articles available free as full-text on the Internet, this is often an excellent place to start, especially for a pro-active and savvy consumer.

In addition to searching MEDLINE and several other databases, such as EMBASE and the CCTR (the Cochrane Collaborations Controlled Trials Register, a particularly useful site as it provides very systematic, up-to-date reviews of relevant RCCTs on health care interventions), we consult with many of the researchers and clinicians involved in active study of the medical condition, as well as specific treatment options for that condition, and from them we are often able to receive copies of peer-reviewed studies we might not be able to obtain from our own vast holdings or from a nearby medical college library or the article retrieval services we use. And of course, the use of relevant medical, drug, and dietary supplement texts and volumes. This allows us to canvas a great deal of information. However, not all consumers have the time or ability to access all of the above. This was an impetus behind a recent article we prepared and published in our monthly newsletter, *Consumer Reports on Health*. Entitled "How to research a medical topic," the article includes many web sites we consider valuable sources of information for helping the consumer to not only learn about a specific medical condition but also to be able to retrieve information about what various treatment options exist for that condition. It is posted in the free area of our web site ([www.ConsumerReports.org](http://www.ConsumerReports.org)) and has recently been highlighted by the National Library of Medicine MEDLINEplus web page.

Clinical trials have played a critical role in the development of effective treatment options for many medical conditions. It's really been only over the last 40 years that results of randomized controlled clinical trials have provided the medical community with reliable information about medical treatments. While the clinical trial can't answer all the questions we need to ask about the safety and efficacy of specific treatments, it's critical that it remain the standard for which we measure these treatments. One additional option to gather additional information that might not be determined by the clinical trial would be to fund more prospective clinical outcome studies, where we would be able to follow large study groups over time who use specific treatments for specific conditions and look at the outcomes.

As Edzart Ernst, M.D., director of the department of Complementary Medicine, School of Postgraduate Medicine and Health Sciences, University of Exeter in England recently stated: "If there are no funds there will be no research. If there is no research, we will be unable to find out whether complementary and alternative medicine does more good than harm." I would also add that without proper regulation, the consumer must take a very active "buyer beware" approach. The government's role in this is very clear. Consumers have won a high level of safety for their food, medications, and medical treatments, and a high level of protection against misleading advertisements. We believe the FDA should have the authority and funding to establish basic rules



regarding botanical and other supplements, to require appropriate labeling, to establish consistent manufacturing standards, and to require reasonable evidence of safety.

We have learned that many serious and life-threatening side effects associated with prescription medications are often not uncovered until after the drug has been approved and has been in the marketplace for some time. This is why postmarketing surveillance is so incredibly important. Can we not set up such a system for many dietary supplements being brought to the market? Or, can we consider the funding of population trials to better monitor use and potential negative outcomes? It is true that here in the U.S. we do have a number of voluntary systems for reporting adverse reactions to dietary supplements. However, such passive surveillance has its weaknesses. Although widely used for hundreds of years, tobacco wasn't clearly associated with an increase in lung and other cancers until epidemiological studies found an association just 50 years ago. And it took many years of research to establish that connection.

The gold standard--the randomized controlled double-blind clinical trial--can't possibly answer all our questions about safety. Just look at the recent experience of some high profile and widely used medications withdrawn from the marketplace, such as dexfenfluramine (*Redux*) for weight control and troglitazone (*Rezulin*) for diabetes. We need comparable postmarketing surveillance for a lot of the botanical and dietary supplements on the market. And the consumer needs package labeling that includes a telephone number they can call to report an adverse effect to a responsible agency.

There's also a need for more randomized controlled clinical trials with adequate washout periods and not only placebos, but "active controls" (would like to see more "active controls" in the prescription drug trials for that matter). We applaud the National Institutes of Health's inclusion of "active controls" in the trial of St. John's wort for depression, which will include the prescription medication sertraline (*Zoloft*); and the upcoming trial of glucosamine and/or chondroitin for osteoarthritis, which will include the prescription medication celecoxib (*Celebrex*).

### **A FEW ADDITIONAL SOURCES OF INFORMATION NOT ALREADY MENTIONED ABOVE**

#### **Specific to botanical and dietary supplements:**

Natural Medicines Comprehensive Database, compiled by the editors of the Pharmacists Letter and the Prescribers Letter. Available as online database or voluminous (1500 page) text. 2000 edition (online version is updated continuously).

Nutrition Action Health Letter, published monthly by CSPI.

PDR for Nutritional Supplements, just released by Medical Economics. 2001 edition.

Rational Phytotherapy: A Physician's Guide to Herbal Medicine, published by Springer, 1998.

The Dietary Supplement, published bimonthly by Paul R. Thomas, Ed.D., R.D.

WHO Monographs on Selected Medicinal Plants, published by the World Health Organization, Geneva, 1999.

#### **Specific to complementary and alternative medicine:**

Alternative Medicine Alert: A Clinician's Guide to Alternative Therapies, published monthly by American Health Consultants.

Complementary Medicine for the Physician, published 10 times a year by Churchill Livingstone.

Focus on Alternative and Complementary Therapies: An Evidence-Based Approach, published monthly by Pharmaceutical Press.

**Internet web sites:**

Agency for Health Care Research and Quality [[www.ahrq.gov](http://www.ahrq.gov)]

McMaster University's Health Care Information Resources  
[[hsl.mcmaster.ca/tomflem/altmed.html](http://hsl.mcmaster.ca/tomflem/altmed.html)]

MEDLINEplus [[www.medlineplus.gov](http://www.medlineplus.gov)]

National Cancer Institute's CancerNet Treatment Options: Complementary and Alternative Medicine [[cancernet.nci.nih.gov/treatment/cam.shtml](http://cancernet.nci.nih.gov/treatment/cam.shtml)]

National Center for Complementary and Alternative Medicine [[nccam.nih.gov/nccam](http://nccam.nih.gov/nccam)]

National Institutes of Health's Office of Dietary Supplements [[dietary-supplements.info.nih.gov](http://dietary-supplements.info.nih.gov)]

Quackwatch [[www.quackwatch.com](http://www.quackwatch.com)]

Rosenthal Center for Complementary and Alternative Medicine  
[[cpmcnet.columbia.edu/dept/rosenthal](http://cpmcnet.columbia.edu/dept/rosenthal)]

University of Wisconsin-Madison, Health Resources Library [[healthweb.org](http://healthweb.org)]

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# Alternative-medicine safeguards

In our cover report, "The mainstreaming of alternative medicine" (page 17), we quote a New York City heart surgeon who suggests that medical school does not teach every single thing about healing.



Our exclusive survey of CONSUMER REPORTS readers, the backbone of our report, shows that a sizable number of patients—and their doctors—now have a positive attitude toward alternative therapies. But as closed minds open and people become more willing to try alternatives, serious questions about the safety and efficacy of such treatments remain and must be addressed.

Consumers in the U.S. pretty much assume that their food and medicines are safe—as well they should. Federal law requires prescription drugs and conventional over-the-counter medications to be proved safe and effective before they are marketed. Unfortunately, that's not the case with herbal remedies. They are among the more popular alternatives, but they're currently classed as nutritional supplements, not medicines.

When you shop for a nutritional supplement, you should have—but you don't—the right to know the following:

- ▶ Is the product safe?
- ▶ Will the herb headlined on the label actually be present in the package?
- ▶ Can you be sure the product will be consistent from bottle to bottle?
- ▶ Is the recommended dosage sensible?
- ▶ Can the product interact adversely with other medications?

Today, the Food and Drug Adminis-

tration doesn't have the power to provide that protection.

Consumers are helped by safety protection, informative product labeling, and straightforward advertising claims. I've met precious few people who prefer to choose blindly. Yet we're forced to do that with supplements. The FDA's authority has been severely restricted, leaving companies free to manufacture supplements however they choose and to make largely unmonitored claims for them.

We believe the FDA should have the authority and funding to establish basic rules regarding herbal and nutritional supplements, to require appropriate labeling, to establish consistent manufacturing standards, and to require reasonable evidence of safety.

Responsible manufacturers agree, and are asking the agency to require companies to meet what are called good manufacturing practice rules. "We need to be able to say this is a well-regulated industry," says an official of a trade group representing supplement makers.

Consumers have won a high level of safety for their food and drugs, and a high level of protection against misleading ads. Reputable sellers of dietary supplements are trying to meet those same standards for safety and honesty. We should recognize that more and more people believe supplements are useful remedies, and ensure that they are safe and effective.

*Rhoda H. Karpatkin*

Rhoda H. Karpatkin  
President

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Monthly newsletter with travel values. \$39 a year. For details, see page 42.

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to CU will help us preserve the critical information that have helped guide consumers for 64 years. For information about leaving a contribution to CU in your will, contact CU Fundraising Dept., 101 Truman Ave., Yonkers, N.Y. 10703-1057



# The mainstreaming of Alternative medicine

More than 46,000 CR readers rate standard and alternative therapies for common medical problems.

**T**he Berlin Wall that has long divided alternative therapies from mainstream medicine appears to be crumbling. Acupuncturists, hypnotists, massage therapists, and meditation instructors are now working at new complementary centers attached to major hospitals. And many conventionally trained doctors have learned to be sympathetic, not scornful,

when their patients say they're trying alternative therapies.

As late as 1998 a national survey published in the *Journal of the American Medical Association (JAMA)* reported that patients did not tell their doctors about 60 percent of the unconventional treatments they used. Indeed, "unmentionable" seemed to be part of the meaning of "alternative" therapy, which was traditionally defined as treatments not generally part of standard medical care. But today, leading medical journals refer to alternative treatments as "complementary" or "integrative" medicine—and the terms are more than mere euphemisms. Now a new survey of *CONSUMER REPORTS* subscribers suggests that the era of "don't ask, don't tell" is coming to an end. Some 60 percent of the readers we surveyed who used alternative therapies did tell their doctors about it.

In our survey—the largest and most detailed study of alternative-medicine use in North America that we're aware of—our readers reported on and rated their experiences with a wide range of alternative and mainstream therapies. We asked them to tell us about the two worst medical conditions they experienced in the past two years, what they did to treat them, and how they rated the results. More than 46,000 readers responded. Among them were more than 16,000—almost 35 percent—who had used such alternative therapies as

STETHOSCOPE BY ESPARZA STUDIOS

megavitamins and nutritional supplements (herbals and natural body compounds); deep-tissue massage (rolfing, myofascial release, neuromuscular massage); chiropractic manipulation and acupressure; and mind-body treatments such as meditation and relaxation therapy. Some got these treatments through their regular doctor or an alternative practitioner. Nearly half tried new remedies on their own—most often the exploding category of herbals.

Overall, 58 percent of conditions were treated with conventional—not complementary—treatments. However, readers report that 25 percent of conditions were treated with both conventional and complementary therapies. Just 9 percent used alternatives only. The remaining conditions were treated primarily with over-the-counter drugs or lifestyle changes (exercise and diet).

This survey is not a clinical test of the worth of any type of therapy; it's a report on the real-life experiences of CONSUMER REPORTS readers. The survey's large size allowed us to do something unique: report on which therapies this group of well-educated, information-seeking CONSUMER REPORTS readers say helped—and didn't—for such common medical conditions as back pain, high blood pressure, insomnia, and respiratory infections. (See "Treating Ten Common Medical Conditions," page 20.) All statements comparing treatments in this article reflect statistically significant differences in reader response. A validation study confirmed that respondents were representative of the universe of CONSUMER REPORTS readers. We did statistical tests to assure there were no biases in treatment response



**Conventional wisdom**  
Howard Beckman, M.D., clinical professor of medicine at the University of Rochester School of Medicine and Dentistry, likes to offer patients a wide range of therapeutic options. "Where evidence exists, physicians should seriously consider integrating complementary therapies into the choices that they offer patients," says Beckman. "They give people who often have few options left in traditional medical care the chance to improve."

caused solely by differences in respondents' age, gender, or severity of illness. The survey offers insights into why many readers are turning to alternative treatments to complement, and sometimes to substitute for, standard medical treatment.

#### AMONG OUR FINDINGS

► The majority of our respondents (65 percent) did not use alternative therapies. The reasons? Most of this group told us they were satisfied with standard medical treatments. Many said they didn't know enough about alternatives, and a smaller group said they distrusted them.

► The 35 percent of readers who did turn to alternatives were looking mainly for relief from troublesome symptoms that had not yielded to conventional treatments. Those who said they were in severe pain or stress were more likely to try alternatives.

► For most medical conditions, the majority who tried alternatives found them very or somewhat helpful. But some highly touted alternatives—melatonin for insomnia, saw palmetto for prostate problems, magnets for pain—scored poorly.

► Despite the boom in alternatives, mainstream medicine is still the people's choice. For nearly all medical conditions, readers said they got the best results from prescription drugs, and from surgery when it was recommended. Even among people who tried herbal therapies, prescription drugs won higher marks for all medical conditions.

► For some difficult-to-treat conditions, notably back and neck pain and the mysterious pain syndrome known as fibromyalgia, some readers said that a complementary approach actually did as well as or better than standard medical practice. In fact, deep-tissue massage was rated significantly more effective than standard physical therapy or prescription drugs for back pain and fibromyalgia.

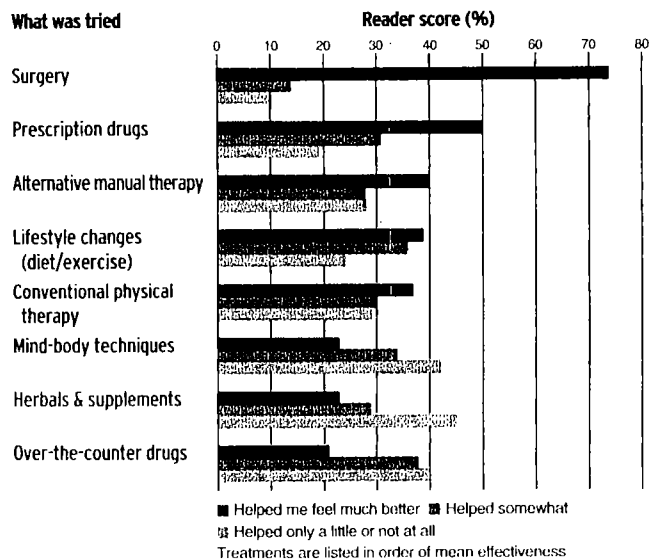
► Most indicative of changing attitudes: When readers felt comfortable enough to tell their doctors about their alternative choices—and 60 percent did—most doctors expressed approval (55 percent) or at least neutrality (40 percent). Only 5 percent of the group said that their doctor disapproved.

► Nearly one of four readers who tried an alternative did so on the recommendation of a doctor or nurse. More than half of those recommendations were for herbals and other supplements, most typically for arthritis and prostate problems. A smaller number of professionals recommended hands-on therapies.

"Some patients may still find themselves rebuffed by physicians for seeking unconventional treatments, but it's getting less and less common," says Mehmet Oz, M.D., a heart surgeon who co-founded the Complementary Care Center at what is now New York-Presbyterian Medical Center. "A lot of physicians are making peace with the

## Reader report card

Our readers told us what helped for a total of 43 medical conditions they experienced (see "Behind the Survey" on page 20 for polling details). In the bar graph below, "alternative manual therapy" includes chiropractic treatment, deep-tissue massage (rolfing, myofascial release, and neuromuscular massage), and acupressure/shiatsu. "Mind-body techniques" include meditation, visualization, progressive muscle relaxation, and biofeedback. We classified exercise and specialized diets as lifestyle changes, not as complementary treatments; we did not inquire about prayer. This summary chart combines results for all medical conditions reported by readers. As the charts on the pages that follow indicate, treatments fared better for some medical conditions than for others.



# State of the art on popular supplements

Supplement studies are usually conducted using pill forms of herbs and body compounds. Interactions of supplements with prescription drugs and with each other are largely unstudied. Recent research has found that some cause unwanted interactions with prescription and over-the-counter drugs. Discuss the situation with your doctor before you combine supplements with medications.

## ECHINACEA

Extracts from the leaves, flowers, and roots of the purple coneflower are among the most widely used botanical products in North America and Europe. A limited amount of test-tube evidence suggests that the herbal stimulates immune processes. Last August, in a review in the *Journal of Family Practice*, researchers concluded that taking echinacea at the first sign of a cold might reduce the infection's duration. But the majority of studies have not found echinacea able to prevent colds. People with an autoimmune disease, such as type 1 diabetes, rheumatoid arthritis, or multiple sclerosis, and people with a suppressed immune system, such as those with tuberculosis, HIV infection, or AIDS, should not take echinacea without consulting their doctor.

## GARLIC

Garlic has been considered a medicinal plant for well over 5,000 years. A component of garlic, allicin, has been shown to inhibit the production of cholesterol by the liver. Population studies have found an association between lower cholesterol levels and increased intake of garlic, onions, and related vegetables. However, over the past five years, only two of eight well-designed clinical trials have found a cholesterol-lowering benefit for garlic supplements. Overall, evidence suggests that it's not worth taking garlic supplements to decrease your blood-cholesterol levels. Adverse effects include mild abdominal discomfort and body and breath odor. There are documented cases of unwanted interactions with the blood-thinning drug warfarin (*Coumadin*).

## GINKGO BILOBA

A 1997 clinical trial found that patients with dementia caused by Alzheimer's disease or ministrokes who took 120 milligrams of

ginkgo biloba extract a day scored somewhat higher on tests of mental performance than those who took a placebo. In most cases, ginkgo appeared to have delayed mental decline; about 20 percent of patients may actually have had a slight improvement. But those effects were modest. At present there's no evidence that ginkgo biloba will cure or prevent Alzheimer's disease or that it will meaningfully improve mental function.

Whether individuals with normal or age-related memory loss might benefit from ginkgo biloba supplements is still unclear. More research is warranted since components of the herb may inhibit formation of potentially dangerous blood clots that may cause ministrokes. Ginkgo biloba appears to be generally safe for healthy people, but it has been shown to interact adversely with blood-thinning medications, such as aspirin and warfarin (*Coumadin*).

## GLUCOSAMINE AND CHONDROITIN

These natural body substances contribute to joint strength and are usually taken together in supplements for treating osteoarthritis. An analysis of 15 studies that was published in the March 15 issue of *JAMA* found a moderate effect on pain relief and improved mobility with glucosamine, and a large positive effect for chondroitin. The researchers caution that some of the studies analyzed may be biased or flawed and expect actual efficacy to be more modest than the studies imply. Comparison studies have shown the supplements to be at least as effective as ibuprofen (*Advil*, *Motrin IB*). There's some evidence that the supplements may actually slow the progression of cartilage loss in affected joints. Supplements may need to be taken for more than a month for full therapeutic effect. The short-term safety profile appears good; analysis of possible long-term adverse effects is under way. There are concerns about drug interactions for people on blood-thinning medications and about harmful effects on insulin resistance, a major cause of type 2 diabetes.

## MELATONIN

This brain hormone helps regulate sleep patterns. While there's evidence that melatonin

supplements can affect the sleep-wake cycle, only a few small clinical trials suggest they can reduce insomnia. The belief that your nighttime melatonin level declines as you age has been challenged by a recent study that found no significant difference in levels among younger and older people. A recent well-controlled trial found the supplement ineffective in reducing symptoms of jet lag.

If you suffer from sleep apnea, melatonin supplements could make your condition worse. Several European countries now regulate melatonin as a prescription drug.

## SAW PALMETTO

This botanical is made from dried ripe berries of the saw palmetto palm tree, indigenous to the Southeastern U.S. It is used for symptoms of prostate-gland enlargement, such as slow urine flow, common in older men. A 1998 review of 18 clinical trials published in *JAMA* found that three-quarters of men who used saw palmetto for two months reported an improvement in their symptoms. A recent trial found saw palmetto as effective as finasteride (*Proscar*) in relieving symptoms. Good comparisons are lacking between saw palmetto and other medications that reduce symptoms of an enlarged prostate: doxazosin (*Cardura*), tamsulosin (*Flomax*), and terazosin (*Hytrin*).

If saw palmetto is going to help, you should notice improvement within a month. Before treating yourself, consult your doctor to rule out other causes of slow urine flow.

## ST. JOHN'S WORT

This perennial herb is grown in many regions of the world, including North America. Short-term studies have found that St. John's wort pills are effective for cases of mild and moderate depression. But the research community—and the public—has been alarmed by the recent finding that the herb might block the therapeutic effect of numerous medications, including birth-control pills. The Food and Drug Administration has issued a public-health advisory specifying that health-care providers should alert patients who are taking St. John's wort and other drugs about the possible loss of therapeutic benefit.



fact that they didn't learn every single thing there is to learn about healing in medical school. Enough physicians are open to these areas of healing that patients will have access if they look around."

Finding the right practitioner to advise you about alternative medicine may be crucial. Readers who tried herbal treatments on the advice of either their health professional or an alternative practitioner were more likely to report good results than those who simply treated themselves. This might be due to the "white coat" effect producing positive expectations of a cure. But given the odd choices of alternatives that some readers made for themselves without guidance—ginkgo biloba for arthritis, garlic for prostate problems, echinacea for allergies—the superior scores may also be because health professionals made more-appropriate choices. For instance, very few doctors recommended magnets for pain, a therapy that a recent small controlled study found to be ineffective.

In our survey, nearly 4 percent of more than 8,000 readers who took herbals and other supplements said they had experienced side effects, such as nausea, drowsiness, and dizziness—but few said the treatments made their condition worse.

Benjamin Druss, M.D., an assistant professor of psychiatry at Yale whose own recent survey of 16,000 U.S. adults shows that complementary treatments are more an "add-on" to conventional care than

a substitute for it, believes the popularity of complementary medicine is part of a larger trend of patients taking increasing interest in choosing their own care. "Paradoxically, as these treatments become more common they're also becoming less 'alternative,'" says Druss. "They are becoming integrated into medical care, into medical-school curricula, and into health-insurance packages."

#### SURGING USE OF ALTERNATIVES

Our readership survey tallied how consumers say they used alternatives to treat specific medical conditions; the use of alternatives for preventive purposes is also common. In all, national telephone polls have found that more than 40 percent of the public—and half of all people ages 35 to 49—have tried alternative measures. Sales of dietary supplements, including vitamins, reached \$14.7 billion in 1999, according to the Nutrition Business Journal, an industry publication. In fact, in 1997 the number of visits to complementary practitioners actually surpassed those to medical doctors, according to a telephone survey reported in JAMA by David Eisenberg, M.D., director of the Center for Alternative Medicine Research and Education at the Beth Israel Deaconess Medical Center in Boston.

"When physicians realized that demand like that was there, more physicians became interested in complementary medicine and began

## Treating ten common medical conditions

### BEHIND THE SURVEY

Our survey shows how readers rated the standard and complementary therapies they used most often for the two most serious or bothersome medical conditions they encountered during the previous two years. Survey questions were included in Consumers Union's 1999 Annual Questionnaire sent to CONSUMER REPORTS subscribers in the U.S. and Canada. We received 46,806 responses; a separate validation study demonstrated that respondents were representative of the universe of our readers.

Seventy percent of the respondents were male; both the men and women tended to have higher education and income levels than the national norms. Our findings may not be directly comparable with other studies for those reasons.

Our survey could not control for the quality of ingredients in supplements, for their dosage, or for the impact of people's expectations (the "placebo effect") on any form of treatment. Only a randomized clinical trial can do that. What our survey reflects is the real-life experiences of a large number of North Americans. Their success or lack of success with nutritional supplements, for example, relates to products most consumers can purchase in local stores, rather than the special preparations often used in clinical studies.

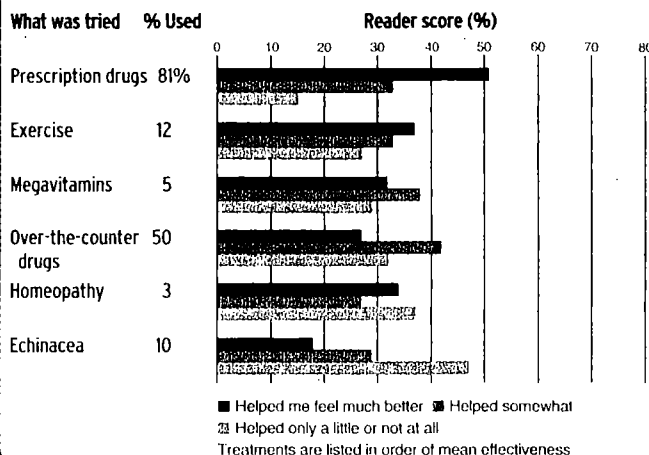
### READING THE BAR GRAPHS

For each treatment they used, readers rated the results on a scale of 1 ("made my condition worse") to 6 ("cured me completely.") The scores for "cured me completely" and "helped me feel much better" are combined in the top bar, "helped only a little" and "did not help at all" in the bottom bar. Since only 2 percent of readers said treatments made their condition worse, and this held steady for all types of therapies, this group was excluded from the graphs. However, treatments are listed in order of their mean effectiveness, a score that combines all six reader-rating categories. Data on surgery are not included in the graphs; where applicable, those findings are noted in the comments for each condition.

### Allergies

**Survey results:** More than 80 percent of readers with allergies tried prescription medicines, the most commonly used remedy; readers also rated them the single most effective treatment. Megavitamins, over-the-counter drugs, and homeopathic medications were deemed less helpful. And echinacea—usually recommended by herbalists for colds, not allergies—was said to be the least effective of all treatments; nearly half of those who used it said it helped little or not at all. Only 3 percent of patients resorted to surgery, such as repair of a deviated septum; half of them said they felt much better afterward.

**Comments:** There are not enough data from good clinical studies on the efficacy of herbal medicines for allergies or asthma, according to a recent review in the Journal of Asthma. Homeopathic treatments have not been adequately studied. Guidelines from the American College of Allergy, Asthma and Immunology recommend prescription steroid nasal sprays as the first-line treatment for allergic rhinitis, particularly when symptoms are severe.



to practice it to some extent," says George Lundberg, M.D., former editor of JAMA and now editor in chief of Medscape, a medical web site. "Insurance companies became pressured to cover some alternative-medicine treatments, and managed-care organizations were pressured by this kind of public demand to offer them as well." Even the American Medical Association, which once ridiculed "fringe" medicine, now hawks in medical journals its new 650-page book on alternative treatments as "authoritative information on today's hottest topics."

All this is largely due to the impact of many Americans voting with their checkbooks. Our survey found that over two years most

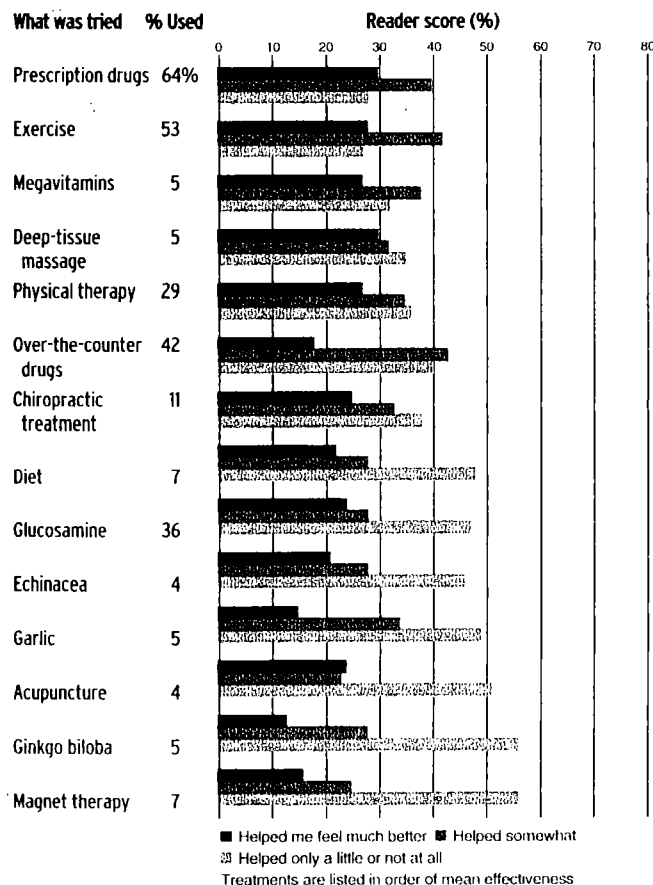
readers who tried them spent up to \$300 on alternative therapies. But 10 percent spent at least \$500 on megavitamins, herbals, and supplements, and 24 percent spent at least that much for such treatments as chiropractic, deep-tissue massage, acupuncture, and homeopathy. Americans have spent about \$27 billion from their own pockets on alternatives, according to Eisenberg's study.

That's a lot of money, considering that clinical trials have only recently begun to separate complementary treatments that may work from those that don't. A small body of clinical studies suggests the worth of some herbal and nutritional supplements (see "State of the Art," page 19). Our survey found that overall, some 23 percent of readers who tried herbals and supplements said they felt much bet-

## Arthritis

**Survey results:** Most readers were helped at least somewhat by the most frequently tried treatments: prescriptions, exercise, and over-the-counter drugs. More than one-third tried the popular dietary supplement glucosamine (now often taken with chondroitin; see "State of the Art," page 19). About half of readers who took glucosamine felt it was somewhat or very helpful, but they evaluated it less favorably than such conventional treatments as prescription drugs and exercise. Most of the patients who tried physical therapy, chiropractic, deep-tissue massage, or megavitamins said they found those treatments at least somewhat beneficial. Magnets and ginkgo biloba were rated less favorably than many other complementary treatments. Of the small percentage of patients who required surgery, most said it helped them feel much better.

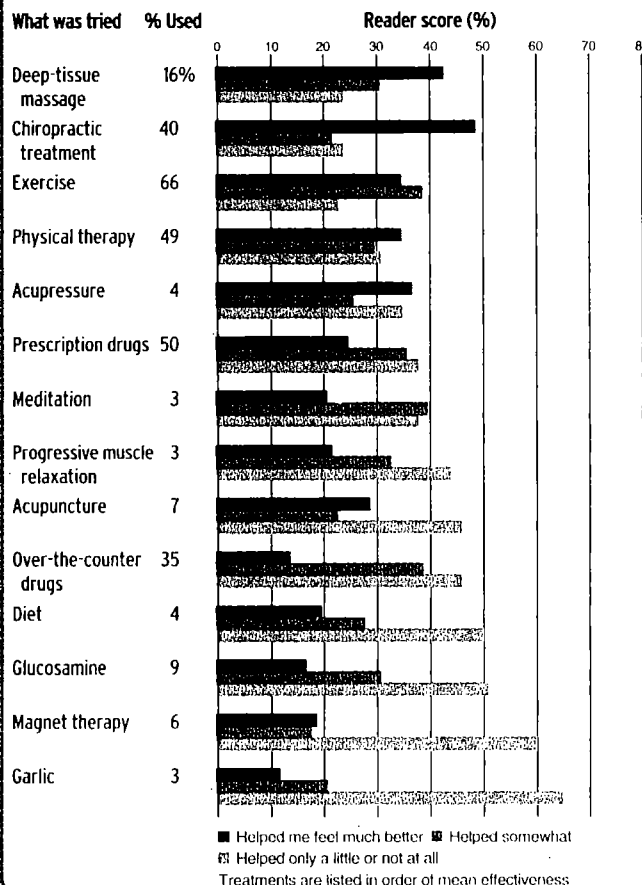
**Comments:** Most people didn't try meditation or other forms of stress reduction, but there is some evidence from clinical studies that these approaches can help ease the pain of arthritis and even improve mobility for some patients. However, it's clear that surgery—usually a hip or knee replacement—is generally the most effective and longest-lasting remedy for severe osteoarthritis.



## Back pain

**Survey results:** Deep-tissue massage, chiropractic treatment, and exercise were among the treatments receiving the highest marks for back pain. Prescription drugs were rated less favorably. Conventional physical therapy and acupressure received comparable scores from readers; each was rated better than acupuncture, diet, glucosamine, and magnet therapy. Readers viewed two mind-body techniques, meditation and progressive muscle relaxation, comparable to prescription medications in effectiveness.

**Comments:** Acute back pain is likely to get better on its own within four weeks, according to major studies. Experts say bed rest should be limited. Some evidence suggests that chiropractic treatments and physical therapy may speed recovery or reduce pain during the first month or so. There's little evidence that acupuncture, glucosamine, magnets, or any other alternative therapy helps much in acute treatment. For some people whose pain persists well beyond four to six weeks, surgery may be an option.



ter as a result, and 29 percent said they felt somewhat better. But more than four of ten readers noticed little if any improvement.

The role of spontaneous recovery and expectations—the “placebo effect”—in evoking positive responses to alternative or mainstream treatments in this survey is unknown. Clinical studies have shown that everything from fake pills to sham surgery and simulated acupuncture can work on some people.

## HANDS-ON THERAPIES

Our readers report that for some conditions, chiropractic care and alternative hands-on therapies were at least as helpful as conventional treatments. Deep-tissue massage is described as releasing chronic muscular tension by using slow strokes across the grain of muscles. Used by 14 percent of our readers who tried alternatives, it was rated significantly more effective than prescription drugs for the treatment of back pain and fibromyalgia.

Just over 25 percent of our readers who used an alternative therapy saw a chiropractor. Forty-three percent of neck-pain patients used a chiropractor, and a majority of them found the manipulation helped at least somewhat. For back pain, chiropractic manipulation was rated more effective than conventional medications and physical therapy. However, readers rated chiropractic manipulation less effective for arthritis, fibromyalgia, and headache than for back pain.

A handful of studies show that medical doctors are referring more patients to chiropractors—once shunned as unscientific rivals. And the American Chiropractic Association reports that its 1997 survey of members found that chiropractors refer 18 percent of their patients to other providers, including 13 percent to medical doctors.

When Stacey Winter, a 33-year-old policewoman from

Rochester, N.Y., experienced shoulder and neck pain so severe that she could barely move her head, she went first to Howard Beckman, M.D., a consultant to our project and clinical professor of medicine and family medicine at the University of Rochester School of Medicine and Dentistry. He recommended neck exercises and offered to prescribe analgesics and anti-inflammatory drugs. But Winter doesn't like taking medications; she worries they'll make her groggy on the job. When her pain did not diminish, she went to a chiropractor recommended by Beckman. Soon, says Winter, “the chiropractor had me back in shape.”

“In trying to help my patients, I want to have as diverse a number of therapeutic options as possible,” says Beckman. “Complementary therapies offer a whole new way for patients to take a more active role in their care and improve their condition.”

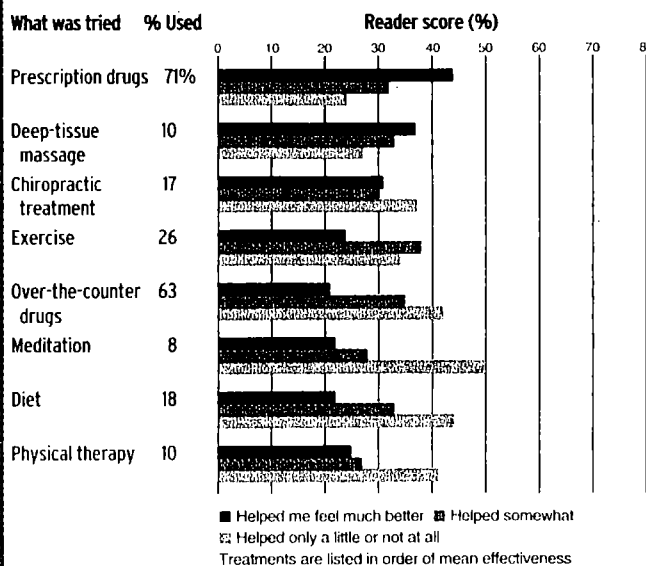
## UNEASY BEDFELLOWS

For interested consumers, the road to finding integrated care can still be bumpy. Sheree Crute of Brooklyn, N.Y., says she was rebuffed by her grandfather Isaac's cancer doctor when she asked about nutritional supplements that she heard could help the 84-year-old tolerate chemotherapy. “I had a family member in pain,” she says, “and the last thing I needed was some arrogant doctor laughing in my face.” Crute talked to a social worker connected with the Memorial Sloan-Kettering

## Headache

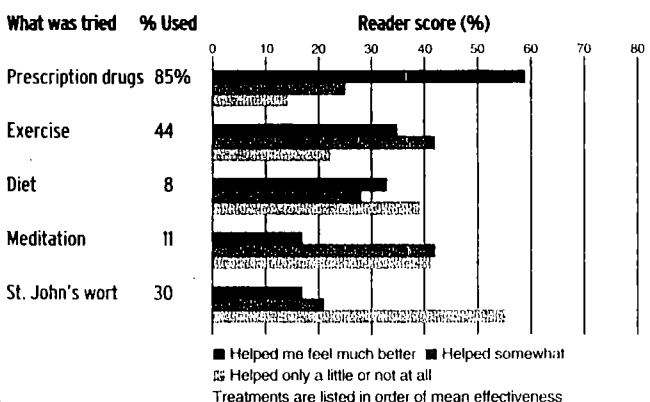
**Survey results:** Prescription medications and over-the-counter drugs were the two remedies most commonly tried by readers. Prescription drugs and deep-tissue massage were among the treatments found most effective. Over-the-counter medications were rated as significantly less effective than prescription medications, especially for severe headache pain. Physical therapy, diet, and meditation were among the treatments viewed as least effective by readers.

**Comments:** Though medications have been proved effective, only a small body of research supports the benefits of complementary treatments for headache or migraine. One small study in the journal *Headache* several years ago found, for patients with recurrent muscle-tension headache, that physical therapy, exercise, massage, and stretching the cervical-spine muscles reduced the frequency and severity of headaches.



**Survey results:** Eighty-five percent of respondents with depression tried prescription medications, which were rated the most effective treatment in our survey. Exercise was seen as the second most effective treatment. Of the 30 percent of patients who tried St. John's wort, most thought the popular herbal remedy helped only a little if at all. In fact, exercise, diet, and meditation were deemed more helpful for depression than the herbal remedy. (We did not inquire about psychotherapy.)

**Comments:** St. John's wort helped far fewer patients for depression than expected, considering that several recent reviews in mainstream medical journals suggest that the nutritional supplement is an effective antidepressant (see “State of the Art,” page 19). However, it came as no surprise that lifestyle changes, including exercise, were deemed helpful. There is now good evidence that diet, aerobic exercise, and resistance exercise do enhance mood.

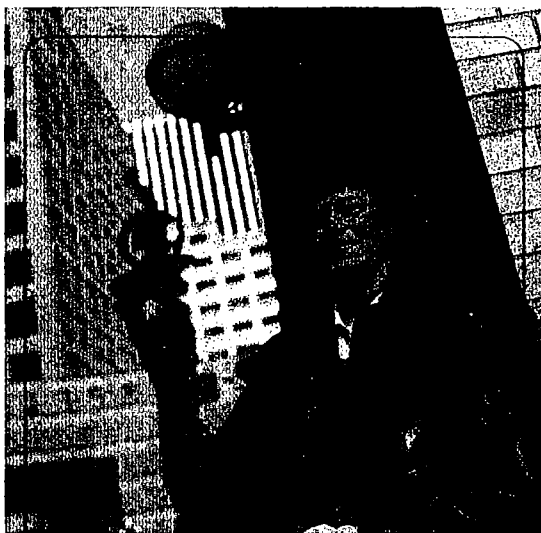


Cancer Center in New York, where the oncologist was affiliated, and learned that the renowned cancer hospital has a complementary-medicine department. "I called and found a nutritionist who stayed on the phone with me for an hour, recommending supplements. The doctor hadn't even mentioned it to me," says Crute.

Barrie R. Cassileth, Ph.D., who runs Memorial's Integrative Medicine Service, says the clinic had only recently opened and, despite heavy publicity, some oncologists apparently hadn't yet heard the word.

The growing insurance coverage of complementary care is bringing it into the fold, and many in the alternative community and the mainstream medical establishment are shedding their animosity. In the past, alternative practitioners "didn't trust the medical establishment to be open-minded," says Fredi Kronenberg, Ph.D., director of the Rosenthal Center for Complementary and Alternative Medicine at Columbia University College of Physicians and Surgeons in New York. "There was mistrust on both sides," she says. "I think the situation has changed. It's not us vs. them anymore. Everybody wants to find out what works best for whom, when."

While the growing rapprochement between mainstream and alternative practitioners is welcomed by some, others in both communities have doubts. Sheila Quinn, former executive director of the



**Open mind** When neck pain struck, Officer Stacey Winter first saw a medical doctor; then she saw a chiropractor for her initial foray into alternative medicine. "The pain was pretty debilitating, and I had to work the next day," says the 33-year-old policewoman. After chiropractic manipulations, she says, "I was able to move and do what I needed to do."

American Association of Naturopathic Physicians, is troubled by medical doctors administering complementary treatments themselves without enough training. "The problem is when somebody who is not trained in the philosophy or the principles simply adds a recipe to his or her cookbook," she says. "My biggest fear is not so much that they'll do anyone harm as that they will lead people to underestimate the power of the medicine because they are not using it in harmony with all the other pieces that bring synergy to the process."

John Renner, M.D., president of the National Council for Reliable Health Information, a nonprofit group that exposes medical quackery, is concerned that physicians are turning their backs on science and pandering to patients' wishes for complementary treatments. "It's the easiest thing in the world to give patients what they want," he says. "But if

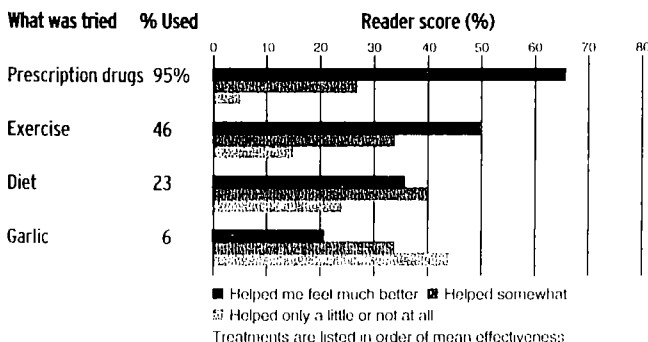
doctors cater too much, patients are going to end up not trusting them when they find out the truth—and the truth is out there. I'm bothered when I hear that there's some synergistic thing about taking 13 herbs together because they put the sun, the moon, and the stars in the right alignment." Renner argues that the scientific method should prevail. "We've got to have some reason—some level of effectiveness—before we recommend different therapies," he says.

PHOTOS OF BECKMAN AND WINTER BY WAYNE CALABRESE

## High blood pressure

**Survey results:** Ninety-five percent of respondents with high blood pressure took prescription medications, which were rated the most effective treatment. Exercise came in second. Only a small proportion tried the popular nutritional supplement garlic, which was rated least effective.

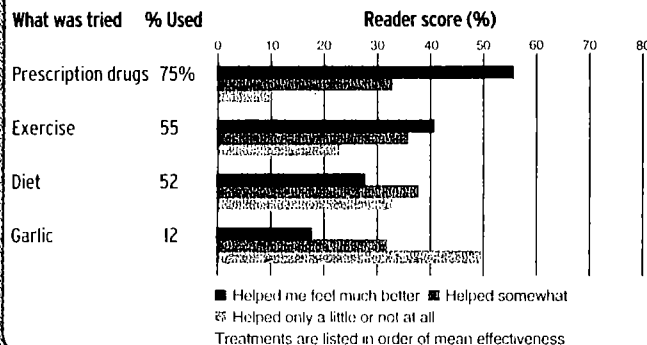
**Comments:** Since even mild hypertension is hazardous, it's important to treat all cases aggressively, often with medication as well as lifestyle measures such as diet and exercise. In fact, regular moderately intense aerobic exercise sometimes produces lasting reductions in blood pressure. (But avoid heavy lifting; straining raises blood pressure and can damage the blood vessels.) It's not yet clear whether garlic can lower blood pressure, but investigations are ongoing.



## High cholesterol

**Survey results:** Three-quarters of patients with high cholesterol tried prescription drugs, which they found more effective than all other treatments. More than half tried exercise, which was rated the second most effective treatment, and diet. Of the small proportion who tried garlic supplements, however, half said that garlic had little or no effect; it was judged less effective than all other treatments.

**Comments:** There's a smattering of evidence linking a high dietary intake of garlic with a small reduction in cholesterol (see "State of the Art," page 19). There's suggestive evidence that adding soy to the diet may lower lipid levels as well. Prescription drugs, such as atorvastatin (*Lipitor*), pravastatin (*Pravachol*), and simvastatin (*Zocor*), are effective in reducing cholesterol. Pravastatin and simvastatin have also been shown to reduce the risk of heart attack.





**East meets West** "I believe in both Eastern and Western medicine," says Sheila George, who is an M.D. and a certified acupuncturist at Memorial Sloan-Kettering Cancer Center's Integrative Medicine Service. She uses acupuncture needles for everything from treating arthritis, lower-back pain, and postoperative pain to strengthening patients' immune systems. "Some of the oncologists are becoming open to complementary medicine and what I do," she says. As for the rest, George muses, "I think it's only a matter of time."

A number of alternative health techniques are based on concepts that many scientists may view as metaphysical and not subject to proof. These include theories that the body has energy paths ("chi") that can be influenced by herbals, acupuncture, and acupressure; the concept of the spine as the locus of health (chiropractic); and the use of undetectable amounts of diluted remedies (homeopathy).

There are still many unsettled boundary issues between medical doctors and all types of alternative practitioners. CONSUMER REPORTS recommends that consumers first seek diagnosis and advice from a medical doctor before consulting any alternative practitioner. For some, hands-on therapies, mind-body treatments, and nutritional supplements may well prove useful complements to standard medicine. But consumers should not risk delaying detection of serious diseases by turning to alternatives before they've been thoroughly tested and diagnosed.

## WANTED: SERIOUS RESEARCH AND REGULATION

Whether the fragile new alliance of alternative and mainstream medicine proves beneficial to consumers depends, to a large extent, on better testing and standardized manufacturing of herbal and other supplements, and more standardized training and licensing of alternative practitioners. The most pressing issue right now is supplements.

With the Dietary Supplements Health and Education Act of 1994 (DSHEA), Congress largely deregulated the industry. The law assumes that since herbal remedies and body compounds are natural, they present few risks and don't need to be regulated as medicines. Instead the law considers them in the food category and permits them to be sold over the counter as dietary supplements. But reports of the effect of some nutritional supplements on medical conditions suggest that they do, indeed, have druglike effects in the body. Interactions between some herbals and prescription medications

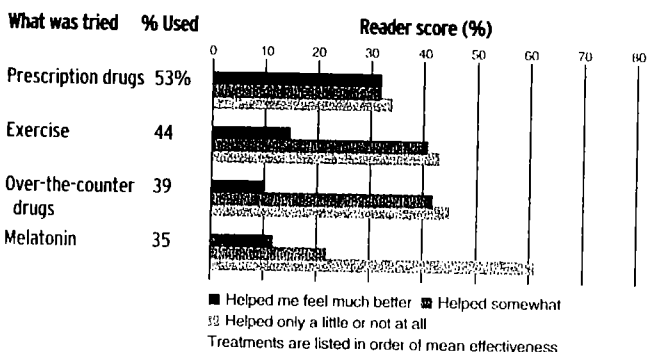
are only now beginning to come to light. In February, for example, the Food and Drug Administration (FDA) issued a warning that St. John's wort, used for mild to moderate depression, may decrease the effectiveness of numerous prescription drugs, including birth-control pills and certain AIDS drugs.

Americans are getting less protection than citizens of some countries where some herbal medicines are standardized and sold as prescription drugs. In the U.S. it's hard for consumers to know if supplements actually contain what's on the label. When CONSUMER REPORTS tested a dozen brands each of ginkgo biloba and echinacea for a March 1999 report, we found wide variations in the amount of those herbals present in different brands—even in different bottles of the same brand. Our 1995 test of ten brands of ginseng also found substantial brand-to-brand variation in the amount of ginseng in the pills.

## Insomnia

**Survey results:** Of the ten medical conditions reported here, insomnia was the least responsive to treatments of any kind, according to respondents. Nonetheless, our readers judged prescriptions to be significantly more effective than other treatments. They judged melatonin less effective than all other treatments, including over-the-counter medications.

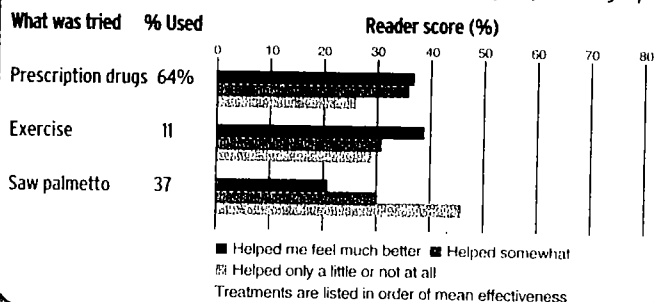
**Comments:** One reason for interest in nondrug alternatives is that chronic use of over-the-counter or prescription sleep aids can lead to drug dependence and side effects from higher and higher doses. Research into melatonin's role is continuing, but a recent Harvard study suggests that melatonin may have less to do with sleep regulation than previous, less well-controlled clinical trials have indicated. (See "State of the Art," page 19.)



## Prostate problems

**Survey results:** About two-thirds of those with noncancerous prostate problems took prescription drugs. Prescriptions and exercise were rated more effective treatments than the herbal remedy saw palmetto, which was taken by one-third of the men with prostate problems. But the herbal remedy helped only about 20 percent of them feel much better; about half thought it did little or nothing. Only a small proportion tried exercise, but two-thirds of those readers thought it helped at least somewhat. Nearly one in four patients needed surgery, which helped the vast majority of those readers feel much better.

**Comments:** Our readers did not find saw palmetto as effective as some clinical trials would suggest (see "State of the Art," page 19). A recent Harvard study showed that brisk walking helps reduce the risk of prostate enlargement by about 25 percent. Studies have also found that symptoms sometimes improve on their own. Severe symptoms that don't respond to medications or other treatments may require surgery.



"The FDA was absent in the four years after DSHEA was enacted," says Bill Soller, a senior vice president with the Consumer Healthcare Products Association, a trade group representing supplement and over-the-counter drug manufacturers. "If the FDA had taken action to establish Good Manufacturing Practices (GMPs) and a strong enforcement program, we would be better off today." Industry and consumer groups hope the GMPs will help the supplement industry clean up its act.

The FDA promises to propose GMPs for nutritional supplements by September and blames the delay thus far on limited resources—a lean budget and minimal staff in the nutritional-supplement area. "We'd be in a better position if we had GMPs," says Joe Levitt, who heads the FDA's Center for Food Safety and Applied Nutrition. But even more fundamentally, he says, "we'd be in a better position if we had a stronger scientific basis beneath this entire category of products."

As we go to press, Congress is taking a second look at DSHEA. The Nutraceutical Research and Education Act was introduced last year by Rep. Frank Pallone (D-N.J.), who says it is "an answer to the chief problem cited by critics of the supplement industry—the lack of a rigorous system for verifying the safety and claims of dietary supplements and other alternative health products." It restores some of the FDA's regulatory oversight of supplements and provides incentives for manufacturers to conduct clinical studies on their products' safety and effectiveness.

At the same time, however, Congress will also consider the Dietary Supplement Fairness in Labeling and Advertising Act, which would not only take the supplements industry even further beyond

the regulatory reach of the FDA but also limit the Federal Trade Commission's power to police the industry's advertising claims.

It's not yet clear whether regulators or deregulators will win the day. But the current free-for-all market has some clear dangers for consumers. For example, the FDA recently warned people with diabetes not to use five brands of Chinese herbal products. The reason: The herbs illegally contained prescription drugs that could cause dangerous reductions in blood sugar. The FDA is also analyzing reports linking a weight-loss and energy supplement, ephedra (ma huang), to heart attacks, strokes, seizures, and fatalities in otherwise healthy adults. Another concern: A recent Washington Post investigation found that state poison-control centers are receiving adverse-reaction reports for some supplements; many of the cases involve children under 6 who were accidentally exposed to supplements. CONSUMER REPORTS agrees with Jane Henney, M.D., commissioner of the FDA, who last year testified before Congress that the agency's challenge is to "strike the right balance between preserving consumers' access to both products and information, and assuring the safety and proper labeling of all of these products."

The need to develop basic safety information on alternative remedies and techniques is clear to many mainstream and complementary practitioners. At the moment there's a rush to fill the information void. The U.S. Pharmacopeia, the nonprofit organization that sets official standards for medical products in the U.S. and Canada, is now producing monographs for professionals on nutritional supplements. The National Institutes of Health's National Center for Complementary and Alternative Medicine, now in its eighth year, is funding nearly \$36 million in research grants. The NIH is also funding 11 alternative research centers; two have opened recently in Chicago and Los Angeles. And the FDA will go back to Congress again this year and push for the \$2.5 million it needs to complete its adverse-reaction database for nutritional supplements.

Self-medication and referrals from alternative and mainstream practitioners were the two routes that led CONSUMER REPORTS readers to use supplements to treat their medical conditions. Practitioner recommendations may lead to better results. Better licensing and credentialing procedures are needed to help consumers identify qualified alternative practitioners among the doctors, naturopaths, herbalists, acupuncturists, nutritionists, and others who practice alternative medicine.

## RECOMMENDATIONS

In the current atmosphere, consumers need to be wary when choosing complementary therapies.

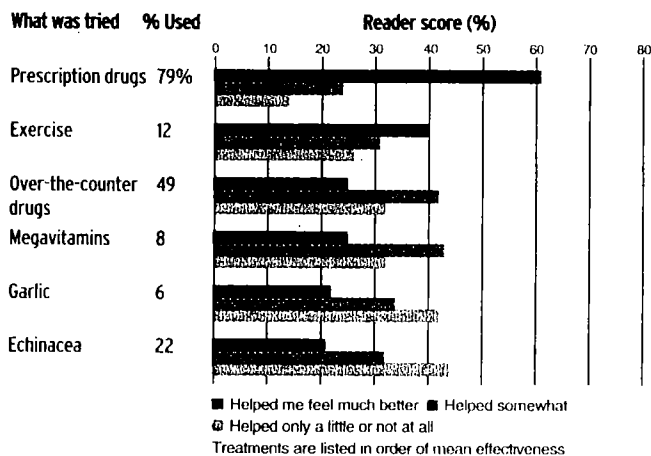
**See your doctor first.** If you're interested in alternatives and your doctor isn't knowledgeable or comfortable discussing them, ask for a referral to someone who is. Find out if there are any alternatives you need to avoid because of your condition or other medications you're taking, including aspirin and other over-the-counter drugs.

**Seek authoritative information.** Professional advice is definitely a plus in guiding consumers to the right alternative choices. The more than 350 hospitals offering complementary services may be able to refer you to prescreened alternative practitioners.

**Keep supplements out of reach of children.** Many supplements are sold without childproof caps. Discuss with your pediatrician before giving a child or adolescent any pill, beverage, or food containing dietary supplements—including those marketed for children. Many of these substances have not been safety-tested. 

**Survey results:** About four of every five readers with respiratory infections used prescription drugs, and most said the drugs helped them feel much better. Prescriptions were rated the most effective treatment. Exercise was rated more effective than echinacea and garlic; those two supplements were among the treatments rated least effective. Almost one reader in four tried echinacea, yet nearly half who did said they felt it helped only a little, if at all. Only a small proportion tried garlic; more than 40 percent of those readers felt largely unimproved.

**Comments:** Though a few studies suggest that high doses of vitamin C might ease cold symptoms slightly, most show no such benefit. The evidence that it can shorten a cold is even weaker. And there's virtually no evidence that it helps prevent colds. One might have expected that more people taking echinacea would have found it effective: A recent review of medical studies found evidence that the herb can reduce the length or severity of the common cold.



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# Emotional 'aspirin'?

We tested what's in the alternative 'mood' pills.

**A**mericans have a long history of altering their moods—with chemicals ranging from alcohol and illicit drugs to prescription medications such as diazepam (*Valium*) for anxiety and fluoxetine (*Prozac*) for depression. Today there's a new trend: the over-the-counter availability of apparently

effective mood modifiers in the form of herbs and other so-called dietary supplements.

Sales of three such do-it-yourself products—St. John's wort, s-adenosyl-methionine (SAM-e), and kava—now approach \$400 million a year, according to the Nutrition Business Journal. Industry and survey data on St. John's wort and kava indicate that most users are merely "looking for something to elevate their mood as a pick-me-up," according to Bernd Wollschlaeger, M.D., clinical assistant professor of medicine and family medicine at the University of Miami. Whether these products have any effect on garden-variety sadness or nervousness is not known, mainly because standard tests aren't sensitive enough to detect any possible impact on temporary bad moods. Experts do say that with the possible exception of kava, these remedies won't elevate a normal, undisturbed mood.

In contrast, there's at least some evidence—ranging from modest for kava to fairly solid for St. John's wort—that these pills can help people with clinically significant mood disorders. In fact, clinical trials have found that SAM-e (a substance in all human cells) and extracts of the plant St. John's wort relieve some types of depression as effectively as a prescription antidepressant. And at least one trial of kava, a Pacific-island pepper plant, suggests it may tame anxiety as effectively as a standard antianxiety drug. (St. John's wort and kava can be made as teas, but whether teas work like pills hasn't been studied. Similarly, it's not known whether the St. John's wort or kava is effective or even safe when added to foods—see "Frontlines" page 8.)

## THE RISKS

One problem is that many people who are treating themselves with these remedies may

be sufficiently anxious or depressed to require professional care and monitoring. Self-treatment can be dangerous, particularly with depression, which causes some 20,000 reported suicides a year in the U.S. In 1999, Cornelia Lange, M.D., of the University of New Mexico Health Sciences Center in Albuquerque, surveyed 83 patients diagnosed

with depression, anxiety, or other psychiatric illnesses and found that more than two-thirds had been self-medicating with herbs such as St. John's wort and kava. (They did not know about SAM-e, which had just hit the shelves.) A major reason, she says, is that "people will do anything to avoid the stigma of seeing a psychiatrist." Another likely reason: While herbal and other alternative remedies can have adverse effects, including harmful drug interactions, they have a reputation of causing fewer significant adverse effects than prescription medications—such as the reduced sex drive caused by fluoxetine (*Prozac*) and other selective serotonin reuptake inhibitors (SSRIs, the most commonly prescribed antidepressants) or the addictive potential of certain antianxiety drugs, such as alprazolam (*Xanax*). However, since dietary supplements have not been studied as intensively as pharmaceutical drugs, it's possible that additional adverse effects

## Tests of St. John's wort pills

Our results were reassuring: All 13 brands contained a reasonably standardized dose of dianthrone, a group of possibly active ingredients. (Our results confirmed that what most labels call hypericin—a member of the dianthrone group—actually refers to the entire group.) Look for the least-expensive brands, as listed below.



Brands listed in order of cost

| ST. JOHN'S WORT CAPSULES<br>(EXCEPT WHERE NOTED)                       | PACKAGE PRICE/<br>NUMBER OF PILLS | DIANTHRONES<br>PER PILL (MG)<br>Labeled/Actual | COST OF<br>DAILY DOSE (1) |
|------------------------------------------------------------------------|-----------------------------------|------------------------------------------------|---------------------------|
| Puritan's Pride St. John's Wort<br>Standardized Extract                | \$5/100                           | 0.9/1.0                                        | \$ 0.15                   |
| Nature's Herbs Power-Herbs<br>St. John's-Power 0.3%                    | 6/90                              | 0.9/1.0                                        | 0.20                      |
| GNC Herbal Plus Standardized<br>St. John's Wort (2)                    | 10/120                            | 0.9/0.8                                        | 0.25                      |
| Spring Valley St. John's Wort 0.3% (Wal-Mart)                          | 5/60                              | 0.9/0.8                                        | 0.25                      |
| Trader Darwin's St. John's Wort Extract                                | 9/100                             | 0.9/1.0                                        | 0.25                      |
| Nature's Way Standardized<br>St. John's Wort Extract                   | 14/90                             | 0.9/0.9                                        | 0.45                      |
| Sundown Herbals St. John's<br>Wort Xtra Advanced Formula               | 9/60                              | 0.9/0.9                                        | 0.45                      |
| Nature Made Herbs St. John's Wort (2)                                  | 10/60                             | 0.9/1.0                                        | 0.50                      |
| Schiff St. John's Wort 300 mg, Mood Support                            | 8/60                              | 0.9/0.7                                        | 0.50                      |
| YourLife St. John's Wort Standardized<br>Herbal Extract, Mood Enhancer | 8/50                              | 0.9/1.0                                        | 0.50                      |
| CVS Herbal Supplement St. John's<br>Wort, Mood Enhancer                | 6/50                              | 0.3/0.4                                        | 0.85                      |
| Nature's Resource Premium<br>Herb St. John's Wort                      | 9/50                              | 0.45/0.5                                       | 0.90                      |
| Nutrillite St. John's Wort with Lemon Balm                             | 36/90                             | 0.9/0.9                                        | 1.20                      |

(1) Cost based on average price paid per package, and on number of pills needed to get about 2.7 mg of dianthrone (equal to 900 mg of St. John's wort extract standardized to 0.3% dianthrone); that's the daily dose used in most of the successful clinical trials. (2) Tablets.



may appear with long-term use.

Another major pitfall is that dietary supplements are largely unregulated by the government, so consumers have almost no protection against substandard preparations. That lack of standardization helps explain why many physicians in the U.S. haven't been recommending those remedies, despite the positive studies. CONSUMER REPORTS' recent tests have found that the amount of certain key ingredients in the supplements saw palmetto, ginkgo biloba, echinacea, and ginseng can vary considerably from brand to brand.

To let consumers and doctors know the actual amount of certain key ingredients in the major mood-changing pills, we tested representative brands of the best sellers: St. John's wort, SAM-e, and kava. We present these findings as a set because many experts now consider depression and anxiety to be interrelated. For example, anxiety can be the first sign of mild depression, and certain antidepressant drugs can also ease anxiety.

We have good and bad testing news to report. For the most part, manufacturers of all three remedies are producing reasonably well standardized products. However, our tests did reveal a significant problem with several SAM-e labels (see box at right).

This report lays out the benefits and risks of these alternative treatments, compares them with conventional medications, and gives our recommendations on when they may be worth considering and what precautions to take. Since most brands we tested turned out to be basically equivalent, we'll also tell you which ones will cost you the least per equivalent daily dose.

#### ST JOHN'S WORT: HERBAL CHALLENGER

Many studies have shown that St. John's wort, the best-selling mood-changing supplement, is effective in relieving mild-to-moderate depression. In September, the British Medical Journal published the impressive results of the largest clinical trial of the herb so far, involving 324 patients. The six-week study, from Germany, found that St. John's wort was therapeutically equivalent to imipramine (*Tofranil*), an older antidepressant that's still moderately popular, and caused fewer intolerable side effects. In theory, St. John's wort may work in multiple ways, including effects on dopamine and other brain chemicals.

In an unprecedented acceptance of an herbal remedy, new treatment guidelines from the American College of Physicians-American Society of Internal Medicine, the nation's largest medical-specialty group,

## Tests of SAM-e pills

Our tests of 12 brands of SAM-e (s-adenosyl-methionine) indicated that manufacturers are generally producing a reasonably stable standardized product. But the labels were often ambiguous, and we considered some misleading. The labels on four brands—*FoodScience of Vermont*, *MotherNature.com*, *Natural Treasures*, and *Nature's Vision*—said they contained 200 milligrams (mg) of SAM-e per pill, but our tests showed that they actually contained 110 mg or less. Apparently, the 200 mg referred not to SAM-e alone but to an entire SAM-e complex, about half of which is a stabilizing compound. (*MotherNature.com*'s label did mention that fact, but only in a small, technically worded note on the side of the bottle.) Those four brands, which contained the least SAM-e per pill, were among the most expensive per daily dose. (Note that three manufacturers said they'll be changing either the label or the amount of SAM-e—see footnotes.) Costs varied widely among all brands, so look for the least-expensive ones.



Brands listed in order of cost

| SAM-E TABLETS<br>[EXCEPT WHERE NOTED]                  | PACKAGE PRICE/<br>NUMBER OF PILLS | SAM-E PER PILL (MG)<br>Labeled/Actual | COST OF<br>DAILY DOSE [1] |
|--------------------------------------------------------|-----------------------------------|---------------------------------------|---------------------------|
| Puritan's Pride SAM-e 200 mg                           | \$18/20                           | 200/240                               | \$1.80                    |
| The Vitamin Shoppe SAMe [2]                            | 19/20                             | 200/240                               | 1.90                      |
| Nature Made SAMe 200 mg [2]                            | 22/20                             | 200/250                               | 2.20                      |
| Natrol SAMe 200 mg [2]                                 | 24/20                             | 200/210                               | 2.40                      |
| GNC SAMe 200 mg                                        | 37/30                             | 200/240                               | 2.45                      |
| Solgar SAMe 200 mg                                     | 44/30                             | 200/210                               | 2.95                      |
| MotherNature.com Enteric<br>Coated SAMe 200 mg [2] [3] | 27/30                             | 100 [4]/110                           | 3.60                      |
| TwinLab SAM-e [2]                                      | 42/20                             | 200/220                               | 4.20                      |
| Nature's Plus SAM-e Rx-Mood [2]                        | 45/20                             | 200/170                               | 4.50                      |
| Natural Treasures SAMe [5]                             | 24/20                             | 200/90                                | 4.80                      |
| Nature's Vision SAMe                                   | 29/20                             | 200/80                                | 7.25                      |
| FoodScience of Vermont SAMe [5] [6]                    | 35/20                             | 200/80                                | 8.75                      |

[1] Cost based on average price paid per package, and on number of pills needed to get about 400 mg, a daily dose used in some successful clinical trials.

[2] Enteric coated for stability and absorbability. [3] Manufacturer says reformulated product will contain 200 mg of SAM-e itself. [4] Labeled 200 mg on front. But side note implies 100 mg. [5] Manufacturer says new product label will show amount of SAM-e itself. [6] Capsules.

have given its members the green light to consider recommending St. John's wort for short-term treatment of mild-to-moderate depression. However, there's no evidence that the botanical will help people who have a severe depression—or who don't have clinical depression but just feel a little blue. The National Institute of Mental Health is now conducting a clinical trial that will put St. John's wort to the crucial test, pitting it against an SSRI antidepressant, sertraline (*Zoloft*); results are due next year.

Taken alone, St. John's wort is generally well tolerated; its only major side effect is increased sensitivity to sunlight. However, the herb does pose one important risk: It can potentially decrease the effectiveness of a host of medications, including oral contraceptives, cholesterol-lowering statin drugs, beta-blockers, and calcium-channel blockers for high blood pressure and coronary heart disease, protease inhibitors for HIV infection, and many other prescription drugs. And it shouldn't be taken with another

antidepressant, since the herb can magnify the medication's effects and side effects.

As for price, the St. John's wort brands we tested cost about \$5 to \$35 per month (which isn't reimbursable) for a 2.7-milligram (mg) daily dose of dianthrones (possibly active ingredients). In comparison, the most popular SSRI, fluoxetine, costs a generally reimbursable \$85 or so, and the generic version of the most popular older antidepressant, amitriptyline, runs about \$20.

#### SAM-E: MOOD MOLECULE?

This omnipresent cellular substance helps cells regulate the brain chemicals dopamine and serotonin. SAM-e is sold over the counter and by prescription in several European countries. Over 40 clinical trials offer some support for using SAM-e to treat various depressive disorders, though many of the studies were very small or brief, or used intravenous SAM-e. The latest study, the largest so far, bolsters the possibility that SAM-e might work even against moderate-to-severe depres-



sion. In that study, a not-yet-published clinical trial from Italy involving 281 patients, SAM-e matched the effectiveness of the antidepressant imipramine, with fewer side effects.

The known side effects of SAM-e are mild—mostly stomach upset, insomnia, and nervousness—though it reportedly can trigger mania, or inappropriate euphoric behavior, so people with manic tendencies should avoid it. SAM-e does not appear to interact with other medications, although it theoretically may increase the effects of antidepressants. Note that SAM-e is expensive: The brands we tested cost roughly an unreimbursable \$55 to \$260 per month for a 400-mg daily dose.

#### KAVA: NATURE'S VALIUM?

The extract of the root of this plant, long used in traditional ceremonies by Pacific islanders, reputedly eases anxiety, elevates mood, and relaxes muscles. Laboratory research suggests that kava may block a nerve-stimulating chemical in the brain or boost the impact of a nerve-inhibiting chemical. Several small clinical trials have found that kava helps curb anxiety. And a six-week German study of 172 patients with anxiety disorders found kava just as effective as the prescription anti-anxiety drug oxazepam (*Serax*).

Kava can magnify the potency of other anti-anxiety medicines and reduce the effectiveness of several other drugs, notably Parkinson's drugs containing levodopa (*Lar-*

*odopa*, *Sinemet*). Though side effects are generally mild, kava can impair coordination and blur vision in some people. So don't take it with alcohol, and use caution if you drive after taking the herb. Kava isn't reimbursable, and the brands we tested cost about 40 cents to \$1.20 for a 200-mg daily dose of kavalactones (the active ingredients), compared with about 50 cents for diazepam, the generic version of *Valium*.

#### RECOMMENDATIONS

Consumers Union's medical consultants advise people who are considering treatment with dietary supplements for depression or anxiety to follow these guidelines:

► **Serious emotional disorders**—particularly depression—should definitely be evaluated by a physician or mental-health professional. Obvious signs of a serious problem include suicidal thoughts; difficulty going to work or school due to distressed moods, anxiety, or fatigue; and significant weight change. Until more study results are in, severe mood disorders should be treated with well-studied medications and/or psychotherapy, not dietary supplements.

► **For mild emotional problems**, some experts feel it's reasonable for people to treat themselves with one of the three mood modifiers, provided they seek help if the trouble persists or gets worse. But distinguishing a mild problem from a serious one can be difficult. Moreover, a professional can suggest treatments you might not have considered. And if you do try a mood-changing supplement, a professional can help you monitor your progress. (That's particularly important if you're taking the pills for more than a few months, since their long-term safety and efficacy are unknown.) Our consultants say the most prudent course is to talk with your doctor before trying such remedies.

► **If you're taking any prescription drugs** and you want to try St. John's wort or kava, ask your doctor or pharmacist to check for possible drug interactions.

► **Optimal dosage** is clearest for St. John's wort. Supplements labeled as containing 600 to 900 mg a day of hypericum extract (St. John's wort)—and standardized to 0.3 percent dianthrones or hypericin (see table introduction on page 60)—have worked in clinical trials. For the other remedies, the daily dosages in successful trials have ranged from 400 to 1,600 mg of SAM-e and 60 to 240 mg of kavalactones.

► **St. John's wort and SAM-e** start working in three to six weeks. Kava takes as little as a half-hour to kick in, so it can be taken intermittently, for isolated bouts of anxiety. ☐

## Tests of kava pills

Our tests determined the amount of kavalactones, the reputed active ingredients, in 15 brands of kava. We found that all 13 brands that claimed to contain standardized extract did contain approximately the amount of kavalactones that their label said. The two powdered-root products, *Spring Valley* and *Botanic Choice*, did not list their kavalactone content. Testing showed that these root products supplied relatively low amounts of kavalactones, even if you took the relatively large maximum number of pills recommended on the label. We advise choosing the least-expensive brands, as shown below.

Brands listed in order of cost

| KAVA-EXTRACT CAPSULES (1)<br>[EXCEPT WHERE NOTED]                         | PACKAGE PRICE/<br>NUMBER OF PILLS | KAVALACTONES<br>PER PILL (MG)<br>Labeled/Actual | COST OF DAILY<br>DOSE (2) |
|---------------------------------------------------------------------------|-----------------------------------|-------------------------------------------------|---------------------------|
| The Vitamin Shoppe Kava Kava Extract (250 mg)                             | \$8/60                            | 75/80                                           | \$0.40                    |
| Sundown Herbals Kava Kava Xtra Advanced Formula (250 mg)                  | 13/60                             | 75/90                                           | 0.45                      |
| CVS Herbal Supplement Kava Kava Standardized Herbal Extract (150 mg)      | 6/50                              | 45/50                                           | 0.50                      |
| Your Life Kava Kava Standardized Herbal Extract (200 mg) (3)              | 9/50                              | 60/70                                           | 0.55                      |
| Nature's Herbs Power-Herbs Kava Kava-Power Standardized Extract (250 mg)  | 9/30                              | 75/90                                           | 0.60                      |
| Nature's Bounty Herbal Harvest Kava Kava (250 mg)                         | 13/60                             | 75/80                                           | 0.65                      |
| Spring Valley Kava Kava Root (450 mg) (Wal-Mart) (4)                      | 5/100                             | Not stated/15                                   | 0.65                      |
| Puritan's Pride Kava Kava 250 mg Standardized Herbal Extract (250 mg) (5) | 23/100                            | 75/80                                           | 0.70                      |
| Botanic Choice Kava Kava (500 mg) (4)(6)                                  | 4/100                             | Not stated/10                                   | 0.80                      |
| Enzymatic Therapy Kava-30 (250 mg)                                        | 16/60                             | 75/80                                           | 0.80                      |
| GNC Herbal Plus Standardized Kava Kava Root (275 mg)                      | 16/60                             | 82.5/80                                         | 0.80                      |
| Nature's Resource Premium Herb Kava Kava Standardized Extract (150 mg)    | 10/50                             | 45/50                                           | 0.80                      |
| Nature's Way Standardized Kava Extract Max 55% Potency (128 mg) (5)       | 18/60                             | 70.4/80                                         | 0.90                      |
| Solaray Kava Kava Two Daily (180 mg)                                      | 33/60                             | 99/110                                          | 1.10                      |
| Natrol Kavatrof Standardized Potency Kava Extract (200 mg)                | 6/15                              | 60/70                                           | 1.20                      |

(1) Kava extract is usually standardized to 30% kavalactones. (2) Cost based on average price paid per package, and on number of pills needed to get about 200 mg, within the range of daily doses used in successful clinical trials. (3) Capslets. (4) Powdered root. (5) Softgels. (6) Tablets.

