Internet Marketing of Herbal Products

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HE DIETARY SUPPLEMENT Health and Education Act passed in 1994 restricted the Food and Drug Administration's (FDA's) control over dietary supplements, leading to enormous growth in their promotion.1 Between 1990 and 1997, use of herbal remedies increased 380% in the United States.² Data from a 1998-1999 survey estimated that 14% of US adults took herbal supplements and approximately 1 in 5 adults taking prescription medications also used an herbal or dietary supplement.^{2,3} In less than a decade, the dietary supplement industry has assumed a substantial proportion of the health market, grossing nearly \$18 billion in 2001.4

The Dietary Supplement Health and Education Act and other more recent regulations^{5,6} defined several types of labeling claims for dietary supplements; examples of these types of claims are shown in TABLE 1.7,8 To satisfy regulatory requirements, claims that describe a relationship between a supplement and a particular condition or disease must be preapproved by the FDA and, similar to drug approval, would entail submission of evidence to substantiate the claims. In contrast, structure or function claims are not preapproved and can be made without submission of substantiating data. However, structure or function claims cannot mention specific diseases and must be accompanied by a standard disclaimer: "This statement has not been evaluated by the Food and Drug Administration. This product is not in-

For editorial comment see p 1519.

Context Passage of the Dietary Supplement Health and Education Act in 1994 restricted the Food and Drug Administration's control over dietary supplements, leading to enormous growth in their promotion. The Internet is often used by consumers as a source of information on such therapies.

Objective To assess the information presented and indications claimed on the Internet for the 8 best-selling herbal products.

Data Sources We searched the Internet using the 5 most commonly used search engines. For each, we entered the names of the 8 most widely used herbal supplements (ginkgo biloba, St John's wort, echinacea, ginseng, garlic, saw palmetto, kava kava, and valerian root). We analyzed the health content of all Web sites listed on the first page of the search results.

Study Selection We analyzed all accessible, English-language Web sites that pertained to oral herbal supplements. A total of 522 Web sites were identified; of these, 443 sites met inclusion criteria for the analysis.

Data Extraction The nature of the Web site (retail or nonretail), whether it was a sponsored link, and all references, indications, claims, and disclaimers were recorded. Two reviewers independently categorized medical claims as *disease* or *nondisease* according to Food and Drug Administration criteria.

Data Synthesis Among 443 Web sites, 338 (76%) were retail sites either selling product or directly linked to a vendor. A total of 273 (81%) of the 338 retail Web sites made 1 or more health claims; of these, 149 (55%) claimed to treat, prevent, diagnose, or cure specific diseases. More than half (153/292; 52%) of sites with a health claim omitted the standard federal disclaimer. Nonretail sites were more likely than retail sites to include literature references, although only 52 (12%) of the 443 Web sites provided referenced information without a link to a distributor or vendor.

Conclusions Consumers may be misled by vendors' claims that herbal products can treat, prevent, diagnose, or cure specific diseases, despite regulations prohibiting such statements. Physicians should be aware of this widespread and easily accessible information. More effective regulation is required to put this class of therapeutics on the same evidence-based footing as other medicinal products.

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tended to diagnose, treat, cure, or prevent any disease." Only drugs can be characterized by statements about disease treatment or prevention and require more stringent FDA approval after a thorough review of available evidence concerning efficacy and safety based on randomized trials. Despite these regulations, there is growing concern in the medical community that the existing legislation inadequately protects consumers from herbal product claims. 9-11

Herbal products are commonly marketed on the Internet, which was used

by approximately 140 million individuals in the United States in 2001.¹² According to the Pew Internet Project for Health, ¹³ 62% of individuals who used the Internet in 2002 sought health information, with approximately half

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seeking information on alternative and complementary therapies. More than half of the Pew survey respondents said they thought "almost all" or "most" online health information they encountered was credible, and only 25% said they routinely scrutinize a health-related Web site's information, references, and sources. More than 4 of 5 Internet users used commercial search engines for their search.

Although the nature of Internet claims for specific products¹⁴ or diseases¹⁵ has been examined, few investigators have systematically analyzed information consumers would find through commonly used Internet search engines.¹⁶ We conducted an analysis of Internet Web sites to assess the nature of marketing claims for the 8 best-selling herbal products.

METHODS

To examine the information a patient would most likely find if using the Internet to learn about herbal supplements, we used the 5 most commonly used search engines (Google, Yahoo, Ask Jeeves, MSN [Microsoft Network], and AOL [America Online])¹⁷ to search for information on the 8 best-selling (year 2000) herbal products. Listed in order of their gross sales and including 1 or more of their commonly promoted uses, these products were ginkgo biloba (dementia), St John's wort (depression), echinacea (treatment and prevention of infections), ginseng (stress, anxiety), garlic (hyperlipidemia, hypertension), saw palmetto (prostatism), kava kava (anxiety, insomnia), and valerian root (anxiety, insomnia). ^{18,19} We then analyzed the health content of all Web sites listed on the first page of the search results, recording the nature of the site (retail or nonretail), whether it was a sponsored link, and all health claims, disclaimers, and references (any citation of a specific article, chapter, book, or other publication with an identifiable primary source; sources did not have to be peer reviewed).

Additionally, we made note of health claims from the Web site text or links that described the uses or benefits of each product and claims made in the product labeling, linked references, or third-party literature. Two nonphysician research assistants independently categorized each statement according to the FDA criteria for disease claims (Box 1).²⁰ A physician reviewer (C.A.M.) reviewed all discrepant categorizations to establish a final designation.

RESULTS

The Internet searches identified 522 accessible English-language Web sites. Of these, 79 were excluded from final analysis because they did not pertain to oral supplementation (eg, agriculture sites or topical preparations), leaving 443 Web sites pertaining to health-related uses of oral herbal products; some were duplicate listings found by different search engines (TABLE 2).

A total of 338 (76%) of the Web sites either sold product or directly linked to a vendor. One hundred twenty (27%)

were sponsored sites, which typically have a fee-based arrangement to be featured prominently by a search engine. All sponsored sites either sold products or were directly linked to a retailer. Nonretail Web sites were more likely to include references than retail sites (52/105 compared with 73/338, *P*<.001), although only 52 (12%) of the 443 Web sites provided referenced information without a link to a distributor or vendor.

Among the Web sites that either sold product or linked directly to a vendor, 273 (81%) of 338 made 1 or more claims regarding health. Of these sites, 149 (55%) claimed to treat, prevent, diagnose, or cure specific diseases (κ for reviewers = 0.67). These statements were often explicit assertions that the product was useful in treating a disease; examples are listed in Box 2. Important clinical information was often omitted: 24 (39%) of the 62 kaya kaya retail sites failed to mention an FDA advisory from March 2002 linking the supplement to fulminant hepatic failure,²¹ and 11 sites proclaimed the herb to be safe with few or no adverse effects

Among all sites with health claims, the standard FDA disclaimer was omitted in more than half (153/292 [52%]). Compared with retail sites, a lower percentage of nonretail sites carried the required disclaimer (3/19 [16%] vs 136/273 [50%]). However, because retail sites were far more common, they comprised most sites without disclaimers.

Tabl	e 1. Types of	Dietary Suppl	ement Claims Re	ecognized and	Permitted by	the Food a	and Drug Administration ^{5,6}
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Type of Claim	Definition	FDA Preapproval Required	Acceptable Examples
Health	Approved claims of relationships between a nutrient and a disease or condition, provided certain other components to the claim are included	Yes	"A diet with enough calcium helps teen and young adult white and Asian women maintain good bone health and may reduce their high risk of osteoporosis later in life"? "Healthful diets with adequate folate may reduce a woman's risk of having a child with a brain or spinal cord defect".
Nutrient content	Descriptions of the relative amounts of a nutrient in a product, as per specific FDA regulations	Yes	Low in sodium, fat free
Structure or function	Role of a nutrient intended to affect the structure or function in humans or that characterize the documented mechanism by which a nutrient acts to maintain such structure, provided that such statements are not disease claims	No	Saw palmetto supports prostate function Echinacea helps to maintain immune function

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COMMENT

This systematic analysis of prominent herbal product Web sites revealed that most available information derives from vendor sites and nearly half of these sites make claims that these products can treat, prevent, diagnose, or cure specific diseases. These were not obscure Web sites but were located on the first page of search results using the 5 most commonly used Internet search engines. These herbal products are widely used, and each has sales exceeding \$50 million a year. The standard disclaimer that health claims have not been evaluated by the FDA and that the product is not intended to diagnose, treat, cure, or prevent disease was omitted on just more than half of the sites that made health claims. Physicians should be aware that there exists no adequate mechanism to protect their patients from such widespread medical misrepresentation.

The results of our Web site review are worrisome for several reasons. Unsubstantiated health claims are unethical and potentially dangerous to patients who might use these treatments instead of therapies with proven efficacy. This is particularly true if sweeping indications are listed and dramatic results promised, as is characteristic of many of the sites reviewed. We also found an abundance of claims that, although supported by some evidence, are still unauthorized. For example, some data suggest that St John's wort

is helpful in mild depression²² and that saw palmetto may alleviate the symptoms of benign prostatic hypertrophy.23 Nevertheless, only drugs that have federally reviewed data on safety and long-term effects may make these disease-modifying claims.

Another troublesome trend is the citation of third-party literature by manufacturers. The FDA mandates that thirdparty literature must be "truthful, nonmisleading, and present a balanced view of the available scientific information,"1 but this definition does not de-

Box 1. Criteria by Which the Food and Drug Administration Considers Claims to Diagnose, Mitigate, Treat, Cure, or Prevent Disease*

- 1. Has an effect on a specific disease or class of diseases
- 2. Has an effect, using scientific or lay terms, on 1 or more signs or symptoms that are recognizable to health care professionals or consumers as being characteristic of a specific disease or of a number of different diseases
- 3. Has an effect on an abnormal condition associated with a natural state or process, if the abnormal condition is uncommon or can cause significant or permanent harm
- 4. Has an effect on disease through 1 or more of these factors:
 - Name of the product
 - Statement about the formulation of the product, including a claim that the product contains an ingredient that has been regulated by the Food and Drug Administration as a drug and is well-known to consumers for its use in preventing or treating disease
 - Citation of a publication or reference, if the citation refers to a disease use
 - Use of the term disease or diseased
 - Use of pictures, vignettes, symbols, or other means
- 5. Belongs to a class of products that is intended to diagnose, mitigate, treat, cure, or prevent a disease
- 6. Is a substitute for a product that is a therapy for a disease
- 7. Augments a particular therapy or drug action
- 8. Has a role in the body's response to a disease or to a vector of disease
- Treats, prevents, or mitigates adverse events associated with a therapy for a disease and if the adverse events constitute diseases
- 10. Otherwise suggests an effect on a disease or diseases

*Source: Federal Register.20

Table 2. Number and Type of Web Sites Found for Each Herbal Supplement

	Herbal Supplement								
	Ginkgo	St John's Wort	Echinacea	Ginseng	Garlic	Saw Palmetto	Kava Kava	Valerian	Total*
2000 Sales, in millions, \$18	290	235	211	187	176	114	69	57	1339
Internet sites identified	49	49	65	52	73	72	81	81	522
Excluded sites	8	1	13	8	38	2	7	2	79
Retail sites	21	29	36	34	35	56	62	65	338
Vendor sites	16	20	28	33	35	49	47	65	293
Sites directly linked to vendor sites	5	9	8	1	0	7	15	0	45
Referenced†	7	15	6	5	20	7	7	6	73‡
Sponsored sites§	10	16	15	11	9	25	18	16	120
Nonretail sites	20	19	16	10	0	14	12	14	105
Referenced†	5	11	10	6	0	7	7	6	52‡

^{*}Includes duplicate listings found by different search engines and duplicate listings found by the same search engine as both sponsored and unsponsored results.

[†]Any citation of a specific article, chapter, book, or other publication; not necessarily peer reviewed. ‡Referenced nonretail sites (52/105) vs referenced retail sites (73/338) (P<.001).

^{\$}Sites prominently featured in search results through an agreement with a search engine.

Box 2. Sample Disease Claims From Herbal Product Web Sites

Ginkgo Biloba

"Its effects in improving circulation also contribute to its use for impotency and peripheral vascular insufficiency. . . . Ginkgo treats depression, headaches, memory loss and ringing in the ears (tinnitus). It is also recommended for Alzheimer's, asthma, eczema, heart and kidney disorders."

St John's Wort

"St John's wort is effective in the treatment of mild to moderate depression . . . recent studies have shown that it could have a potent anti-viral effect against enveloped viruses."

Echinacea

"Because it has natural antibiotic actions, Echinacea is considered an excellent herb for infections of all kinds. In addition, it works to boost lymphatic cleansing of the blood, enhances the immune system and has cortisone like properties which contribute to its anti-inflammatory action. It is recommended for stubborn viral infections, yeast infections and for arthritic conditions."

Ginseng

Q: "(I have) high blood pressure (170/90). Will American ginseng lower blood pressure and if so, how much should one take and how long before results show?" A: "While American Ginseng will help, we have a combination product that will do a much better job. Look at product #1960 American Ginseng/Garlic/Tien Chi. This is a great product."

"It is potentially beneficial for AIDS, radiotherapy, and chemotherapy patients, as it reduces the side effects of toxic drugs by increasing red and white blood cell counts. Dang Shen is given for breast cancer, asthma, diabetes, heart palpitations, memory or appetite loss and insomnia."

Saw Palmetto

"The lipophilic extract of the saw palmetto (ser repens) berries is the most widely used herbal preventive and therapeutic agent for benign prostatic hyperplasia (BPH)."

Kava Kava

"It is a valuable urinary antiseptic, helping to counter urinary infections and to settle an irritable bladder. . . . Kava kava's analgesic and cleansing diuretic effect often makes it beneficial for treating rheumatic and arthritic problems such as gout."

Valerian Root

"The herb valerian is most effective in treating a wide range of stress conditions such as irritability, depression, fear, anxiety, nervous exhaustion, hysteria, delusions, and nervous tension. . . . The herb is useful for treating shingles, sciatica, neuralgia, multiple sclerosis, and epilepsy."

ter vendors from using highly dubious references. For example, one retailer-linked resource was a 1931 reference recommending St John's wort for "pulmonary complaints" and advocated comfrey, an herbal product linked to hepatotoxicity, ²⁴ "for all pulmonary complaints, consumption and bleeding of the lungs . . . to be taken every two hours till the haemorrhage ceases." ²⁵

Passage of the Dietary Supplement Health and Education Act in 1994 restricted the FDA's control over oral supplements and made it easier for manufacturers to make health claims and harder for regulatory agencies to prevent them. For example, supplement manufacturers are not required to submit supporting data to the FDA in advance of marketing, as is required of prescription drug manufacturers. The responsibility for policing fraudulent Internet claims became a daunting postmarketing task for federal agencies. The FDA, which primarily regulates product labeling, and the Federal Trade Com-

mission, which is responsible for advertising, have both pursued Internet vendors, with limited success. A joint initiative, "Operation Cure.All," which targets Internet supplement marketers that make unsubstantiated claims, recently generated 280 advisory letters, which informed retailers that their Web site claims must be supported by scientific evidence. This initiative has resulted in legal action against companies by the Federal Trade Commission for deceptive advertising. 27,28

However, although both agencies have regulatory power to cite unscrupulous vendors, a reliance on postmarketing surveillance by overwhelmed federal agencies is unlikely to halt the proliferation of unsubstantiated medical claims. The fact that our survey found so many such statements after the recent "Operation Cure.All" Internet "surf" demonstrates the inadequacy of relying on post hoc enforcement; the anonymity and ease of Internet marketing allow new violators to rapidly fill any resultant voids.²⁹

The volume of Internet claims found is particularly troublesome at a time of reduced enforcement of regulations concerning the promotion of prescription drugs. ^{30,31} Expecting patients to assess a Web site's medical accuracy (a buyer beware strategy) is also problematic. Although there are tools available for evaluating the quality of health-related Web sites, ^{32,33} it is unlikely that most consumers regularly use such strategies while perusing information on the Internet.

Ineffective premarketing regulations, a reliance on postmarketing regulation, a proliferation of manufacturers, and the public's misperception of a regulated industry³⁴ all contribute to an inadequate regulatory framework in which the public's health is poorly served.³⁵ Several legislative changes have been suggested to remedy the situation, including mandatory registration of supplement manufacturers and vendors, required evidence of efficacy and safety before marketing, mandated adverse event reporting by manufacturers,⁹ and standardization of purity and potency.³⁶

Additional efforts are needed to clarify the blurred distinctions be-

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tween labeling and advertising on the Internet. Clearer identification is needed concerning federal responsibility for supplement advertising, perhaps including mandatory review of all advertisements that contain real or implied health benefits. The required FDA disclaimer is of limited utility even when present because it does little to undo the much more prominent statements about these products' purported curative properties. A recent study found that more than half of supplement users believed that advertising related to their product was "generally true."37

In light of these concerns, physicians have an important role in educating their patients about supplements and encouraging critical appraisal of claims. Physicians need to include supplement use when taking medical histories and should remind patients that these products need not meet the efficacy, safety, and potency standards required of prescription drugs. Patients should be warned about misinformation on retail Web sites, including sponsored sites. Interested patients can be directed to an FDA Web site for guidance in safely navigating the Internet for dietary supplement information (http://www.cfsan.fda .gov/~dms/ds-savvy.html). Physicians should also be vigilant for potential adverse events from dietary supplements and report these to MedWatch (http: //www.fda.gov/medwatch/report /hcp.htm).

We did not collect evidence that patients believe the specific claims we found on the Internet about herbal supplements or that this information influences individual buying habits. Nevertheless, the Pew Internet Project for Health¹³ reported that a large percentage of Internet users search for health information, use search engines for their searches, and find credibility in what they read, providing a disturbing context for our findings. By using major search engines as points of departure and visiting the highest-ranked sites found by each engine, we used the same strategy a typical patient might use when seeking information about popular herbal products. Some herbal products have demonstrated therapeutic benefits

and toxic effects³⁵; such properties make them similar to prescription and over-thecounter drugs. At a time when increased attention is being focused on the efficacy, safety, and cost of prescription drugs, herbal products should receive the same scrutiny. Physician and consumer vigilance, coupled with more effective regulation, will be required to put these products on the same evidence-based playing field as other forms of treatment.

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