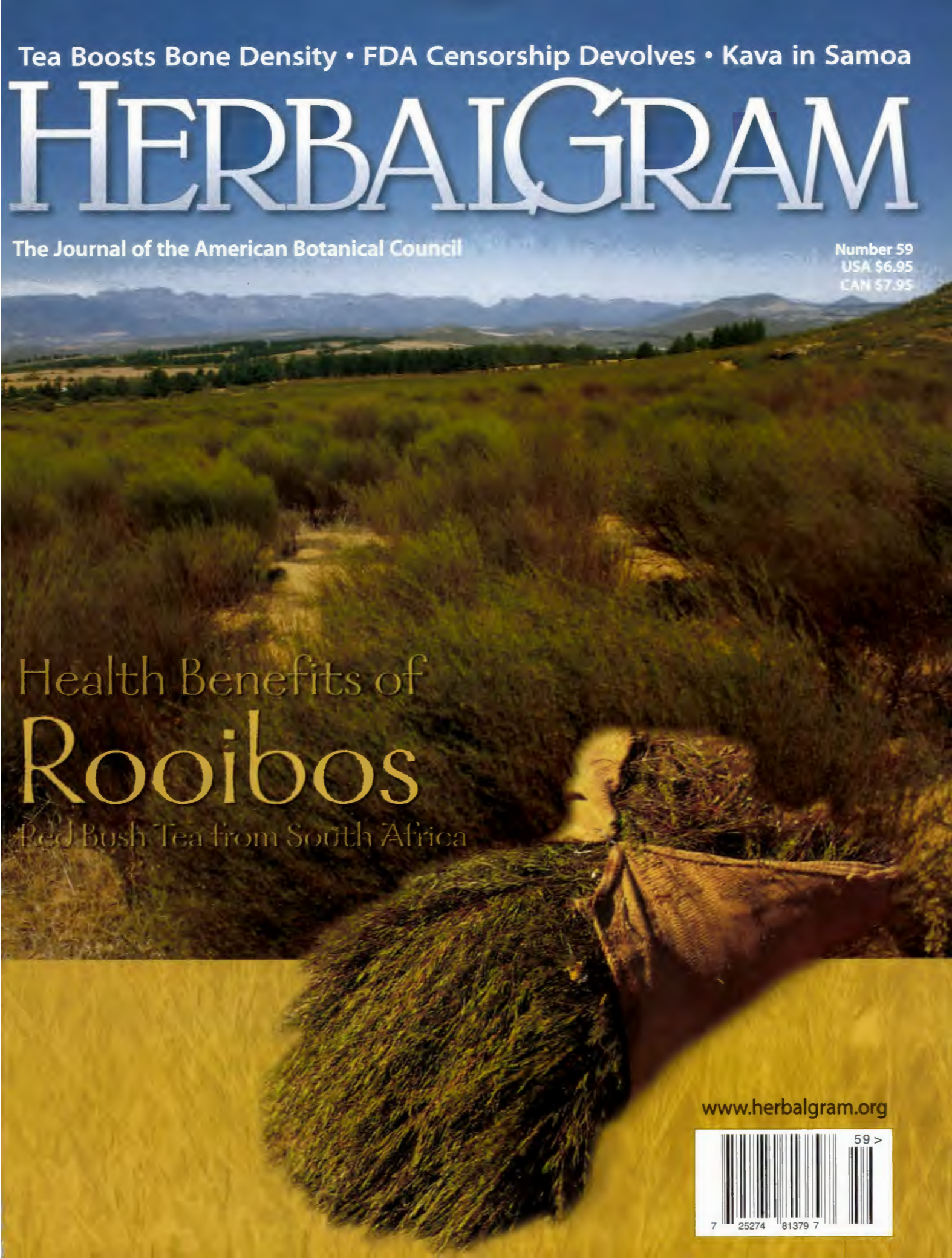
Tea Boosts Bone Density • FDA Censorship Devolves • Kava in Samoa

HERBALGRAM

The Journal of the American Botanical Council

Number 59
USA $6.95
CAN $7.95



Health Benefits of Rooibos

Red Bush Tea from South Africa

www.herbalgram.org

59 >

7 25274 81379 7

Get the Leucoselect® effect.

There's something special about Indena's Leucoselect®. Something we've even been telling your customers directly through a radio campaign. Leucoselect® is the most clinically tested grape seed extract. Its optimal distribution range of oligomers guarantees maximum performance. The proof is in the one hundred per cent chemical characterization that only Indena is able to perform on grape seed extracts. It helps improve vascular function, inhibits destructive enzymes, and is a powerful anti-oxidant that combats the action of free radicals*. In short, Leucoselect® works. That's why it has a powerful effect on customer loyalty. And just as powerful an effect on your business.

*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

www.indena.com **botanicals@indena.com**
Indena S.p.A. – Viale Ortles, 12 – 20139 Milan – Italy – tel. +39.02.574961
Indena USA, Inc. – 811 1st Avenue, Suite 218 –
Seattle, WA 98104 – tel. +1.206.340.6140
Indena USA East, Inc. – 1719 Route 10 East, Suite 311 –
Parsippany, NJ 07054 – tel. +1.973.401.0077

indena
science is our nature™

Nature's Resource® is listening.

Consumers asked for more information to help make educated decisions about herbal supplements.

Nature's Resource is providing it with our new multi-page label called Herbal ABCs™.

- **Multi-page educational booklet** provides safety and usage information for consumers on 21 Nature's Resource herbs.
- Written in a **consumer-friendly** way in a format our consumers can understand.
- A prime example of Nature's Resource's **commitment to educating our consumers.**
- Consumers get the information they need at **no additional cost.**
- Nature's Resource's new bottles with the informational label will be **in stores starting Fall 2003.**

NEW HERBAL ABCs™ LABEL INCLUDES:

- **Herbal Information**
- **Contraindications**
- **Pregnancy & Lactation Guidelines**
- **Adverse Effects**
- **Drug Interactions**
- **Safety Statement**
- **Suggested Other Products**

The new multi-page label is a joint effort of Nature's Resource® and the American Botanical Council.

NATURE'S RESOURCE®
HERBAL SUPPLEMENT

For additional information, call 1-800-314-HERB, or visit www.naturesresource.com

HERBAL ABCs™

Individuals, organizations, and companies who share our vision support our goals through membership.

The American Botanical Council Invites You to

The American Botanical Council is the leading nonprofit education and research organization using science-based and traditional information to promote the responsible use of herbal medicine.

Founded in 1988, the member-supported American Botanical Council works to educate consumers, healthcare professionals, researchers, educators, industry, and the media on the safe and effective use of medicinal plants.

Your membership supports these important programs and services:

- Our highly acclaimed journal, ***HerbalGram***;
- News and information on our website, **www.herbalgram.org**;
- **HerbClip™** provides critical reviews and original copies of seminal news articles drawn from professional and mainstream sources. The HerbClip Online™ database contains more than 2,000 critical reviews and is available in the members-only section of our website;
- **Continuing education for healthcare professionals**: *The ABC Clinical Guide to Herbs* is a reference work and continuing education module. It offers comprehensive monographs, clinical overviews, patient information sheets, a table of clinical studies, studied brands, and other unique features;
- **Media Education Campaign** responds to inaccuracies and misrepresentations in the media and provides proactive, science-based information about herbal medicine through press releases, articles, and media interviews;
- **Education department** supports research projects and answers questions from members, healthcare professionals, media, and industry representatives. We also provide an active internship program for students of pharmacy and dietetics;
- **ABC's home: The Historic Case Mill Homestead** includes education and research facilities, medicinal theme gardens, rain water collection systems, and a state-of-the-art greenhouse;
- **Educational literature:** a range of health and therapeutic information: booklets, pamphlets, reports, and online information that are available to consumers, students, educators, healthcare professionals, and researchers.

If you value the services we provide,
please take a moment to become a member:

Call us at 800/373-7105, x 119

Fill out an application online at www.herbalgram.org

AMERICAN BOTANICAL COUNCIL

Join Us

To join, please fill out this form or and fax or mail or call us at 800/373-7105 x 119 or fill out an application online at www.herbalgram.org

Membership Levels *Please add $20 for addresses outside the U.S.*

Individual - $50

- Subscription to our highly acclaimed journal, *HerbalGram*
- Access to members-only information on our website, www.herbalgram.org
  - *HerbalGram* archives
  - *Complete German Commission E Monographs*
  - *Herbal Medicine: Expanded Commission E Monographs*
  - Botanical Booklet Series
  - Herb Reference Guide
  - Common Herbs Pamphlet
- Free 1/2 hour research session with our Education Department
- 40% discount on additional research from our Education Department
- One complimentary book, *Echinacea: The Immune Herb* by C. Hobbs
- 10% discount on publications from our Herbal Education Catalog
- Membership card

Academic - $100

All Individual membership benefits, plus:

- Online access to :
  - HerbClip™ Online critical reviews
  - HerbMedPro™ evidence-based herbal studies
- Complimentary CD, *Herbal Medicine: Expanded Commission E Monographs* ($39 value)

Professional - $150

All Academic membership benefits, plus:

- 50% discount on first order of ABC publications
- Membership certificate

Organization - $250

For nonprofit organizations, all Professional membership benefits, plus:

- 1 additional subscription to our highly acclaimed journal, *HerbalGram*
- 3 user logins to members-only information on our website, www.herbalgram.org

Corporate and Sponsorship

Small to large organizations can receive additional benefits, including the bi-weekly HerbClip service, and also extend their support of ABC's mission through Corporate or Sponsor level membership. To learn more, please contact Wayne Silverman, PhD, at wsilverman@herbalgram.org, or 800/373-7105 x120.

Yes, I want to join ABC!

Please detach application and mail to: American Botanical Council, P.O. Box 144345, Austin, TX 78714-4345 or join online at www.herbalgram.org

- ❑ Individual — $50
- ❑ Academic — $100
- ❑ Professional — $150
- ❑ Organization — $250

(Add $20 postage for international delivery for above levels.)

- ❑ Corporate and Sponsor levels.

(Contact Wayne Silverman, PhD, 512/926-4900, ext. 120.)

Payment instructions

- ❑ Charge credit card (Visa or MC only)

_____

exp. date: _____

(Please include the 3-digit number following the account # on signature line on back of card.)

_____

- ❑ Send invoice to the address below
- ❑ Check enclosed
- ❑ Do not share my contact info
- ❑ Include me ABC e-mail updates

_____
name

_____
company, organization or agency

_____
profession/title

_____
phone fax

_____
address

_____

_____
city state/province

_____
zip/postal code

_____
country

_____
e-mail

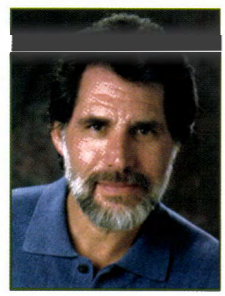
advisory board

Each issue of *HerbalGram* is peer reviewed by members of our Advisory Board and other qualified experts before publication.

dear reader

from the desk of Mark Blumenthal

ABC continues its rollout of strategic educational projects. In our last issue, we introduced the publication of *ABC Clinical Guide to Herbs*, our new book for health professionals. We now introduce our new Safety Labeling Program (SLP), intended for consumers and healthcare professionals alike. SLP was initiated with the help of Pharmavite Corporation for its new expanded labels on its Nature's Resource® line of herbs. The labels contain a 4-page "brochure" that peels back from the front panel of a bottle, offering guidelines for responsible use by consumers. The label text is based on ABC's comprehensive peer-reviewed assessments of the safety literature. These new labels will be on 4 million bottles within a year on 21 Nature's Resource products. SLP labeling is available to other qualified manufacturers. This nonprofit/industry initiative is particularly significant since there are few FDA label guidelines regarding the safety of herb products.



FDA's proposed good manufacturing practices (GMPs) for dietary supplements are causing considerable concern among many industry groups. FDA has based the GMPs upon those for drugs, despite Congressional guidance that they be modeled on food GMPs. The differences are significant in the amount of testing required for ingredients and finished products — the testing is expected to be so prohibitively expensive that even FDA spokespersons are said to have acknowledged that if the proposal is finalized in its present form, several hundred small companies could be forced out of business. Although some industry groups are filing critical comments with constructive suggestions to FDA, industry leaders are careful not to appear to be against the GMPs in general, so as not to appear in the media as "anti-quality," an epithet that no one can afford at a time of continuing negative media articles and mounting Congressional pressure on the industry.

Along these lines, U.S. Senator Richard Durbin (D-IL) has introduced the Dietary Supplement Safety Act of 2003 (S. 722), a bill that, if passed with any of its current provisions, would substantially alter the way the dietary supplement industry conducts business, in addition to the changes required by the Bioterrorism Act (see last issue) and the proposed new GMPs. Sen. Durbin has held several hearings on the safety of ephedra, the new bill being a direct result of his and others' mounting concerns over its safety. S. 722 would require companies to submit reports of all serious adverse event reports (AERs) to the FDA within 15 days, file an annual report of all AERs, obtain FDA approval for the safety of many ingredients, and would require FDA approval of all supplements intended as "stimulants" (except coffee and caffeine). In this sense, the bill takes an interesting strategic step: instead of going after specific individual ingredients used for stimulation or weight loss, the bill targets the entire category. The recent National Nutritional Foods Association convention in Las Vegas was buzzing about

Continues on page 74

HERBALGRAM

Number 59
2003

The Journal of the American Botanical Council

contributors

Anthony Almada
Cindy Bloom
Joan Borel
Gordon Boy
Josef Brinckmann
Christina Chase
Paul Alan Cox
James Duke
Jonathan Emord
Laurie Erickson
Margi Flint
Krisa Fredrickson
Diane Graves
Steven King
Heather Oliff
Diane Ragone
Bill Schoenbart
Sarah Snyder
Patricia Stewart
Gaugau Tavana
Densie Webb
Anthony Young

departments

features

Guest Commentary

On the cover:
Rooibos *Aspalathus linearis.*
Photos ©2003 Rooibos Ltd./ SunnRooibos

HERBALGRAM

The Journal of the American Botanical Council

Mark Blumenthal
Editor / Publisher
Karen Robin
Managing Editor
Sean Barnes
Art Director
Steven Foster
Associate Editor
Maureen Jablinske
Proofreader
Sarah Jackson
Editorial Intern

Advertising Sales
Jared Hensley
Rector-Duncan & Associates Inc.
512/454-5262 ext. 123
jhensley@rector-duncan.com

American Botanical Council

Wayne Silverman, Ph.D.
Chief Administrative Officer

Kathleen Coyne
Sales Coordinator
Cheryl Dipper
Executive Assistant
Stacy Elliott
Receptionist
Gayle Engels
Education Coordinator
Lori Glenn
HerbClip Managing Editor
Tara Hall
Special Projects Coordinator
George Solis
HerbClip Production Assistant
Nate Sponseller
Gardener
Cecelia Thompson
Finance Coordinator
Kim West
Membership/Development Coordinator
Margaret Wright
Accounting Coordinator

Subscriptions are a benefit of membership at every level. One year memberships: Individual $50; Academic $100; Professional $150; Organization $250; Corporate; Sponsor. Add $20 for memberships outside of the U.S. Student, Senior, and Business Memberships also available, see ad in this issue.

ISSN #0899-5648. Printed in the U.S.A.

HerbalGram is printed on recycled paper at Branch-Smith Printing, Ft. Worth, Texas

ABC Expands Safety Information for Herbal Product Labels

by Mark Blumenthal, Gayle Engels, and Wayne Silverman, Ph.D.

Consumers, patients and clinicians, who use or recommend herbal supplements as a part of an integrative approach to healthcare, all face the same dilemma: confidence in herbal supplements has eroded in recent years. This has happened, in part, because of continued negative reports in the media (some erroneous and biased, some warranted). Safety seems to be a key question. In the face of concerns about safety and the preference for additional safety information on the labels of herbal supplements, Pharmavite Corporation approached the American Botanical Council (ABC) to request the development of a program to address these concerns. As a result of this collaboration, ABC launched its Safety Labeling Program (SLP), a program that provides expanded safety information for manufacturers. Pharmavite Corporation is using the SLP information on its Nature's Resource® herbal product labels in a new program called Herbal ABCs™.

ABC's Safety Labeling Program

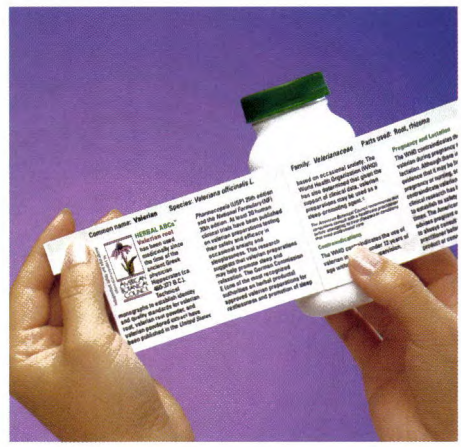
To help bring greater clarity to the safe use of herbs (including potential interactions, adverse effects, and contraindications), and through consumer research, suggestions, and initial funding by Pharmavite, ABC initiated SLP to provide some guidance in this area. SLP provides science-based safety information on specific herbs for manufacturers to use as a basis to develop product labels (see How SLP works, below). This program will benefit consumers and patients, who need more information about the herbs they use, and healthcare professionals, who can use such information to help assess the potential risk and appropriate use of many popular herbs.

First use of SLP

Pharmavite Corporation, which produces Nature's Resource herbs, a brand marketed in mass-market locations, worked with ABC to develop the SLP and is the first company to print expanded label information based on ABC's research and bear the ABC logo. By the end of 2003, approximately 4 million labels on 21 Nature's Resource products will contain peel-back, multi-page safety text based on information provided by ABC. Other manufacturers are also considering participation in the SLP.

Rationale for SLP: Responsible use of herbs

Concern about the safety of herbs and herbal products is one of the most significant issues affecting consumer and healthcare practitioner decisions about use of herbal supplements. Recent survey results show that 50 percent of *all* consumers are concerned about interactions between



supplements and prescription drugs, and 61 percent of herb users are concerned about the same topic.[1] Unless consumers interested in herbal alternatives know where to look for the information, or have a knowledgeable healthcare practitioner with whom they can discuss their questions about herbs, they may have difficulty finding accurate information that explains which herbs are safe for them to use, and how to use them. Likewise, clinicians and pharmacists are increasingly expected to serve as educators when it comes to safety issues. While continuing education on these matters is essential for healthcare professionals, expanded safety information on the label may be an effective part of the overall solution.

Several surveys have suggested that a significant number of people use herbs concurrently with conventional drugs. A *Prevention* magazine survey a few years ago suggested that about one-third of herb users also are taking either over-the-counter (OTC) or prescription (Rx) drugs.[2] In a more recent report of 2,590 participants, 81 percent stated that they used at least one medication (Rx or OTC), 50 percent took at least one prescription drug, and 7 percent took five or more drugs simultaneously.[3] Fourteen percent said they used herbs and supplements while 16 percent of the prescription drug users also take an herbal supplement. The authors concluded that one in seven adults consumes at least one herbal supplement annually and that one in six patients taking a prescription drug is concurrently taking one or more herbal supplements, raising the potential for interactions.

With the potential for herb-drug interactions increasing, how do consumers and health professionals gain access to reliable information on what constitutes a potential interaction? Many interactions reported in the literature are either theoretical or speculative, often based on *in vitro* laboratory data or animal studies, which are inconclusive for humans. A recent systematic review of herb-drug interactions concluded that of the 108 interactions evaluated from reports in the medical literature, 74 (68.5 percent) were unable to be evaluated due to the lack of adequate information, 20 (18.5 percent) were considered "possible" interactions, and 14 (13 percent) were considered "well-documented" and thus likely. The authors emphasize the need for better documentation of all relevant data in case studies of potential interactions.[4]

How SLP works

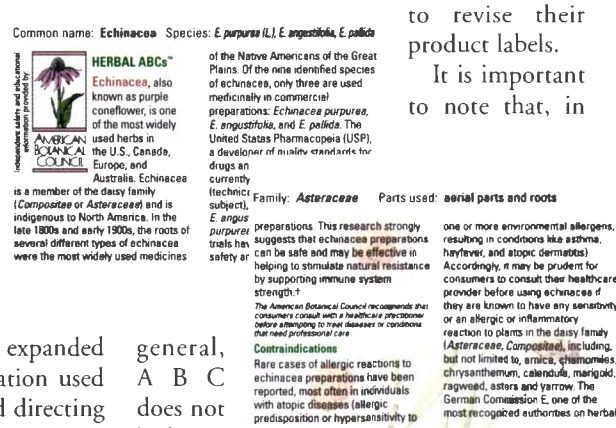
As an independent organization, ABC conducts a literature search on a particular herb, evaluates the data and formulates a review of essential safety information, and then licenses the use of the manufacturer's version of the ABC information along with the ABC name and logo to qualifying manufacturers. The safety information is initially provided in a format called a Safety Information Sheet (SIS).

The SIS presents a rational interpretation of the literature on the safety of a particular herb, and provides accurate, useful information on contraindications, adverse effects, actual and potential interactions with Rx and OTC drugs, as well as pregnancy and lactation warnings and guidelines. A draft version of each SIS is sent to expert reviewers who check accuracy and clinical relevance. Reviewers' comments are then evaluated and researched by ABC and may be included in the final version of the SIS.

Each SIS includes information about

ABC and disclaimers relating to ABC's liability (e.g., noting that ABC has neither verified the contents of a herbal package nor tested the product). In addition, after the manufacturer creates its revised safety information based on the SIS for its label, ABC then reviews the proposed label text to determine whether it is accurate and adequately reflects the information in the SIS. This step is required before ABC will allow the label to display the ABC name and logo.

This label text is formatted into a product label, which may include accordion-style labels, peel-out labels, package inserts, or a box panel. In some cases, a manufacturer may decide not to dedicate the extra cost or space required for an expanded label or to minimize the information used on the label from the SIS, instead directing the patients to find more information on the company website where space is not an issue. In all cases, the consumer, patient, and healthcare professional are provided significantly expanded, independent safety information to help promote the safe and beneficial use of herbs.


Common name: **Echinacea** Species: *E. purpurea (L.), E. angustifolia, E. pallida*

HERBAL ABCs™

Echinacea, also known as purple coneflower, is one of the most widely used herbs in the U.S., Canada, Europe, and Australia. Echinacea is a member of the daisy family (*Compositae* or *Asteraceae*) and is indigenous to North America. In the late 1800s and early 1900s, the roots of several different types of echinacea were the most widely used medicines of the Native Americans of the Great Plains. Of the nine identified species of echinacea, only three are used medicinally in commercial preparations: *Echinacea purpurea, E. angustifolia,* and *E. pallida*. The United States Pharmacopeia (USP), a developer of quality standards for drugs an currently (technic subject), *E. angus purpurea* trials hav safety ar

Family: ***Asteraceae*** Parts used: **aerial parts and roots**

preparations. This research strongly suggests that echinacea preparations can be safe and may be effective in helping to stimulate natural resistance by supporting immune system strength.†

The American Botanical Council recommends that consumers consult with a healthcare practitioner before attempting to treat diseases or conditions that need professional care

Contraindications

Rare cases of allergic reactions to echinacea preparations have been reported, most often in individuals with atopic diseases (allergic predisposition or hypersensitivity to one or more environmental allergens, resulting in conditions like asthma, hayfever, and atopic dermatitis). Accordingly, it may be prudent for consumers to consult their healthcare provider before using echinacea if they are known to have any sensitivity or an allergic or inflammatory reaction to plants in the daisy family (*Asteraceae, Compositae*), including, but not limited to, arnica, chamomiles, chrysanthemum, calendula, marigold, ragweed, asters and yarrow. The German Commission E, one of the most recognized authorities on herbal

Sources of safety information

The primary source of information for many of the current SIS is *The ABC Clinical Guide to Herbs* (*The Guide*),[5] a new reference book that includes comprehensive monographs, abbreviated clinical overviews, patient information sheets, clinical studies tables, and extensive references for 29 of the most commonly used herbs and 13 clinically tested proprietary products and herb combinations. ABC also accesses and reviews safety information that is not included in *The Guide* to help ensure that the SIS accurately reflects a comprehensive view of each herb's safety considerations. This includes, but is not limited to, various authoritative sources, including official and non-official monographs (e.g., the German Commission E, the European Scientific Cooperative on Phytotherapy, the World Health Organization, and the American Herbal Pharmacopoeia), plus primary references (clinical and pharmacological studies, case reports, etc.), and secondary reference texts and online updates (e.g., *Herb Contraindications and Drug Interactions*).[6] For herbs not included in *The Guide*, ABC researches current literature sources that generally are accepted as reliable by the scientific herbal community, including some of the sources named above.

As part of the ongoing activity of the SLP, key safety information in the SIS will be updated on an as-needed basis, and the updated SIS will be forwarded to participating manufacturers so that they may consider whether to revise their product labels.

It is important to note that, in general, ABC does not believe that there is a safety problem with appropriate use of herbs. However, ABC considers it part of its educational mission to provide consumers and health professionals with accurate guidelines for the responsible use of herbal products. *The Guide,* provides both extensive guidance information on the therapeutic use of herbs as well as up-to-date safety information. Consumers have expressed their desire for more information on how to use dietary supplements responsibly, and yet manufacturers are not permitted to label and market their products with therapeutic information (i.e., how the product might prevent or treat a disease or condition) beyond the truthful and non-misleading "structure/function" claims allowed by DSHEA. Therefore, ABC considers it appropriate to assist the manufacturer, patient, and clinician in obtaining independent and science-based safety information.

[T]he consumer, patient, and healthcare professional are provided significantly expanded, independent safety information to help promote the safe and beneficial use of herbs.

The future of SLP

ABC has reviewed the literature on interactions, contraindications, adverse effects, warnings, and other potential risks in order to clarify their significance (or lack thereof) in each SIS. Ultimately, however, it is the manufacturer's responsibility to determine the extent of disclosure on a product's label and in marketing materials. It is the responsibility of the clinician and pharmacist to adequately inform patients about potential risks and interactions associated with herbal supplements, and to work with patients to interpret this information and make rational decisions for individual therapy. It is the responsibility of consumers, many of whom choose to self-medicate, to become better informed about the safety of the products they are considering using to improve or maintain health. As the SLP expands, it may help to facilitate this process for health professionals, manufacturers, patients, and consumers, and may reverse some recent trends by increasing confidence in the responsible use of herbal dietary supplements and related products.

For more information about ABC or SLP contact Wayne Silverman, Ph.D., at <*wayne@herbalgram.org*>.

Reference:

1. Natural Marketing Institute. Annual Health and Wellness Trends. Philadelphia, PA: Natural Marketing Institute; 2003. <www.nmisolutions.com>:
2. Johnston BA. *Prevention* magazine assesses use of dietary supplements. *HerbalGram* 2000;48:65.
3. Kaufman DW, Kelly JP, Rosenberg L, Anderson TE, Mitchell AA. Recent patterns of medication use in the ambulatory adult population of the United States. The Slone Survey. *JAMA* 2002;287(3):337-44.
4. Fugh-Berman A, Ernst E. Herb-drug interactions: Review and assessment of report reliability. *Br J Clin Pharmacol* 2001;52:587-95.
5. Blumenthal M, Hall T, Goldberg A, Dinda K, Brinckmann J, Wollschlaeger B. *The ABC Clinical Guide to Herbs.* Austin, TX: American Botanical Council; 2003.
6. Brinker F. Herb Contraindications and Drug Interactions, 3rd edition. Sandy, Oregon: Eclectic Medical Publications; 2001.

Sustainable Health and Beauty: Aveda Sponsors Benefit for ABC

Stepping from a taxi onto a busy street in the SoHo district of Manhattan, New York, one could not feel further removed from the rainforest, the Andes, or any similarly enriching space. Yet something magical happened on the Avenue of the Americas, on the top floor and roof of a beautiful, newly refurbished historic building. As the elevator doors opened, South American music wafted through the air, mixing the scent of essential oils and delectable food and drink with the sounds of laughter and conversation. This was the site of an evening of ideas and connections sponsored by the Aveda Corporation; "Sustainable Health and Beauty – An evening with Andrew Weil and the American Botanical Council Celebrating the Benefits of Medicinal Plants."

On the evening of June 11, 2003, Aveda Corporation hosted an event for more than 100 academic and healthcare professionals, leaders in the field of integrative medicine, people from the herbal industry, and representatives of the media from the New York region. In keeping with their vision of "connecting beauty, environment and well-being," Sustainable Health and Beauty was the theme for the evening. Aveda hosted the event to showcase its new Manhattan marketing offices; to support the educational and research work of ABC and launch ABC's new book, *The ABC Clinical Guide to Herbs*; and to provide an educational and social opportunity for those in attendance. This theme captures the link between the mission of ABC and the vision of Aveda. Sustainability has been a guiding principle for progressive economic development of agricultural and other natural resources. In the same way, progressive companies, organizations and individuals are now increasingly concerned about using sustainable resources and finding ways to maintain the health of entire ecosystems. Sustainable Health and Beauty implies that the methods by which we improve our health and beauty follow the same concepts. Whenever possible, the raw materials, herbs, plants, drugs, and cosmetics used on and in our bodies should be derived from resources that can be renewed, are healthy, and are harvested and tested using ethical, sustainable, and renewable practices. The idea can go further. Through the use of *healthy* substances and practices, we will *sustain* health and beauty for our planet and ourselves for many years to come. ABC advocates the use of sustainable practices in harvesting and cultivating the herbs used in herbal medicine. Likewise, Aveda has always advocated the use of organically produced products and sustainable practices in the development of its product lines and business practices.

Sustainable health & beauty

Authentic South American music was provided by Ch'uwa Yacu Bolivia. Photo ©2003 Patrick McMullan.

Julie Naughton of *Women's Wear Daily* and Chris Molinari, vice president of communications for Aveda, enjoy the evening with their inscribed copes of *The Guide* in hand. Photo ©2003 Patrick McMullan.

In addition to Dr. Weil, speakers included Aveda Founder Horst Rechelbacher (now founder and president of Intelligent Nutrients), and ABC Founder and Executive Director Mark Blumenthal. Chris Hacker, Aveda's senior vice president for marketing and design, welcomed more than 100 guests and explained the design and purpose of Aveda's environmentally friendly Manhattan office (Aveda headquarters are in Minneapolis). Rechelbacher then sketched a brief history of the company, and his professional and personal relationship with ABC. Blumenthal expressed his appreciation to Aveda and the many old and new friends who attended the event, saying, "We are deeply grateful for the excellent support ABC receives from Aveda. Just as ABC has been an innovative leader in the field of nonprofit herbal education, Aveda is a universally recognized pioneer and innovator in the cosmetics and salon industries by using ethical

From left: Aveda founder Horst Rechelbacher (now founder/president of Intelligent Nutrients), ABC founder/executive director Mark Blumenthal, best-selling natural medicine author, Andrew Weil, M.D. Photo ©2003 Patrick McMullan.

and sustainable techniques and practices." He went on to say that "ABC continues to be a primary supplier of science-based information on the benefits of herbs and phytomedicines. For 15 years, ABC has consistently reported on clinical research on herbs — especially when few people even realized that there even was scientific research on herbs." He also provided highlights on ABC's new book and Safety Labeling Program.

Dr. Weil, a member of ABC's Advisory Board, discussed the state of integrative medicine. He praised ABC's role as a leader in bringing solid, science-based herbal information to health practitioners, consumers, government officials, the industry, and the media. Weil and Blumenthal were in New York as faculty members of the eighth Columbia University conference, "Integrating Botanical Medicine into Modern Clinical Practice."

Aveda provided an elegant, all vegetarian, all organic assortment of hors d'oeuvres and beverages. Guests contributed financial support to ABC and were each given an inscribed copy of *The Guide*, the latest issue of *HerbalGram*, general information about ABC, information about Aveda, and sample products from Aveda. They also had the opportunity to purchase other ABC books and have *The Guide* and the other books inscribed by Blumenthal and the other speakers as a memento of the event. Many guests toured Aveda's new offices, which include plans for an extensive rooftop herbal garden.

During the evening and in the weeks that followed, many people commented that the event was informative, entertaining, and enjoyable. Among the participants was Jill Baron, M.D., a New York city physician who practices integrative medicine. She said, "The event at Aveda was inspiring and informative," she said. "Having such luminaries as Andrew Weil speaking to reinforce the need for complementary and alternative therapies in healing, was supportive of the work of many of the guests. It is really a tribute to Mark Blumenthal and ABC for diligence and hard work in putting botanical medicine on the map as a viable and necessary discipline in the healing armamentarium."

Horst Rechelbacher answers questions in front of the "Aveda Environmental Lifestyle Store," a prototype retail environment. ABC photo.

Thieme Publishing <www.thieme.com>, a leading publisher of medical books in Europe, is ABC's exclusive worldwide distributor of *The Guide* and of all four of ABC's German Commission E books and CDs. A representative from Thieme's US/New York office, Melissa Parsons, coordinated the book signing, distribution, and sales at the event.

Representatives from the national media in attendance were: *Business Week*, *E The Environmental Magazine*, *Holistic Primary Care*, *Newsweek*, *Nutraceuticals World*, *Shape Magazine*, *Vanity Fair*, and *Women's Wear Daily*. Industry representatives came from Abkit/Lichtwer Pharma, Bristol-Myers Squibb, Estee Lauder, Maitake, New Chapter, Novagen, and Vitamin Shoppe, among others.

Aveda and ABC's evening of "Sustainable Health and Beauty" provided a gathering place for individuals with a common purpose: responsible use of natural renewable resources for long-term natural health. ABC is grateful to all who attended and to Aveda for transporting guests from the busy streets of Manhattan to a magical space of learning and harmony.

— Laura and Wayne Silverman

Scott Hoyt of Hoyt Tea and Fredi Kronenberg, PhD, of Columbia University and member of ABC's Board of Trustees. Photo ©2003 Patrick McMullan.

Federal Employees Can Support ABC through Workplace Giving

The American Botanical Council, listed under the name Herbal Medicine Institute (Combined Federal Campaign code # 1220), is participating in the Combined Federal Campaign (CFC) as a member organization of the Independent Charities of America federation.

The CFC is the annual workplace fund-raising drive conducted by federal employees between September 1 and December 15. Each year federal employees and military personnel raise millions of dollars through the CFC to support thousands of non-profit charities. Friends of ABC, who are also federal employees at any level, can support ABC through their local campaign.

The CFC is the only authorized solicitation of employees in the federal workplace on behalf of charitable organizations, and is the largest and most successful workplace fundraiser in the world. The CFC allows federal employees to contribute to organizations of their choice through a single brochure and to make their contributions through cash, check, or payroll deductions.

The campaign's mission is to promote and support philanthropy through a program that is employee-focused, cost-efficient, and effective in providing every federal employee the opportunity to improve the quality of life for all. It also encourages and enables active employee participation in the community, which fosters collaboration with the business and nonprofit sectors to achieve this goal.

— Stacy Elliott

Dietetic Interns from Mayo Clinic Help ABC While Learning

This past May, ABC hosted two dietetic interns from the Mayo School of Health Related Sciences, of Rochester, Minnesota. Heather Rasmussen and Cassie Chamis spent a week with ABC, developing continuing education materials for dietitians.

The women approached ABC on their own. In the summer of 2002, Chamis' sister was a dietetic intern with ABC, and she gave such a glowing recommendation to Cassie that she sought out Gayle Engels, Education Coordinator for ABC, to inquire about an internship for herself and Rasmussen.

Mayo Clinic interns Heather Rasmussen (left) and Cassie Chamis (right) on the front porch of ABC's headquarters, the Case Mill Homestead.

"We saw the ABC as a good way to explore our interests and incorporate that knowledge into our future profession of dietetics," said Rasmussen.

The benefit went both ways, as the Education Department also received valuable help in the construction of continuing education classes relating to ABC's latest book *The ABC Clinical Guide to Herbs* (2003). The templates and formats designed by Rasmussen and Chamis will help form the basis for courses to follow.

ABC has offered continuing education modules since 1995. One module, "Popular Herbs in the U.S. Market," was released in 1997 and accredited for and distributed to almost 100,000 pharmacists. Plans for the next generation of continuing education include live and online sessions.

Chamis and Rasmussen worked on the online version of the courses. They created the initial drafts of the course introduction and the post-test for the cardiovascular section.

In addition to working on the module, both Rasmussen and Chamis worked for a day in ABC's gardens, gaining "hands-on" experience with herbs.

ABC has hosted many interns in the past. Dietetics students at Southwest Texas State University are required to intern with ABC for a week and pharmacy doctoral candidates at the University of Texas have the option of a six-week rotation with ABC.

Chamis sees ABC's internship program as a vital educational opportunity for dietitians. "As a dietetic intern it is important to be exposed to as much new information as possible so that you can better assist your patients with decisions," she said. "I also think that the experience at ABC is so much better than textbook learning. I knew the information was from a reliable source and that the organization is not out to 'sell a product' but rather to inform the public."

As part of her garden experience, intern Heather Rasmussen repots Plumeria with ABC Education Coordinator, Gayle Engels.

Rasmussen had some early family experience in gardening and botany, and ABC's historic Case Mill Homestead felt familiar to her. As she noted in her final report on her time at ABC, "Having a family full of self-proclaimed botanists provides for good exposure. Like them, it is apparent that the people at the American Botanical Council love growing, researching, writing and sharing information about herbs, herbal supplements, and plants in general."

Engels describes the real hindrance to the internship program is a lack of funding. At present, ABC usually hosts interns from Central Texas. Those who are interested in an internship, but are outside that area, must travel to Austin and find accommodations on their own, as ABC lacks the means to offer a stipend or reimburse travel expenses. Requests for internship information come from as far away as Europe, Africa, and India, but, because of lack of funding, those people must gain their internship experience elsewhere.

— Sarah Jackson

Basil: Herb of the Year

Basil (*Ocimum basilicum* 'Genovese' and *O. basilicum* 'Dark Opal') growing in the American Botanical Council's gardens. Basil is the International Herb Association's Herb of the Year for 2003. Not only is basil great in pesto, it has numerous medicinal and aromatherapy uses in the United States and various cultures around the world. ABC photo.

ABC Board of Trustees Adds Three Members

The American Botanical Council Board of Trustees has expanded to include three new members. Peggy Brevoort, Tom Kurt, M.D., and Morris Shriftman bring new ideas and energy to ABC's mission of research and education into herbal medicine.

Peggy Brevoort and her husband, Bill, founded East Earth Herb, Inc. in 1971, working to place Chinese herbal products in the American and, later, worldwide markets. She served as CEO of the company from 1990 to 1999 and as president from 1997 to 1999. The company was acquired in 1999 by the A.M. Todd Company. After that purchase, Brevoort served as president of A.M. Todd Botanicals until her retirement in April of 2000.

Brevoort has also served as a member of the boards at Biomed Comm Inc.; United Plant Savers; Bastyr University Board of Regents; the Corporate Alliance for Integrative Medicine, Inc.; Citizens for Health; and the American Herbal Products Association, where she is a past president.

She was named 1990 Woman of the Year by the Association of Women in Natural Foods, and earned Natural Business Communication's 1999 Leadership in Business Award. She was also a member of the first herbalist delegation to the People's Republic of China in 1988.

Her literary credits include material published in *HerbalGram* and *Pharmaceutical News*. She has also delivered dozens of presentations on botanical issues.

Thomas (Tom) L. Kurt, M.D., M.P.H., the founder of the certified regional poison center in Dallas, is a consultant in medical toxicology, pharmacology, and adverse drug reactions. He is also a clinical professor in the Department of Internal Medicine at the University of Texas Southwestern Medical School.

Dr Kurt, who received his B.S. from Notre Dame, his MD from Kansas, and MPH from Harvard, served as regional medical officer for the U.S. Food and Drug Administration (FDA) from 1989 to 1991 and continues to serve on FDA panels, as well as being a member of the Texas Drug Utilization Review Board, which sets Medicaid outpatient prescription policies. He has published more than 150 scientific papers and is an editorial reviewer for medical journals.

Morris Shriftman is the CEO of Mozart, Inc., of Ponte Vedra Beach, Florida, a marketing communications firm which specializes in the natural and organic food, and herbal and alternative medicine industry, offering identity and branding, strategic marketing and positioning, advertising, packaging, public relations, and interactive digital communications. Mozart clients include Tree of Life, United Natural Foods, Whole Foods Market, Horizon Organic Dairy, Smucker Quality Beverages, and Traditional Medicinals.

Shriftman has also been a speaker and panelist at natural product expositions, most recently at the 2003 Organic Trade Association's "All Things Organic" conference. At the BioFach 2003 Congress in Nuremberg, Germany, Shriftman spoke on what European natural and organic product companies can do to create marketing success in the U.S. market.

Shriftman earned a B.S. degree in industrial and labor relations from Cornell University in 1964. His M.A. degree from New York University is in British and American literature, and he completed all but the dissertation on a doctoral degree in the same program. He has been a visiting professor of marketing at Davis College of Business at Jacksonville University.

Another change in the Board makeup will result from ABC Founder and Executive Director Mark Blumenthal resigning in October from his position as board president. Blumenthal will still be involved with the board, acting as an *ex officio* member, contributing information and ideas. The new president has not been elected yet. Blumenthal will continue to lead ABC as its executive director and editor of *HerbalGram* and HerbClip.

Traditionally, ABC's Board of Trustees has been comprised of people with significant experience in fields such as pharmacognosy, ethnobotany, and the merging of botanical and conventional medicine. However, Blumenthal said, "Non-profit organizations have experienced a difficult time in the economy of a post-9/11 world. ABC's Board must go in a different direction, and draw upon broader experience.

"I believe it is necessary to begin to add people to the board who have expertise in business, marketing, finance, and medicine," Blumenthal said. He also expects that the changes will "help ABC grow to a new level of public service to meet the growing needs for reliable herbal information and at the same time help develop and maintain financial stability for ABC."

One of the seats being filled had been occupied by Prof. Varro E. Tyler, who died suddenly in August, 2001. Blumenthal explained the delay in filling the seat, "Out of respect to his memory and the major role he played in helping set ABC's direction and policy, we waited to fill his Board seat, leaving it empty in a kind of 'missing man' formation in military memorial rituals."

Blumenthal looks forward to the future of the ABC Board, expecting that the changes being implemented will be of lasting benefit to the Board and to those involved in herbal medicine.

"I believe that the new composition of the ABC Board will continue to help guide ABC so it will retain its position as the leading nonprofit organization disseminating accurate, responsible, reliable information on the benefits of herbs and phytomedicines," Blumenthal said. "At the same time, it will help ABC establish a strong financial basis to expand our educational programs and publications."

— Sarah Jackson

CRN Aims for Congressional Education, Dialog with New Ads

The Council for Responsible Nutrition (CRN) has released a new campaign designed to educate the U.S. Congress on the benefits of dietary supplements and the role of the Dietary Supplement Health and Education Act (DSHEA) as a "viable framework" for regulation. CRN, an industry trade association based in Washington, D.C., also sees the program reaffirming its role as a reliable source of information on science-based dietary supplements.

"With all the recent controversy surrounding a few specific products, we felt it important to point out that our industry encompasses a wide range of products that are valued for their health benefits by more than 150 million Americans," said CRN President Annette Dickinson, Ph.D.

The campaign, "DSHEA: It Makes Sense, Let's Make it Work," includes display ads appearing between June and September in *Roll Call* and *The Hill*, publications aimed at members of Congress and their staffs.

The ads complement monthly mailings to more than 500 congressional offices. Each mailing focuses on a different category: multivitamins, calcium, folic acid, ginkgo, antioxidants, echinacea, glucosamine/chondroitin, and omega-3 fatty acids.

"We really want to open a dialog," said Judy Blatman, CRN vice president of communications. "It's a little too early to tell with the ads, but the response to the mailings has been positive. People are really receptive."

A sample of the ad is available online at <www.crnusa.org/images/DSAD_web.jpg>.

— Sarah Jackson

[Source: Council for Responsible Nutrition. CRN Launches Outreach Effort to Congress and Staffers (press release). 23 June, 2003.]

AHP Adds Ginkgo Leaf Monograph to Series

The American Herbal Pharmacopoeia (AHP), a California-based non-profit research organization, will release its quality control standards and therapeutic compendium for Ginkgo Leaf-Ginkgo Leaf Dry Extract (*Ginkgo biloba* L., Ginkgoaceae) this summer. Each of the 18 monographs in the series establishes national standards for assuring authenticity, purity, and quality control of the monographed botanical. The Therapeutic Compendium provides a complete and critical review of the pharmacological and safety data currently available.

Ginkgo leaf is used by many for its reported effects on improving cognitive functions. According to AHP Executive Director Roy Upton, "Between 1975 and 2002, more than 40 controlled trials were published concerning the use of ginkgo leaf extract to treat patients with cerebrovascular insufficiency. The overwhelming majority of the available studies report positive findings such as improved cognition and even a slowdown in the progression of Alzheimer's disease. Management and treatment of patients with Alzheimer's is one of the greatest drains on Medicare costs and costs the United States in excess of $100 billion annually. This latter benefit alone could save hundreds of millions in health care costs."

Each monograph represents a thorough and critical review of all aspects of the particular herbal medicine available. They provide complete and reliable information regarding the true therapeutic potential and safety of the herb so that people and health professionals can make educated decisions about its use.

The new ginkgo monograph costs $24.95 each. Others in the series are available for $19.95 (except St. John's Wort which costs $9.95 each). The full set of 18 monographs costs $328. Order through AHP or through the American Botanical Council's website <www.herbalgram.org>, email to <custserv@herbalgram.org>, or by telephone 800/373-7105 or 512/926-4900. A list of the species in the series is in the Herbal Education Catalog, which begins on page 75 of this issue of *HerbalGram*.

[Source: American Herbal Pharmacopoeia Publishes Ginkgo Leaf / Ginkgo Leaf Dry Extract *Ginkgo biloba* L. Monograph [press release]. American Herbal Pharmacopoeia May 30, 2003.]

Herb Day USA Postponed to Fall 2004

Herb Day USA, a national education event, has been postponed until the fall of 2004, organizers announced. The event, sponsored by a coalition of six leading botanical medicine organizations, had been scheduled for this fall.

The intention is to present consumers with accurate, contemporary, and useful information about the beneficial role of herbs in modern health care. The six organizations that make up the coalition are the American Herbal Products Association, American Herbal Pharmacopoeia, American Herbalists Guild, United Plant Savers, Herb Research Foundation, and American Botanical Council. The broad vision for Herb Day USA was described in *HerbalGram* 57. As future plans are confirmed, information will appear in these pages. For information, contact Aviva Romm, email <ahgoffice@earthlink.net>.

Georgetown School of Medicine Creates First-ever Masters Program in Complementary and Alternative Medicine

This fall the Georgetown School of Medicine, Washington, D.C., will start the first masters-level basic sciences program in complementary and alternative medicine. Students who complete the three- to four-semester-long program will receive an M.S. in Physiology.

In an email dated April 3, 2003, Adriane Fugh-Berman M.D., a Georgetown School of Medicine alumna, described the course as focused on training basic science researchers. The integrative curriculum includes courses in the fundamentals of biochemistry and physiology as well as "mind-body medicine, experimental design, and biostasis." The principals of pharmacology of drugs, supplements, and herbal medicines are also part of the planned curriculum.

"The course came about after a faculty member received an R25 Grant from the National Center for Complementary and Alternative Medicine," said Adam Myers, Ph.D., who, along with Hakima Amri, Ph.D., will direct the program. "The purpose of the master's program is to promote complementary medicine as an academic field. We're looking to build a doctoral track as well. It's developing parallel to the master's program, but more work still needs to be done."

Response to the course has already been positive, Myers said. "A survey course was held last year and students were very enthusiastic about the ideas.

"The thrust of the program is to teach people to look critically at alternative medicine, not necessarily to practice. Experimental Design and Biostatistics are required courses for any scientific background, but they would be especially important with the study of alternative medicine. We're trying to create a new academic field — the histories and theories of CAM and how to use it scientifically."

The university's home page for the program is online, <http://som.georgetown.edu/cam/>

— Sarah Jackson

Australasian College of Herbal Studies Receives National Accreditation

The Accrediting Commission of the Distance Education and Training Council (DETC) has awarded national accreditation to the Australasian College of Herbal Studies (ACHS).

"The accreditation is yet another validation that Australasian College's distance learning and on-line classes, in addition to its on-site programs, offer quality educational opportunities to students," said ACHS Vice-President Erika Yigzaw.

The DETC has been monitoring and accrediting educational institutions for more than 75 years, and has been recognized and approved of by the U.S. Department of Education and the Council for Higher Education Accreditation, both based in Washington, D.C.

The two-year process began with a thorough review by the college, based in Portland, Oregon, going through every aspect of its operations. Program materials that would be part of the courses were sent to experts chosen by the DETC for review.

Most of the documentation was triplicate copies of course and material descriptions for 15 courses, including master herbalist, diploma in aromatherapy, flower essences, and nutrition.

Accreditation will make students' coursework and credits more likely to be accepted if they transfer to another institution. Tuition assistance from the military or employers is more readily available when students are enrolled in an accredited school.

ACHS was founded in 1978 in New Zealand by Dorene Petersen and relocated to Portland in 1991. More information about ACHS can be found at the college's website <www.herbed.com>

— Sarah Jackson

[Australasian College of Herbal Studies. Australasian College Granted National Accreditation [press release]. June 12, 2003.]

Evidence-Based Naturopathic Medicine Residency Program Started by Standard Process

Standard Process Inc. (SP), a supplier of dietary supplement formulations for healthcare practitioners, is providing naturopathic physicians with experience in evidence-based medicine. The program teams SP with the National College of Naturopathic Medicine (NCNM), of Portland, Oregon, to administer a naturopathic medicine residency program.

This is the program's first year; two naturopathic physicians are working at different conventional and complementary medical facilities as well as in the research department and the employee wellness program at SP's headquarters in Palmyra, Wisconsin.

"This program is a culmination of several issues," said Tim Birdsall, N.D., residency program director. "SP wants to stay abreast of scientific development, create a robust scientific approach to nutrition, and support the naturopathic and herbal medicine professions in general." Birdsall is assisted by Clyde Jensen, Ph.D., director of scientific and integrative affairs at SP, and former president of NCNM.

For the research requirements of the Natural Healthcare practicum, residents design and conduct clinical trials, and analyze related healthcare outcomes data. Additionally, the residents are enrolled in the physician investigator program at the Medical College of Wisconsin, leading to a master's degree in epidemiology. The residents will gain industry awareness by shadowing SP managers and observing operations of the herbal and dietary supplement product industry, such as new product development, production, quality control, sales and marketing, and management.

"This program is unique in that it blends practical clinical training and experience with hands-on training in the natural products industry," Birdsall said. "Those who complete the residency will have unique experience, not only clinical training, but training with natural products."

In addition to their work at SP, residents also learn about integrated medicine, blending both conventional and complementary methods when participating in rotations in other healthcare and research areas. Rotations include emergency medicine, geriatrics, intensive care, pain management, pediatrics, sports medicine, and women's health. Residents also make or participate in presentations every two weeks about their cases to review the safety and impact of their work.

"In their work at the SP employee wellness clinic, they will report to me," Birdsall said. "There will also be a quarterly evaluation process through the residents' school. Standard Process employees who participate in the wellness program will complete evaluation sheets as well."

The program lasts one year, with the possibility of returning for a second year or joining the SP staff. Birdsall said plans to continue the program have been made, and one resident has been selected for next year.

— Sarah Jackson

New Official Monographs Published in the European Pharmacopeia

Five new monographs for herbal standards have become official in the 6th supplement to the *European Pharmacopoeia, 4th edition*, and will be implemented by January 1, 2004, at the latest. The new monographs include the following (noted in their U.S. common names, with the European Union monograph name in brackets and Latin binomials in parenthesis):

- Belladonna leaf tincture, standardized (*Atropa belladonna* L.)
- Goldenrod, European (*Solidago virgaurea* L.)
- Milk thistle fruit [Milk-thistle fruit] (*Silybum marianum* (L.) Gaertn.)
- St. John's wort for homeopathic preparations [Hypericum for homeopathic preparations] (*Hypericum perforatum* L.)
- Sweet orange oil (*Citrus sinensis* (L.) Osbeck)

Also, several existing herbal monographs have been technically revised since their last publication; the revisions to be implemented on January 1, 2004:

- Chamomile flower, German/Hungarian [Matricaria flower] (*Matricaria recutita* L.)
- Dog rose (*Rosa canina* L.)
- Eleuthero [Eleutherococcus] (*Eleutherococcus senticosus* (Rupr. & Maxim.) Maxim.)
- Eucalyptus oil (*Eucalyptus globulus* Labill.)
- Gentian root (*Gentiana lutea* L.) and Gentian tincture
- Ipecac [Ipecacuanha] liquid extract, standardized (*Cephaëlis acuminata* Karsten or *Cephaëlis ipecacuanha* (Brot.) A. Rich.) and Ipecacuanha tincture, standardized
- Kelp [formerly listed as Fucus] (*Fucus vesiculosus* L. or *F. serratus* L. or *Ascophyllum nodosum* Le Jolis)
- Peppermint oil (*Mentha* x *piperita* L.)

A few other herbal monographs have had corrections made which are to be taken into account from the publication date of *European Pharmacopoeia* Supplement 4.6:

- Bitter-orange flower (*Citrus aurantium* L. ssp. *aurantium*)
- Oregano (*Origanum onites* L. or *O. vulgare* L. ssp. *hirtum* (Link) Ietswaart)
- Plantain, English [Ribwort Plantain] (*Plantago lanceolata* L.)
- Tolu balsam (*Myroxylon balsamum* (L.) Harms)

The monographs in the *European Pharmacopoeia* represent the collective consensus of leading phytomedicinal experts and regulatory authorities in the European Union countries, and often contain different standards for identity and purity than standards monographs issued by the United States Pharmacopeia (USP). For more information on the *European Pharmacopoeia*, visit <www.hpeur.org>. To obtain copies of the new *European Pharmacopoeia* monographs, price lists and order forms are online at: <www.pheur.org/site/pricelist.php3>.

For more information on the United Nation's Market News Service for Medicinal Plants & Extracts, please visit <www.pmaps.org/mns/medplants.php> or e-mail <brink@sonic.net>.

—Josef Brinckmann

[Source: Brinckmann J. (ed.). Market News Service for Medicinal Plants & Extracts. June 2003, Number 7. Geneva: International Trade Centre/UNCTAD.]

Effects of Juice on Kidney Stone Formation

Reviewed: Kessler T, Jansen B, Hesse A. Effect of black currant-, cranberry- and plum juice. *European Journal of Clinical Nutrition* 2002;36:1020-1023.

High fluid intake is widely regarded as the most important preventive treatment for kidney stones, reducing the concentration of constituent ions and saturation of stone-forming salts. The most suitable fluids for this purpose are mineral water, orange juice, apple juice, and fruit and herbal teas. Patients with a history of kidney stones should avoid fluids that contain stone-forming agents and promoters; these include coffee, black tea, alcohol, and cola soft drinks. Cranberry juice has been used extensively to prevent and treat urinary tract infections, and small studies on the effects of ingestion of black currant juice and prunes (dried plums) have shown an acidifying effect on urine in humans. Various shortcomings in these studies and a lack of scientific evidence have led these researchers to evaluate the influence of these three juices on urinary composition and kidney stone formation.

Twelve healthy male subjects (ages 18–38 years) with no history of kidney disorders participated in four consecutive trial phases of five days each. All phases were equivalent in dietary intake and included a four-day adaptation period during each phase before the experimental load on the fifth day. Creatinine was measured on days 1–4 to ensure compliance with the diet, and 24-hour urine samples were collected each day. Day five of each phase was the experimental day with consumption of 330 ml of either mineral water (control, assumed to have no effect on urinary composition), or juice from either plums (*Prunus domestica* L., Rosaceae), cranberries (*Vaccinium macrocarpon* Aiton, Ericaceae), or black currants (*Ribes nigrum* L., Grossulariaceae).

Changes were noted in several urinary parameters following consumption of each juice. Black currant juice significantly alkalized the urine ($P < 0.01$), increased citric acid excretion ($P < 0.01$), and oxalic acid excretion ($P < 0.05$). Cranberry juice significantly acidified the urine ($P < 0.05$) and showed a small, not statistically significant decrease in citric acid excretion. Oxalic acid excretion was significantly increased after ingestion of cranberry juice ($P < 0.05$). Black currant juice did not significantly affect the relative supersaturation for calcium oxalate, uric acid, brushite, and struvite, but cranberry juice significantly increased the relative supersaturation of uric acid ($P < 0.05$) and decreased the relative supersaturation of struvite and brushite. Plum juice had no statistically significant effect on any of the urinary parameters measured. Excretion of calcium, magnesium, and uric acid were not significantly changed by any of the experimental juices.

The increased excretion of oxalic and citric acids with black currant juice was attributed to the content of these acids and ascorbic acid (which is metabolized to oxalic acid) in the consumed juice. The alkalizing effect of black currant juice did not decrease the relative supersaturation of calcium oxalate and uric acid as would be expected, which the authors attributed to the increase in oxalic acid excretion. The decrease in pH with cranberry juice was expected and is associated with increased risk of uric acid stone formation; however, the relative supersaturation for struvite and brushite were slightly decreased. The authors speculate that the effect of cranberry juice might be larger if more juice was ingested.

The authors conclude that black currant juice could be used as a preventive and treatment for uric acid stones due to its alkalizing effect on the urine. Cranberry juice could be of use when acidification of the urine is indicated, as with apatite, brushite, and struvite stones as well as with urinary tract infection.

This well-designed study compensated for the perpetual problem of quantifying food and beverage intake by requiring subjects to consume a standardized diet, followed by biochemical and physical measurements to ensure compliance. Adequate research and annotation supported the study topic. The claims made for black currant and cranberry juices were not completely substantiated by the results; however, the authors noted that this study was conducted in healthy subjects and suggested that further research into the usefulness of these juices should be done in patients with a history of kidney stone formation.

However, it should be noted that there are different types of kidney stones. If possible, stones that are passed should be caught in a strainer and then analyzed for their content. Most are calcium, but a minority are uric acid (an indication of gout) or oxalic acid (an inherited trait). Calcium kidney stones are best treated with acidic drinks, but the acid stones need basic (bicarbonate, etc.) drinks to dissolve. Treating uric acid and oxalic acid kidney stones with acidic beverages is ineffective. Uric acid kidney stones comprise only 20–30 percent of kidney stones, yet universal statements about kidney stone treatment must be considered in this context.

— Diane S. Graves, MPH, RD

Effectiveness of Ginkgo Extract in Persons with No History of Neurocognitive Dysfunction

Reviewed: Mix J, Crews WD. A double-blind, placebo-controlled, randomized trial of *Gingko biloba* extract EGb 761® in a sample of cognitively intact older adults: neuropsychological findings. *Human Psychopharmocology: Clinical and Experimental* 2002;17:267-277.

In recent years, the use of ginkgo (*Ginkgo biloba* L., Ginkgoaceae) extract for the treatment of dementia and cerebral insufficiency has increased significantly. The results from a number of clinical trials have demonstrated the efficacy of ginkgo extract in cognitively impaired persons. In the last decade, ginkgo was approved as a treatment for dementia in Germany. The majority of studies have been conducted in Europe. Relatively few studies (approximately eight) have examined the effectiveness of ginkgo extract in persons with no history of neurocognitive dysfunction. The importance of such clinical research appears paramount in light of the number of products containing ginkgo with claims of enhanced cognitive performances that are currently being widely marketed to cognitively intact adults.

The purpose of this research was to conduct the first known, large-scale clinical trial to ascertain the efficacy of ginkgo extract (EGb 761, Dr. Willmar Schwabe GmbH & Co., Karlsruhe, Germany) on the neuropsychological functioning of cognitively-intact older adults. This study was intended to expand upon the authors' previous smaller study, which found that the extract had a positive effect on this particular group.[1]

In the current study, 262 male and female volunteers, 60 years of age and older, who reported no history of dementia or significant neurocognitive impairment were enrolled and randomized. The study utilized a 6-week, randomized, double-blind, fixed-dose, placebo-controlled, parallel-group experimental design. Individuals were randomly assigned to either the ginkgo extract (180 mg daily, 60 mg three times per day) or placebo for six weeks. Prior to the beginning of the study, participants were asked to complete an initial medical history questionnaire. Those with unremarkable medical or psychiatric history were administered the MMSE (Mini-Mental State Examination). Participants meeting the preliminary cognitive and medical inclusion criteria were subsequently administered a series of neuropsychological tests immediately prior to the initiation of ginkgo or placebo therapy, again after 6 weeks of treatment, and just prior to the termination of the study. Efficacy measures consisted of participants' raw changes in performance scores from pretreatment baseline to those obtained just prior to termination of treatment on the following standardized neuropsychological measures: Selective Reminding Test (SRT), Wechsler Adult Intelligence Scale-III Block Design (WAIS-III BD), Digit Symbol-Coding (WAIS-III DS) subtests, and the Wechsler Memory Scale-III Faces I (WMS-III FI) and Faces II (WMS-III FII) subtests. A subjective, follow-up, self-report questionnaire was also administered to participants just prior to termination of the treatment phase.

The analysis of the data revealed that participants who received 180 mg of ginkgo per day exhibited significantly more improvement on SRT tasks involving delayed (30 minutes) free recall ($P < 0.04$) and recognition of noncontextual, auditory-verbal material ($P < 0.01$), compared with the placebo controls. The ginkgo group also demonstrated significantly greater improvement on the WMS-III FII subtest assessing delayed recognition of visual material (human faces), compared with the placebo group ($P < 0.025$). However, there was a significant difference found between the two groups' pretreatment baseline scores on the WMS-III FII ($P < 0.03$), suggesting that this result should be interpreted with caution. Overall, the results from both objective, standardized, neuropsychological tests and a subjective, follow-up, self-report questionnaire provided complementary evidence of the potential efficacy of ginkgo extract in enhancing certain neuropsychological/memory processes of cognitively intact, older adults.

Only one serious adverse effect was reported during the current study and that was in the placebo group. All of the remaining adverse events reported were rated as either mild or mild to moderate in intensity and no causal relationship was determined with the ginkgo treatment. Overall, more adverse events were reported in the placebo group than the treatment group.

The results bolster the findings from the few previously published, small-scale studies that have found improvements in cognitive functioning among older cognitively intact adults and young, healthy volunteers. Although the precise mechanisms responsible for the current findings remain speculative, it seems plausible that several factors may have interacted additively to promote the enhancement of the ginkgo groups' memory processes.

—Densie Webb, Ph.D.

Reference:

1. Mix J, Crews D. An examination of the efficacy of *Ginkgo biloba* extract EGb 761 on the neuropsychologic functioning of cognitively intact older adults. *J Altern and Complement Med* 2000;6:219-29.
2. Solomon PR, Adams F, Silver A, Zimmer J, DeVeaux R. Ginkgo for memory enhancement: a randomized controlled trial. *JAMA* 2002;288:835-40.

Habitual Tea Drinkers May Have Increased Bone Mineral Density

Reviewed: Wu C, Yang Y, Yao W, Lu F, Wu J, Chang C. Epidemiological evidence of increased bone mineral. *Archives of Internal Medicine* 2002;162:1001-1007.

After water, tea (*Camellia sinensis* (L.) Kuntze, Theaceae) is the most common, regularly consumed beverage in the world. It is categorized into three types: green (nonfermented), oolong (partially fermented), and black (fermented). Tea contains several hundred compounds that may affect the body. According to epidemiological studies, the evidence strongly suggests that tea (particularly green tea) may prevent cardiovascular disease, atherosclerosis, and some types of cancer; however, information about the effects of tea consumption on bone mineral density (BMD) is limited. This study sought to answer:

1) Is there relationship between tea consumption and BMD?

Continues on next page

2) Is there a dose-response effect? and
3) Which characteristics of tea consumption influence BMD?

This prospective epidemiological survey of chronic disease in Tainan, Taiwan included a total of 1,037 subjects (497 men and 540 women), 30 years or older in the final analysis. Subjects were questioned on their lifestyle and tea consumption, and had BMD screening of total body, lumbar spine (L1–L4), hip neck, and Ward's triangle (a specific region of the hip bone, or femur, within the narrowest part of the hip).

There was a positive correlation between duration of habitual tea consumption and BMD in the four body regions. Five hundred and two subjects (48.4 percent) were habitual tea drinkers, with a mean duration of tea consumption of approximately 10 years. Compared with nonhabitual tea drinkers, subjects with habitual tea consumption of 6–10 years showed higher lumbar spine BMDs when compared to nonhabitual tea drinkers, and those with consumption of more than 10 years showed the highest BMDs in all measured regions. There was no significant difference in BMD between habitual tea drinkers with 1 to 5 years' duration and nonhabitual tea drinkers. Men had higher BMDs than women, and BMD decreased with age for both genders. Total physical activity also had a positive effect on BMD of the total body, hip, and neck. After adjustment for all covariants, no significant differences of BMD could be found between those who drank green or oolong tea compared with those who drank black tea.

Consistent with other findings, tea had a protective effect on BMD of the total body, lumbar spine, and hip regions. To the authors' knowledge, this was the first study to compare the three types of tea and BMD in both sexes concomitantly. Duration of tea consumption, not amount of daily tea consumption, was the only independent determinant of BMD. The authors found that the change of BMD is always gradual. Long-term, moderate tea consumption appears to influence BMD more than short-term consumption of high amounts of tea.

According to the authors, tea's bone protective effects may be due to its fluoride content. Fluoride intake can alleviate osteoporosis progression. Also, tea contains flavonoids which have been shown to improve BMD. (The authors mistakenly suggest tea contains ipriflavone — a synthetic flavonoid preparation not found in tea.) Any or all of these hypotheses may explain tea's protective effect on BMD.

—Heather S. Oliff, Ph.D

Lavender Oil May Help Agitation in Severe Dementia

Reviewed: Holmes C, Hopkins V, Hensford C, MacLaughlin V, Wilkinson D, Rosenvinge H. Lavender oil as a treatment for agitated behaviour in severe dementia: a placebo controlled study. *International Journal of Geriatric Psychiatry* 2002;17:305-8.

Between 18–65 percent of people with dementia exhibit agitated behavior. Pharmacological treatment using neuroleptics (antipsychotic drugs that reduce confusion, delusions, hallucinations, and psychomotor agitation in patients with psychoses; also known as major tranquilizers and antipsychotic drugs) is often the first line of treatment. However, neuroleptics have only modest efficacy, are not approved in the U.S. for this indication, and can result in severe adverse side effects, including stroke.

Essential oil of English lavender (*Lavandula angustifolia* Mill., Lamiaceae) flower, used in aromatherapy as a relaxant, has been shown in animal and human studies to have sedative qualities upon inhalation. According to Dr. Duke's Phytochemical and Ethnobotanical Databases <www.ars-grin.gov/duke/plants>, lavender contains cholinesterase inhibitors — 1,8-cineole, borneol, coumarin, and limonene — that also have analgesic, anesthetic, antinociceptive (reduces perception of pain), myorelaxant, narcotic, and tranquilizing effects.

The authors hypothesized that inhaled lavender oil would have a beneficial effect on agitated behavior in patients with severe dementia. Fifteen patients (mean age 79 years) with severe dementia and agitated behavior participated in this placebo-controlled study. The common area of a long-term care unit was diffused for two hours with either standard 2 percent concentration of lavender oil (Tisserand; Tunbridge Wells, Kent, England) or water (placebo) on alternate days. During the final hour, an independent blinded (wearing nose clips) rater, unaware of the study design, assessed individual behavior of the patients with the Pittsburgh Agitation Scale (a 16-point observer rating scale of four domains: aberrant vocalization, motor agitation, aggression, and resistance to care). Five treatments and five placebo periods were carried out for each patient over two-weeks.

During aromatherapy, nine patients (60 percent) showed improvement, five (33 percent) showed no change, and one patient (less than 7 percent) showed a worsening of agitated behavior compared to placebo. Results were described as "modest efficacy" by the authors. This was the first published placebo-controlled study of lavender oil in agitated dementia patients. Even though the patient number is small, essential oil of lavender may be a non-invasive, beneficial method for treating agitated behavior in patients with severe dementia. Since one patient worsened following aromatherapy, a group setting may not be the best way to administer treatment.

This study focused on patients with severe dementia. Lavender oil aromatherapy may benefit patients with mild to moderate dementia as well. A larger study exploring different modes of administration and different degrees of dementia is needed.

—Heather S. Oliff, Ph.D.

Intake of Dietary Catechins May Reduce Risk of Death from Ischemic Heart Disease

Reviewed: Arts ICW, Hollman PCH, Feskens EJM, deMesquita HBB, Kromhout D. Catechin intake might explain the inverse relationship between tea consumption and ischemic heart disease: The Zutphen Elderly Study. *American Journal of Clinical Nutrition* 2001;74:227-32.

Some epidemiological studies have found evidence that drinking tea (*Camellia sinensis* (L.) Kuntze, Theaceae) may protect against cardiovascular and cerebrovascular diseases. However, other studies found either no effect or a slightly higher risk of ischemic heart disease (IHD, inadequate blood circulation to the heart, usually as a result of coronary artery disease) with greater tea consumption. Tea contains flavonoids, natural plant chemicals that appear to be responsible for any protective effects of tea. Scientists have identified over 4,000 different flavonoids, which are found in numerous plants. One subgroup of the flavonoid family is known as the catechins.

Catechins are the main components of tea, accounting for approximately 30 percent of the dry weight of green tea and 9 percent of the dry weight of black tea (black tea is fermented green tea). Researchers have identified several possible mechanisms by which catechins could inhibit the development of cardiovascular disease. Catechins may prevent oxidative damage to low-density lipoprotein cholesterol by scavenging free radicals, and inhibit inflammatory processes involved in atherosclerosis. Other potential mechanisms have been proposed, but *in vivo* studies have not yet confirmed any of these theories.

Tea is not the only source of catechins in human diets — apples and chocolate are two other examples of dietary sources. Catechin intakes from other foods may have confounded the results of previous studies that attempted to link tea consumption to risk of cardiovascular disease. Also, reliable data on the catechin contents of various foods were not available until recently, when the authors developed a method for measuring the six major catechins in foods.

This article describes the authors' evaluation of the possible link between catechin intake and incidence of and mortality from IHD and stroke. They used data from the Zutphen Elderly Study, a prospective cohort study of Dutch men who were 65 to 84 years old at study entry in 1985. Complete data were available from 806 men.

The results showed that the mean catechin intake of the 806 subjects was 72 ± 47.8 mg/day (range: 0–355.4 mg/day) at baseline in 1985. Black tea accounted for 87 percent of catechin intake, and apples and chocolate contributed 8 percent and 3 percent, respectively. Legumes and fruits other than apples were minor sources of catechins, whereas vegetables did not contribute any catechins. The authors write, "Because tea was the most important source of catechins in this population, tea consumption increased dose-dependently with catechin intake." However, it would seem that the reverse would be the case (i.e., catechin intake increasing with tea consumption).

The subject population was followed for 10 years, during which time 374 men (46 percent) had died. The cause of death was stroke for 47 men and IHD (as either the primary or secondary cause) for 90 men. A significant inverse association was found between total catechin intake and risk of death from IHD; the adjusted risk ratio was 0.49 in the highest category of catechin intake. Thus, IHD mortality risk was reduced by 51 percent in the highest third of catechin intake. The three groups of total catechin intake were defined as low (0–49.0 mg/day), middle (49.1–85.8 mg/day), and high (85.9–355.4 mg/day). The authors also found that a 50-mg increase in catechin intake was linked to a 25 percent decrease in risk; 50 mg is found in 1 cup of black tea plus a small piece of dark chocolate or in two large apples.

The association between total catechin intake and risk of death from IHD remained essentially unaltered after adjustment for other variables, including prevalence of myocardial infarction or angina pectoris at baseline, physical activity, age, body mass intake, alcohol intake, smoking, dietary factors, prevalent hypertension or diabetes, serum total or HDL cholesterol, and systolic blood pressure. The authors note that prevalent myocardial infarction (heart attack) or angina at baseline had an important influence on mortality. However, "catechin intake was inversely associated with IHD mortality both in subjects free of disease at baseline and in subjects with prevalent disease at baseline."

The data were also analyzed to identify possible associations between catechin intake and both myocardial infarction and stroke. For incidence of fatal and nonfatal myocardial infarction, the age-adjusted reduction in risk with higher catechin intake was not as large as that for IHD mortality. The risk ratio for incidence of myocardial infarction was 0.70 for the highest category of catechin intake, but this was no longer statistically significant after adjustment for possible confounders. For stroke incidence and mortality, there was no relationship with catechin intake.

The authors conclude, "in our study of elderly men in the Netherlands, catechin intake was inversely associated with IHD mortality but not with [heart attack] incidence or stroke." Their study was the first to evaluate links between cardiovascular diseases and catechin intake. However, the study was limited in its ability to distinguish between the effects of tea, catechins from all sources, and dietary flavonols. Future research should attempt to confirm these results and also investigate whether catechins or other substances in tea have protective effects against IHD.

—Christina Chase, MS, RD

Treatment of Constipation-Predominant Irritable Bowel Syndrome with Padma Lax

Reviewed: Sallon S, Ben Arye E, Davidson R, Shapiro H, Ginsberg G, Ligumsky M. A novel treatment of constipation-predominant irritable bowel syndrome using Padma Lax, a Tibetan herbal formulation. *Digestion* 2002;65:161-171.

Irritable bowel syndrome (IBS) is a gastrointestinal disorder characterized by pain, disturbed defecation, bloatedness, and distention, which are unexplained by structural or biochemical abnormalities. According to three studies cited in this article under discussion, 15-20 percent of people worldwide suffer from IBS. Drugs, dietary modifications, behavioral treatments, and alternative therapies are current treatment strategies. Herbal remedies are growing in popularity, but the value of such treatments has not been well studied. Based on a Tibetan recipe traditionally used to treat constipation and aid in digestion, Padma®Lax is a complex formula of 15 herbs and minerals. This article reports on a pilot study evaluating the efficacy and safety of Padma Lax in patients with constipation-predominant IBS.

Eighty men and women (aged 20–81 years) with diagnosed constipation-predominant IBS participated in this randomized, double-blind, placebo-controlled study. All patients entered the 2-week run-in period where an initial gastroenterological screening, blood tests, and daily diaries were recorded for a baseline measurement. After the 2-week run-in, patients took 2 capsules of Padma Lax (n = 42) or an identical looking placebo (n = 38) for 12-weeks. Padma Lax (Padma AG, Schwerzenbach, Switzerland) 482 mg capsules contain: 12.5 mg Aloe standardized extract (*Aloe vera* (L.) Burm. f., Aloaceae and *A. ferox* Mill.), 10 mg calumba root (*Jateorhiza palmata* (Lam.) Miers, Menispermaceae), 10 mg condurango bark (*Marsdenia cundurango* Rchb. f., Apocynaceae), 52.5 mg frangula bark (*Frangula alnus* Mill., Rhamnaceae), 35 mg gentian root (*Gentiana lutea* L., Gentianaceae), 35 mg elecampane rhizome (*Inula helenium* L., Asteraceae), 35 mg chebulic myrobalan or tropical almond fruit (*Terminalia chebula* Retz. var. *tormentella* (Kurz) C.B. Clarke, Combretaceae), 3.5 mg long pepper (*Piper longum* L., Piperaceae), 52.5 mg cascara sagrada bark (*Frangula purshiana* (DC.) J.G. Cooper, Rhamnaceae; syn. *Rhamnus purshiana* DC.), 70 mg Chinese rhubarb root (*Rheum palmatum* L. var. *tangaticum* Regel, Polygonaceae), 1.75 mg nux vomica seed (*Strychnos nux-vomica* L., Loganiaceae), 70 mg ginger root (*Zingiber officinale* Roscoe, Zingiberaceae), 25 mg heavy kaolin (clay), 15 mg sodium bicarbonate, and 35 mg sodium sulfate.

Symptoms, stool consistency, bowel movement frequency, pain, urgency, incomplete evacuation, and abdominal distension were recorded.

Both groups increased their stool frequency throughout the study. However, by the end of three months, subjects receiving Padma Lax increased their mean stool frequency to 6 days per week compared to 5 days per week for placebo-treated subjects (P = .002). Severity of constipation improved in both groups, but was significantly better in patients treated with Padma Lax by the end of the study (P = .0001). After three months of treatment, there was a significant decline in the severity of abdominal pain in the Padma Lax-treated subjects (P = .05). Compared to baseline, subjects receiving Padma Lax experienced a significant decline in flatulence (P < .05) and abdominal distension (P < .01) after three months of treatment. At the end of the study, a general improvement in bowel habit was reported by 70 percent of Padma Lax subjects, compared to 11 percent of placebo subjects (P = .001). Of the 34 Padma Lax subjects who completed the study, 10 had mild side effects, including slight headache, nausea, and hoarseness. Seven subjects developed diarrhea, including one who additionally complained of a mild episode of dizziness, shortness of breath, and chest pain which resolved within 24 hours. Patients with diarrhea were permitted to decrease the dose to 1 capsule per day. There was no difference in final outcomes between patients who maintained the regimen of 2 capsules daily and those who lowered their dosage to 1 capsule per day.

IBS is a chronic condition with spontaneous fluctuations, so three months is the minimum time required to see an effect. During the first month of treatment, placebo and Padma Lax caused nearly the same amount of improvement. An effect at three months may indicate that the patients were receiving more benefit from Padma Lax therapy. Laboratory investigations showed no clinically relevant changes after three months for either the Padma Lax or placebo group in electrolyte levels, in liver and kidney function tests, or blood tests.

The manufacturer's website notes that those who take the product without a doctor's supervision should not take it more than 1–2 weeks, and that exceeding the recommended dose can lead to depletion of essential electrolytes, especially potassium, which can lead to health complications. Patients taking cardiac glycosides are cautioned to exercise particular care with stimulant laxatives. Further, taking laxatives beyond the recommended duration can damage intestinal mucosa and lead to dependency, a significant reduction in the ability to perform normal bowel functions without the use of laxatives. Laxative products should not be used for longer than 1 week, unless directed by a doctor.

It should also be noted that the American Herbal Products Association's *Botanical Safety Handbook* states that the aloe species listed above are contraindicated in "... any inflammatory condition of the intestines ... [including IBS]." That same source notes that products containing cascara sagrada bark, frangula bark, and/or rhubarb root should be labeled to caution consumers to follow directions carefully, and not to use if they have diarrhea, loose stools, or abdominal pain.

Padma Lax has been marketed in Switzerland for more than 30 years, the authors report, with no adverse effects reported to the Swiss health authorities.

—Heather S. Oliff, Ph.D.

Using Plants for Coloring, and as a Potential Treatment for Melanoma

by Anthony L. Almada

The Colors of Money: Extending the Lifespan of Natural Colors

Pattent No.: USA 6572906
Date of issuance: 3 June 2003
Assignee: San-Ei Gen FFI, Inc. (Japan)
Priority date (Japan): 16 March 2000
Method for inhibiting the fading of natural colorants with oligosaccharides

Background

The consumer-driven search for natural colors is not altruistic: natural food colorants generate approximately $1 billion on a global scale, with U.S. sales just under $300 million.[1] Nearly half of the sales are garnered by Europe, with the United States (30 percent) and Japan (20 percent) making the balance. The leaders in natural colorants are Roche, Sensient, Wild Flavors, GNT, Chris Hansen, and San-Ei Gen. This last company has a suite of natural colorants derived from various plant sources. One derived from the juice of purple sweet potatoes is a red to purple anthocyanin-rich extract. San-Ei Gen also manufactures carotenoid colors. The company has used plant cell cultures to produce commercial quantities of colorants. San-Ei Gen first filed for this patent in Japan in March of 2000. This patent described a natural ingredient-based method to prolong the durability and stability of natural colorants, the lack of which has been a primary disadvantage, the other being generally higher prices compared to synthetic dyes and colorants.

Claims

The lead independent (broadest) claim involves the addition of one or more specific oligosaccharides to a natural colorant, or one or more specific oligosaccharides and an antioxidant to a natural colorant, as a method to inhibit fading. In general, oligosaccharides are complex, short-chain sugar compounds. The oligosaccharides called out are *panose* (PAN), an isomalto-oligosaccharide that is a trisaccharide composed of three glucose units with two different types of linkages (alpha-1,4 and alpha-1,6), *maltooligosaccharide* (MOS), an oligosaccharide defined by 2-10 glucose units, linked by 1-4 links, and *nigerooligosaccharide* (NOS), a mixture of nigerose (a disaccharide of glucose with alpha-1,3 links, present in honey and beer, for example) and larger chains (the niger- prefix originates from the discovery of this class of carbohydrates in the cell wall of the mold *Aspergillus niger*).

Numerous antioxidants are described in the patent specifications, including a number of phytochemical and botanical antioxidants. Those specifically described (yet consistently omitting basic botanical identification of the species) are "Chinese bayberry extract, rutin extract, coffee bean extract, rosemary extract" and similar plant extracts, and "enzymatically modified rutin, and enzymatically modified isoquercitrin."

The inventors undertook a series of proof-of-concept experiments, using different concentrations of the three oligosaccharides, with or without antioxidants, and various natural colorants. The applied stress conditions were exposure to room or ultraviolet (UV) light, or heat. The natural colorants assessed were: red cabbage (anthocyanin-based), "Carthamus Yellow" (flavonoid-based), "Gardenia Blue," purple sweet potato (flavonoid-based), and purple corn (flavonoid-based). A common finding was a dose-dependent increase in color persistence with any of the colorants and any of the oligosaccharides used, compared to a control without oligosaccharides. Similar findings were noted with food samples, including juices, syrups, and jellies. A comparison was made to other sugars and oligosaccharides, revealing superior anti-fading properties with the carbohydrates claimed in the invention (NOS was used most frequently). The antioxidant used in combination with the claimed oligosaccharides was an enzymatically modified isoquercitrin (15 percent by weight; other constituents not disclosed; an ingredient sold by San-Ei Gen). Subjecting the natural colorants to UV irradiation, when combined with an oligosaccharide and the isoquercitrin antioxidant, showed substantially greater color persistence. A primary disadvantage of using a natural colorant is the limited shelf stability and color retention. This starts with processing-associated heat exposure and continues through light and oxygen exposure with an on-shelf product, in addition to interactions with other constituents in the product.

Notes

Increasing the shelf stability of a naturally colored food product has large economic implications, presuming the cost of the colorant system is not prohibitive. The allure of a natural color system from a consumer/marketing perspective continues to be a very attractive value offering. What is not addressed in the patent is whether other sensory features of a product are altered (e.g., microbial shelf stability or taste), but the typical concentrations added were less than 3 percent. Those who are keenly interested in natural colorants may consider attending the 5th International Symposium on Natural Colorants, scheduled for November 8–12, 2003, in San Diego, CA. Contact Peter C. Hereld/Hereld Organization (203/281-6766) for more information.

Reference:

1. Anon. Natural colors making a splash. *Food Ingred News* 2003;11:1-2.

Anthony L. Almada is the co-founder/past-president of Experimental and Applied Sciences, of Golden, Colorado, and is the founder/CSO of IMAGINutrition, Inc., of Laguna Niguel, California, a nutritional technology creation, clinical research, and intellectual property-driven think tank/incubator. He has been a co-investigator on more than 60 university clinical trials, ranging from AIDS/HIV to arthritis, and is currently studying for the patent bar exam.

Almada

Betulinic Acid Derivatives for Skin Melanoma

Patent No.: EP 0981341
Date of issuance: 11 June 2003
Assignee: University of Illinois
Priority date (Japan): 16 May 1997
Betulinic acid derivatives for treating and preventing melanoma

Background

Betulinic acid (BetuA) is a steroidal triterpene that has been explored as an anti-cancer agent for over a decade. Its mechanism of action involves activating apoptosis (programmed cell death) by targeting mitochondria (the organelle in every cell that provides energy for cellular function), a mechanism similar to that exerted by hyperforin, found in St. John's wort (*Hypericum perforatum* L., Clusiaceae).[1] Pezzuto and his former colleagues from the University of Illinois first described the selective induction of apoptosis in human melanoma cells[2] (Pezzuto is now at Purdue University). Undoubtedly, this work compelled the leaders of this group to pursue synthetic derivatives of BetuA as agents capable of topically treating or preventing melanoma.

Claims

The patent has only four claims, the primary and lone independent (broad) claim being a composition for topical treatment of metastatic melanoma of the skin, comprising BetuA modified at its C-3 position. The described modifications include a hydrogen atom, alkyl groups of varying lengths, or bromine, chlorine, fluorine, iodine (halide) atoms. The patent asserts that modification of BetuA renders the derived compound much more water soluble and, as a result, more bioactive, suited for topical delivery.

Sourcing of BetuA, as described in the patent specifications, is described in two ways. The abundant presence of betulin (22–25 percent) in the bark of birch (*Betula pubescens* Ehrh., Betulaceae, syn *B. alba* L.) is mentioned, but, due to the 1,000-fold lower BetuA content, a semi-synthetic process of converting betulin into BetuA is suggested. The inventors used a biological assay to assess antitumor activity of the extract. The extract is described as extracting air-dried, milled stem bark of a species of jujube (*Zizyphus mauritiana* Lam., Rhamnaceae) with 80 percent aqueous methanol. This extract was then partitioned successively with hexane and ethyl acetate to provide hexane, ethyl acetate, and aqueous extracts. The ethyl acetate extract that demonstrated cytotoxicity against a cultured melanoma cell line was chromatographed to yield 10 additional fractions.

The patent describes several cytotoxicity studies with various tumor cell lines, using BetuA and other anticancer agents. Related to the claimed invention, a few of the synthetic derivatives were compared to BetuA using cultured human melanoma cells. Several of the derivatives displayed similar selective cytotoxicity, with one, derivative 9, showing superior melanoma cytotoxicity.

Notes

Although the patent claims topical use of the invention, no experiments delivering BetuA or any of its derivatives were described. Moreover, the experiments where BetuA was evaluated *in vivo* (mice with a compromised immune system, injected subcutaneously with human melanoma cells) employed intraperitoneal injections. Japanese researchers have also undertaken the chemical modifications (C3 position) described in the invention, and showed superior apoptosis induction in *mouse* melanoma cells *in vitro*.[3] It will be of interest to see if this semi-synthetic natural product derivative enters the drug development pipeline and demonstrates significant therapeutic and/or prophylactic effects as part of a topical therapeutic for a difficult-to-treat condition (melanoma) of increasing concern in public health.

Reference:

1. Schempp CM, Kirkin V, Simon-Haarhaus B, Kersten A, Kiss J, Termeer CC, et al. Inhibition of tumour cell growth by hyperforin, a novel anticancer drug from St. John's wort that acts by induction of apoptosis. *Oncogene* 2002;21:1242-50.
2. Pisha E, Chai H, Lee I-S, Chagwedera TE, Farnsworth NR, Cordell GA, et al. Discovery of betulinic acid as a selective inhibitor of melanoma that functions by induction of apoptosis. *Nature Med* 1995;1:1046-51.
3. Hata K, Hori K, Takahashi S. Differentiation- and apoptosis-inducing activities by pentacyclic triterpenes on a mouse melanoma cell line. *J Nat Prod* 2002;65:645-8.

CANCELLATION NOTICE

The Role of Botanicals in Healthy Aging

The Role of Botanicals in Healthy Aging, scheduled for August 9–10, was cancelled due to lack of enrollment.

On behalf of the planning organizations, American Botanical Council, American Herbal Products Association, and the American Herbalists Guild, we apologize for any inconvenience this presented and thank our participants, Rutgers University, the presenters and all who put time and energy into this event.

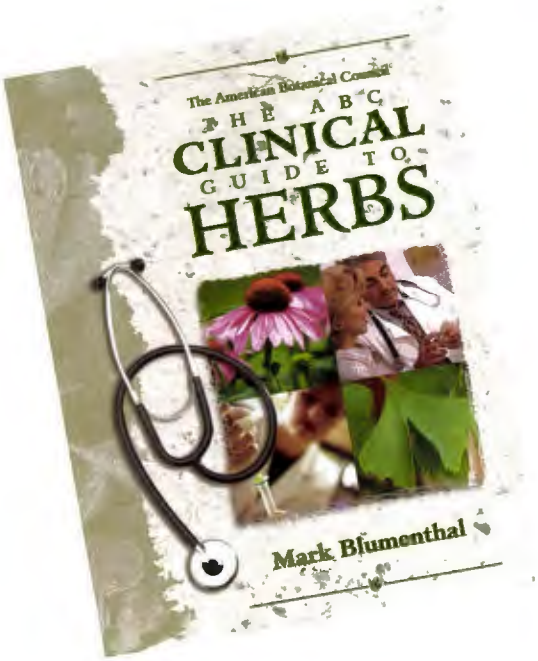
We are very grateful to the sponsors who had committed funds to support this event: Access Business Group/Nutrilite Products, Herbalist & Alchemist Inc., Hoyt Tea, Nature's Way, PhytoPharmica, Reliance Vitamin Company Inc., Standard Process/MediHerb, Virgo Publishing Inc., Vitality Works Inc., and The Vitamin Shoppe Industries Inc.

The Questions:

Consider the Herbs that You and Your Patients Might be Taking:

- How do they interact with conventional medications?
- What are the potential side effects?
- What is the common therapeutic result that can be expected?
- What are the safety issues and contraindications?
- Is the brand being taken backed by clinical studies?
- How long should they be taken?
- How much should be taken?
- Where can healthcare professionals turn to for reliable guidance?

The Answer.



The ABC Clinical Guide to Herbs

Mark Blumenthal, Senior Editor

Scientifically-Based. Objective. Useful.

- Self-paced course/reference guide includes comprehensive clinical monographs, clinical overviews, patient information sheets, and tables of clinical studies, for 29 widely used herbs, as well as additional information about popular combination proprietary products
- Clear, science-based information about safety and drug interactions
- Descriptive dosage and administration guidance

A 512-page, peer-reviewed medical guide offering comprehensive information about the top selling herbs, *The Guide* includes information about the history of the herbs, their use, potential drug interactions, safety information, clinical studies, and a proprietary products section. Nationally approved for Continuing Education Credit, The Guide is unique in that it provides healthcare professionals with in-depth data, as well as offers their patients easy-to-take-home information sheets.

"Fortunately, a 512-page scientific evaluation of herbal supplements, *The ABC Clinical Guide to Herbs*, was just published by the American Botanical Council, a non-profit education and research group I belong to. Although intended as a reference book for doctors and other health professionals, it's rich in facts for consumers, too."

— **Jean Carper**
USA Weekend, EatSmart Section, June 6–8, 2003

Healthcare Professionals and Patients Will Benefit From:

- Comprehensive Clinical Monographs
- Focused, concise Clinical Overviews
- Useful, one-page Patient Information Sheets
- 29 Single herb chapters
- 13 Proprietary product monographs
- 588 Clinical studies summarized
- 180 Branded products noted in studies
- 52 Tables (46 tables of clinical studies)
- 53 Black & white photographs
- 31 Illustrations
- 5 Healthcare professions eligible for continuing education credit
- 512 pages, hardbound

Buy your copy now for $49.95 (plus shipping and handling)
Please call **800-373-7105**, ext.118 or visit **www.herbalgram.org**
or use the order form on the inside back cover of this issue.

Thieme

Exclusive Worldwide Trade Distributor,
Thieme New York 800-782-3488, 212-760-0888 or visit
www.thieme.com

AMERICAN BOTANICAL COUNCIL

Lack of Evidence of Kava-Related Hepatotoxicity in Native Populations in Savaii, Samoa

According to a Survey of Traditional Healers and Biomedical Practitioners

Kava — a beverage consisting of a cold-water infusion of the roots, rhizomes, or basal internodes of *Piper methysticum* Forst., Piperaceae — has long been a symbol of respect and hospitality throughout the islands of Polynesia, western Melanesia, and Micronesia. Kava is served ceremonially to welcome village guests, to inaugurate new chiefs, and to bind communities together. Although specific kava rituals differ from place to place, the basic structure of the kava ceremony is surprisingly similar from island to island. Typically, kava ceremonies are accompanied by ornate rhetoric and supplications to God, coupled with expressions of respect to the chiefs and other dignitaries present. Kava is mildly psychoactive, but its tranquilizing effects are both subtle and nuanced; as a result, kava tends to facilitate social interactions in contrast to plant-based hallucinogenic snuffs or mushrooms, which produce such powerful experiences that indigenous peoples believe their souls are transported to another world.[1]

by Gaugau Tavana, Ph.D.,
Patricia Stewart, D.O.,
Sarah Snyder,
Diane Ragone, Ph.D.,
Krisa Fredrickson,
Paul Alan Cox Ph.D.,
and Joan Borel

Perhaps because of the gentle tranquilizing effects of kava, during the last two decades non-indigenous use of kava-based products skyrocketed throughout North America, Western Europe, and Asia. In 2001 in the United States alone, kava products garnered over $9 million in sales in mainstream retail outlets (a statistic that does not include sales in Wal-Mart stores, some healthfood stores, mail order, multilevel marketing companies, or from health professionals).[2] The estimated total sales for kava in the United States alone could thus be in the range of $30–50 million in 2001, according to a June 2002 letter from the American Botanical Council's Mark Blumenthal. The resultant impact of global commercialization of kava on the economies and cultures of small island nations has been large. Many island nations in the Pacific Ocean, faced with the loss of *copra*, or dried coconut (*Cocos nucifera* L., Arecaceae alt. Palmae) and cocoa (*Theobroma cacao* L., Sterculiaceae) as viable export commodities, have been dependent on kava cultivation as a major source of hard currency earnings. In contrast to the previous colonial plantation economies, kava cultivation has been largely compatible with indigenous agroforestry systems, allowing small family and village-based enterprises to spring up along lines sensitive to local folkways and mores.[3]

Kava *Piper methysticum* Photo ©2003 Diane Ragone

"Although the main economic attraction of kava," writes Vincent Lebot a decade ago, "is its high cash return per work day, it has other advantages over coconuts, cocoa, coffee [*Coffea* spp., Rubiaceae], and, to some extent, black pepper [*P. nigrum* L., Piperaceae]. It matures earlier than major tree crops. As population pressure on land resources increases, the shorter time from planting to harvest will make kava an even more attractive crop for small holders."[3(p177)]

The promise of kava as a culturally benign, economically viable model of village-based development came to an abrupt halt when concerns were recently raised about the safety of kava products. Precipitated by events in Germany and Switzerland where both governments issued statements concerning the potential hepatotoxicity (liver damage) of kava, the U.S. Food and Drug Administration (FDA) stated that it "is advising consumers of the potential risk of severe liver injury associated with the use of kava-containing dietary supplements." In its March 25, 2002, Consumer Advisory the FDA reported:

"Liver-related risks associated with the use of kava have prompted regulatory agencies in other countries, including those in Germany, Switzerland, France, Canada, and the United Kingdom, to take action ranging from warning consumers about the potential risks of kava use to removing kava-containing products from the marketplace. Although liver damage appears to be rare, FDA believes consumers should be informed of this potential risk."

As a basis for its warning, the FDA relied on adverse event reports from European countries as well as reports that it had received since it requested information about adverse events in the United States in a public statement in December 2001. The March Consumer Advisory summarized these reports in this way:

"Kava-containing products have been associated with liver-related injuries — including hepatitis, cirrhosis, and liver failure — in more than 25 reports of adverse events in other countries. Four patients required liver transplants. In the U.S., FDA has received a report of a previously healthy young female who required liver transplantation, as well as several reports of liver-related injuries."

To the authors' knowledge, no studies in animal models or clinical observations in a carefully controlled double-blinded study in human beings have been made to examine potential hepatotoxicity of kava or kava extracts.[4] Two case reports of liver toxicity from kava products where there was no history of concomitant use of other medications or alcohol were recently published.[5] Since some European regulatory settings accept a history of traditional folkloric use of an herb to contribute towards a broad picture of safety and presumed efficacy, patterns of kava use within indigenous societies might be of interest. Given the authors' previous ethnobotanical studies in the islands of the South Pacific,[6] we decided to investigate indigenous knowledge about adverse effects, including hepatotoxicity, from kava consumption among islanders who consume kava on a regular and frequent basis, and who have traditions of doing so for thousands of years. The purpose of our study — based on interviews conducted on Savaii Island, Samoa in May 2002 — was to investigate the availability of evidence of liver damage in native residents of Samoa resulting from kava consumption.

The *tautu* serves kava to the village *matai*. Photo ©2003 Jim Wiseman

Research Site and Methods

Savaii, the largest island (1,820 square km) in the independent nation of Samoa (13° S, 172° W), has a rugged mountainous interior and a tropical climate. Its rainfall is 200 cm or more per year and annual temperatures average 26°C (79°F). Savaii is the least Westernized of the islands in the archipelago, with most people living in villages as subsistence agriculturists and reef foragers. Traditional culture, preserved by a system of village chiefs or *matai* who are responsible for the village and law enforcement, remains strong. At the beginnings of meetings of the village council, kava is usually served according to rank, reaffirming village chiefly titles and hierarchy.

In none of our interviews with traditional healers or with Western-trained healthcare professionals was a linkage reported between kava drinking and liver dysfunction despite nearly universal participation by adult males in kava ceremonies or informal kava use.

In Savaii, we interviewed chiefs (typically male) and traditional healers (typically female) in the villages of Saipipi, Falealupo, and Tafua. In Saipipi, we interviewed four *matai* and one female healer. In Falealupo, one interview was conducted immediately following a kava ceremony, and questions were addressed to the assembly of 30–40 chiefs and orators. One *matai* and one healer also were interviewed individually at Falealupo. One healer was interviewed in Tafua. Informants ranged in age from their late 30s to 70s. We interviewed two Western-trained physicians and two nurses at Matietoa Tunumafili hospital in the village of Tuasivi, the main hospital on the island of Savaii. All interviews were conducted in the Samoan language except for the hospital interviews of western-trained healthcare professionals. Informed consent was obtained from each informant for our use of notebooks, cameras, video cameras, and tape recorders as documentation aids.

We sought to ascertain the informants' knowledge of the different cultivars of kava, how kava is prepared, how and when kava is used, and the effects of kava drinking, especially from excessive or long-term consumption. Questions were asked about any possible contraindications involving kava, and where none were noted, we specifically asked about any possible effects of excess kava consumption on the liver. Together with the physicians on our team, we listened carefully for any descriptions of signs and symptoms related to liver dysfunction. In the case of the interviews with healers, we asked specific questions about liver dysfunction only after we had exhausted opened-ended inquiry about effects of excessive kava consumption.

We also investigated origin myths, social customs, and restrictions related to kava consumption. During our interviews, we participated in three kava ceremonies and drank infusions of kava prepared according to tradition. We observed informal kava consumption by men at work and heavy kava drinking by men in the marketplace.

Results

In Samoa, words for kava are typically binomials, with the generic level term *'ava* being modified by a specific level epithet. In Savaii island, two principal cultivars of kava are in cultivation: *'ava la'au* and *'ava le'a*. The most widely used cultivar of *P. methysticum* was *'ava la'au*, which is distinguished by its short internodes. *'Ava le'a* has internodes up to 30 cm long. Our informants identified six additional varieties of kava. *'Ava toga* has a strong taste and ordinarily is not used for drinking. *'Ava talo* and *'ava tuna* are foreign cultivars not considered appropriate for traditional ceremonial use. Other names given were *'ava mumu*, or red kava, *'ava Samoa*, and *'ava inu*, which means "drinking kava." Our informants distinguished these cultivar names from others given to forms of kava during kava ceremonies to fulfill ritual dictates. Hence kava that is chopped up into small pieces is called *uga o le i'a sa* ("turtle scales"), small roots bundled together are called *fetaia'i ma uso* ("fellowship and brotherhood"), long ceremonial kava sticks are called *lupe sina* (white pigeons), and stout kava sticks are called *tugase* ("standing alone"). In addition, the generic level term *'ava* appears reduplicated as the local name of the forest vine *Macropiper graeffei* Warb., Piperaceae, *'ava'ava a'itu* (*a'itu* = "demon") and as an unrelated term for bioactive water infusions including the fish poison derived from *'ava sa* (*Tephrosia purpurea* (L.) Pers., Fabaceae alt. Leguminosae)[7] and the imported *ava niukini* (*Derris malaccensis* (Benth.) Prain, Fabaceae). Liquor is also called *'ava malosi* (*malosi* = "strong")

Preparation and Uses of Kava

Consistent with information obtained in published ethnobotanical accounts, our group found that *'ava* is consumed during formal ceremonies, at informal social gatherings, and as medicine.[8]

According to our informants, kava is also used frequently by men doing hard labor.

For ceremonies the *'ava* is prepared by the *taupou*, traditionally the virgin daughter of a paramount chief, who mixes the dried powdered roots with water in a special bowl, the *tanoa* *'ava* which is invariably made from the dense timber of *ifilele* (*Intsia bijuga* Kuntze, Fabaceae alt. Leguminosae). She strains the solids from the liquid with a strainer made from the vascular bundles of the leaf petioles of *Heliconia paka* A.C. Smith, Musaceae. The kava is then sequentially served in a coconut shell bowl to the *matai* and guests in strict order of rank. *Tugase*, the ceremonial kava sticks made from the long stems and root balls of the kava plants, are presented formally as gifts to distinguished visitors.

Presenting kava to one of the village *matai* (Metuli Ah-Chew). Photo ©2003 Jim Wiseman

Kava is also consumed in non-ceremonial situations. As a beverage drunk prior to and during physical labor, amounts between one to eight liters or more may be consumed. Drinking *'ava* is said to slake thirst and hunger, promote sweating, and reduce the heat of the sun on the skin.

Recreational drinking also occurs in Samoa. At public markets in Salelologa on Savaii and in Apia, on the island of Upolu, we observed groups of men seated around large kava bowls, drinking continuously, and playing *mu*, a game similar to checkers. Excessive *'ava* drinking, however, is frowned on by the community, and some churches oppose the use of *'ava* except in ceremonial situations, viewing the idleness associated with marketplace drinking as a bane in and of itself.

Kava is also used in traditional healing. Samoan healers use *'ava* as medicine in treating both men and women for a variety of ailments. An infusion of stems and bark is used for back pain and stomach upset. For severe back or stomach pain, they use an infusion of roots, which they believe are stronger in effect.

Effects of Kava Use

Kava is a mild, non-addictive drink that creates feelings of well-being and promotes cooperative social behavior.[1,9] Consuming quantities of kava leads to sleepiness and unsteadiness without the loss of mental faculties. While participating in *'ava* ceremonies, we noted that after drinking *'ava* there was a tingling sensation and slight numbness in the mouth, presumably a result of the well-documented local anesthetic effect of kava. No other symptoms were experienced by the authors during kava ceremonies in which they participated.

No one reported major clinical signs of liver malfunction in association with kava drinking, such as yellowing of the eyes, brown urine, and changes in stool, even when asked specifically for signs of such symptoms.

The men of the villages who drink *'ava* on a regular basis reported that drinking *'ava* helps a person to relax, think more clearly, and sit cross-legged on floor mats for long periods of time during the *'ava* ceremonies. For working men, *'ava* promotes strength and suppresses thirst and appetite.

All informants reported that excessive consumption of *'ava* is very rare and that its symptoms are reversible. Men, such as those who drink *'ava* all day in the markets, may experience transitory dizziness, dry pale skin conditions, weight loss due to appetite suppression, drowsiness, watery eyes, hair loss, or upset stomach. In contrast to literature reports,[10] the healers did not identify ichthyosis (a type of dermatitis) as a consequence of excessive kava consumption, but did describe for the dermatologist in our team a condition of dry, pale skin. The healers indicated a simple cure for problems associated with excessive kava consumption: cessation of *'ava* consumption, and sweating through hard work. They reported that when *'ava* consumption stops and the person works up a sweat that the symptoms quickly disappear. The difference between the effects of *'ava Samoa* and *'ava palagi* (alcohol) were strongly emphasized by the *matai* and hospital staff interviewed.

Offering a *tali*, libation or blessing, of kava before drinking. Photo ©2003 Jim Wiseman

Two of the village healers, one from Saipipi and one from Falealupo, were able to describe in detail the signs and symptoms

of liver dysfunction including jaundice and abdominal distention to the satisfaction of the physician and medical student on our team. Patients with *ma'i ake* (liver dysfunction) are referred by the healers to the Western hospital for treatment. Both healers and hospital personnel report an association between excessive alcohol consumption and liver dysfunction, or with a combination of excessive alcohol and kava consumption, but no liver problems were reported from patients who have a history of drinking only kava. Two nurses reported seeing liver damage and peptic ulcers among patients with a history of alcohol and kava drinking, but specifically stated that they have never seen liver problems among those who drink kava exclusively. We did not, however, see patients or review case histories, and so this conclusion is based solely on interviews with hospital physicians and nurses.

Smiling *taupou*, daughter of a high-ranking *matai*, who mixes the kava, surrounded by *matai* of her village. Photo ©2003 Diane Ragone

Discussion

In none of our interviews with traditional healers or with Western-trained healthcare professionals was a linkage reported between kava drinking and liver dysfunction despite nearly universal participation by adult males in kava ceremonies or informal kava use. Many Samoans were familiar with the effects of excessive kava use, especially sleepiness and dry skin, but reported that excessive consumption was rare. No one reported major clinical signs of liver malfunction in association with kava drinking, such as yellowing of the eyes, brown urine, and changes in stool, even when asked specifically for signs of such symptoms. The native healers we interviewed are able to recognize the symptoms of liver injury, and their diagnoses have been confirmed in hospitals, yet they maintain that they have never seen liver damage as a result of kava drinking. Physicians and nurses working at the hospital agree. Based on the uniformity of these reports and the complete lack of any diagnostic symptoms of liver damage reported among the Samoans who are heirs to thousands of years of knowledge and experience with kava, we believe that the assertion by the FDA and other groups that moderate consumption of kava may result in liver dysfunction should be subjected to rigorous testing and verification. Given their economic stake in kava production, Pacific nations would likely welcome research applications to study the effects of kava on liver enzymes and liver function among traditional kava consumers.

Tugase, ceremonial kava sticks, presented to visitors by the high ranking *matai* of the host village. Photo ©2003 Diane Ragone

Acknowledgments

The authors thank Fuiono Masé'e Lilo Manuele, Lemau Seumanutafa, Tiuli Paulo, Tapusoa Utu, Nu'uleleinokise, Fa'ifili Malo, Tamara Rasmussen, M.D., Leutogi Tè'o, Lupe Levila, and Lusila Tinei Tofa and the villagers of Falelaupo and Saipipi, Samoa for assistance.

Gaugau Tavana is Director of Education at the National Tropical Botanical Garden (NTBG) in Hawaii and a Samoan chief; Patricia Stewart is a dermatologist in Santa Barbara, California; Sarah Snyder is a medical student at the University of Utah; Diane Ragone is Director of Horticulture & Conservation at the NTBG; Krisa Fredrickson is an anthropologist studying at the University of Canterbury, Kent; Paul Alan Cox is Director of the NTBG; and Joan Borel is an anthropologist who works in Key West, Florida.

References

1. Balick MJ, Cox PA. *Plants, People, and Culture: An Introduction to the Science of Ethnobotany.* New York: W. H. Freeman; 1997. p. 160-4.
2. Blumenthal M. Herb sales down in mainstream market, up in natural food stores. *HerbalGram* 2002;55:60.
3. Lebot V, Merlin M, Lindstrom L. *Kava: The Pacific Drug.* New Haven, Connecticut: Yale University Press; 1992.
4. Blumenthal M. Kava safety questioned due to case reports of liver toxicity. *HerbalGram* 2002;55;26-32.
5. U.S. Centers for Disease Control and Prevention. Hepatic toxicity possibly associated with kava-containing products—United States, Germany, and Switzerland, 1999-2002. *JAMA* 2003;289:36-7.
6. Cox PA, Banack SA, eds. *Islands, Plants, and Polynesians.* Portland, Orgeon: Dioscorides Press; 1991.
7. Cox PA. Use of plants as fish poisons in Samoa. *Economic Botany* 1980;33(4):397-9.
8. Whistler WA. *Plants in Samoan Culture.* Honolulu, Hawaii: Isla Botanica; 2000.
9. Singh YN, Blumenthal M. Kava: An overview. *HerbalGram* 1997;39:33-56.
10. Ruze P. Kava-induced dermopathy: a niacin deficiency? *The Lancet* 1990;335:1442-5.

American Herbalists Guild

©Photos Courtesy of Martin Wall (336.834.4143)

Symposium 2003

American Herbalists Guild

October 17-19, 2003

Preconference intensives
will be held on October 16

La Posada de Albuquerque, New Mexico

Keynote Speaker

Tieraona LowDog, M.D.

Over 40 workshops by leading herbalists. Teachers include:

Mary Bove
Francis Brinker
Isla Burgess
Bevin Clare
Mitch Coven
Steven Dentali
Robin Dipasquale
Margi Flint
Daniel Gagnon
Christopher Hobbs
Phyllis Hogan
KP Khalsa
Brigitte Mars
Michael Moore
Aviva Romm
Robert Rountree
James Snow
Kevin Spelman
Jill Stansbury
Shelley Torgove
Jonathan Treasure
David Winston
Donald Yance
and many others.

NEW!!! 2-DAY POST-CONFERENCE CLINICAL INTENSIVE. OCTOBER 20 & 21.

Improve your clinical skills and gain valuable hands-on experience. Special opportunity for in-depth study with AHG teachers.

Continuing education credits for nurses, pharmacists, acupuncturists, and naturopathic physicians.

For information contact:
AHG
1931 Gaddis Rd
Canton GA 30115

770.751.6021
fax: 770.751.7472

email: ahgoffice@earthlink.net
www.americanherbalist.com

Rooibos Tea

Research Into Antioxidant and Antimutagenic Properties

by Laurie Erickson

Above and below: Rooibos growing in the Cedarberg region of South Africa.

Left: During spring, the Cedarberg region is transformed as wild flowers in the millions carpet the earth with brilliant color.
Photos ©2003 Rooibos Ltd./SunnRooibos

Antioxidants are hot topics in the health news these days, and an herbal tea called rooibos (pronounced ROY-boss) is becoming popular partly because it is being marketed as a healthy beverage with high levels of antioxidants. The rooibos plant (*Aspalathus linearis* (Burm. f.) Dahlgren, Fabaceae) is a South African flowering shrub used to make a mild-tasting tea that has no caffeine, very little tannin, and significant amounts of polyphenol antioxidants. Although the tea is new to many Americans, it has been made in the Cedarberg mountain region of South Africa for generations. Distributors are promoting the tea for numerous health benefits, citing recent studies that show some antioxidants found in rooibos tea may protect against cancer, heart disease, and stroke. What's the evidence for these claims?

A Note on Tea Terminology

In the strict sense, the word *tea* has been reserved for infusions made from leaves of the evergreen shrub *Camellia sinensis* (L.) Kuntze, Theaceae, while infusions made from herbs such as rooibos have been called *tisanes.* Over time, however, the common use of the word tea has been extended to include herbal infusions, and this relaxed usage is followed here. Rooibos is often referred to as red tea because it makes a vibrant red-colored tea, which can be confusing because black tea and hibiscus herbal tea are also sometimes called red tea.

Botanical Description

Rooibos is a shrubby legume that is indigenous to the mountains of South Africa's Western Cape.[1-3] The genus *Aspalathus* includes more than 200 species native to South Africa.[2-5] *A. linearis* is a polymorphic species; various wild forms have been described, each with characteristic morphology and geographical distribution.[1-3] Some forms are prostrate and remain less than 30 cm (1 foot) tall, while other forms grow erect and may reach up to 2 m (about 6 feet) in height.[1-3,6] The types of wild rooibos that have been used to make tea are sometimes referred to as the Red, Black, Grey, and Red-Brown types.[1,2]

The type of *A. linearis* that is cultivated commercially for tea is the Red type, also known as the Rocklands type;[1,6] it is native to the Pakhuis Pass area in the northern Cedarberg region.[6] The Rocklands type grows erect, up to 1.5 m (about 5 feet) in height. It has a single basal stem that divides just above the ground surface into multiple thin branches that carry bright green, needle-like leaves of about 10–40 mm (0.4–1.6 inches) in length.[7] The plant produces small yellow flowers in spring through early summer,[6] and each flower generates a one-seeded leguminous fruit.[4,5]

Rooibos has adapted to coarse, nutrient-poor, acidic soil and hot, dry summers.[4,5,8] In addition to a network of roots just below the soil surface, the plant has a long tap root that reaches as deep as 2 m (about 6 feet) and helps the plant find moisture during summer drought.[5] As a legume, rooibos contains nodules of nitrogen-fixing bacteria on its roots; this characteristic helps the plant survive in the poor Cedarberg soils and minimizes the need for fertilizing commercial crops with nitrogen.[8] The bacteria convert nitrogen dioxide to biologically useful ammonia in a process known as *nitrogen fixation.* The plant absorbs the nitrogen and benefits from it in exchange for providing the bacteria with food sources created from photosynthesis.

One study found genetic variations between four morphologically different populations of *A. linearis.*[1] The authors suggest that the wild forms of *A. linearis* might be used to improve characteristics, such as yield and disease resistance, of the cultivated form. They also observe that because the cultivated Rocklands form is being grown outside of its original Pakhuis Pass location, this introduction of the cultivated form into new areas could threaten the genetic integrity of the wild forms in these areas.

A later study[7] showed genetic differences between populations of *A. linearis* that are *sprouters* (plants that can resprout from a deep rootstock to regenerate after a fire) and populations that are *seeders* (plants that rely on producing plentiful seeds to reproduce). The authors suggest that reseeding is the primitive character state in *A. linearis* and resprouting is a derived state that evolved to help the plant survive in a region prone to wildfires. The rooibos plant that is commercially grown for tea is the seeder type.[7]

In addition to differences in morphology and genetics,

Above : Rooibos growing in the Cedarberg region of South Africa. Photos ©2003 Rooibos Ltd./SunnRooibos

Left: Workers process traditional rooibos on a tea court, where the leaves and stems are spread to dry in the sun. Photo courtesy ASNAPP.

researchers have found differences in chemistry between various populations of *A. linearis*.[6,9] Van Wyk, of the Department of Botany at Rand Afrikaans University, presented results of his tests on the different wild populations of rooibos, showing significant variations in the polyphenol profile by population.[9]

Historical Background

More than 300 years ago, indigenous inhabitants of the mountainous regions of South Africa's Western Cape were the first to collect wild rooibos and use it to make tea.[10] These people discovered that they could brew a sweet, tasty tea from rooibos leaves and stems that they cut, bruised with wooden hammers, fermented in heaps, and then sun-dried. Botanists first recorded rooibos plants in 1772 when they were introduced to the tea by the Khoi people.[10]

Flowering Rooibos. Photo ©2003 Rooibos Ltd./SunnRooibos

Rooibos became a cultivated crop by the early 1930s, has been grown commercially since World War II, and now is exported to countries worldwide, including Germany, Japan, the Netherlands, England, Malaysia, South Korea, Poland, China, and the United States.[10] In 1999, about 29 percent of South Africa's total rooibos sales were exported to 31 countries.[10] The quantity of rooibos exported in 2000 was two and a half times greater than the quantity exported in 1999, and exports continue to grow.[10] The small towns of Clanwilliam and Wupperthal, north of Cape Town in the Cedarberg region, have a long history of rooibos cultivation; these towns are popular tourist stops because of their beautiful rural scenery and their role in the rooibos industry.

Roughly 70 percent of the bulk rooibos that is exported goes through Clanwilliam-based Rooibos Ltd. <www.rooibosltd.co.za>, a partnership of private growers/processors and a cooperative of large and small farmers in the area. The rooibos is sold in a variety of products in Europe, Asia, and, increasingly, America. Other South African companies that market rooibos tea products include Khoisan, Cape Natural Tea Products, and Coetzee & Coetzee. International demand for rooibos has been increasing since trade sanctions against South Africa were lifted following the demise of apartheid in the 1990s. Since 1999, the nonprofit organization Agribusiness in Sustainable Natural African Plant Products (ASNAPP, <www.asnapp.org>) has helped small farmers in and around Wupperthal to introduce sustainable methods of rooibos cultivation that allow them to compete in the world market. ASNAPP is sponsored by the U.S. Agency for International Development, Rutgers University, and Stellenbosch University. Through Stellenbosch University, ASNAPP also helped the farmers at Wupperthal fund construction of a tea court to process rooibos.

Rutgers University provides a quality control program for ASNAPP's Wupperthal tea program, evaluating parameters such as color, taste, aroma, pH, moisture content, cleanliness, total phenol content, and antioxidant capability for tea samples collected from the industry in general and from all the growers in the Wupperthal tea program.[11] Data from their analyses are made available to the farmers and also to prospective buyers via product specification sheets.

The Perishable Products Export Control Board (PPECB) of South Africa ensures that all exported rooibos products pass a phytosanitary inspection and are certified to be free of bacteria and impurities.[4,10] In order to pass these health and safety tests, rooibos producers steam pasteurize the tea as the final step before packing. Organic rooibos is also monitored by various international organizations that provide organic certification, such as the German firms Ecocert and Lacon.

Harvesting and Processing: Fermented and Unfermented Rooibos

When rooibos is cultivated commercially, the needle-like leaves and stems are usually harvested in the summer, which corresponds to January through March in South Africa.[4] The plants are cut to about 30 cm (1 foot) from the ground at harvest time and begin another major growth cycle the following spring. The harvested rooibos is processed two different ways, producing two types of tea. The green leaves and stems are either bruised and fermented or immediately dried to prevent oxidation. The traditional fermented

tea is processed today in much the same way as the indigenous people processed it hundreds of years ago, including the sun-drying step, but the tools are more sophisticated now.

The fermented type is called red tea because fermentation turns the leaves and the resulting tea a rich orange/red color; this distinctive color led to the Afrikaans name *rooibos*, which means "red bush." The unfermented type, often called green rooibos, contains higher levels of polyphenol antioxidants because fermented rooibos loses some antioxidants during the fermentation process. The unfermented type was developed to maximize antioxidant levels in response to recent interest in the health benefits associated with the antioxidants found in *C. sinensis* teas. Unfermented rooibos tea is a tan/yellow color rather than the rich reddish color of fermented rooibos.

Both types of rooibos tea are available plain or flavored, loose or in tea bags, organic or conventionally grown. Rooibos is graded according to color, flavor, and cut length, with the highest grade labeled "supergrade." The tea has a smooth, non-bitter flavor that is pleasant hot or chilled. The unfermented variety has a very mild "green" taste reminiscent of green tea but without the astringency; the fermented type is quite different, with a stronger sweet and fruity taste. The mild flavor of rooibos has made it popular in multi-ingredient herbal tea blends.

Antioxidants in Rooibos

Free radicals (unstable molecules that have lost an electron) can damage the DNA in cells, leading to cancer, and they can oxidize cholesterol, leading to clogged blood vessels, heart attack, and stroke. Antioxidants can bind to free radicals before the free radicals cause harm. Some antioxidants are called polyphenols because these substances contain a phenolic ring in their chemical structure. Polyphenols are common in plants; they act as pigments and sunscreens, as insect attractants and repellants, and as antimicrobials and antioxidants.[12,13] The polyphenol group is further divided into subgroups such as flavonoids and phenolic acids. Polyphenols can also be classified as *monomeric* (molecules containing a single unit) or polymeric (larger molecules containing more than one unit). As described in this section, laboratory studies have found that rooibos tea contains polyphenol antioxidants, including flavonoids and phenolic acids, that are potent free radical scavengers.

Flavonoids: The polyphenol antioxidants identified in rooibos tea include the monomeric flavonoids aspalathin, nothofagin, quercetin, rutin, isoquercitrin, orientin, isoorientin, luteolin, vitexin, isovitexin, and chrysoeriol.[14-19] Currently, rooibos is the only known natural source of aspalathin.[15] Nothofagin is similar in structure to aspalathin and has only been identified in one other natural source besides rooibos: the heartwood of the red beech tree (*Nothofagus fusca* (Hook F.) Oerst, Nothofagaceae), which is native to New Zealand.[20]

A recent analysis of fermented rooibos measured the levels of all the flavonoids listed above except nothofagin (see Table 1).[19] Of the 10 flavonoids measured, the three that occurred in largest amounts were aspalathin, rutin, and orientin, followed by isoorientin and isoquercitrin. Nothofagin was identified by mass spectrometry but was not quantified because a standard was not available. The amount of nothofagin in fermented and unfermented rooibos was estimated to be about three times less than aspalathin in one study.[20] Aspalathin and nothofagin are present in relatively large amounts in unfermented rooibos tea,[19,20] but some of the aspalathin and nothofagin oxidizes to other substances during fermentation; thus, fermented rooibos contains less aspalathin and nothofagin than unfermented rooibos.[20] The change in polyphenol composition is the reason the tea changes color with fermentation.[20]

Phenolic Acids: In addition to flavonoid antioxidants, rooibos also contains phenolic acids that have been shown to have antioxidant activity.[14,18,21] Like flavonoids, phenolic acids are polyphenol substances that are found in fruits, vegetables, and whole grains. The phenolic acids identified in rooibos tea, in decreasing order of antioxidant activity as measured in one study[21] with the commonly used 1,1-diphenyl-2-picrylhydrazyl (DPPH) radical scavenging assay, include caffeic acid, protocatechuic acid, syringic acid, ferulic acid, vanillic acid, *p*-hydroxybenzoic acid, and *p*-coumaric acid.[14,18] Using the DPPH assay, caffeic acid was just as active an antioxidant as the most potent flavonoids tested (quercetin, isoquercitrin, and aspalathin).[21]

Rooibos grows in the Cedarberg Mountain region of South Africa.

Total Polyphenol Content: Despite some promotional claims, a serving of rooibos tea has less total polyphenols than the same size serving of green or black tea. Serving size varies, but for comparison purposes a 150 to 200 ml serving is often used (about 3/4 of a standard baking measuring cup). Elizabeth Joubert, Ph.D.,

Table 1: Flavonoids in Aqueous Extract of Fermented Rooibos (mg/g +/- SD)

Flavanoid	(mg/g +/- SD)
isoorientin	0.833 +/- 0.007
orientin	1.003 +/- 0.010
aspalathin	1.234 +/- 0.010
vitexin	0.330 +/- 0.002
rutin	1.269 +/- 0.006
isovitexin	0.265 +/- 0.002
isoquercitrin and hyperoside	0.429 +/- 0.002
luteolin	0.029 +/- 0.001
quercetin	0.107 +/- 0.002
chrysoeriol	0.022 +/- 0.001
total	5.521 +/- 0.003

Note: The extracts were prepared using 1 g of rooibos in 60 ml of hot distilled water, steeped for 10 minutes. After removal of the tea leaves, the solution was cooled and filtered. The table gives the amounts of flavonoids in mg per g of extract.

Source: Bramati L, Minoggio M, Gardana C, Simonetti P, Mauri P, Pietta P. Quantitative characterization of flavanoid compounds in Rooibos tea (Aspalathus linearis) by LC-UV/DAD. *J Agric Food Chem* 2002 Sep 25;50(20):5513-9.

specialist researcher at South Africa's ARC Infruitec-Nietvoorbij and a rooibos expert, says that the total polyphenol content of an average 150 to 200 ml serving of rooibos tea can be as much as 60 to 80 mg, depending on factors such as the brewing time and amount of leaves used.[22] For comparison, one study found that brewing black tea leaves for 1 to 3 minutes at a concentration of 1 g leaves per 100 ml water resulted in black tea that contains 128 to 199 mg of polyphenols per 200 ml serving of tea.[23] The types of polyphenols in rooibos tea are different than those in green and black teas, so the potential health benefits of the teas cannot be compared solely on their total polyphenol content. Rooibos tea does not contain epigallocatechin gallate (EGCG), which is a polyphenol in green tea that has shown anticarcinogenic and antioxidant capabilities, but many of the polyphenols in rooibos tea are also strong antioxidants.

Quercetin and Luteolin: Two of the flavonoids in rooibos tea, quercetin and luteolin, are potent antioxidants found in many fruits and vegetables. Studies *in vitro* (in the test tube) have shown that these antioxidants can cause cancer cells to "commit suicide," referred to as apoptosis.[24-27] Quercetin decreased primary tumor growth and prevented metastasis in a model of pancreatic cancer.[25] Luteolin and quercetin inhibited proliferation of thyroid[28] and colon[29] cancer cells, respectively, *in vitro*. Quercetin inhibited cyclooxygenase-2 (COX-2) expression in colon cancer cells, which may help prevent colon cancer.[30,31] Both luteolin and quercetin can block the formation of lipid peroxides.[32-34]

Although studies like these show quercetin and luteolin are strong antioxidants, researchers haven't yet determined whether enough of either of these two flavonoids are present in rooibos tea and absorbed by the body to have beneficial effects. As shown in Table 1, recent analysis of fermented rooibos found considerably more quercetin than luteolin,[19] but even quercetin was present in much lower amounts than aspalathin, orientin, and rutin.

Based on the data in Table 1, a 150 ml serving of fermented rooibos tea made with 2.5 g of tea leaves has about 0.27 mg of quercetin; for comparison, one study found that *C. sinensis* contains 1.5 to 3.75 mg of quercetin per 150 ml serving of tea.[35] A previous study[36] found 1.5 mg of quercetin per 150 ml serving of fermented rooibos, but that may be an upper limit. Joubert says that the 1.5 mg estimate is probably high,[22] but emphasizes that these estimates will vary with parameters such as the brewing time and the amount of water and tea leaves used. At any rate, the amount of quercetin per serving of rooibos is a small percentage of the total polyphenol content per serving of rooibos.

Rooibos growing in the Cedarberg region of South Africa. Photo ©2003 Rooibos Ltd./SunnRooibos

Aspalathin and Nothofagin: A unique polyphenol that is one of the most abundant monomeric flavonoids in rooibos tea,[19,20] aspalathin seems to contribute to the antioxidant capabilities of rooibos,[21] but aspalathin is not as well studied as quercetin and luteolin. Nothofagin is similar in structure to aspalathin and may have similar antioxidant capabilities.

Joubert says that chief research technologist Petra Snijman of the Program on Mycotoxins and Experimental Carcinogenesis (PROMEC) at the Medical Research Council of South Africa recently developed a way to isolate pure aspalathin and nothofagin from rooibos. Joubert says, "According to unpublished *in vitro* studies done at ARC Infruitec-Nietvoorbij, aspalathin compared well with quercetin in terms of antioxidant activity, except in a fat medium where quercetin demonstrated much higher potency than aspalathin. What is important in these comparative studies is the test environment. Relative efficacy will depend on the test system used (the polarity of the medium, the type of free radical that needs to be scavenged, etc.)."[22]

Joubert co-authored a study[21] that found aspalathin compared well to other antioxidants with the DPPH radical scavenging assay. The study measured the antioxidant capability of many of the flavonoids and phenolic acids found in rooibos tea and compared them to several reference standards such as alpha-tocopherol (vitamin E). The percent inhibition of the DPPH radical by quercetin, isoquercitrin, aspalathin, rutin, luteolin, and alpha-tocopherol was 98.27, 91.99, 91.74, 91.18, 90.85, and 75.10, respectively (using a 0.25 mole ratio of antioxidant to DPPH). All of the flavonoids tested showed potent hydrogen donating abilities with DPPH except for vitexin, which only had a 7.26 percent inhibition even at a 0.5 mole ratio to DPPH.

According to the data in Table 1, a 150 ml serving of fermented rooibos made with 2.5 g of tea leaves has about 3 mg of aspalathin; since the amount of nothofagin was measured to be three times less than aspalathin in one study,[20] a 150 ml serving of fermented rooibos has on the order of 1 mg of nothofagin. A serving of unfermented rooibos has considerably more aspalathin and nothofagin than an equal serving of fermented rooibos because a portion of these flavonoids oxidizes to other substances during fermentation.[20]

Orientin and Rutin: Orientin and rutin are two of the other most abundant monomeric flavonoids in rooibos,[19] and both have been associated with health benefits. Orientin is a potent free radical scavenger. It reduced by half the number of cancer-associated changes in cells of human blood exposed to radiation.[38] When mice were exposed to radiation, orientin protected against lipid peroxidation in the liver and also reduced damage to the bone marrow and gastrointestinal tract.[39,40] Rutin, a flavonoid found in buckwheat (*Fagopyrum esculentum* Moench, Polygonaceae) and some fruits and vegetables, seems to help maintain the strength of capillary walls; oral rutin as well as oral and topical o-(beta-Hydroxylethyl)-rutoside (HR) have been used to treat hemorrhoids, varicose veins, and the lower leg edema associated with venous insufficiency and venous hypertension.[41-46] According to the data in Table 1, a 150 ml serving of fermented rooibos tea made with 2.5 g of tea leaves has about 2.5 mg of orientin and 3.2 mg of rutin.

Total Antioxidant Capability: Although the 10 flavonoids in Table 1 are important because they are known to have antioxidant properties, they only represent a small percentage of the total polyphenol content of a serving of fermented rooibos tea. A 150 to 200 ml serving of rooibos can have up to 60 to 80 mg of total polyphenols,[22] and Table 1 shows that a 150 ml serving of fermented rooibos made with 2.5 g of leaves has about 14 mg of the 10 flavonoids in the table. Many other polyphenols are present, but they have not all been identified or quantified.

To assess the antioxidant capability of rooibos tea as a whole, researchers compared the antioxidant activity of rooibos tea extracts to thar of green and black tea extracts with the DPPH radical scavenging assay as well as the beta-carotene bleaching method.[47] All the teas showed strong antioxidant activity with both methods. Using the DPPH method, the ranking from highest to lowest antioxidant activity was green tea (90.8 percent inhibition), unfermented rooibos (86.6 percent), fermented rooibos (83.4 percent), and black tea (81.7 percent). Green tea was significantly higher than the others ($P < 0.05$), but the other three teas did not differ from each other significantly with respect to DPPH inhibition. Using the beta-carotene bleaching method, the ranking was green tea, black tea, fermented rooibos, and unfermented rooibos. The relative ranking varies with the type of test because the substance to be tested will have different reactivity to the different oxidizing agents used. These tests only measure the antioxidant capability of substances outside of the body and don't provide data on whether the antioxidants are absorbed by the body and effective after the food is consumed.

In this study, all the tea extracts were diluted to the same amount of soluble solids rather than to the amounts of solids found in the teas.[47] This method allows a comparison of antioxidant capability on a mass equivalent basis, but does not reflect a comparison of the antioxidant strength of equal volume servings of the teas. Although the soluble solid content varies with the method of tea preparation, it usually decreases in the order green tea, black tea, unfermented rooibos, fermented rooibos.[47] The percent of soluble solids represented by polyphenols is similar for the four teas and the DPPH antioxidant activity is similar on a mass equivalent basis, so the DPPH antioxidant capability of equal-sized servings will decrease in the order of the soluble solid content.[47] Black and green teas have over twice as much soluble solids as rooibos tea when prepared conventionally, so over two 200 ml servings of rooibos tea would need to be consumed to receive the same antioxidant benefit (as measured by DPPH) as one 200 ml serving of black or green tea (or the rooibos would need to be brewed to twice the standard concentration).[47] This result agrees with the data given previously for 60 to 80 mg polyphenols for a 150 to 200 ml serving of rooibos tea[22] as compared to 128 to 199 mg polyphenols for a 200 ml serving of black tea.[23]

The studies referenced above show that rooibos tea contains antioxidants that have positive effects when tested as isolated substances and that the tea as a whole has good antioxidant activity *in vitro*. So, do all these antioxidants in rooibos tea lead to health benefits for tea drinkers?

Rooibos Research in Live Animals and Animal Cells

Laboratory studies have demonstrated potential health benefits of rooibos *in vitro* (in test tubes) and *in vivo* (in live animals), but human studies have not been conducted. Much more research is needed, but the studies so far look intriguing.

Fermented Rooibos against Mutagens: Researchers found that fermented rooibos tea reduced cancer-associated changes in animal cells induced by the mutagens benzo[a]pyrene (B(a)P) and mitomycin C (MMC) both *in vitro* and *in vivo*.[48] The *in vitro* part of the study measured chromosomal aberrations in animal cells caused by exposure to the mutagens. The cells were treated with tea extract either at the same time as the mutagen or after the muta-

gen. Some of the tests used rat liver microsomal enzyme, called S9, to provide metabolic activation of the mutagen; B(a)P requires metabolic activation, but MMC can act with or without it.

Both green tea and rooibos tea suppressed aberrant cells caused by B(a)P and MMC in the presence of S9, but rooibos showed a greater suppression of aberrant cells than did green tea (see Table 2). In fact, when the cells were exposed to B(a)P and S9 simultaneously with rooibos tea, the highest concentration of rooibos tea (1000 microgram/ml) completely inhibited the aberrant cells, bringing their percentage down to the level of the controls that were not exposed to any mutagen. Also, rooibos tea suppressed aberrant cells caused by MMC both with and without the presence of S9, but green tea showed no suppression without S9. Treating the cells simultaneously with the mutagen and tea extract caused a greater protective effect than treating the cells with tea extract following exposure to the mutagen (compare Tables 2 and 3).

In the *in vivo* part of this study, mice were given oral doses of tea and an injection of B(a)P or MMC.[48] The researchers measured the frequency of micronucleated reticulocytes (MNRETs), which are cells with damaged DNA that may lead to cancer. In one experiment, a single oral dose of tea (1 ml of 0.2 percent green tea or 0.1 percent rooibos tea) was given 6 hours prior to an injection of MMC and the number of MNRETs was counted at 24, 48, and 72 hours after the MMC. Rooibos tea and green tea provided similar inhibition of the frequency of MNRETs. After 48 hours, rooibos tea reduced the level of MNRETs by about 34 percent, and green tea reduced the level by about 38 percent. When the mice received the single dose of tea either after the mutagen or 24 hours prior to the mutagen, neither green tea nor rooibos tea reduced the frequency of MNRETs.

Table 2: Percent Aberrations in Cells Treated Simultaneously with Tea Extract and the Mutagen B(a)P or MMC (+/- S9)

Mutagen	Tea Extract (microgram/ml)		without S9 (%)	with S9 (%)
None	None		3	4
B(a)P	None		NA	35
	Green tea	125	NA	25
		250	NA	20 *
		500	NA	19 *
		1000	NA	8 ***
	Rooibos	125	NA	9 ***
		250	NA	7 ***
		500	NA	6 ***
		1000	NA	3 ***
MMC	None		40	43
	Green tea	125	42	38
		250	41	35
		500	38	23 **
		1000	44	18 ***
	Rooibos	125	25 *	15 ***
		250	15 ***	10 ***
		500	9 ***	8 ***
		1000	8 ***	9 ***

Note: Tea extracts were prepared with 50 g of tea leaves and 1.5 l of boiling water. Cells were treated with 100 microM B(a)P and S9 for 3 hours or 1 microM MMC (+/- S9) for 1 hour. Significant difference: *0.01 < P < 0.05, ** 0.001 < P < 0.01, *** P < 0.001.

Key: S9 = rat liver enzyme; B(a)P = benzo[a]pyrene; MMC = mytomycin C

Source: Sasaki YF, Yamada H, Shimoi K, Kator K, Kinae N. The clastogen-suppressing effects of green tea, Po-lei tea and Rooibos tea in CHO cells and mice. *Mutat Res* 1993;286(2):221-32.

Aspalanthus linearis seedlings with tap roots. The long tap roots evolved to reach deep into the ground for moisture in drought-prone South Africa.
Photo courtesy ASNAPP.

When the teas were given as one oral dose daily for 28 days and then the mutagen was injected on day 29, both rooibos tea and green tea reduced the frequency of MNRETs caused by B(a)P. Daily doses of 0.2 percent green tea reduced MNRETs by about 62 percent 48 hours after B(a)P exposure, and daily doses of 0.1 percent rooibos tea reduced MNRETs by about 49 percent. Daily doses of 0.1 percent rooibos tea reduced MNRETs by about 34 percent 48 hours after MMC exposure, but daily doses of green tea did not provide a significant reduction with MMC.

Fermented Rooibos against Irradiation: Another research group found that extract of fermented rooibos tea reduced cancerous transformation of mouse cells exposed to x-rays *in vitro*.[49] The amount of protection correlated with the dose of rooibos, and an extract concentration of 10 percent reduced the cell transformations to a level similar to the spontaneous level of the controls. Interestingly, green tea in equivalent concentrations did not show any detectable protective effect. In another study, fermented rooibos tea reduced cell damage in live mice that were exposed to irradiation two hours following a single dose of rooibos administered by gastric intubation.[34]

Fermented Rooibos against Brain Lipid Peroxidation: Rats given fermented rooibos tea daily *ad libitum* (free access) from the age of 3 months to 24 months had greatly reduced age-related lipid peroxide accumulation in four areas of their brains compared to rats that drank plain water.[50] Increases in lipid peroxides in the brain may damage neuronal cells and contribute to age-related diseases.[50] The lipid peroxide levels were evaluated by measuring the amounts of thiobarbituric acid reactive substances (TBARS) in eight regions of the brain. The 24-month-old rats that had been drinking plain water had significantly higher TBARS in the frontal cortex, occipital cortex, hippocampus, and cerebellum compared to 5-week-old rats, but the 24-month-old rats that had been drinking rooibos tea had no increase in TBARS in those four areas of the brain. The TBARS of the 24-month-old rooibos group were similar to the TBARS of the young 5-week-old group (see Table 4).

The authors give a bar chart that summarizes the TBARS data for each area of the brain.[50] The TBARS values in nmol/g for 24-

month-old rats without rooibos tea, 24-month-old rats given rooibos tea, and 5-week-old rats, respectively, were approximately 120, 80, 80 in the frontal cortex; 115, 70, 80 in the occipital cortex; 80, 40, 50 in the hippocampus; and 115, 80, 85 in the cerebellum. The authors say these results suggest that the administration of rooibos tea protected several regions of the rat brain against lipid peroxidation accompanying aging. Magnetic resonance images taken of the brain were consistent with the TBARS data.

Fermented vs. Unfermented Rooibos: Another study found that both fermented and unfermented rooibos tea exhibits antimutagenic properties *in vitro* as measured by the *Salmonella typhimurium* mutagenicity assay with several different mutagens; the antimutagenic activity was stronger against the metabolically activated mutagens 2-acetylaminofluorene (2-AAF) and aflatoxin B_1 (AFB_1) than it was against three direct-acting mutagens.[51] Further research showed that the fermentation process causes a decrease in the antimutagenic and antioxidant activity of rooibos tea as measured by the *Salmonella typhimurium* mutagenicity assay (with 2-AAF), the hydrogen donating ability (assessed with DPPH), and the superoxide anion radical scavenging assay.[52] The researchers suggest that fermented rooibos may show less antioxidant and antimutagenic activity because it has less polyphenols than unfermented rooibos. One analysis showed that polyphenols represent about 41 percent of the total solid matter in unfermented rooibos tea extract, but only about 30 percent of the total solid matter in fermented rooibos tea extract.[51]

One of the authors of both these studies is senior research scientist Jeanine Marnewick of the Program on Mycotoxins and Experimental Carcinogenesis (PROMEC) at the Medical Research Council of South Africa. She says, "Rooibos showed protective effects against DNA damage when tested in an *in vitro* assay as well as in an *in vivo* animal system." [53] The *in vitro* studies found unfermented rooibos was generally more protective against DNA damage than fermented rooibos. But Marnewick says her group's research shows that fermented rooibos has a stronger effect against some mutagens. She says, "Both the fermented and unfermented rooibos showed a significant protection, and we're busy elucidating the mechanisms."[53] She is currently evaluating the protective effect of rooibos on liver, esophageal, colon, and skin cancer induced in live animal models. The studies are in the early phases and she cautions, "Very little is known about the effect of rooibos on cancer development." [53]

Aspalanthus linearis. Photo courtesy ASNAPP.

Joubert also adds a cautionary note, saying that many questions about rooibos still need to be answered.[22] She says that researchers need to determine which of the antioxidant substances in rooibos tea are absorbed by the body and how much tea is needed to produce a measurable benefit. She also emphasizes that no human studies have been conducted yet.

Whole Foods vs. Isolated Antioxidants: The full benefits of teas are likely to come from a combination of all the antioxidants in them rather than from just one substance. Quite a few studies have found that isolated antioxidants don't have as positive an anticancer effect as the mixture of antioxidants found in natural food sources; whole apple extracts were better than pure quercetin at inhibiting the growth of cancer cells *in vitro*,[13,54] tomato powder

Table 3: Percent Aberrations in Cells Treated With B(a)P or MMC and Post-Treated With Tea Extract +/- S9

Mutagen	Tea Extract (microgram/ml)		without S9 (%)	with S9 (%)
B(a)P	None		44	35
	Green tea	25 or 125	40	28
		50 or 250	45	19 *
		100 or 500	48	19 *
		200 or 1000	42	20 *
	Rooibos	25 or 125	35	23
		50 or 250	34	19 *
		100 or 500	27 *	17 **
		200 or 1000	22 ***	11 ***
MMC	None	42	44	
	Green tea	25 or 125	49	48
		50 or 250	48	43
		100 or 500	40	33
		200 or 1000	43	27 *
	Rooibos	25 or 125	45	48
		50 or 250	36	38
		100 or 500	22 **	29 *
		200 or 1000	22 **	23 **

Note: Tea extracts were prepared with 50 g of tea leaves and 1.5 l of boiling water. Cells were treated with 100 microM B(a)P and S9 for 3 hours or 1 microM MMC (no S9) for 1 hour, and then cells were post-treated with tea extracts for 3 hours with S9 or for 20 hours without S9. The larger concentrations of tea extracts were used with S9. Significant difference: *$0.01 < P < 0.05$, **$0.001 < P < 0.01$, ***$P < 0.001$.

Key: S9 = rat liver enzyme; B(a)P = benzo[a]pyrene; MMC = mytomycin C

Source: Sasaki YF, Yamada H, Shimoi K, Kator K, Kinae N. The clastogen-suppressing effects of green tea, Po-lei tea and Rooibos tea in CHO cells and mice. *Mutat Res* 1993;286(2):221-32.

Table 4: Thiobarbituric Reactive Substances (TBARS) (nmol/g)

Area of Brain	24-month old no rooibos	24-month old with rooibos	5-week old no rooibos
frontal cortex	120	80	80
occipital cortex	115	70	80
hippocampus	80	40	50
cerebellum	115	80	85

Source: These data are approxmated from the bar chart in Figure 1 of Inanami O, Asanuma T, Inukai N, Jin T, Shimokawa S, Kasai N, Nakano M, Sato F, Kuwabara M. The suppression of age-related accumulation of lipid peroxides in rat brain by administration of Rooibos tea (*Aspalathus linearis*). *Neurosci Lett* 1995;196(1-2):85-8.

was better than pure lycopene at extending the life of rats with prostrate tumors,[13,55] and freeze-dried strawberries exhibited better anticancer properties in animals than did pure ellagic acid.[13,56] Also, white and green tea extracts demonstrated better antimutagenic properties *in vitro* than mixtures of nine polyphenols found in the teas (mixed according to their relative proportions in the teas).[57] Researchers believe these results indicate that other substances in the whole food products besides the identified antioxidants probably contribute to the total anticancer effect of the food, and that the relative amounts of all these substances could be important. Different teas have different mixtures of antioxidants, and they will protect against different mutagens. Sorting out all of these interactions will take time.

Rooibos Folklore: What's Proven?

Although rooibos does contain active antioxidants, many of the other health claims made for rooibos tea are not well documented (based only on anecdotal evidence) or are not supported by science. Researchers are still investigating many of these claims to evaluate all the potential benefits of rooibos.

Vitamins And Minerals: Despite some promotional claims that rooibos is a source of vitamin C, Joubert says it is not. "We have tested both the traditional rooibos and green rooibos, and vitamin C was not present," she says.[22]

With the exceptions of fluoride and copper, the trace amounts of minerals in rooibos are not enough to make the tea a meaningful dietary source of minerals for the average consumer. As shown in Table 5, the nutritional labeling that is given on some packages of rooibos tea and on some websites of distributors[4,5] indicates that the amounts of iron, potassium, zinc, calcium, and magnesium in a 200 ml serving of rooibos tea are all less than 1 percent of the U.S. reference daily intake (RDI). A 200 ml serving of rooibos provides over 5 percent of the RDI of fluoride for adults and over 7 percent of the RDI for copper (see Table 5). Marc S. Micozzi, M.D., Ph.D., director of the Policy Institute for Integrative Medicine in Bethesda, Maryland, notes that when rooibos is used as a fluid replacement throughout the day, as is done with some athletes in South Africa, it does provide measurable amounts of several minerals and electrolytes.[58]

Table 5: Minerals in a 200 ml Cup of Rooibos Tea

Mineral	Amount (mg)	RDI/AI (mg)	% DV
Iron	0.07	8, 18	0.9, 0.4
Potassium	7.12	3500	0.2
Sodium	6.16	<2400	0.3
Calcium	1.09	1000	0.1
Copper	0.07	0.9	7.8
Zinc	0.04	11, 8	0.4, 0.5
Magnesium	1.57	420, 320	0.4, 0.5
Fluoride	0.22	4, 3	5.5, 7.3
Manganese	0.04	2.3, 1.8	1.7, 2.2

Note: RDI is the US reference daily intake. AI is the US adequate intake, which is used when an exact RDI is not well established. Percent DV is the percentage of the daily reference value that is provided by a serving of the food. Values are for adults; when two values are given, the first is for men and the second is for women.

Sources: Values for minerals in mg are from the Rooibos Limited website: <http://www.rooibosltd.co.za>. The RDI/AI data are from the dietary reference intake tables on the US government website: <http://www4.nationalacademics.org>.

Colic, Allergies, And Other Ailments: Distributors of rooibos tea often suggest it can help allergies, sleep problems, digestive problems, headache, and other ailments,[4,5] but these claims have not been verified by scientific research. If the indigenous people of the Cedarberg region used rooibos tea medicinally, that tradition was lost and rooibos was just enjoyed as a good-tasting beverage until the recent interest in its health benefits.[10] Many of the health claims for rooibos tea began in 1968 when a South African woman, Annekie Theron, found that rooibos tea eased her infant's colic.[10] As the story goes, she found no documentation on the benefits of rooibos and began her own experiments with local babies who had colic and allergies.[10] She concluded that rooibos helped these babies, and she published a book in 1970 titled *Allergies: An Amazing Discovery.* Since then, she patented a rooibos extract that is now used in cosmetic products, and she started her own line of health and cosmetic products.[10]

Today, South African physicians recommend rooibos for infant colic.[59] South Africans also use it to calm digestive upset in adults, to help induce sound sleep, and topically to sooth eczema, skin allergies, and diaper rash.[59] Not enough research has been done to know if these folk remedies really are effective or to identify the substances in the tea that might be responsible for any observable benefits. Joubert says the tea does seem to help infant colic, but no formal studies have been done.[22]

Immune Function: An *in vitro* and *in vivo* study showed that rooibos might enhance immune function, but very little research has been done on this topic.[60] One study found that a polysaccharide in rooibos leaves may have antiviral activity against the HIV virus, but the polysaccharide had to be chemically extracted from the leaves and is not found in tea made by steeping the leaves in water.[61] There's no evidence that rooibos tea fights the HIV virus.

Zero Caffeine And Low Tannin: Several other health advantages of rooibos tea that are often mentioned are its zero caffeine content and its low tannin content. Because rooibos is naturally caffeine-free, it does not have to be subjected to a decaffeination process and, therefore, does not lose any of its polyphenol content (as occurs when green and black teas are decaffeinated). The zero caffeine content also means rooibos can be enjoyed by those who want to avoid the stimulating effects of caffeine and can be consumed in quantity by those who want to use it as a fluid replacement.

Rooibos only has about 4.4 percent tannin content,[51] which means that it does not have the astringent taste associated with *C. sinensis* and will not become bitter even after long steeping times. Rooibos tea can be a good alternative to *C. sinensis* for people who prefer the milder taste of a less astringent herbal tea or for those who have digestive problems with tannin-rich beverages. And as Micozzi observes, some people can receive a higher total antioxidant intake from rooibos than from green or black tea because the low tannin content and caffeine-free nature of rooibos allow it to be consumed in larger quantities.[58]

Iron Absorption: Other disadvantages have been attributed to tannins; they can bind to non-heme iron (iron from non-meat sources), reducing iron absorption, and they can decrease the metabolism and utilization of proteins.[62-69] Black and green teas reduce the amount of non-heme iron absorbed by the body when the tea is consumed at the same time as the iron source.[62-66] These effects do not cause problems for most people, but they can cause problems for people who have nutritionally marginal diets or low intake of heme iron sources (meats).[69]

Other polyphenol-rich beverages besides *C. sinensis* teas can also inhibit iron absorption. One study found that the inhibition of iron was 79 to 94 percent for black tea, 84 percent for peppermint

tea, 73 percent for hot cocoa, and 47 percent for tea of chamomile (*Matricaria recutita* L., Asteraceae).[62] The teas still inhibited iron absorption to the same degree even if milk was added to them. Some of these beverages contain only low levels of tannins, but other polyphenols in foods and beverages can also reduce iron absorption.[62,64] The ability of polyphenols to chelate prooxidant metal ions might provide some antioxidant protection, but it can also be a disadvantage by decreasing absorption of necessary dietary minerals such as iron.[64]

The low tannin content of rooibos is sometimes used to infer that rooibos tea won't inhibit iron absorption, but that conclusion is not automatic since rooibos is rich in other polyphenols that might decrease iron absorption. In one small study, three groups of 10 young healthy men were given an oral dose of iron, followed by rooibos tea, *C. sinensis* tea, or plain water.[71] Iron absorption was measured to be 7.25 percent for rooibos tea, 1.70 percent for *C. sinensis* tea, and 9.34 percent for plain water. The result for *C. sinensis* was significant ($P < .0001$), but the data for rooibos did not reach statistical significance (that is, the data for rooibos were not good enough to determine whether this result can be generalized to the whole population or whether the result was just chance). More studies are needed to better document the effect of rooibos on iron absorption, but this study implies that rooibos might not inhibit iron absorption nearly as much as *C. sinensis* tea.

The Bottom Line

Rooibos tea has become popular because of its fruity, sweet taste and its caffeine-free, low tannin, antioxidant-rich status. Although more research is needed, rooibos appears to be safe and free of side effects. The antioxidants present in rooibos may help protect against free radical damage that can lead to cancer, heart attack, and stroke. Unfermented (green) rooibos has a higher amount of polyphenols than traditional fermented rooibos and generally demonstrates higher antioxidant and antimutagenic capabilities *in vitro*. Future research should reveal whether the antioxidant benefits of rooibos observed *in vitro* and in animals translates into health benefits for humans.

Acknowledgments

The author thanks Elizabeth Joubert, Ph.D., specialist researcher at South Africa's ARC Infruitec-Nietvoorbij, and Jeanine L. Marnewick, senior research scientist at the Program on Mycotoxins and Experimental Carcinogenesis (PROMEC) at the Medical Research Council of South Africa, for their quotes and technical input, as well as for providing copies of several research papers. Their expertise on rooibos has contributed much valuable information to this article. Lorenzo

Rooibos growing in the Cedarberg region of South Africa. Photo ©2003 Rooibos Ltd./SunnRooibos

Bramati, Ph.D., research scientist at the Instituto Tecnologie Biomediche CNR in Italy, provided helpful input and copies of several research papers. Erica Renaud, a member of the quality control program for ASNAPP (Agribusiness in Sustainable Natural African Plant Products) at the Center for New Use Agriculture and Natural Plant Products at Rutgers University provided valuable input and photos. Marc S. Micozzi, M.D., Ph.D., director of the Policy Institute for Integrative Medicine, offered helpful review and comments. Rooibus Ltd./SunnRooibos also provided valuable insight and photos.

Laurie Erickson, a freelance writer in Mountain View, California, is interested in the medicinal and horticultural aspects of herbs. She began investigating rooibos out of personal curiosity and has no financial connections with the rooibos industry. Her educational background includes a B.S. in Environmental Earth Science and an M.S. in Geomechanics from Stanford University. She has also written the medical website <http://www.tendinosis.org> and has been published in the garden section of several newspapers.

Reference:

1. Van der Bank M, Van Wyk B-E, Van der Bank H. Biochemical genetic variation in four wild populations of *Aspalathus linearis* (rooibos tea). *Biochem Syst Ecol* 1995;23(3)257-262.
2. Dahlgren R. Revision of the genus *Aspalathus* II. The species with ericoid and pinoid leaflets. 7. Subgenus *Nortieria*, with remarks on rooibos tea cultivation. *Bot Notiser* 1968;121,165-208.
3. Dahlgren R. *Aspalathus*. In *Flora of Southern Africa*. National Botanical Institute, Pretoria. 1988;16(3,6)1-430.
4. Rooibos Limited website: <www.rooibosltd.co.za>. (Rooibos Ltd. is the largest producer/distributor of rooibos in South Africa.)
5. Red Bush Tea website: <http://www.redbushtea.com>. Text discusses the tap root; also see photo of rooibos seedling with tap root on this site.
6. Van Wyk B-E, Van Oudtshoorn B, Gericke N. *Medicinal Plants of South Africa*. Briza Publications, Pretoria, South Africa. 1998. 304 p. Online condensed version available at <http://www.african-medicines.com>.
7. Van der Bank M, Van der Bank FH, van Wyk B-E. Evolution of sprouting versus seeding in *Aspalathus linearis*. *Plant Syst Evol* 1999;219(1,2)27-38.
8. Muofhe ML, Dakora FD. Nitrogen nutrition in nodulated field plants of the shrub tea legume *Aspalathus linearis* assessed using 15N natural abundance. *Plant and Soil* 1999;209(2)181-6.
9. Van Wyk, B-E. Presentation at the 28th Annual Conference of the South African Association of Botanists at Rhodes University, 2002. Summary at <www.herbsforafrica.co.za/features/recent-herb-research.asp>.
10. WESGRO, Western Cape Investment and Trade Promotion Agency, Cape Town, South Africa, website: <www.wesgro.org.za>. Wesgro Background Report: The Rooibos Industry in the Western Cape. April 2000 (updated April 2001).
11. Renaud, E. Center for New Use Agriculture and Natural Plant Products, Rutgers University, New Jersey. Quality control program for ASNAPP (Agribusiness In Sustainable Natural African Plant Products, website: <www.asnapp.org>). Personal communication. Dec 2002.
12. Pietta PG. Flavonoids as antioxidants. *J Nat Prod* 2000;63(7):1035-42.
13. Joseph J, Nadeau D, Underwood A. *The Color Code: A Revolutionary Eating Plan For Optimal Health*, Hyperion, New York, 2002, p. 8-10, 33, 44, 57.
14. Rabe C, Steenkamp JA, Joubert E, Burger JF, Ferreira D. Phenolic metabolites from rooibos tea (*Aspalathus linearis*). *Phytochem* 1994;35:1559-65.
15. Koeppen BH, Roux DG. C-glycosylflavonoids. The chemistry of aspalathin. *Biochem J* 1966;99:604-9.
16. Koeppen BH, Roux DG. C-glycosylflavonoids. The chemistry of orientin and iso-orientin. *Biochem J* 1965;97:444-8.
17. Koeppen BH, Smit CJB, Roux DG. The flavone C-glycosides and the flavonol O-glycosides of *Aspalathus acuminatus* (Rooibos tea). *Biochem J* 1962;83:507-11.
18. Ferreira D, Marais C, Steenkamp JA, Joubert E. Rooibos tea as a likely health food supplement. In *Proceeding of Recent Development of Technologies on Fundamental Foods for Health*, Korean Society of Food, Science and Technology: Seoul, Korea 1995:73-88.
19. Bramati L, Minoggio M, Gardana C, Simonetti P, Mauri P, Pietta P. Quantitative characterization of flavanoid compounds in Rooibos tea (*Aspalathus linearis*) by LC-UV/DAD. *J Agric Food Chem* 2002;50(20):5513-9.
20. Joubert E. HPLC quantification of the dihydrochalcones, aspalathin and nothofagin in rooibos tea (*Aspalathus linearis*) as affected by processing. *Food Chem* 1996;55(4):403-11.
21. Von Gadow A, Joubert E, Hansmann CF. Comparison of antioxidant activity of aspalathin with that of other plant phenols of rooibos tea (*Aspalathus linearis*), alpha-tocopherol, BHT and BHA. *J Agric Food Chem* 1997;45:632-38.
22. Joubert, E. Personal communication. First reference Nov 2002, all other references Aug 2002.
23. Hakim IA, Hartz V, Harris RB, Balentine D, Weisgerber UM, Graver E, Whitacre R, Alberts D. Reproducibility and relative validity of a questionnaire to assess intake of black tea polyphenols in epidemiological studies. *Cancer Epidem Bio & Prev* 2001; 10:667-78.

Rooibos in cultivation at a plantation. Photo courtesy ASNAPP.

24. Lee LT, Huang YT, Hwang JJ, Lee PP, Ke FC, Nair MP, Kanadaswam C, Lee MT. Blockade of the epidermal growth factor receptor tyrosine kinase activity by quercetin and luteolin leads to growth inhibition and apoptosis of pancreatic tumor cells. *Anticancer Res* 2002;22(3):1615-27.
25. Mouria M, Gukovskaya AS, Jung Y, Buechler P, Hines OJ, Reber HA, Pandol SJ. Food-derived polyphenols inhibit pancreatic cancer growth through mitochondrial cytochrome C release and apoptosis. *Int J Cancer* 2002;98(5):761-9.
26. Yamashita N, Kawanishi S. Distinct mechanisms of DNA damage in apoptosis induced by quercetin and luteolin. *Free Radic Res* 2000;33(5):623-33.
27. RoyChowdhury A, Sharma S, Mandal S, Goswami A, Mukhopadhyay S, Majumder HK. Luteolin, an emerging anti cancer flavonoid, poisons eukaryotic DNA topoisomerase I. *Biochem J* 2002;366(Pt 2):653-61.
28. Yin F, Giuliano AE, Van Herle AJ. Growth inhibitory effects of flavonoids in human thyroid cancer cell lines. *Thyroid* 1999;9(4):369-76
29. Mori H, Niwa K, Zheng Q, Yamada Y, Sakata K, Yoshimi N. Cell proliferation in cancer prevention; effects of preventive agents on

estrogen-related endometrial carcinogenesis model and on an *in vitro* model in human colorectal cells. *Mutat Res* 2001;480-481:201-7.
30. Mutoh M, Takahashi M, Fukuda K, Matsushima-Hibiya Y, Mutoh H, Sugimura T, Wakabayashi K. Suppression of cyclooxygenase-2 promoter-dependent transcriptional activity in colon cancer cells by chemopreventive agents with a resorcin-type structure. *Carcinogenesis* 2000;21(5):959-63.
31. Mutoh M, Takahashi M, Fukuda K, Komatsu H, Enya T, Matsushima-Hibiya Y, Mutoh H, Sugimura T, Wakabayashi K. Supression by flavonoids of cyclooxygenase-2 promoter-dependent transcriptional activity in colon cancer cells: structure-activity relationship. *Jpn J Cancer Res* 2000;91(7):686-91.
32. Rifici VA, Schneider SH, Khachadurian AK. Lipoprotein oxidation mediated by j774 murine macrophages is inhibited by individual red wine polyphenols but not by ethanol. *J Nutr* 2002;132(9):2532-7.
33. Hirano R, Sasamoto W, Matsumoto A, Itakura H, Igarashi O, Kondo K. Antioxidant ability of various flavonoids against DPPH radicals and LDL oxidation. *J Nutr Sci Vitaminol* (Tokyo) 2001;47(5):357-62.
34. Shimoi K, Masuda S, Shen B, Furugori M, Kinae N. Radioprotective effects of antioxidative plant flavonoids in mice. *Mutat Res* 1996;350(1):153-61.
35. Hertog MG, Hollman PC, Van De Putte B. Content of potentially anticarcinogenic flavonoids in tea infusions, wine and fruit juices. *J Agric Food Chem* 1993;41:1242-6.
36. Snyckers FO, Salemi G. Studies of South African Medicinal plants. Part 1. Quercetin as the major *in vitro* active component of rooibos tea. *JSA Chem Inst* 1974;27:5-7.
37. Hillis WE, Inoue T. The polyphenols of *Nothofagus* species – II. The heartwood of *Nothofagus fusca. Phytochem* 1967;6:59-67.
38. Vrinda B, Uma Devi P. Radiation protection of human lymphocyre chromosomes *in vitro* by orientin and vicenin. *Mutat Res* 2001;498(1-2):39-46.
39. Uma Devi P, Ganasoundari A, Rao BS, Srinivasan KK. *In vivo* radioprotection by ocimum flavonoids: survival of mice. *Radiat Res* 1999;151(1):74-8.
40. Uma Devi P, Ganasoundari A, Vrinda B, Srinivasan KK, Unnikrishnan MK. Radiation protection by ocimum flavonoids orientin and vicenin: mechanisms of action. *Radiat Res* 2000;154(4):455-60.
41. Cesarone MR, Belcaro G, Incandela L, Geroulakos G, Griffin M, Lennox A, DeSanctis MT, Acerbi G. Flight microangiopathy in medium-to-long distance flights: prevention of edema and microcirculation alterations with HR (Paroven, Venoruton; 0-(beta-hydroxyethyl)-rutosides): a prospective, randomized, controlled trial. *J Cardiovasc Pharmacol Ther* 2002; 7 Suppl 1:S17-20.
42. MacLennan WJ, Wilson J, Rattenhuber V, Dikland WJ, Vanderdonckt, Moriau M. Hydroxyethylrutosides in elderly patients with chronic venous insufficiency: its efficacy and tolerability. *Gerontology* 1994;40(1):45-52.
43. Gouny AM, Horovitz D, Gouny P, Sauvage E, Nussaume O. Effectiveness and safety of hydroxyethyl-rutosides in the local treatment of symptoms of venous insufficiency during air travel. *J Mal Vasc* 1999;24(3):214-20.
44. Titapant V, Indrasukhsri B, Lekprasert V, Boonnuch W. Trihydroxyethylrutosides in the treatment of hemorrhoids of pregnancy: a double-blind placebo-controlled trial. *J Med Assoc Thai* 2001;84(10):1395-400.
45. Nocker W, Diebschlag W, Lehmacher W. A 3-month, randomized double-blind dose-response study with 0-(beta-hydroxyethyl)-rutoside oral solutions. *Vasa* 1989;18(3):235-8.
46. Cataldo A, Gasbarro V, Viaggi R, Soverini R, Gresta E, Mascoli F. Effectiveness of the combination of alpha tocopherol, rutin, melilotus, and centella asiatica in the treatment of patients with chronic venous insufficiency. *Minerva Cardioangiol* 2001;49(2):159-63.
47. Von Gadow A, Joubert E, Hansmann CF. Comparison of the antioxidant activity of rooibos tea (*Aspalathus linearis*) with green, oolong and black tea. *Food Chem* 1997;60(1):73-7.
48. Sasaki YF, Yamada H, Shimoi K, Kator K, Kinae N. The clastogen-suppressing effects of green tea, Po-lei tea and Rooibos tea in CHO cells and mice. *Mutat Res* 1993;286(2):221-32.
49. Komatsu K, Kator K, Mitsuda Y, Mine M, Okumura Y. Inhibitory effects of Rooibos tea, *Aspalathus linearis*, on X-ray-induced C3H10T1/2 cell transformation. *Cancer Lett* 1994;77(1):33-8.
50. Inanami O, Asanuma T, Inukai N, Jin T, Shimokawa S, Kasai N, Nakano M, Sato F, Kuwabara M. The suppression of age-related accumulation of lipid peroxides in rat brain by administration of rooibos tea (*Aspalathus linearis*). *Neurosci Lett* 1995;196(1-2):85-8.
51. Marnewick JL, Gelderblom WC, Joubert E. An investigation on the antimutagenic properties of South African herbal teas. *Mutat Res* 2000;471(1-2):157-66.
52. Standley L, Winterton P, Marnewick JL, Gelderblom WC, Joubert E, Britz TJ. Influence of processing stages on antimutagenic and antioxidant potentials of rooibos tea. *J Agric Food Chem* 2001; 49(1):114-7.
53. Marnewick JL. Personal communication. Aug 2002.
54. Eberhardt MV, Lee CY, Liu RH. Antioxidant activity of fresh apples. *Nature* 2000;405(6789):903-4.
55. Hadley CW, Miller EC, Schwartz SJ, Clinton SK. Tomatoes, lycopene, and prostate cancer: progress and promise. *Exp Biol Med* 2002;227(10):869-80.
56. Stoner, JD, Kresty LA, Carlton PS, Siglin JC, Morse MA. Isothiocyanates and freeze-dried strawberries as inhibitors of esophageal cancer. *Toxicol Sci* 1999;52(2 Suppl):95-100.
57. Santana-Rios G, Orner GA, Amantana A, Provost C, Wu SY, Dashwood RH. Potent antimutagenic activity of white tea in comparison with green tea in the *Salmonella* assay. *Mutat Res* 2001;495(1-2):61-74.
58. Micozzi, MS. Personal communication via email. June 2003.
59. Morton JF. Rooibos tea, *Aspalathus linearis*, a caffeineless, low-tannin beverage. *Econ Bot* 1983;37(2):164-73.
60. Kunishiro K, Tai A, Yamamoto I. Effects of rooibos tea extract on antigen-specific antibody production and cytokine generation *in vitro* and *in vivo*. *Biosci Biotechnol Biochem* 2001;65(10):2137-45.
61. Nakano M, Itoh Y, Mizuno T, Nakashima H. Polysaccharide from *Aspalathus linearis* with strong anti-HIV activity. *Biosci Biotechnol Biochem* 1997;61(2):267-71.
62. Hurrell RF, Reddy M, Cook JD. Inhibition of non-haem iron absorption in man by polyphenolic-containing beverages. *Br J Nutr* 1999;81(4):289-95.
63. Disler PB, Lynch SR, Torrance JD, Sayers MH, Bothwell TH, Charlton RW. The mechanism of the inhibition of iron absorption by tea. *S Afr J Med Sci* 1975;40(4):109-16.
64. Samman S, Sandstrom B, Toft MB, Bukhave K, Jensen M, Sorensen SS, Hansen M. Green tea or rosemary extract added to foods reduces nonheme-iron absorption. *Am J Clin Nutr* 2001;73(3):607-12.
65. Hallberg L, Rossander L. Effect of different drinks on the absorption of non-heme iron from composite meals. *Hum Nutr Appl Nutr* 1982;36(2):116-23.
66. Zijp IM, Korver O, Tijburg LB. Effect of tea and other dietary factors on iron absorption. *Crit Rev Food Sci Nutr* 2000;40(5):371-98.
67. Chung KT, Wong TY, Wei CI, Huang YW, Lin Y. Tannins and human health: a review. *Crit Rev Food Sci Nutr* 1998;38(6):421-64.
68. Bravo L. Polyphenols: chemistry, dietary sources, metabolism, and nutritional significance. *Nutr Rev* 1998;56(11):317-33.
69. Butler LG. Antinutritional effects of condensed and hydrolyzable tannins. *Basic Life Sci* 1992;59:698-8.
70. Zeyuan D, Bingying T, Xiaolin L, Juinming H, Yifeng C. Effect of green tea and black tea on the metabolisms of mineral elements in old rats. *Biol Trace Elem Res* 1998;65(1):75-86.
71. Hesseling PB, Klopper JF, van Heerden PD. The effect of rooibos tea on iron absorption. *S Afr Med J* 1979;55(16):631-2.

Using Cultural Items for Science is No Longer Acceptable

Objections to "The Patterson Bundle"

Guest Commentary by Cindy Bloom

I would first like to thank the American Botanical Council for its support and commitment to outstanding educational programs regarding herbal medicine, and for its attempts to promote and preserve a better understanding of indigenous cultures.

I have numerous concerns, though, regarding the article entitled "The Patterson Bundle," from *HerbalGram* 55. Though I cannot express the views of tribal people who lived in the area of the Bundle's origin, I can share my own 17 years of experience in working with repatriation officers and elders from federally recognized tribes concerning these issues.

The article states on page 35: "The Bundle was *discovered* by the Pattersons in the 1980s on BLM land. Ms. Patterson *dug* the layers of bark that must have served to protect and preserve the contents." (emphasis mine) [Note: it has since become illegal to disturb or dig up Native American artifacts on public lands.]

This distortion of facts is a perversion of my understanding of several laws. The Antiquities Act of 1906 was strengthened by several other laws including the Archaeological Resources Protection Act of 1979. These laws make the actions of the Pattersons *illegal* for almost one hundred years, punishable by substantial fines and jail sentences. The Pattersons did not *discover* the Bundle. They illegally desecrated an ancient and sacred Indian site and then *stole* a sacred object. Why were the Pattersons never charged with these two crimes?

The Bundle, along with a large assortment of other artifacts, was buried on the ledge of a cave in a pit lined with juniper bark. To Native people, the excavation of this site evokes centuries of desecration and scientific mutilation of the bodies of their ancestors and their most sacred possessions.

The Native American Graves Protection and Repatriation Act (NAGPRA) of 1990 was created in response to the cries of tribal people for the return of over two hundred thousand ancestral remains and tens of thousands of sacred objects and objects of cultural heritage. The passing of NAGPRA and individual state burial protection laws heralded the new era of Native control over their own cultural heritage. The subsequent formation of intertribal coalitions and the appointment of NAGPRA representatives throughout the many Native Nations marked the ensuing stance of self-determination that characterizes the Indian in the 21st century.

Pemina Yellowbird, official NAGPRA representative for the Sahnish and Hidatsa First Nations of Fort Berthhold Reservation,

North Dakota, has spoken many times about U.S. government policies that define "trust responsibility." Federal agencies (the Bureau of Land Management or BLM, National Park Service, Corps of Engineers, etc.) are supposed to interpret laws in favor of Native people and as Native people would understand them. As one of the original consultants during the formation of NAGPRA, Pemina has stated, "Nothing in NAGPRA should be construed as authorizing any new scientific study." Maurice Eben, former Repatriation Officer for the Pyramid Lake Paiute Nation, has said, "NAGPRA is a spiritual law that was created for Indian people."

In January of 1998, I attended a NAGPRA Committee meeting in which the discussion centered on compliance with the mandate that all private and federal institutions were to have completed inventories of ancestral remains and objects of cultural patrimony by November 16, 1995. Penalties were already in effect for smaller institutions (i.e., museums and universities could be fined as much as $200 a day for being past the inventory deadline). It was revealed at this meeting that federal agencies had failed to meet the deadline across nearly all of its divisions. Upon asking BLM representative Stephanie Demadis for a projected completion date, she stated flatly, "It could take decades." The BLM houses some of its collections in private museums, and these museums do not report such additional holdings, so it is impossible even to get an accurate estimate. At the meeting, the federal agencies were advised that coming into compliance, which involves compulsory consultation with tribes, *must* be a priority as it was required by law. In this light, what justification did the BLM have for turning over the Bundle to non-Indian people for scientific research? Why was the legal process, binding to all private and federal institutions, ignored?

To Western thinking, using American Indian collections for intellectual pursuit and educational research is both acceptable and desirable. To most American Indians, it is a crime against their spiritual beliefs and rights as sovereign people. In many tribes, only specific individuals have the right to share information concerning sacred objects. The knowledge, songs, prayers, etc., are often not shared with others even within the same tribal clans. The following two examples demonstrate the intense respect required in handling sacred objects.

Curly Bear Wagner, Repatriation Officer of the Blackfeet Nation, received 32 of his Nation's ancestral remains from the Field Museum of Chicago. A sacred object that was identified as belonging to his great-grandfather, Chief Red Crow, was *not* claimed for return because no one now knows the prayers and songs associated with it. To take it home to tribal land could have devastating spiritual implications for all of his people.

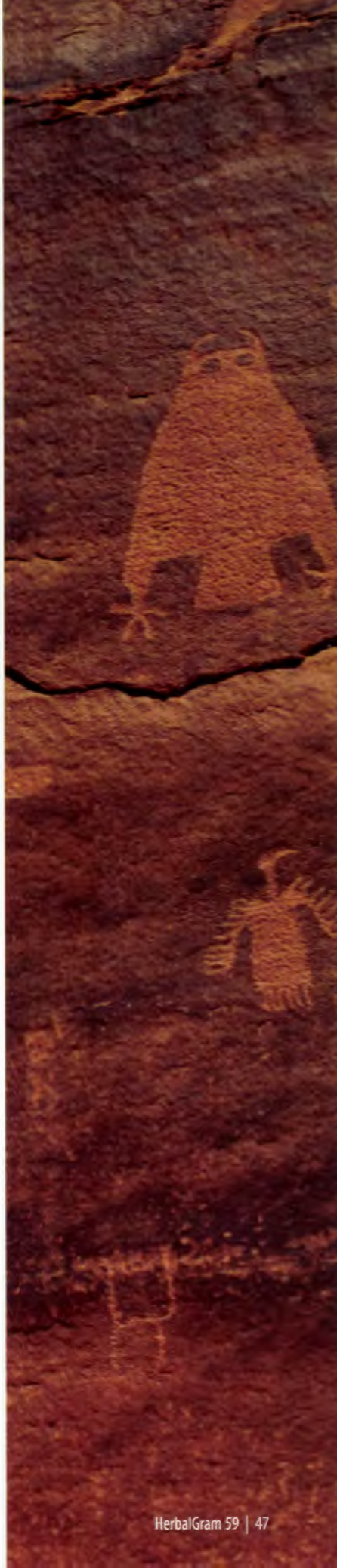
Indian people have a social and sacred relationship, not only to their ancestors, but to the heritage and objects they have created.

David Smith, Repatriation Officer of the Winnebago Tribe of Nebraska, had been asked to reveal specific information about objects claimed by his people. Since this information would become public record, he chose to leave the objects in the institutions, as this transfer of knowledge would violate the "intellectual property rights" that Native people continue to struggle to protect.

Cultural items can no longer be thought of as scientific specimens. NAGPRA requires non-Indian and federal institutions to consider what is *sacred* from an Indian perspective. In the article, Bennie Le Beau and Woableza made the definition very clear, as well as the spiritual impact of desecrating Indian sites: "Whether it is a burial, pot, an arrowhead or Bundle, this is all sacred to us and when it's disturbed, we believe it causes things in the world to be out of balance" (p. 38). Native religious beliefs and the sacred nature of the Bundle are fully recognized throughout the article but they are continually and deliberately ignored. Why wasn't the study "blocked or curtailed" (p. 37) immediately?

Indian people have a social and sacred relationship, not only to their ancestors, but to the heritage and objects they have created. A bundle, clay pot, mask, baskets, etc., are all *living*. Each has a spirit that cannot be separated from its originating Nation, and this connection continues beyond death.

The dichotomy between the treatment bestowed on the author and Mr. Le Beau is striking. The author was given complete permission to view, photograph, and physically handle the Bundle and a carton of other artifacts. The spiritual leader was first interrogated by the BLM, but "once it was estab-



Left and right: Native American petroglyph from southeastern Utah. Photo ©2003 Jim Blazik

lished that he was not there to officially claim the Bundle, he was given permission to sing prayer songs *in the parking lot.*" (emphasis mine). Only after that was he allowed to pray over the Bundle in the display case. NAGPRA provides a mechanism for Indian people to *make* claims on sacred objects, not to *prevent* them from doing so. Another congressional directive, the American Indian Religious Freedom Act of 1978, states that all federal agencies have a responsibility to avoid infringement of American Indian religious practices, and this applies to the illegal transfer of the Bundle into layman's hands.

To prevent the mishandling of our sacred objects, correct cultural information must be available to the public. The racially-biased language and misleading information in the article perpetuate a romantic stereotype and an invented mythology surrounding Indian identity. Examples include:

"I noticed nothing of European nature included in the contents, i.e., no metal, woven fabrics or thread."

"There was nothing exotic such as macaw feathers or pigments from another part of the world ..."

Such erroneous comments obscure the rich ancient heritage of Indian people. To the readers, it might appear that the items mentioned only exist outside of pre-Columbian American, yet American Indian metallurgy dates back 5,000 years, intricate weaving 10,000 years, and the trade network for transporting diversely constructed materials was active for many thousands of years throughout the Americas. Macaw or owl feathers have specific ceremonial meaning to individual tribes. Red ocher is a sacred paint and its use in burials, ceremonies and rituals dates back 6,000–7,000 years.

Off-handed comments that liken the impression of the Bundle contents to "seeing the contents of a woman's purse," and "... the collection wasn't as 'sexy' as the fascinating hunting Bundles ..." trivialize the Bundle's cultural importance and are used as an oppressive tactic for justifying invasive studies of sacred materials. This type of exploitation contributes to the ongoing genocide of American Indian cultures and religions. Thus readers have not only been misled, they lack imperative information needed to evaluate the article with accuracy.

The American Botanical Council's first obligation is to the indigenous cultures it *chooses* to interact with, and secondly, to the ethnobotanists and others who have worked to protect and honor the lifeways and intellectual property rights of these cultures. Its third responsibility is to its readers, to provide a comprehensive and credible format, and finally, to all the people who handled the Bundle or associated artifacts. Not only are there spiritual repercussions involved in having contact with these sacred objects, but there are physical dangers now associated with the routine methods of preservation, including pesticides, arsenic, mercury, and other hazardous substances. These toxins now pose a health threat to both the examiner and the tribal inheritors of repatriated items, and *all* individuals involved need to be forewarned.

These engraved ceremonial shell cups are not actual artifacts, but, to protect the sacred nature of Native American objects, have been replicated by Dan Townsend, a contemporary Native American artist. Photo courtesy of the author.

To Western thinking, using American Indian collections for intellectual pursuit and educational research is both acceptable and desirable.

To most American Indians, it is a crime against their spiritual beliefs and rights as sovereign people.

Native people live anything but romantic lives. They endure the highest rates of unemployment, poverty, and violent crime victimization. Indian youth suffer the highest suicide and school dropout rates of any cultural group. This article is a dangerous step backwards for the harm lies not only in the irretrievable losses of life and culture in the past, but in the continued ignorance and misunderstanding in the present.

In the spirit of cooperative change, I urge all to see an upcoming Native American exhibit at the Art Institute of Chicago entitled, "Hero, Hawk and Open Hand: American Indian Art of the Ancient Midwest and South" (scheduled for the fall of 2004 then travelling to the St. Louis Museum of Art and the Smithsonian National Museum of Natural History). Curators are consulting with tribal representatives and advisors regarding this exhibit, and the *Native* worldview and perceptions of what is sacred will determine what art pieces are shown. My friend, Dan Townsend (Creek/Cherokee), has been given tribal permission to replicate ancient shell engravings and to speak about the traditions. Plants

that were used in ceremony over 1,000 years ago are still mixed today for the same purposes.

I believe that an article written *through Indian eyes* could address many of the concerns of tribal people that I have covered in this letter. The American Botanical Council must be accountable to a higher consciousness and vision that better reflects its goals of respect and justice. I see ABC and an increasing number of people in the community working to honor those high goals. In that I was granted this opportunity to address these issues here, I'm deeply grateful.

The actions of all involved in this matter set in motion a spiritual travesty that cannot be called back. Ultimately, only the people whose ancestors created the Bundle can spiritually care for it.

Cindy Bloom was born of Cherokee heritage from the southeastern U.S. She has served on the board of the American Indian Council of Illinois and other Native-based organizations focused on the protection and conservation of sacred sites and the return of ancestral remains and sacred objects. Her 19 years of archaeological experience and the study of Indigenous medicines and cultures throughout the Americas include essential knowledge of the state and federal laws that govern human rights issues of Native peoples. The results of this work include the restoration of native flora and fauna at numerous sites as well as the acquisition of an Illinois burial site for the estimated 12,000 ancestral remains yet to be repatriated. She lives with her family outside of Chicago on 50 acres of land formally designated as a sanctuary, where she grows endangered native plants that are used for medicine, food and ceremony, and fibers and dyes for traditional basket weaving. She also teaches on-site classes in Native medicine, Indian lifeways, and pre-Columbian cultures.

Native American petroglyph from southeastern Utah. Photo ©2003 Jim Blazik

The Slow Demise of FDA Censorship

Recent Court Cases on Health Claims that Define the Scope of Speech Rights for the Manufacturers and Distributors of Herbs and Other Dietary Supplements

by Jonathan W. Emord

Summary: Certain herbs, like saw palmetto, have physiological effects upon the body that are useful in mitigating or preventing disease and health-related conditions. Even in the presence of credible scientific evidence supporting claims for such products, the Food and Drug Administration has often censored them, denying manufacturers of such products the right to inform consumers of truthful and nonmisleading health information. The loss of that information harms consumers. Indeed, in certain instances it may be responsible for the worsening of human health. This article provides a detailed history of recent federal court decisions that spell a new day for those who wish to communicate on dietary supplement product labels and in labeling truthful and nonmisleading health information concerning the effects of herbs and other nutrients upon disease.

[Editor's note: Just before presstime, on July 11, 2003, the U.S. Food and Drug Administration announced plans to allow "qualified health claims" for foods and dietary supplements under the Nutrition Labeling and Education Act of 1990, the subject of much of the article below. HerbalGram *will cover the new FDA policy in a future issue.]*

For decades the U.S. Food and Drug Administration (FDA) censored nutrient-disease relationship claims (so-called "health claims") with impunity. Agency scientists and officials have long believed it was FDA's unique role to determine for Americans what is in their own best interest and to deny them access to information on how nutrients, and foods in general, could affect disease, reasoning that less-than-certain information of this kind could result in dangerous self-medication by consumers. The era of censorship with impunity is now coming to a close. A new era of agency respect for the First Amendment* appears in the offing.[1] Nevertheless, legal battles against FDA censorship of claims concerning a nutrient's effect on existing disease continue.

As explained in greater detail below, in 1999 the U.S. Court of Appeals for the District of Columbia (D.C.) Circuit held in *Pearson v. Shalala* that FDA violated the First Amendment by denying all health claims except those backed by near-conclusive proof of a nutrient-disease relationship. Although at first unwilling to comply with that decision,[2] FDA became chastened by three lower federal court orders that demanded immediate compliance, repeatedly finding agency noncompliance incompatible with the Court of Appeals' orders. Indeed, the lower court (Judge Gladys Kessler presiding) imposed injunction after injunction on the agency to prevent continued acts of censorship.[3]

The federal courts have made it clear that if a statement is true, or is capable of being rendered so through the addition of a disclaimer, the FDA has no power under the First Amendment's free speech provision to censor the statement (even if FDA believes scientific evidence inconclusive or not fully supportive of the claim, or that consumers cannot be trusted to act responsibly if they receive the claim). At first FDA was quite reluctant to follow the Court's decision. A change of administration brought new officials to the agency in late 2002, like Commissioner Mark B. McClellan, M.D., Ph.D., Associate Commissioner Lester M. Crawford, and Chief Counsel Daniel E. Troy, all of whom share a profound respect for the need to comply with the Court's orders. While that respect has led FDA to allow a series of nutrient-disease prevention claims, it has not led FDA to change its position on claims of a nutrient's effect on an existing disease (so-called "treatment" claims). With respect to the latter, FDA still refuses to allow them to be made as health claims for dietary supplements. FDA will only allow such claims for drugs, following approval of new drug applications. That position of the agency, however, is now the subject of litigation in the federal courts. In *Whitaker v. Thompson*, now pending before the U.S. Court of Appeals for the D.C. Circuit (the same court that held against FDA health claim suppression in *Pearson v. Shalala*), the court will decide whether FDA may constitutionally suppress a claim associating consumption of saw palmetto (*Serenoa repens* (W. Bartram) Small, Arecaceae) extract with a reduction in the symptoms of benign prostatic hyperplasia (BPH).

FDA originally justified its claim bans with anti-fraud and with health and safety rationales.[4] It largely ignored the implications of its actions on First Amendment-protected freedom of speech.[5] Touted as a means to end fraud and enhance health and safety, FDA's censorship never produced those effects;[6] it may well have encouraged fraud and diminished health and safety. By denying consumers access to truthful and nonmisleading information about how nutrients affect disease, FDA may well have created an environment where fraud could flourish uncontested by truthful health information and may well have sacrificed public health. Hucksters depend upon ignorance to defraud consumers. Consumers armed with accurate health information are less likely to be victimized by fraud than those denied that information and are also more apt to make health-enhancing market choices.[7] Conversely, consumers unaware of the actual effects of nutrients are more apt to believe falsehoods about those products and less likely to make health-enhancing market choices.

Under the current administration, which is committed to "putting credible, science-based information in the hands of consumers,"[8] FDA seems willing to comply with the federal court orders, but will that compliance be complete? In at least one area, that of claims concerning the effect of a nutrient on an existing disease, the answer appears to be no. There FDA censorship continues as it had before the Pearson decision; consequently, the battle for First Amendment freedom continues. The battle centers on whether FDA will allow consumers to receive information about how foods and food ingredients, including dietary supplements, affect existing diseases and their symptoms. FDA takes the position that such claims are not allowable as health claims, but only as "drug claims," by which FDA means that no one may be

* The First Amendment is part of the Bill of Rights, the first 10 amendments to the U.S. Constitution ratified in 1791. The First Amendment reads, "Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the government for a redress of grievances."

allowed to make such claims on foods and on dietary supplements without first obtaining FDA new drug approval for the products. That approval is a virtual impossibility. The cost of the new drug approval process ranges from a conservative low of $200 million to a high of $800 million or more. Most foods and most dietary supplements are unpatentable, so even were food or supplement companies wealthy enough to file a new drug application for a product, few, if any, could recoup their investments in the market, lacking the monopoly protection that patents provide. Moreover, few could afford to leave their present distribution and market channels and market products anew as drugs.

FDA has historically viewed scientific information destined for consumer markets as a potential enemy: either a possible source of sophistication beyond the reach of the average consumer that could beguile, or a source of truth so profound that consumers could not be trusted to act rationally with it. The agency has long viewed itself as the nation's ultimate authority on the interpretation of science, the first and last determiner of what nutrient-disease and nutrient content information may appear on the labels and in the labeling of the commercial goods the agency regulates. In the exercise of health claims regulation,[9] FDA has heeded precious few external voices — whether from leading scientists of the world* or from other federal public health agencies.**

Folic Acid and the Health Consequences of Censorship

The paradigmatic example of how FDA censorship can affect public health arose during the administration of former Commissioner David Kessler, M.D. Dr. Kessler, and several of the agency's top scientists, believed folic acid was not adequately proven to be a safe and effective means to reduce the incidence of neural tube defects (NTDs). NTDs (e.g., spina bifida) are horrific and often lethal conditions afflicting about 5,000 live births annually in the United States. Despite overwhelming scientific evidence that 0.4 mg of folic acid did reduce the incidence of NTDs by 40 percent to 50 percent, and the endorsement of the U.S. Public Health Service and the U.S. Centers for Disease Control and Prevention for a folic acid/neural tube defect risk reduction claim, Dr. Kessler maintained (until the winds of political and legal change became unbearable for him) that there was not "significant scientific agreement" among qualified experts that folic acid could safely reduce the risk of neural tube defects and that there existed a risk (unproven then and now) that those consuming folic acid may mask a vitamin B_{12} deficiency. On those grounds, he suppressed the folic acid claim for more than a year, finally relenting to demands from U.S. Senator Orrin Hatch (R-UT) and then Congressman (now Governor) Bill Richardson (D-NM) on the eve of a U.S. Senate Labor and Human Resources Committee hearing (at which Dr. Kessler would have been made to account publicly for his refusal to allow the claim.)[10]

The U.S. Senate Committee on Labor and Human Resources investigated FDA's refusal to allow the folic acid claim, while Durk Pearson, Sandy Shaw, the American Preventive Medical Association, and Citizens for Health sued the agency for its refusal. At the conclusion of its deliberations, the Senate Committee observed:

> In September, 1992, the Public Health Service issued a recommendation that all women of child-bearing age have adequate folic acid to prevent against birth defects. The Centers for Disease Control had made a similar recommendation one year before. Despite these two recommendations, and despite the fact that the FDA participated in the PHS proceedings leading up to the announcement, FDA did not issue a regulation proposing approval of a health claim for folic acid until October, 1993, one week before the committee's hearing on dietary supplements.
>
> Absent approval of a health claim by the FDA, it was illegal for manufacturers or retailers to advise the public about the benefits of folic acid, even though those benefits had been endorsed by the leading Federal public health agencies.[11]

Upon review of that same evidence three years later, the same committee found FDA squarely to blame for neural tube defect births that could have been prevented by prompt allowance of the folic acid/neural tube defect risk reduction claim:

> The history of the folic acid and neural tube defects health claim dramatizes the critical need for [passage of the FDA Modernization Act]. In 1992, the Centers for Disease Control and Prevention (CDC) issued the following recommendation to women of childbearing age, aimed at reducing the risk of pregnancies affected by neural tube defects:
>
> All women of childbearing age in the United States who are capable of becoming pregnant should consume 0.4 mg of folic acid per day for the purpose of reducing their risk of having a pregnancy affected with spina bifida or [other neural tube defects].
>
> ... The CDC estimated that this recommendation could reduce the number of cases of spina bifida and other neural tube defects in the United States by 50 percent.
>
> Despite the significant scientific agreement among qualified experts concerning the evidence supporting the recommendation, manufacturers of foods containing folic acid were prohibited from making claims about the benefits of folic acid in reducing the risk of neural tube defects until FDA approved the claim through a notice and comment rulemak-

* Each health claim filed with the agency has been accompanied by a scientific report from leading experts who study the nutrients in question.

** For example, in 1992, the Centers for Disease Control and Prevention (CDC) recommended that all women of childbearing age be informed of the need to consume 0.4 mg of folic acid daily to reduce a woman's risk of neural tube defects by an estimated 50 percent (CDC. *Morbidity and Mortality Weekly Report*, September 11, 1992). FDA at first refused to follow CDC by authorizing a claim for folic acid and neural tube defects. It finally changed its position in March 1996 only after the *Pearson* litigation began (which included this claim until FDA relented). See Senate Report 105-43, "Food and Drug Administration Modernization and Accountability Act of 1997," 49-50 (1997). In addition, despite CDC's determination that elevated homocysteine levels were an independent risk factor for vascular diseases in 1999 (CDC. *Morbidity and Mortality Weekly Report*, November 12, 1999), FDA refused to recognize it as such and to permit a B_6, B_{12}, and folic acid claim for vascular disease risk reduction due to those nutrients' accepted homocysteine-lowering effects until after Julian M. Whitaker, M.D., and others sued the agency in 2001. Compare Letter from FDA to Jonathan Emord denying B_6, B_{12}, Folic Acid/Vascular Disease claim, November 30, 1999, to Settlement Reached for Health Claim Relating B Vitamins and Vascular Disease, May 15, 2001 found online at <www.cfsan.fda.gov/ ~dms/ds-hclbv.html>.

ing procedure.

Without appropriately accounting for the CDC recommendation, FDA promulgated a rule in January 1993, prohibiting claims concerning the relationship. In the wake of controversy concerning FDA's action, and despite the absence of any change in the scientific evidence, the Agency reversed course, proposing to authorize such claims in October, 1993. Final regulations authorizing the claim were promulgated in March 1996. *Undoubtedly, many children suffered from preventable neural tube defects as a result of FDA's delay in authorizing health claims based on the 1992 CDC recommendation.* [Emphasis added.][12]

Although Congressional angst reached a fever pitch in response to FDA's refusal to allow the folic acid/neural tube defect claim, the world fundamentally changed for the FDA as a result of a series of judicial, not political and not legislative, decisions. Those decisions repeatedly held FDA censorship of health claims unconstitutional under the First Amendment and enjoined FDA from doing so. The world changed further when a new administration arrived in 2002, including Commissioner McClellan, Associate Commissioner Crawford, and Chief Counsel Troy. Those officials have dedicated the agency to fulfillment of the First Amendment mandate given FDA by the federal courts. Although it would be a hasty generalization to conclude at this early date that FDA's days of censorship are over, it may now be said with confidence that addressing First Amendment issues has become obligatory for agency censors as a result of the new leadership at the agency.

Pearson v. Shalala I

A bellwether of health claims regulation until 1999, FDA censorship first met the superior and countervailing force of the American Constitution when the U.S. Court of Appeals for the D.C. Circuit decided *Pearson v. Shalala.*[13] In that landmark decision, written for the Court by Senior Judge Laurence H. Silberman, the Court of Appeals for the D.C. Circuit held that FDA violated the First Amendment by censoring four health claims, held that FDA had to favor disclosure of information over suppression as the operative rule in health claims review, held that claims not passing FDA's scientific standard would nevertheless have to be allowed if they could be rendered nonmisleading with disclaimers, and held that FDA had to rely on disclaimers as a less restrictive alternative to censorship in all instances except the extremely rare circumstance in which a claim was backed by *no* credible scientific evidence.[14]

The *Pearson I* Court began its First Amendment assessment quoting *In re R.M.J.*, 455 U.S. 191, 203 (1982): that the government "may not place an absolute prohibition on ... potentially misleading information ... if the information also may be presented in a way that is not deceptive."[15] The *Pearson I* Court explained the importance of the presumption at some length and the fact that the burden cannot be met except upon adduction of empirical evidence of misleadingness (a complete ban is only appropriate if the government "demonstrate[s] with empirical evidence that disclaimers ... bewilder consumers and fail to correct for deceptiveness"[16]).

Under *Pearson I* and its progeny, before resorting to censorship, FDA must determine based on empirical evidence that the claim before it (not the nutrient-disease relationship *per se* or in the abstract) cannot be rendered nonmisleading through the addition of a reasonable disclaimer. Every disclaimer that could be used to eliminate a proven potential to mislead must be carefully assessed. Only after establishing that no disclaimer can cure that proven potential may the FDA suppress the claim.

The *Pearson I* Court explained that disclaimers not only correct for what the Court termed "misleadingness" by informing consumers of scientific inconclusiveness but also of adverse reactions that may occur to some who use a dietary supplement, writing, "... [T]he government's interest in preventing the use of labels that are true but do not mention adverse effects would seem to be satisfied — at least ordinarily — by inclusion of a prominent disclaimer setting forth those adverse effects."[17] It is thus not enough to justify suppression that at some dose level or in some contexts a nutrient may cause an adverse reaction. That, too, is reason for a disclaimer, not censorship.

AHPA's Input on Saw Palmetto Health Claims Filed in Court

The American Herbal Products Association (AHPA) filed a friend of the court brief[1,2] in the U.S. Court of Appeals for the District of Columbia Circuit in support of Julian Whitaker, M.D., and others who have filed for a health claim from FDA for saw palmetto (*Serenoa repens*) and its relationship to the symptoms of benign prostatic hyperplasia (BPH).[3] The brief was filed May 28, 2003, on behalf of AHPA by its General Counsel, Anthony L. Young, a partner at Kleinfeld, Kaplan and Becker, LLP.

According to AHPA, FDA refused to evaluate the merits of Dr. Whitaker's health claim petition on the basis that it describes how saw palmetto "treats" the symptoms of BPH. Such claims, according to FDA, may only be made for drugs and the health claim provision of the Nutrition Labeling and Education Act (NLEA) of 1990 does not authorize health claims concerning a nutrient's ability to treat diseases or their symptoms.[4] FDA prevailed with these arguments in the lower court and Dr. Whitaker appealed. (See accompanying article.)

AHPA's friend of the court brief pointed out that NLEA requires FDA to consider any claim regarding the relationship between a nutrient and disease and that FDA never took the "no treatment claims" position in regulations promulgated under NLEA.[5] AHPA also pointed out that the District Court's rationale for determining that the health claim provision of NLEA is ambiguous is flawed because the statute clearly permits treatment claims to be made as health claims.[4]

AHPA also countered FDA's long-held position that allowing a treatment claim for saw palmetto would discourage men from seeking proper medical evaluation and noted that AHPA recommends that the following or similar language appear on the label of any products containing saw palmetto:

"Notice: The National Institute on Aging recommends that men get regular medical checkups with a thorough prostate exam. You should inform your health care practitioner that you are using this

The *Pearson I* Court relied heavily on First Amendment precedent in crafting its decision, delving into the philosophical underpinnings for the requirement that the claims in issue be protected from government suppression. Repeatedly in its decisions over the last two and a half decades, the U.S. Supreme Court has emphasized that full and faithful implementation of the First Amendment leads inexorably to preservation of a free and open idea and information marketplace and that, while imperfect, the free idea market nevertheless serves as the best engine for advancement, innovation, and truth discovery. To be sure, the Court loathes censorship and prior restraint, particularly when predicated on the paternalistic notion that those in government know better than the average individual how best to pursue that individual's own self interest. The constitutional presumption favoring disclosure of information over its suppression is a strong one therefore, arising from the well-accepted and often cited conclusion of the Court that under the First Amendment commercial speech doctrine, there is no legitimate role of government in censoring, let alone restricting access to, truthful information.

The Court of Appeals had little difficulty rejecting FDA's justifications for refusing to rely on disclaimers as a less speech restrictive alternative to censorship. It unceremoniously rejected each of the agency's justifications. It rejected the notion that a claim not backed by "significant scientific agreement" was by that fact alone inherently misleading and could lawfully be censored, reasoning that a claim could be true and protected under the First Amendment even if it failed to satisfy the agency's chosen scientific standard.:

> As best we understand the government, its first argument runs along the following lines: that health claims lacking "significant scientific agreement" are inherently misleading because they have such an awesome impact on consumers as to make it virtually impossible for them to exercise any judgment *at the point of sale*. It would be as if consumers were asked to buy something while hypnotized, and therefore they are bound to be misled. We think this contention is almost frivolous. See *Peel [v. Attorney Registration and Disciplinary Comm'n of Illinois]*, 496 U.S. 91, 105 (1990) (rejecting paternalistic assumption that the recipients of a letterhead are "no more discriminating than the audience for children's television"). We reject it.[18]

The Court held FDA's scientific standard arbitrary and capricious under the Administrative Procedure Act because it was largely undefined but, the Court reasoned, even were FDA able to define a standard for health claims review, that could not serve as a lawful basis upon which to reject a health claim, writing: "[E]ven if 'significant scientific agreement' were given a more concrete meaning, appellants might be entitled to make health claims that do not meet that standard — with proper disclaimers."[19]

The Court also rejected the notion that unless information is scientifically certain, it will mislead consumers and cause them to waste their resources, writing:

> Because it is not claimed that the product[s] [are] harmful, the government's underlying — if unarticulated — premise must be that consumers have a limited amount of either attention or dollars that could be devoted to pursuing health through nutrition, and therefore products that are not indisputably health enhancing should be discouraged as threatening to crowd out more worthy expenditures. We are rather dubious that this simplistic view of human nature or market behavior is sound, but, in any event, it surely cannot be said that this notion — which the government does not even dare openly to set forth — is a *direct* pursuit of consumer health; it would seem a rather indirect route, to say the least. See *Bates v. State Bar of Arizona*, 433 U.S. 350, 375 (1977) ("We view as dubious any justification that is based on the benefits of public ignorance."); *cf. 44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 503 (1996) (opinion of Stevensw, J., joined by Kennedy, J., and Ginsburg, J.) ("The First Amendment directs us to be especially skeptical of regulations [of indisputably non-misleading information] that seek to keep people in the dark for what the government perceives to be their own good.").[20]

The Court of Appeals understood FDA to have a high First

product."

AHPA's brief said:

"In the final analysis, there is no reason to believe that men will improperly use dietary supplements containing saw palmetto if they are marketed with the proposed health claim. Indeed, approving the saw palmetto health claim with accompanying language concerning the need for routine prostate exams would benefit, not harm, the public health. If approved, the labels of most saw palmetto products will likely bear the health claim along with any additional language regarding the need for regular prostate exams required by FDA. Thus, approval of the proposed health claim would likely result in a wider dissemination of the National Institute on Aging's important recommendation for regular prostate exams.

"We are pleased to support Julian Whitaker and his allies in seeking reversal of FDA's position which seeks to rewrite the NLEA's health claims provision.

"FDA's refusal to look at Dr. Whitaker's proposed BPH claim on the merits needs to be brought up short. FDA must be open to receiving and reviewing health claims for foods and supplements on their merits so that the claims may be properly qualified and consumers can receive information about these products. Information was the abiding goal of both NLEA and DSHEA and FDA has simply lost sight of that goal."[2]

Reference:

1. American Herbal Products Association. AHPA Files Friend of Court Brief on Health Claim for Saw Palmetto. AHPA Update. May 28, 2003.
2. *Amicus Curiae* Brief of the American Herbal Products Association, *Whitaker v. Thompson* No. 03-5020, D.C. Cir. Friend of the court briefs, called briefs *amicus curiae*, are permitted in all courts with the permission of the litigants and the court. They are often used by trade associations (e.g., AHPA) and other interest groups (e.g., the Sierra Club) to present points of view of interest to their members and to the Court.
3. Brief of the Appellants, *Whitaker v. Thompson* No. 03-5020, D.C. Cir.
4. 21 U.S.C. §343(r)(6).
5. 21 C.F.R. Part 101, Subpart E.

Amendment burden of proof to justify censorship and meant to reverse FDA's penchant for denying the public access to nutrient-disease relationship information. To satisfy its high constitutional burden, FDA could not rest on a determination that a claim failed to meet some FDA-decreed objective or subjective scientific standard or a determination that use of the claim could result in some members of the public engaging in behavior FDA found inappropriate. Rather, FDA had to find empirical evidence that a claim was inherently misleading and that *no* disclaimer could be used to eliminate the misleading connotation. If the science supporting a claim was inconclusive, if only a minority of scientists endorsed it, or if there remained controversy in the scientific community concerning it, those qualifications were precisely the kind that the Court expected FDA to write into disclaimers. *Pearson I* has therefore made it incumbent upon FDA in the discharge of its constitutional duties to stand aside, permitting as much information as possible to reach the public and relying on reasonable disclaimers as its primary corrective mechanism because that mechanism is invariably a less speech restrictive alternative to outright suppression.

Enforcing *Pearson v. Shalala (Pearson II, Pearson III, and Whitaker I)*

Even after the Court of Appeals' remand order, FDA continued to censor the very claims the Court held protected by the First Amendment. In *Pearson v. Shalala II*,[21] the U.S. District Court for the District of Columbia held unconstitutional under the First Amendment FDA's continuing refusal to allow the following health claim (held protected by the First Amendment in *Pearson I*) to appear on the label and in the labeling of folic acid containing dietary supplements: "0.8 mg of folic acid in a dietary supplement is more effective in reducing the risk of neural tube defects than a lower amount in foods in common form." The Court enjoined FDA from enforcing a second, post-*Pearson I* order denying the claim and ordered FDA to come up with "one or more alternative disclaimers which may be chosen by designers, sellers, and manufacturers of dietary supplements" for use on folic acid-containing dietary supplements.[22] The Court found FDA noncompliance with *Pearson v. Shalala I* wholly unjustified, writing: "[I]t is clear that the FDA simply failed to comply with the constitutional guidelines in Pearson. Indeed, the agency appears to have at best, misunderstood, and at worst, deliberately ignored, highly relevant portions of the Court of Appeals Opinion."[23] The Court found that FDA "continually refused to authorize the disclaimers suggested by the Court of Appeals — or any disclaimer, for that matter . . . ."[24] The Court reiterated that inconclusiveness in science does not justify banning a claim backed by credible evidence. In such circumstances the First Amendment protects the speech in issue and the government must rely on the less restrictive alternative of more speech, in the form of a disclaimer, to cure any potential misleadingness:

> [A]s the Pearson opinion strongly suggests, the FDA may not ban the Folic Acid Claim simply because the scientific literature is inconclusive about whether synthetic folic acid is superior to naturally occurring folate. . . . The question which must be answered under Pearson is whether there is any "credible evidence" that synthetic folic acid is superior to naturally occurring food folate. . . . There clearly is such evidence, as the FDA itself acknowledged. Consequently, the agency erred in concluding otherwise. In short, even if the FDA's criticism of the sub-claim is valid, this criticism does not make the Claim inherently misleading; rather, it suggests the need for a well-drafted disclaimer, which the FDA has steadfastly thus far refused to even consider.[25]

The Court emphasized that FDA could not suppress health claims with impunity but had to satisfy a very high First Amendment burden of proof to show that suppression was constitutional; indeed, in no instance would suppression be allowed when disclosure could serve as a less restrictive alternative:

After three court decisions, it is hard to believe that the FDA would continue to suppress information, but that is precisely what it did

> In sum, the FDA has simply failed to adequately consider the teachings of Pearson: that the agency must shoulder a very heavy burden if it seeks to totally ban a particular health claim. With respect to the two disclaimers which the Pearson Court suggested might cure all potential misleadingness, the FDA did not consider one of them at all, and summarily rejected the other in a single sentence. Nor did the FDA "demonstrate with empirical evidence that disclaimers similar to the ones" suggested by the Court of Appeals would "bewilder consumers and fail to correct for deceptiveness." Indeed, the FDA did not consider any other disclaimers, except for "The FDA has not evaluated this claim," a disclaimer no one has suggested and which is obviously inaccurate.[26]

The FDA refused to accept this second decision and moved to have it reconsidered by the trial judge, despite the absence of new evidence, new law, or clear error warranting reconsideration. In *Pearson v. Thompson*[27] (*Pearson III*), the Court denied the government's motion, finding the motion further evidence of the FDA's "reluctance to fully comply with Pearson I. . . ."[28] Significantly, the Court used this opportunity to reiterate that FDA could not justify censorship of a health claim simply because it deemed the evidence in support of the claim insubstantial. Rather, FDA would have to produce specific evidence that contradicted the very claim in issue and would have to show that the contradictory evidence substantially outweighed the evidence in support of the claim. In the end, only if the evidence for the claim was patently incredible by comparison to the evidence specifically against it, could the claim be censored. In all other circumstances, the claim would have to be allowed (with disclaimers performing the role of qualifying the relative level, quality, and quantity of evidence for the claim). The Court wrote:

> With respect to Defendants' request for clarification, which asks under what circumstances the FDA may totally ban a health claim, this issue is adequately addressed when Pearson II is considered in conjunction with Pearson I. Pearson I indicates that "the FDA [may] impose an outright ban on a claim where evidence in support of the claim is qualitatively weaker than evidence against the claim — for example, where the claim rests on only one or two old studies" or "where evidence

> in support of a claim is outweighed by evidence against the claim." Pearson II fleshes out the term "against": "The mere absence of significant affirmative evidence in support of a particular claim ... does not translate into negative evidence 'against' it ... ."[29]

While from the outside looking in, one would find it hard to believe that after three decisions condemning FDA censorship (one from the U.S. Court of Appeals and two from the U.S. District Court) the FDA would continue along its speech suppressive course; that is precisely what the agency did. Rather than heed the Courts' orders and permit an antioxidant/cancer risk reduction claim (e.g., "Consumption of antioxidant vitamins may reduce the risk of certain kinds of cancer."), properly disclaimed (e.g., "The scientific evidence in support of this claim is inconclusive."), the FDA chose censorship once again, resulting in a second court battle on that claim, a claim already held protected by the First Amendment in *Pearson I*.

In *Whitaker v. Thompson* (*Whitaker I*),[30] the Court evaluated FDA's decision to refuse, on remand, to allow a claim associating consumption of antioxidant vitamins with a reduction in the risk of certain forms of cancer. In holding FDA's censorship unconstitutional under the First Amendment and enjoining FDA's rule suppressing the claim, the Court explained in the greatest detail to date that FDA was utterly powerless to suppress a health claim unless under no circumstances the claim could be rendered nonmisleading through use of a disclaimer. The Court explained:

> Specifically, Pearson I identified two situations in which a complete ban would be reasonable. First, when the "FDA has determined that no evidence supports [a health] claim," it may ban the claim completely. ... Second, when the FDA determines that "evidence in support of the claim is qualitatively weaker than evidence against the claim — for example, where the claim rests on only one or two old studies," it may impose an outright ban. ... Even in these two situations, a complete ban would only be appropriate when the government could demonstrate with empirical evidence that disclaimers similar to the ones [the Court] suggested above ["The evidence in support of this claim is inconclusive" or "The FDA does not approve this claim"] would bewilder consumers and fail to correct for deceptiveness.

Thus, two conclusions emerge from a close reading of *Pearson I*. First, the Court of Appeals did not rule out the possibility that disclaimers would not be able to correct the inherent misleadingness of some claims. Second, the Court stated that any complete ban of a claim would be approved only under narrow circumstances (i.e., when there was almost no qualitative evidence in support of the claim and where the government provided empirical evidence proving that the public would still be deceived even if the claim was qualified by a disclaimer).[31]

With *Whitaker I*, First Amendment protection for credible nutrient/disease relationship claims appears well-established. However, as revealed in *Whitaker II*, that protection applies only in the context of claims about a nutrient reducing the risk of, or preventing, a disease. The Court has held the First Amendment not violated when FDA refuses to evaluate health claims that concern the effect of a nutrient on an existing disease (i.e., a so-called "treatment" effect). That decision, *Whitaker v. Thompson*[32] (*Whitaker II*), is now on appeal. The appeal will determine whether sellers of an unpatentable herbal dietary supplement, saw palmetto, may inform consumers of the truthful and nonmisleading fact that the herb (usually in extract form) affects symptomology of benign prostatic hyperplasia (BPH).[33] The case calls into question basic First Amendment tenets. The outcome will determine whether FDA may censor all health claims that accurately convey an unpatentable nutrient's effect on an existing disease (a so-called "treatment" effect).

Challenging *Whitaker II*

Neither the plain language of the Nutrition Labeling and Education Act (NLEA) nor the intent of Congress as articulated by key committees, bill sponsors, or members reveal any evidence that the health claims definition found in 21 U.S.C. § 343(r)(1)(B) limits the scope of nutrient-disease relationship claims to disease *prevention* claims. To the contrary, the plain language permits the filing of health claims that "expressly or by implication ... characterize the relationship of any nutrient ... to a disease or a health-related condition."[34] Despite that fact, the FDA prohibited review of a truthful and nonmisleading saw palmetto/BPH claim on the basis that the health claims provision did not contemplate permitting a claim concerning an effect on an existing disease. The claim is documentable and supportable by a large body of generally accepted scientific and medical research, enough in fact to possibly qualify for the "significant scientific agreement" standard, which would not be necessary to permit claim use under the *Pearson* precedent.[35,36]

FDA's decision not to permit this claim to be processed as a dietary supplement health claim under NLEA (this is significantly different from a structure/function claim under the Dietary Supplement Health and Education Act of 1994, which does not require FDA preapproval) left only one alternative for the petitioners: to seek new drug approval (NDA) for the supplement as a condition precedent to making the claim. New drug approval would cost at least $58 million according to the economic expert retained by the petitioners. Neither the petitioners nor any other company that makes saw palmetto could afford such an exorbitant cost. Moreover, even if a company could afford the cost, the fact that the nutrient is unpatentable ensures that none would file. It would be impossible to recoup that extraordinary investment (relatively modest in comparison to the cost of patentable new chemical entity drugs, whose NDA costs can run in the hundreds of millions of dollars, such costs being recoupable with exclusive marketing rights deriving from the patent and other statutory protection). Moreover, the petitioners would be sorely disadvantaged because they would also incur the costs of transforming themselves from dietary supplement to drug manufacturers, the latter operating in a new market with an entirely different distribution system. Despite those costly, indeed practically prohibitive, burdens on the right to communicate a truthful message, neither the FDA nor the U.S. District Court for the District of Columbia felt compelled to evaluate the claim under the First Amendment standards applicable to state suppression of speech.

In the view of the petitioners, the FDA simply ignored the First Amendment in its decision. The U.S. District Court based its First Amendment decision on a hasty generalization unsupported by commercial speech precedent. Under the governing *Central Hudson*[37] four-part test, the first inquiry is to discern whether the speech in issue concerns an unlawful activity. If so, then it may be banned outright. The District Court made the mistake of defining

the speech here in issue (a health claim) as concerning an unlawful activity (the filing of an ungranted health claim petition), but the filing of a health claim petition, even an ungrantable one, is a perfectly legal action. Were the filing of a petition seeking a government approval an "illegal" activity within the meaning of *Central Hudson*, it would have been impossible for any party to have ever won a commercial speech case against the government, to have ever surmounted the first prong. That is because at this level of abstraction every pleading defined *post hoc* as seeking ungrantable relief from government censorship would be *ipso facto* an illegal action. It would thus be entirely within the government's power to define out of existence all First Amendment protection for commercial speech. In every prior commercial speech case decided against the government, the government's proscription against speech did not define an "illegal activity" within the meaning of *Central Hudson*. No, the government's speech proscription was the very fact in issue. Thus, the Court erred by deciding the case on an erroneous interpretation of the first prong of *Central Hudson* and by thereafter not applying the remaining three parts of the *Central Hudson* test. Were it to have applied all four parts of the test, the Court should have found under the last part an obvious less speech restrictive alternative to the extraordinary burden placed upon the claim by the demand that a new drug application be filed as a condition precedent for the utterance of truthful speech in the market. The obvious less restrictive alternative of a health claim petition is one not proscribed by statute and one that comports fully with the First Amendment requirement placed upon FDA by *Central Hudson* and its progeny.

Moreover, the Court ignored its obligations under what is known as the "avoidance doctrine" — a constitutional rule of construction that our Supreme Court expects to be followed when it is possible to interpret statutory language to avoid a constitutional issue. In this case, the First Amendment issue could have been avoided in its entirety were the Court to have interpreted the statute in accordance with its plain meaning. Deference to an administrative agency taking a contrary interpretation in such instances is forbidden.[38] Yet that is precisely what the Court did.

This case is now pending before the U.S. Court of Appeals for the D.C. Circuit. Resolution of the case will likely trigger a petition to the U.S. Supreme Court from the losing party, seeking that Court's review. Ultimate resolution of this case will determine whether companies that manufacture unpatentable nutrients will enjoy the freedom to inform consumers of accurate, known disease treatment effects of these nutrients. If the Court sides with the government, those truths will remain locked out of the marketplace for the foreseeable future because no company will be able to afford the high cost of the drug approval process as a condition precedent to telling the public the truth. Furthermore, few would be willing to abandon established markets, enter costly new drug markets and fight for new drug distribution channels. As with *Pearson v. Shalala I*, this case, *Whitaker v. Thompson III*, will determine whether the right to communicate a truthful and nonmisleading message will survive the contrary will of the FDA.

Ensuring Freedom of Informed Choice

It has become a truism that eternal vigilance is the price of freedom. Those individuals who, and companies that have fought the FDA to ensure freedom of informed choice have paid the price, and others also will have to guard against a loss of liberty attendant to FDA's regulatory encroachment on free speech rights. Commissioner McClellan, Associate Commissioner Crawford, and Chief Counsel Troy are all committed to ensuring freedom of informed choice, but they stand in contrast to an entrenched bureaucracy originally responsible for unconstitutional health claims suppression. While disease prevention claims are now enjoying the benefits of the new administration's labors to implement *Pearson v. Shalala*, the task of protecting truth remains unfulfilled so long as the saw palmetto/BPH claim and others like it remain effectively suppressed by the agency. Once again, parties have turned to the courts for relief from government censorship. As before, so now freedom hangs in the balance.

Jonathan W. Emord is a principal with Emord & Associates, P.C. in Washington, D.C. Mr. Emord practices constitutional and administrative law before the federal courts and agencies. He served as the lead counsel in Pearson v. Shalala and each of the other three federal court decisions holding FDA suppression of health claims unconstitutional under the First Amendment. He also represented Dr. Jonathan V. Wright before the U.S. Department of Justice. He is also the author of Freedom, Technology, and the First Amendment (Pacific Research Institute for Public Policy, 1991).

Reference:

1. On December 18, 2002, FDA Commissioner Mark B. McClellan, M.D. announced that henceforth FDA would "make available more and better information about foods and dietary supplements to help American consumers prevent diseases and improve their health by making sound dietary decisions." See Anon. FDA Announces Initiative to Provide Better Health Information for Consumers. *FDA News*, Dec. 18, 2002. The initiative is a dramatic departure from preceding agency history which was characterized by claim suppression. In the words of the U.S. Court of Appeals for the D.C. Circuit: "FDA appears quite reluctant to approve health claims on dietary supplements." *Pearson v. Shalala*, 164 F.3d 650, 654 n.3 (D.C.Cir. 1999).
2. See *Pearson v. Shalala*, 172 F.3d 72 (D.C. Cir. 1999) (wherein FDA unsuccessfully sought rehearing of the Court's decision).
3. See *Pearson v. Shalala*, 130 F.Supp.2d 105 (D.C.D.C. 2001); *Pearson v. Thompson*, 141 F.Supp.2d 105 (D.C.D.C. 2001); *Whitaker v. Thompson*, 2002 U.S.Dist. LEXIS 25299 (D.C.D.C. 2002).
4. See, e.g., *Pearson v. Shalala*, 164 F.3d at 655 (fraud rationale); 164 F.3d at 656 (safety rationale).
5. See, e.g., *Pearson v. Shalala*, 164 F.3d at 654 (explaining that when the Plaintiffs presented FDA with First Amendment argument in favor of use of disclaimers as less speech restrictive alternatives to censorship, "FDA declined to consider [that] alternative … ").
6. See, e.g., *Pearson v. Shalala*, 164 F.3d at 659 (rejecting government conjecture of public harm as an insufficient substitute for proof that the harms recited are real and that the restrictions will in fact alleviate the alleged harms to a material degree).
7. Ippolito PM, Pappalardo JK. *Advertising Nutrition & Health: Evidence from Food Advertising 1977–1997*. Bureau of Economics Staff Report, Federal Trade Commission, September 2002.
8. Anon. FDA Announces Initiative to Provide Better Health Information for Consumers. *FDA News*. Dec. 18, 2002.
9. Under the NLEA, 21 U.S.C. § 343(r)(1)(b), a claim of a relationship of a nutrient to a disease or a health-related condition may not appear on the label or in the labeling of a dietary supplement or conventional food unless pre-approved by the FDA. That pre-approval process requires, in the case of foods (by statute, 21 U.S.C. § 343(r)(3)) and dietary supplements (by regulation, 21 U.S.C. § 343(r)(5)(D)) that FDA find "based on the totality of publicly avail-

Continues on page 67

Industry Increasingly Nervous about Drug Orientation of FDA's Proposed GMPs for Dietary Supplements: High Costs Threaten Smaller Companies

by Mark Blumenthal

Much of the activity in herb industry circles over the spring and summer has focused on the proposal by the U.S. Food and Drug Administration (FDA) for current good manufacturing practices (cGMPs) for dietary supplements.[1] As discussed in the last issue of *HerbalGram*,[2] the 106-page proposal published on March 13 has been long-awaited and was initially welcomed by industry organizations. They have been pleading with FDA for years to publish new rules for the manufacture of dietary supplements (including herbs), as authorized by Congress in 1994 when it passed the Dietary Supplement Health and Education Act (DSHEA). Congress included this provision in DSHEA to help ensure that dietary supplement products were properly manufactured, and the materials were properly identified and free of potentially harmful contaminants, so that consumers could have confidence in these products.

The biggest issue of concern among industry members is the apparent drug orientation of the cGMPs. Although DSHEA clearly stipulates that new cGMPs should be "modeled" on GMPs that are in effect for the manufacture of conventional foods, the FDA has added numerous testing provisions that are clearly based on pharmaceutical drug GMPs, not food GMPs. The costs involved are estimated to be so significant that the general consensus is that many smaller to medium size firms will not be able to meet the requirements and will be forced out of business. Ironically, this may result in consumers finding a smaller variety of herbal supplements from which to choose in the marketplace, while at the same time there may be a higher level of confidence in the remaining products.

For example, one manufacturer of Chinese herbal formulas, who relies on a third-party contract manufacturer to produce the products, as is the case with many companies, told *HerbalGram* that the continuous testing required under drug GMPs for pharmaceutical companies might work for so-called "nutraceutical" ingredients (e.g., luteine, lycopene) where there is one plant-derived pure substance (or a group of chemically related compounds) where the manufacturer produces and sells millions of dosage forms of the one product or ingredient. However, he said, his company markets more than 100 products, each containing up to a dozen ingredients. If each ingredient is subjected to quality control testing, and then the finished product is also required to be tested, the costs were simply too high and were not reasonable nor sustainable, he said. He would simply have to go out of business. In an email to the author on June 26, 2003, he wrote:

> I had a chance to go over in some more detail the GMP proposal by FDA. The rather extreme testing protocols that had been relayed to me previously do not seem entirely evident from the proposal. For example, [another Chinese herb manufacturer] suggested that every material would have to be tested thoroughly prior to use in manufacturing, and again after manufacturing, including tests of microbiology, pesticides, heavy metals, etc. Such testing, especially double testing, is ruinous to a small organization such as ours where we produce over 150 different formulas, with an average of two batches per year, and 500 different raw materials, with little mark-up to make sure the formulas are affordable. However, it was not [originally] clear that this is the nature of the [FDA's] requirements.

The apparent confusion about how the proposed rules require ingredients and finished products to be tested twice appears to be fairly common within some parts of the herb industry. Annette Dickinson, Ph.D., president of the Council for Responsible Nutrition (CRN), a leading industry trade association, attempted to clarify the situation, explaining that the proposed rule's *primary requirement* is to test everything in the *finished product*. If the available testing methodology is not suitable, such testing, as an alternative, may be done on all raw ingredients before manufacturing and again at some point during the manufacturing process. This, in effect, will result in double testing of ingredients to some degree if the finished product does not lend itself to the required testing, and to the extent that the supplier(s) of the ingredient(s) presumably tested each ingredient prior to sending them, and then they are tested again during the processing of the product.

AHPA Holds Regional GMP Meetings

The American Herbal Products Association (AHPA) held a series of five meetings with its members around the country to discuss the cGMP proposal. Each of the meetings (in Los Angeles; Portland, Oregon; San Francisco; Salt Lake City; and New Brunswick, New Jersey) was facilitated by AHPA President Michael McGuffin. A total of 94 individuals from 65 companies (including 50 AHPA members, about 25 percent of the AHPA membership) attended one of these meetings.[3]

The agenda for each meeting included the following items:

- a general overview of the proposed cGMP rule and of FDA Press Release of March 7, 2003;
- a brief discussion of the impact of the rule on various industry segments (e.g., raw material processors; finished product manufacturers; marketers);
- an in-depth review of the proposed rule (from an AHPA prepared worksheet);
- a brief review of FDA's 1999 survey of the dietary supplement industry;
- discussion of FDA's economic analysis of the projected impact of the proposed cGMPs.

"Visiting our members in their own neighborhoods has been, if somewhat too fast a pace, a very satisfying process," said McGuffin. "I have heard several clear messages from the industry, which clearly support prompt implementation of cGMP for supplement products that will meaningfully address manufacturing issues, but who see real problems with FDA's proposal and especially with that agency's erroneous assumptions about this trade. The input that we have now received from AHPA's members and others has been essential to the initial preparation of our comments." The period for public comment on the cGMPs was extended to August 11. They were originally due June 11, but FDA responded favorably to industry requests for the extension due to the massive amount of material to evaluate in the proposal.

AHPA has now prepared a report that summarizes all of the input from the participants at these five regional meetings. The document can be accessed by AHPA members at the AHPA

website, <www.ahpa.org/members/03_0618_Proposed cGMP_Cumulated Input.pdf>. Non-members may request a copy by contacting Natasha Hall via email, <nhall@ahpa.org>.

CRN Releases In-Depth GMP Comparison

CRN has also held meetings in the process of developing its comments to FDA. According to Dickinson, due to the many details involved in producing comments on so many technical areas, CRN will submit several separate comments to FDA by the August 11 deadline.

Dickinson noted that high costs may indeed be a threat to the viability of small companies, but they are also a major issue for large companies. She stated that the CRN comments to FDA will deal with these problems. "FDA's analysis does not come close to accurately predicting the amount of increased testing or the related costs for large companies, and we will be providing data on realistic cost estimates," she wrote in an email to *HerbalGram* on July 8, 2003. "We will also be suggesting some offsetting health benefits to consumers, to help balance the cost and benefit sides of the equation."

[T]he proposed cGMPs are based on such a pharmaceutical model that the expenses necessary for their full implementation . . . will significantly affect the way the herb industry operates, and may eliminate some of the small and medium-sized companies.

CRN's Regulatory Affairs committee held three full-day meetings since the cGMP proposal was published. Representatives of numerous leading companies helped analyze the proposed rules and their impact in detail. "We are extremely concerned that the rule seems to attempt to test quality into the product, rather than pointing the way to designing well-controlled processes that will effectively assure quality," Dickinson wrote to *HerbalGram*. She noted that former FDA official Carl Reynolds, who is an expert in cGMPs and has audited many dietary supplement companies enrolled in various third-party cGMP certification programs, "will be assisting CRN's development of its comments to FDA relating to the philosophy and underlying principles of quality assurance."

Dickinson wrote that CRN will also recommend that the cGMP rules include a number of provisions requiring written procedures. "These were included in the industry draft published as the ANPR [Advance Notice of Proposed Rulemaking, published by FDA in 1997 based on a proposal submitted by industry groups[4]], but FDA omitted them, on the assumption that they merely increase the recordkeeping burden without providing commensurate benefit. Our member companies believe that, on the contrary, written procedures are essential to creating a well-controlled process and to the training and supervision of personnel. Helping companies develop a well-controlled process may be the key to helping small companies (as well as large ones) achieve GMPs."

To help its members understand the details of the proposed cGMPs, CRN posted an 84-page spreadsheet[5] that compares the new proposal to one previously submitted to FDA by an industry working group and published in the Federal Register in 1997,[4] and to the current GMPs for conventional foods[6] and for drugs.[7,8] The four-way comparison was produced by Paul Bolar, vice president of regulatory and legal affairs, and his staff at Pharmavite LLC. Bolar is also the chairman of CRN's Regulatory Affairs Committee. The table will be submitted to FDA as part of CRN's public comments and is available on the CRN website, <www.crnusa.org>.

No-Win Situation?

In a speech this past June at the annual convention of the National Nutritional Foods Association (NNFA) in Las Vegas,[9] Loren D. Israelsen, director of the Utah Natural Products Alliance, noted that the serious economic challenges posed to the industry by the new cGMP proposal and the prospect that many manufacturers may not be able to meet the requirements would probably put many companies out of business — a point he said was acknowledged by FDA officials. But, he cautioned, any attempts by industry members and their trade associations to publicly criticize this aspect of the cGMPs might be portrayed in the increasingly-hostile media as an "anti-quality" position by the industry critics — regardless of how legitimate and justified the criticisms might be. This puts the industry in a potentially serious no-win situation, he said.

As noted in the previous *HerbalGram* article on cGMPs, the final regulation will not be forthcoming from FDA until, presumably, some time in 2004. Then it will go into effect in one year for large companies, two years for medium-sized companies, and three years for small companies. Thus, as a practical matter, it will be at least three-and-a-half to four years before all manufacturers of dietary supplements will have to comply with the new cGMPs. This situation creates market opportunities for the various organizations providing third-party certification of GMP and quality control so that companies can show consumers that their products are reliable and contain in the package what is declared on the label.

As noted above, the proposed cGMPs are based on such a pharmaceutical model that the expenses necessary for their full implementation — as they are currently proposed — will significantly affect the way the herb industry operates, and may eliminate some of the small and medium-sized companies. There have been legitimate concerns about the quality of many of the herb and other dietary supplement products manufactured and sold in the U.S. and so it may be understandable why FDA would propose standards that are similar to those required in the conventional drug industry. However, as stated by the Chinese herb formula manufacturer, such requirements may be reasonable for single chemical products like drugs, vitamins, and so-called nutraceuticals, but present a serious analytical challenge to manufactures of herbal products. It will probably take FDA until the beginning of 2004, or possibly later, to sort through the public comments and publish final cGMP regulations. Whether FDA will modify its proposal in response to the public comments is one of the big questions on the minds of many industry leaders; a question whose answer will not be forthcoming for months.

Reference:

1. Current Good Manufacturing Practice in Manufacturing, Packing or Holding Dietary Ingredients and Dietary Supplements: Proposed Rule. Federal Register Volume 69, No. 49, Docket No. 96N-0417. Washington, DC: Food and Drug Administration. March 13, 2003.
2. Blumenthal M, Watts D. FDA proposes GMPs for dietary supplements. *HerbalGram* 2003;58:62-64,65,80.

Continues on page 74

Phytomedicine Sales Off Slightly in Germany

Despite increasing sales of conventional medicines, the sale of herbal preparations (phytomedicines) dropped almost two percent in Germany in 2002, according to recent data obtained from a leading organization that compiles sales statistics of conventional drugs, phytomedicines, and conventional nutritional supplements. All data in the table below are related to the "ambulatory" or retail sector (i.e., excluding sales in hospital pharmacies), and include wholesale sales by distributors and sales directly to pharmacies by the manufacturer at factory-direct prices. The sales data reflect net sales, with promotional and volume rebates and returns already deducted.

Table 1: Conventional Drug, Phytomedicine, and Nutritional Supplement Sales in Germany 2002*

Product Class	Euro value (change from 2001)	Units sold (change 2001)
Human medicines	16.7 billion Euros (+ 8.8%)	1.341 billion packs (+ 0.2%)
Phytomedicines	965 million Euros (-1.8%)	185 million packs (-6.2%)
Nutritional supplements	133 million Euros (-11.3%)	23 million packs (-11.9%)
Total market	18.7 billion Euros	1.654 billion packs

*12-month period from October 2001 to September 2002
[Source: Mertens, G. Personal communication to M. Blumenthal. Nov. 30, 2002 with data from Remed'X Gesellschaft für Trendanalysen im Gesundheitssektor [Remed'X Society for Trends Analysis in the Health Sector], Mainz, Germany.]

Third World Congress on Medicinal and Aromatic Plants for Human Welfare

by Bill Schoenbart, L.Ac.

The Third World Congress on Medicinal and Aromatic Plants for Human Welfare (WOCMAP III) was held in Chiang Mai, Thailand, on February 3–7, 2003. Occurring every five years, this latest WOCMAP conference was attended by more than 500 participants from 50 countries. Over the course of the week, there were 130 oral presentations, 415 poster presentations, and 120 exhibitors. This article can only summarize the topics discussed and highlight a few of them.

The theme of WOCMAP III was "Biodiversity and Sustainable Use through Science and Technology, Trade and Industry." The conference had many co-sponsors and was co-hosted by the International Council for Medicinal and Aromatic Plants, the Faculty of Science at Chiang Mai University, the International Society for Horticultural Science, and in association with the National Research Council of Thailand, the Ministry of Agriculture and Cooperatives, the Ministry of University Affairs, the Science Society of Thailand Under the Patronage of His Majesty The King of Thailand, the National Center for Genetic Engineering and Biotechnology, the Government Pharmaceutical Organization, and the United Nations Food and Agricultural Organization Regional Office for Asia and the Pacific.

The opening ceremony featured Her Royal Highness Princess Maha Chakri Sirindhorn, who welcomed the attendees to Thailand. The princess, who speaks five languages and holds a degree in chemistry, also stressed the need to preserve and protect medicinal and aromatic plants worldwide and encouraged everybody to appreciate the importance of Thailand's rich botanical heritage.

On the first evening, a reception was held for all the attendees on the campus of Chiang Mai University. Showing their renowned hospitality, the Thai hosts went out of their way to make everybody feel welcome. Students from the university, wearing traditional dress, offered aromatic garlands and gifts to the guests at the entrance to the lakeside area. Numerous booths offered delicious *lanna* (Northern Thai) food, while dozens of small glowing hot air balloons were released into the night sky. Traditional musicians and dancers performed on the main stage, while a small replica village displayed a wide variety of village crafts, foods, and herbal preparations. This extraordinary show of affection and hospitality by the Thai hosts was greatly appreciated by all the attendees.

The official opening ceremonies of the exhibit of WOCMAP III in Chiang Mai, Thailand, included students in traditional Thai dress releasing illuminated hot air balloons into the night.

Back at the conference, the numerous excellent presentations included a husband-and-wife team from Israel, Dr. Uriel Bachrach and Prof. Zohara Yaniv. Dr. Bachrach showed that epigallocatechin-3-gallate (EGCG), one of the well-known polyphenols in tea (*Camellia sinensis* (L.) Kuntze, Theaceae), is able to shut off a gene related to the transformation of normal cells into cancer cells. The EGCG had no effect on normal cells, while it inhibited the growth of transformed cells. For many in the audience, this was the first time they had seen the direct effect an herb can have on a gene. Prof. Yaniv presented epidemiological data that showed an association between green tea consumption and lower rates of prostate and stomach cancers in China. She also pointed out that the addition of milk or soy milk to tea can inactivate many of the polyphenols. The conclusion of these two researchers was that green tea, and specifically EGCG, can be used to prevent and possibly to cure certain types of cancer.

Her Royal Highness Princess Maha Chakri Sirindhorn welcomed the attendees to Thailand and opened the exhibition hall with a formal ribbon cutting ceremony.

In another look at green tea, Dr. K. Ingkaninan and his associates from Thailand reported on a clinical trial using green tea and guava (*Psidium guajava* L., Myrtaceae) fruit as a mouthwash. The randomized, double-blinded crossover study demonstrated that the herbal mouthwash was just as effective as Listerine® in suppressing mouth odor.

There were quite a few oral and poster presentations that demonstrated the efficacy of medicinal and aromatic plants as antibacterial and antifungal agents. Dr. Rudolf Bauer, professor at the Institut für Pharmakognosie, Karl-Franzens-Universität, Graz, and a researcher widely known for his work on echinacea (*Echinacea* spp.) and the anti-inflammatory effects of Chinese herbs, presented his findings on a traditional Thai herb used for diarrhea. Along with Dr. O. Luanratana and Dr. M. Phadungkit of Thailand, he showed that fractions of the herb shoe-button ardisia (*Ardisia elliptica* Thunb., Myrsinaceae) were active against various species of *Salmonella, Shigella, Staphylococcus,* and *Escherichia coli.*

A number of oral and poster presentations discussed the antifungal and antibacterial properties of essential oils of cloves (*Syzygium aromaticum* (L.) Merr. & L.M. Perry, Myrtaceae) and cinnamon (*Cinnamomum verum* J. Presl, Lauraceae). In one study, a concentration of 1 percent w/v of each essential oil inhibited bacteria and fungi better than synthetic chemical preservatives.

In summary, the topics discussed during WOCMAP III include the following:

- The importance of biodiversity and sustainable management practices to the survival and development of existing and new

products from medicinal and aromatic plants.
- The issues and implications of regulation on the economics and marketing based on the European experiences, and the restrictive issues for suppliers and manufacturers.
- The role played by plant alkaloids in the world pharmaceutical industry.
- The significance of biodiversity as fundamental to plant improvement by breeding and biotechnology of medicinal and aromatic plants.
- Sustaining the harvest of medicinal and aromatic plants and the challenges to be met in both production and marketing, based on current and future likely demands, consumer preferences, perceptions, and demographics.
- An in-depth evaluation of the use of Chinese medicinal plants in western medicine.
- The biologically active substances from medicinal and aromatic bryophytes and inedible mushrooms.
- The research approaches for bio-prospecting and screening of medicinal and aromatic plants.
- Issues relating to conservation of medicinal and aromatic plants, specifically the huge conservation efforts for more than 1,700 medicinal and aromatic plants in China.
- Standards and quality control of medicinal and aromatic plant products.
- Use of marker technologies and genomics for quality control and efficacy of medicinal and aromatic plants.
- The myriad of medicinal and aromatic plant products produced and sold in Thailand.
- Positive scientific proof that the polyphenol oxidases (PPOs) found in green tea can prevent and possibly cure cancers of various kinds. PPOs' mechanisms of action have also been discovered.
- The announcement of a project involving the production of organically certified medicinal, aromatic and dye plants in Asia to be undertaken by member countries with the Food and Agriculture Organization of the United Nations.
- Creating livelihood-based systems involving medicinal and aromatic plants for smallholder farmers in Asia.

The exhibition hall included 120 different vendors and exhibits, including those that demonstrated the biodiversity of Thailand and other regions. Photos by the author.

At the conclusion of the conference, the participants all agreed that it was highly informative and inspiring. We all look forward to the next WOCMAP conference in five years.

Bill Schoenbart is a licensed practitioner of traditional Chinese medicine. He is the author of two books on herbal medicine and is a contributing author for the American Herbal Pharmacopoeia. Bill is the manager of botanical science for the Perrigo Company of Greenville, South Carolina, and is a member of the Board of Trustees for the American Herbal Products Association.

International Council for Medicinal and Aromatic Plants Background

The International Council for Medicinal and Aromatic Plants (ICMAP) was founded on June 8, 1993 at the Secretariat of the International Union of Biological Sciences (IUBS) in Paris by nine international organizations. They decided to establish, following the recommendation of the First World Congress on Medicinal and Aromatic Plants (WOCMAP-I), an international non-governmental body with the name International Council for Medicinal and Aromatic Plants, with the general objective of promoting international understanding and cooperation between national and international organizations on the role of medicinal and aromatic plants in science, medicine, and industry, and to improve the exchange of information between them.

This Council coordinates and stimulates cooperation between partners by providing a forum for mobilizing ideas, actions, discussions, long term visions, measures in education and training in all fields related to these plants that play such an important part in the lives of human beings throughout the world. Its website is <www.icmap.org>.

The Second World Congress on Medicinal and Aromatic Plants for Human Welfare (WOCMAP-II) in Mendoza, Argentina in 1997, was attended by more than 1,200 delegates from 52 countries. WOCMAP-I was organized in 1993 in Maastricht, The Netherlands.

ICMAP is a scientific activity of IUBS and is based at the IUBS Headquarters in Paris. The Secretariat is at TBAM, Anadolu University, Eskisehir, Turkey. Newly appointed governing Bureau members were installed at WOCMAP-III:

President: Prof. Dr. Chlodwig Franz, of the Institute for Applied Botany at the University of Veterinary Medicine Vienna, Austria

Vice-President: Prof. Dr. K. Husnu Can Baser, of the Department of Pharmacognosy, Faculty of Pharmacy at Anadolu University in Eskisehir, Turkey

Vice-President: Prof. Dr. P. Pushpangadan, Director, National Botanical Research Institute (NBRI), in Lucknow, India

Secretary-General: Prof. Dr. Henk van Wilgenburg, of the Pharmacology Laboratory, Universiteit van Amsterdam, Academic Medical Centre, The Netherlands

Newsletter Editor: Dr. Matthias Lorenz

Member: Prof. Dr. Arayar Jatisatienr, of the Department of Biology, Faculty of Science, Chiang Mai University, Thailand

Member: Prof. Dr. Mahabir P. Gupta, of the Centro de Investigaciones Farmacognóstica dela Flora Panameña (CIFLORPAN), Facultad de Farmacia, Universidad de Panamá, Rep. de Panamá

Previous President: Prof. Dr.Vernon H. Heywood, of the Centre for Plant Diversity and Systematics, School of Plant Sciences, the University of Reading, UK.

book reviews

Vetiveria: The Genus *Vetiveria*, edited by Massimo Maffei. Taylor & Francis: New York; 2002. 191 pp., hardcover, includes index, photos, tables, references. $96.00 ISBN 0-415-27586-5.

This is my second review of a useful book in the ongoing Taylor & Francis series, Medicinal and Aromatic Plants: Industrial Profiles. Perhaps it is my personal bias, but I did not feel this book was as tightly edited as the volume I previously reviewed (*Artemisia* in *HerbalGram* 57). However, all in all, it is a useful volume.

Vetiver (*Vetiveria zizanoides* (L.) Nash ex Small, Poaceae) is one of those rare plants that is both economically and ecologically important. The essential oil from the roots, consisting of a complex mixture of sesquiterpene hydrocarbons and alcohols, has been used since ancient times in perfumery and medicine. It also is a natural barrier against erosion and soil conservation.

Maffei's introductory chapter notes that vetiver's fame resides more in its aroma than its pharmacology. He adds a few folkloric items that seem to be absent in Chapter 5, Ethnopharmacology and Pharmacological Properties. Maffei also gives a half page of colloquial names, including approximately 30 Sanskrit names alone.

In Chapter 2, contributing authors Bertea and Camusso cover the anatomy, biochemistry and physiology. Zarotti, in Chapter 3, covers collection, harvesting, processing, alternative uses, and production of the essential oil. The updated U.S. Department of Agriculture phytochemical database (online at < http://www.ars-grin.gov/duke/>) suggests a much wider range of essential oil content than Zarotti (USDA database 0.2–3.3 percent, compared to Zarotti's 0.5–2 percent).

Akhilka and Rani in Chapter 4, Chemical Constituents and Essential Oil Biogenesis in *Vetiveria zizanoides*, lamentably give no quantitative data, but they are generous with structural diagrams (more than 75) and essential chemical details, well referenced. I have added those that were new to the USDA phytochemical database, and will make the updated list of more than 100 phytochemicals available to *HerbalGram* readers who so request, along with a summary of reported indications and activities reported for vetiver.

Chia's Chapter 5, Ethnopharmacology and Pharmacological Properties of *Vetiveria zizanoides* — Including Pharmacologic and Pharmacokinetic Properties, is admittedly "a short communication" on the "personal Cameroonian experience of Dr. Nwaimbi Simon Chia who collected a certain amount of data."

"[R]oots...have been shown to take care of a variety of unrelated health hazards. Amongst such uses are antibiotherapy, antimalarial treatment, anti-inflammatory effects, and the treatment of stomatological and dietetic problems."

I suspect that the following quote derived from a study of one patient: "Roots ... have a hypoglycemic action. On consumption of two divided doses daily of one teaspoonful (3.9 g) in boiled 50 ml fresh water, the release of insulin from the pancreas was triggered and consequently reduced the Blood Sugar Level of a known insulin-dependent diabetic. The drop in the Blood Sugar Level was very remarkable (14.1 mg/ dl)."

Chia seems rather confident: "Two grams of the ground powder of the roots ... when chewed will relieve toothache in less than fifteen minutes. This treatment can be repeated as often as four times a day."

In Chapter 6, Vetiver Grass Technology, Truong discusses the morphology, physiology, ecology, and weed potential, and how the plant can be used in erosion control; soil conservation and stabilization; reclaiming saline and acid sulfate soils, mine rehabilitation, trapping agrochemicals and nutrients, etc. In Chapter 7, Biotechnology, Mucciarelli and Leupin stress cell and tissue culture methods, underscoring the importance of preserving and investigating the gene pool to find useful traits that might be improved or engineered.

In Chapter 8 (Economic Importance, Market Trends and Industrial Needs, and Environmental Importance), Pease suggests that creating a "vetiver hedge" can cost less than US$30 per hectare compared to more than $500 for conventional engineered terraces. But in the same chapter Pease cites costs of US$11.55 equivalent per linear meter. He even offers some medicinal information: sleep inducer, nerve tranquilizer, and diaphoretic; and mentions its insect

New Book Profiles

Due to economic considerations and the natural evolution of book marketing and sales, the American Botanical Council is adding to its catalog very few of the good new books that are being published. However, we do intend to keep our readers informed of books of particular interest that have arrived in our offices. In this issue we launch a new feature, New Book Profiles. Here, we only describe these new books; we have not yet had them reviewed.

If you wish to purchase any of these books or those that have been reviewed fully, please go to the book review section on our website <www.herbalgram.org/herbalgram/deptarticlelist.asp?d=11> and click on the "Order from Amazon.com" button. ABC will receive a small rebate from your order. If the book is not available through Amazon.com, we provide the publisher's website.

If you are interested in reviewing any of the books listed here, please contact Karen Robin, *HerbalGram* managing editor, at <KRobin@HerbalGram.org>.

The Herbal Internet Companion: Herbs and Herbal Medicine Online, by David Owen, MLS, PhD. The Haworth Press: Binghamton, NY; 2002. 193 pp., softcover. $49.95 ISBN 0-7890-1051-8.

Explains how to assess the quality of health information on the internet; use online indexes and database such as Medline; find mailing lists, chat rooms, and newsgroups; examine evidence about specific products; access internet resources in specialized health areas; research product side effects, adverse reactions, drug interactions and more.

Phytochemicals in Nutrition and Health, edited by Mark S. Meskin, Wayne R. Bidlack, Audra J. Davies and Stanley T. Omaye. CRC Press: Boca Raton, FL; 2002. 203 pp., hardcover. $109.95 ISBN 1-58716-083-8.

Provides answers to questions concerning the mechanisms of action associated with beneficial phytochemical groups. It examines new areas such as the efficacy and safety of medicinal herbs, the use of biotechnology to manipulate and enhance the phytochemical profiles of various plants, and the pharmacokinetics of phytochemicals in humans.

Natural Medicine Instructions for Patients, by Lara U. Pizzorno, Joseph E. Pizzorno Jr., ND, Michael T. Murray, ND. Churchill Livingstone: Philadelphia, London; 2002. 374 pp., softcover, illustrated, CD-ROM. $49.95 ISBN 0-443-07128-4.

continues on next page

repellent qualities, especially against fleas and moths. He further mentions its use as a leaf tea, curry seasoning, meat spice, and pleasant aroma, as well as adding roots to drinking water or insect repellant sachets. Vietmeyer, in the final chapter, Beyond the Vetiveria Hedge — Organizing Vetiver's Next Steps to Global Acceptance, notes that controlling soil erosion is, by far, the best understood and farthest advanced property. "This coarse grass with its roots like chicken mesh projecting several metres into the soil probably can strengthen earthen structures such as small dams and dikes." It holds soil. It converts greenhouse gases into useful solids.

If vetiver could be of use to you, this book would be of use to you. Unfortunately, the peoples of the Third World who need it most can afford it least.

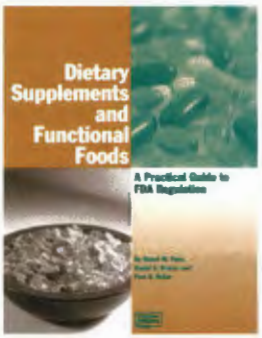
— James A. (Jim) Duke, Botanist
Green Farmacy Garden
Fulton, MD

Dietary Supplements and Functional Foods: A Practical Guide to FDA Regulation, by Stuart M. Pape, Danial A. Kracov, Paul D. Rubin. Thompson Publishing Group: Tampa, FL; 2001. 394 pp., including nine appendices, plus index, softcover. $307 ISBN 1-930872-02-X.

Comprehensive is the signal word that describes *Dietary Supplements and Functional Foods: A Practical Guide to FDA Regulation*. Authored by three seasoned and experienced food and drug lawyers, the book tracks the history of dietary supplement law and regulation, and the political basis for the stunning passage of the Dietary Supplement Health and Education Act of 1994 (DSHEA). All of the relevant Federal regulatory authorities and their jurisdictions are described. The role of the States is also briefly discussed. Most importantly, this book, in detail and with substantial citation to the law and to FDA's regulations, puts the lie to the national press mantra that dietary supplements are not regulated.

The authors organize this book into relevant subject areas that correspond to the areas of most interest to product developers and manufacturers, with chapters that include history, safety, good manufacturing practices, labels, claims, advertising, inspections and enforcement, and an overview of international regulations. They address in detail the most popular relevant product categories: conventional foods, so-called functional foods and dietary supplements, and medical foods. The regulatory framework for dietary supplements is described, as are the interaction of the food, drug, homeopathic drug and dietary supplement definitions. Against this framework, there is a discussion of the present state of law enforcement. Importantly, there is a substantial discussion of the complex regulatory scheme for the ingredients used in foods and dietary supplements.

There is a good and understandable explanation of DSHEA's new dietary ingredient notification provision, the gatekeeper provision that applies to dietary ingredients that were not on the market in dietary supplements at the time DSHEA was enacted in October of 1994. This provision and this discussion is important because this is the provision that allows the Food and Drug Administration (FDA) to look at, evaluate, and provide its views on new ingredients that are intended for use in dietary supplements. The book is instructive with respect to the do's and don'ts of notifications under this provision and provides a listing of "allowed" and "rejected" new dietary ingredient notifications. It is interesting to note that the listing of allowed new dietary ingredient filings shows that important new dietary ingredients have met the requirements of the act (e.g., huperzine, SAM-e, astaxanthin, plant stanol fatty esters, vinpocetine, 7-keto DHEA, and stevia). This demonstrates that the dietary supplement industry is being attentive to the requirements of law.



Since this book was only recently published, it does not discuss the newly proposed dietary supplement current Good Manufacturing Practices (cGMPs) that were published by FDA in early March 2003. This does not detract from the value of the book to the industry because it will take FDA some time to sort out the many comments it will receive on its proposal and to put together final cGMP regulations. It took FDA almost eight years to evolve from the industry's draft cGMPs to a *Federal Register* proposal. Moreover, the publisher provides an on-line service that provides more current materials. The on-line service

Gives clear, concise, accurate, and readable information for patients about natural medicine approaches to the treatment of more than 70 specific conditions. In addition to helping patients to understand their condition better, it covers more than 70 conditions with full descriptions of each condition, prevention measures, expected outcomes, and treatment options. Created as a companion to *The Textbook of Natural Medicine* (Churchill Livingstone, 1999), the book is intended to be photocopied as needed for patients; accompanying CD-ROM enables users to select and print files.

Herbal Medicine: Chaos in the Market Place, by Rowena K. Richter, MPH, MBA. Haworth Press; Binghamton, NY; 2003. 220 pp., softcover. $19.95 ISBN 0-7890-1619-2.

Contains a thorough historical account of botanical regulation including insight into the development of the most relevant current law, the Dietary Supplement Health and Education Act of 1994. In addition, it provides pertinent information on the regulation of herbal products in other nations, including Canada, Germany, France, and the United Kingdom. Illustrative examples of potentially useful and potentially harmful herbs are also discussed.

Herbs in the Treatment of Children: Leading a Child to Health, by Julian Scott, PhD, Teresa Barlow. Churchill Livingstone: St. Louis, MO; 2003. 333 pp., softcover, photographs. $36.95 ISBN 0-443-07163-2.

Guides readers through the use of therapeutic herbs in the treatment of childhood illnesses, focusing on methods that lead a child back to health rather than just suppressing symptoms. It also provides information on recurrent and chronic illnesses, cause and patterns of each illness, and complications and dangers associated with using herbs to treat children.

CRC Handbook of Medicinal Spices, by James A. Duke, PhD, Mary Jo Bogenschutz-Godwin and Judi Ducellier. CRC Press: Boca Raton, FL; 2003. 348 pp., hardcover, illustrated. $119.95 ISBN 0-8493-1279-5.

Provides the science behind the folklore of more than 60 popular spices. It presents a chemical analysis of each spice, their biological activities, indications, and the culinary aspects of many medicinal spices. It also lists septic organisms killed or whose growth is curbed by each spice.

Lavender: The Genus *Lavandula*, edited by Maria Lis-Balchin. Taylor & Francis: New York; 2002. 268 pp., hardcover, photographs. $128.00 ISBN 0-415-28486-4.

A comprehensive volume covering all aspects of our current knowledge of lavender, including: taxonomy, history of usage and nomenclature; lavender cultivation; phytochemistry of the genus; chemistry of *Lavandula* oils; pharmacology and therapeutic properties; use of lavender oil in aromatherapy, cosmetics, perfume, and food processing; theory and practice of distillation and standardization of lavender oils.

continues on next page

Phytomedicines for Respiratory Tract Diseases, by Sigrun Chrubasik, MD, Basil Roufogalis. Australian Pharmaceutical Publishing Company: Balmain, NSW, Australia; 2002. 80 pp., softcover. $A27.50 (±US$18) ISBN 0-9580664-0-X.

Lists 45 phytomedicines traditionally used to treat respiratory tract diseases. Each entry lists the effectiveness of the product based on clinical studies, human pharmacological investigations, and *in vivo* and *in vitro* experiments. It also provides the recommended dosage, information on adverse events, toxicity, contraindications, warnings and precautions.

Growing At-Risk Medicinal Herbs: Cultivation, Conservation and Ecology, by Richo Cech in cooperation with United Plant Savers. Horizon Herbs: Williams, OR; 2002. 323 pp., softcover, illustrated. $14.95 ISBN 0-9700312-1-1.

Provides information needed to grow at-risk plants from the foundation knowledge of a seedsman, grower, and conservationist. A compelling book on one of the most important issues facing the future of botanical medicine: the demise of native medicinal plants in their natural habitat and what can be done to conserve these important wild resources.

The Last Sorcerer: Echoes of the Rainforest, by Ethan Russo, MD. Haworth Press: Binghamton, NY; 2002. 368 pp., softcover. $39.95 ISBN 0-7890-1270-7.

In this remarkable novel, American physician David Abravanel travels to the Peruvian Amazon to pursue research on rainforest plants. With his mentor, botanist Bart Campbell, he embarks on an expedition to learn the plant medicine secrets of a "lost tribe" of the Amazon.

Herbal Medicine and Botanical Medical Fads, edited by Frank Hoffmann, PhD, MLS, Martin Manning, MLS. Haworth Press: Binghamton, NY; 2002. 241 pp., softcover. $24.95 ISBN 0-7890-1149-2.

Combines the comprehensive information of a reference book with a colorful look at the histories and backgrounds of herbs and spices both commonplace and exotic. Integrating information from many sources, this book deals with history, folklore, clinical research, and popular culture. Topics covered range from aconite to zedoary, and include fascinating accounts of aphrodisiacs, stinging nettle, St. John's wort, and kava kava.

Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals, edited by Pulok K. Mukherjee, PhD. Business Horizons: New Delhi, India; 2002. 800 pp., hardcover. $295.00 ISBN 81-900788-4-4.

Presenting elements of both methods and theoretical backgrounds of different aspects on quality control and standardization of herbal drugs and formulations, this book also provides information on their analysis by different means of quality control approach for crude drugs to individual chemical entity as well as their biological activities.

continues on next page

is helpful, but attention to FDA's and FTC's websites and their reports on current matters can be used to keep current.

As Casey Stengel used to say, "You can look it up." This book puts FDA enforcement powers and actions near the end of the text, appropriately enough. Enforcement has, so far, been at the end of FDA's list of priorities, and you can look it up on FDA's website for Warning Letters to dietary supplement marketers and for seizures, injunctions, and criminal prosecutions in the dietary supplement industry. This lack of enforcement led the trade associations of the dietary supplement industry to ask Congress to earmark funding for FDA to enforce DSHEA. In contrast, the book places dietary supplement and functional food advertising ahead of FDA enforcement and describes the controlling principles for advertising, including the competent and reliable scientific evidence standard that controls with respect to substantiation of advertising claims under the Federal Trade Commission (FTC) Act. The FTC is where much of the action is, insofar as enforcement is concerned. In contrast to the FDA, where there has been institutional gridlock with respect to enforcement, the FTC has demonstrated that it can, and will, bring actions against those companies that do not observe the requirements of law. Only in the first half of 2003 has FDA shown a similar resolve.

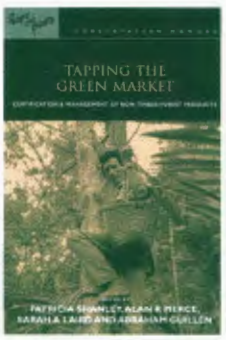
Most regulatory texts include relevant agency policy and regulations as appendices and this book is no different. It contains FTC's dietary supplement advertising guide, FDA's structure/function claim regulation and new dietary ingredient notification regulation. All of these are valuable and important to anyone in this business. Indeed, these are regulations and guidance that no executive in the dietary supplement industry should fail to read. And this *Practical Guide to FDA Regulation of Dietary Supplements and Functional Foods* is a good accompaniment to those documents. Think about it. You invest personal and/or stockholder funds in a line of commerce. If it's important enough to invest in, is it not important enough to spend the time necessary to read and to learn the regulatory system under which this business will be operated? If they don't teach that in business success school, they should. This book is a great vehicle to learn about that system, and even though it's priced at just over $300, it's certainly less expensive than one hour of time from any of the lawyers who wrote it.

Hopefully, this book will not become yet another unregarded primer on regulatory compliance and lawful business practices in an industry so blinded by non-enforcement and indifference that it has a very difficult time staying on the right side of the road. This book should be read and followed — and copies should be provided by the industry to the press so that they can heft the weight of regulation on this industry.

— Anthony L. Young
Kleinfeld, Kaplan & Becker, LLP
Washington, D.C.

Tapping the Green Market: Certification & Management of Non-Timber Forest Products, edited by Patricia Shanley, Alan Pierce, Sarah A. Laird & Abraham Guillen. Earthscan Publications Ltd., London, U.S. distributors: Stylus Publishing <www.styluspub.com>. 2002, 400 pp. with figures and tables. Hardcover $99.00 ISBN 1-85383-871-3, softcover $39.95 ISBN 1-85383-810-1.

This is another excellent contribution from the People and Plants Conservation Series, a collaboration of the World Wildlife Fund (WWF), the Royal Botanic Gardens at Kew, and the United Nations Educational, Scientific and Cultural Organization (UNESCO). The series includes several other books including *Biodiversity and Traditional Knowledge* and *People Plants and Protected Areas*, among several others described on the Earthscan Publishing website, <www.earthscan.co.uk>.



Tapping the Green Market: Certification & Management of Non-Timber Forest Products is a state-of-the-art document on this fascinating and complex topic. The book features the work of 38 contributing authors from around the world. The backgrounds of this collection of people are highly diverse; they include ecologists, foresters, ethnobotanists, presidents of companies, geographers, agronomists, biologists, and environmentalists.

The book is organized into four sections, with a total of 31 chapters. Section 1 introduces the entire concept of certification

systems, with a focus on the relationship of timber certification to the certification of non-timber forest products (NTFP). The editors of this volume have extensive expertise in the area of timber certification and the realities of people and communities in biodiversity-rich nations. The last part of Section 1 provides an overview of three field tests of guidelines (presented Appendix I) for NTFP certification of sapodilla or *chicle* (*Manilkara zapota*) in Mexico, Brazil nuts (*Bertholletia excelsa*) in Bolivia, and hearts of cabbage palm (*Euterpe oleracea*) in Brazil.

These three cases are fascinating. The fact that there was no *chicle* harvest in 1999, due to a drop in demand from Japan, clearly illustrates that certification of NTFPs as a value-added marketing tool will always need to be closely linked to creating and maintaining markets. In fact, the innovative company called Wild Things is creating awareness and demand in the U.S. and European marketplace with it *chicle*-based "Jungle Gum." The Brazilian case study presents a number of details and observations. One of the reasons that the Brazilian palm heart harvesting operation sought NTFP certification from the Forest Stewardship Council (FSC) was that the environmental policies of financial investors required third-party verification of the company's forest management practices.

The second section of the book presents profiles of NFTP species from around the world. The list includes *chicle*, Brazil nuts, palm heart, pau d'arco (*Tabebuia impetiginosa*), cat's claw (*Uncaria tomentosa*), breu resin (*Protium* spp.), titica vine (*Heteropsis* spp.), amapá (Parahancornia spp. and *Brosimum* spp.), copaíba (*Copaifera* spp.), and dragon's blood croton (*Croton lechleri*, or *sangre de drago*) from Latin America. The North American species include American ginseng (*Panax quinquefolius*), maple trees (*Acer saccharum*) and fiddlehead ferns (*Matteucia struthiopteris*). African species include griffonia (*Griffonia simplicifolia*), baobab (*Adansonia digitata*), yohimbe (*Pausinystalia johimbe*), and rattan (various spp.). Asian species include amla (*Phyllanthus emblica*), and Sumatra benzoin tree (*Styrax* spp.). The Mediterranean species include mastic gum (*Pistacia lentiscus*), cork oak (*Quercus suber*), pine nut (*Pinus pinea*), argan (*Argania spinosa*), and chestnut (*Castena sativa*).

The species profiles present the sociological, ecological, cultural, and marketing details for each of the species. Also, the pros and cons of potential certification are presented and discussed. The species described represent a diverse cross section of plant parts including resins, barks, roots, fibers, and herbs.

The profiles of greatest interest to *HerbalGram* readers will be the medicinal plants that are sold as phytomedicines and dietary supplements: American ginseng, griffonia, yohimbe, amla, pau d'arco, cat's claw, *sangre de drago*, and copaíba. I was especially fascinated with the profile of griffonia, and the impact of the rapid rise in demand for extracts containing 5-HTP, considered a possible weight-loss product, that began in 1997. One of the important and common lessons learned from the griffonia story is that the creation of extraction facilities in West Africa can greatly enhance the local value of the NTFP in the country of origin. One plant that would have been a good addition would be devil's claw (*Harpagophytum procumbens*) from the south Africa region. Much has been published recently on harvesting and social/benefit sharing issues associated with this medicinal herb.

The third section of the book discusses the fundamental elements of NTFP certification, including chapters on the issues associated with marketing, ecology, technical problems and the social framework of harvesting communities. A very important chapter discusses the importance of NTFPs as part of subsistence livelihoods among the cultures that harvest these plants.

The fourth and final section of the book provides an overview of what primary lessons have been learned about the process of working to certify NTFPs and the challenges that will need to be addressed in order to create a functional system of NTFP certification. The actual technical guidelines for assessing the management of NTFP and resources for doing this are presented in Appendix I, II, III.

This is an excellent book, offering much detail, history, and practical data on the entire issue of how to approach the certification of NTFP. We will need many more such books and works, if we are going to create sustainable and equitable long-term managed production of many of the plants described in this book. This is, in many ways, *terra incognito* and this publication is an invaluable primary resource. If a company wishes to suggest that they are producing a product that is part of a sustainable harvesting system, this book helps provide a reality

Alkaloids: Nature's Curse or Blessing? by Manfred Hesse. Verlag Helvetica Chemica Acta, Wiley-VCH: Zurich, Switzerland; 2002. 413 pp., hardcover, photographs, illustrations. $135.00 ISBN 3-906390-24-1.

Provides detailed information regarding alkaloids. Information includes classification and structure, synthesis and chemotaxonomy, and chiroptical properties of alkaloids. Also talks about biogenesis and biological significance of alkaloids, active principles from selected alkaloid sources, and their cultural and historical significance.

Case Studies in Natural Medicine, edited by Melvyn R. Werbach, MD. Third Line Press Inc.: Tarzana, CA; 2002. 408 pp., hardcover with diskette. $49.95 ISBN 1-891710-02-8.

A compilation of 668 individual case reports in the field of natural medicine selected for their educational value. The reports are grouped according to the illness whose treatment they best illustrate, and contain actual stories of people treated with nutrition and supplements. In addition, it provides information on dietary, nutritional, and herbal treatments for 155 different illnesses.

Ancient Herbs, Modern Medicine: Improving Your Health by Combining Chinese Herbal Medicine and Western Medicine, by Henry Han, OMD, Glenn E. Miller, MD, and Nancy Deville. Bantam: New York; 2003. 468 pp., softcover. $13.95 ISBN 0-553-38118-0.

Demonstrates the many important, highly effective ways Chinese medicine and Western medicine can complement each other in treating everything from allergies and insomnia to mental illness and cancer. It also offers informative case studies on the importance of Western techniques in diagnosing serious diseases, and why Chinese medicine offers the most effective treatment for many chronic/recurrent illnesses, restoring essential balance to the five energetic systems (the heart, lung, spleen, liver, and kidney).

Mosby's Handbook of Herbs and Supplements and Their Therapeutic Uses, edited by Steven Bratman, MD, and Andrea M. Girman, MD, MPH. Mosby: St. Louis, MO; 2003. 1334 pp., softcover. $34.95 ISBN 0-323-02015-1.

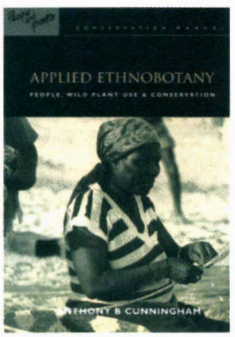
Provides information on approximately 85 herbs, 80 supplements, and 75 common conditions. It focuses on the issues most relevant to actual clinical practice, such as drug interactions, safety issues, and identification of the natural products patients may be using. For each herb and supplement, provides scientific evidence (double-blind trials) regarding the uses, dosage, and mechanism of action, safety, and drug interactions.

check for consumers, scientists, journalists, development workers and environmentalists. Congratulations are due to the editors and authors for helping to lead the way toward responsible and sustainable approaches to the management of NTFP.

— Steven R. King, Ph.D.
Vice President of Ethnobotany & Conservation
PS Pharmaceuticals Inc.
South San Francisco, California

Applied Ethnobotany: People, Wild Plant Use and Conservation, by Anthony B. Cunningham. Earthscan Publications Ltd, London, U.S. distributors: Stylus Publishing <www.styluspub.com>. 2001, 256 pp., figures and photos, softcover. $40.00 ISBN 1-85383-697-4.

Applied Ethnobotany, by Anthony Cunningham, is an extremely practical conservation manual. The author is one of the leading world experts on African ethnobiology and the interface of cultural and biological diversity. This manual is intended to provide detailed tools to individuals working on conservation, rural development, national park management or to companies that seek to create sustainable harvesting programs for plant species contained in their products.



This book is also part of the People and Plants Conservation Series, a collaboration of the World Wildlife Fund (WWF), the Royal Botanic Gardens at Kew, and the United Nations Educational, Scientific and Cultural Organization (UNESCO). The series includes several other books, which are described on the Earthscan Publishing website, <www.earthscan.co.uk>.

The manual has eight chapters with nearly 130 figures, tables and boxes. The second chapter (Local Inventories, Values and Quantities of Harvested Resources) features a wonderful section that describes "Taxonomy with all your senses: the use of field characters." This passage encourages field scientists to focus on the knowledge of local people as they describe the characteristics of species that are being inventoried. The author provides numerous examples of the color of roots, bark or wood, the scent, texture, taste, and even the sound created when bark is slashed.

The third chapter (Settlement, Commercialization and Change) contains an amazing series of tools to understand the movement of plant species of trade into and out of local and regional markets. The 35 pages on this topic begin with subheading "Local Markets: order within chaos." Like most ethnobotanists, I have always been fascinated and intrigued by markets around the world. After reading this section, I will never look at market the same way again. For resource management studies, this chapter is an invaluable tool for understanding the flow of plants within a region. The structured analysis provided is applicable to any market in the biodiversity-rich nations.

The fourth and fifth chapters (Measuring Individual Plants and Assessing Harvest Impacts, and Opportunities and Constraints on Sustainable Harvest: Plant Populations, respectively) provide extensive and detailed methodology to measure the impact of harvest on a great diversity of plant parts including bark, exudates, and leaves. Methods to measure and quantify flower, fruit and seed production, along with tree bark thickness and bark mass, are presented. My favorite section, "Underground ethnobotany: roots, tubers, bulbs and corms," provides expertise to assess the impact of harvesting underground plant parts, a challenging but important process. The excellent fifth chapter, "Bridging the Gaps in Knowledge: Life Forms, Plant Architecture and Reproductive Strategies," provides a very concise description of plant life forms in the context of their basic ecological characteristics.

One aspect of these chapters that I greatly appreciate is the description of simple, basic, and inexpensive equipment that can be used to conduct this type of research. Items such as tape measures, aluminum tags, field notebooks, pencils, hand lens, paint, and measuring scale can all be obtained in any capital city. There is at times, in my view, a near-fetish focus on expensive technology for fieldwork, which is often not necessary or available to young ethnobiologists or members of local communities who may be otherwise highly qualified to conduct this type of research. The author does not, however, exclude advanced technology. Chapter 6 (Landscapes and Ecosystems: Pattern, Process and Plant Use) moves the reader into the "big picture" of resource utilization. This includes information on how to utilize aerial photographs and satellite images, along with local knowledge, to create maps as part of participatory mapping programs. The final part of Chapter 6 mentions cultural views of landscapes, which provides a wonderful introduction to the complex and critical cultural component of resource use, conservation, and management.

Chapters 7 and 8 (Conservation, Behavior, Boundaries and Belief, and Striving for Balance: Looking Outward and Inward, respectively) seek to weave together the cultural and community boundaries of this manual on applied ethnobotany. There is a strong focus on common property management, community-based conservation programs, land tenure, cultural practices, mapping programs, and a section called "ritual, religion and resource control." And, finally, Chapter 8 provides some very appropriate reminders about the limits of any natural system to produce sustainable levels of plants. There is also a fascinating figure on global consumption pressure, as a measure of the burden placed on the environment by people as of 1995. Once again, U.S. readers will be reminded of the high level of pressure that our national level of consumption places on the global environment.

In summary, this is a must-have manual for anyone working with people and plant resources. It is especially useful for anyone associated with the management of national parks or protected areas anywhere in the world. This manual is a practical tool that, fortunately, already has been translated into Spanish; a Chinese translation is expected to be published next year. There is a delightful tone of respect and affection for the people with whom the author has worked over the past several decades. That is evident in the smiles and facial expressions of the people in the photographs of this book. It is obvious that the author loves his work, and he also inspires his colleagues wherever he goes. That is another component of the gift of this manual and the author's dedication to exploring the magic of plants, people, and culture.

— Steven R. King, Ph.D.
Vice President of Ethnobotany & Conservation
PS Pharmaceuticals Inc.
South San Francisco, California

FDA

Continued from page 56

able scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate [the] claims, that the claim is supported by such evidence."

10. *See generally Pearson v. Shalala,* 164 F.3d at 654 (D.C.Cir. 1999) ("A … folate-neural tube defect claim supported by appellants — that consumption of folate reduces the risk of neural tube defects — was initially rejected but ultimately approved for both dietary supplement and food labels. … The parties disagree on what caused the FDA's change of position on this claim. Appellants contend that political objections — Senator Hatch was one of the complainers — concentrated the agency's mind. The FDA insists that its initial denial of the claim was based on a concern that folate consumption might have harmful effects on persons suffering from anemia, and that its concern was alleviated by new scientific studies published after the initial denial of the claim.").]
11. Senate Report 103-410, "Dietary Supplement Health and Education Act of 1994" (October 8, 1994) at 16.
12. Senate Report 105-43, "Food and Drug Administration Modernization and Accountability Act of 1997" (July 1, 1997) at 49-50.
13. 164 F.3d 650 (D.C.Cir. 1999) ("*Pearson I*").
14. FDA asked for rehearing of the case, but its request was denied in an 11-0 opinion of the entire Court of Appeals for the D.C. Circuit. See *Pearson v. Shalala,* 172 F.3d 72 (D.C.Cir. 1999).
15. 164 F.3d at 655.
16. 164 F.3d at 659-660.
17. 164 F.3d at 659.
18. 164 F.3d at 655.
19. 164 F.3d at 654.
20. 164 F.3d at 656.
21. 130 F.Supp.2d 105 (D.C.D.C. 2001).
22. 130 F.Supp.2d at 121.
23. 130 F.Supp.2d at 112.
24. 130 F.Supp.2d at 114.
25. 130 F.Supp.2d at 118.
26. 130 F.Supp.2d at 118.
27. 141 F.Supp.2d 105 (D.C.D.C. 2001).
28. 141 F.Supp.2d at 108.
29. 141 F.Supp.2d at 112.
30. 2002 U.S.Dist. LEXIS 25299 (D.C.D.C. 2002).
31. 2002 U.S. Dist. LEXIS 25299, *27-*29.
32. 2003 U.S. Dist. LEXIS 777 (D.C.D.C. 2003).
33. The claim in issue reads: "Consumption of 320 mg daily of Saw Palmetto extract may improve urine flow, reduce nocturia and reduce voiding urgency associated with mild benign prostatic hyperplasia (BPH)."
34. 21 U.S.C. § 343(r)(1)(B).
35. Wilt T, Ishani A, Stark G, *et al.* Saw palmetto extracts for treatment of benign prostatic hyperplasia: a systematic review. *JAMA* 1998;280(18):1604-9.
36. Wilt T, Ishani A, Stark G, *et al. Serenoa repens* for benign prostatic hyperplasia. *Cochrane Database Syst Rev* 2000;2:CD001423.
37. *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of N.Y.,* 447 U.S. 557 (1980).
38. See, e.g., *Solid Waste Agency of Northern Cook County v. United States Army Corps of Engineers, et al.,* 531 U.S. 159, 173 (2001), citing *De Bartolo Corp. v. Florida Gulf Coast Building & Constr. Trades Council,* 485 U.S. 568, 575 (1988), "where an otherwise acceptable construction of a statute would raise serious constitutional problems, the Court will construe the statute to avoid such problems unless such construction is plainly contrary to the intent of Congress."

in memoriam

Paul Githinji Kabochi
1942 – 2003

An extraordinary talent for habituating wild animals earned Paul Kabochi, who died tragically on the morning of his 61st birthday on 8 February 2003, a near-legendary status among wildlife researchers and filmmakers the world over.

At the time of his death, he was — as on countless previous occasions — paving the way for the filming, near Kenya's Tsavo West National Park, of a wildlife documentary for television, this time on the behaviour of a pack of Dwarf Mongooses.

The visiting film crew, from France's Aster Productions, was operating from the Taita Discovery Centre (TDC) run by East African Ornithological Safaris (EAOS), for whom Kabochi was for many years a Senior Guide. On that fateful morning, neither Kabochi nor the crew could locate the mongoose pack they had been working with. So they drove around for a while, searching for their subjects.

Instinctively, Kabochi pointed to some termite mounds where he felt the pack might be hiding. His hunches, born of a lifetime spent in the bush, were nearly always vindicated. But he offered to "stalk" the anthills first, just to make sure. His lean, sinewy form soon disappeared amid the intervening "cover" of dry thorn scrub.

Paul Kabochi was never seen alive again. Hours later, when EAOS trackers located his body, it was more than three kilometers beyond the nearest of the anthills. The cause of death was plain to see. Kabochi had been trampled to death by an elephant.

For Steve Turner, managing director of EAOS, Kabochi's employer for the last 17 years, Paul's death came as a terrible shock. "I have often told people down the years," Turner says, "that, if ever I were to be cast into some remote jungle, and told I could choose only one companion in the ensuing battle for survival, I should pick Paul Kabochi. For Paul would always know exactly what to do in such a predicament — which fruits to eat (and which to avoid), which plants to use in treating different ailments, and so on. His intuitive understanding of the natural world really was extraordinary."

Ethnobotany was Kabochi's lifelong passion, and he was often described as a "walking encyclopaedia" of African medicinal plants and their properties. Turner admits that, "At first, I was sceptical about some of the things Paul said about plants. But when, a few years ago, he took a party of U.S. Food and Drug Administration scientists out on safari, they were all amazed by the soundness, and breadth, of his knowledge."

Paul Githinji Kabochi was born in 1942 near Nyeri, on Kenya's Aberdare Mountains, of mixed Ogiek and Kikuyu parentage. He received some formal education at the nearby Kiriti Primary School, but his real training ground was always the forest. This he would enter at every possible opportunity, while tending the family goats as a boy.

The Mau Mau uprising and the ensuing State of Emergency, declared in 1952, brought this idyllic childhood to an abrupt end. Like other families, the Kabochis were relocated to pyrethrum plantations at Ndondori, North Kinangop, to serve as farm labourers. But the life of a farm hand was not for Paul, and in 1960 he drifted to Nakuru, in the Rift.

There, in 1961, he landed his first "real" job: that of a tracker on "leopard control" duty for Colonial cattle ranchers in what is now Lake Nakuru National Park. This was risky work, and he emerged from one skirmish with a leopard minus a large chunk from one of his buttocks. Ironically, he was arrested in 1963 for possessing the skin of a leopard he had been paid to kill. But, instead of being jailed, he was drafted into the Kenya Armed Forces and sent to the then Northern Frontier District to help track down 'shifta' bandits.

On leaving the army in 1966, he became a collector and skinner of specimens for the National Museums of Kenya, accompanying ornithologist John G. Williams and other eminent naturalists on field trips throughout East and Central Africa. During the 1970s, while still with the Museums, he prepared casts for the conservationist and sculptor of wildlife bronzes, Rob Glen, under whom he was able to hone his taxidermy skills.

This work led to associations with the likes of naturalist Jonathan Kingdon and Alistair Fothergill of the BBC Natural History Unit. With the proliferation in the early 1980s of wildlife filmmaking and field-based wildlife studies, came an unprecedented demand for animal trapping and handling skills. For both activities required habituated wild animals.

Such skills were second nature to Kabochi, who had kept wild animals (usually injured individuals he had rescued and nursed back to health) as pets since the earliest days of his childhood. He could have a wild serval eating out of his hand in just three weeks. These talents were to keep him busy for the rest of his life on a succession of wildlife documentary films set all over Africa, including some in Sir David Attenborough's *Trials of Life* series.

His great cunning was instrumental at times in enabling scientists to examine little-known species. Three years ago, in nets mounted atop "rugby poles," he succeeded in catching some giant African free-tailed bats for researchers from Bat Conservation International, a feat described in SWARA (Vol 24:3). Until then, this high-flying species had been well out of the researchers' range.

Kabochi was himself the subject of a 30-minute documentary, *Der Tiermagier* (*Animal Magician*), made in 2000 by Sam and Armin Dhillon for German Television.

He was remarkable, above all, for always putting the welfare of the animals first. This did not always endear him to film crews, who were often behind schedule and eager to force the pace, even at the expense of harming the animals they were filming. Kabochi walked out on one crew who, protesting that "Time is money," refused to accept that an elephant shrew that was clearly stressed and hyperventilating needed a timeout.

Kabochi was a tireless promoter of nature's smaller creatures — reptiles, bats, insects. "While at TDC," his EAOS brochure entry reads, "be sure to explore the fascinating world of the 'small game' that is overshadowed by Africa's famous megafauna."

Less well known, but no less important, is the legacy of conservation awareness he spread among communities of local people, especially in the Rumuruti area where his family still lives. There, he will long be remembered as *Awa* ('father' in Kikuyu),

"who loved animals and who liked to carry a chameleon around on his head."

The chameleon stunt was Kabochi's way of discrediting a superstition, rife in Africa, that chameleons attach themselves to the tops of people's heads and never let go. The result of this irrational fear is that chameleons everywhere are needlessly battered to death.

Never less than totally at home in the bush, Kabochi himself had no fear of wild animals. "And it was this loss of all fear, maybe, that got him in the end," laments Steve Turner.

Paul Kabochi leaves his wife, Margaret Wakuhi, one son Daniel, and six daughters: Mary, Virginia, Catherine, Florence, Caroline and Ann.

— Gordon Boy, editor, SWARA, journal of the East African Wild Life Society with reporting by Gichuki Kabukuru and Trupti Shah
Reprinted from *SWARA* by permission

William LeSassier 1948 – 2003

I am honored to write words of remembrance for William LeSassier: the mystical teacher of all my teachers. He who dropped under the radar for so many years. The famous and infamous William LeSassier.

In the late '60s, William opened *The Christos School of Herbal Medicine* in Taos, New Mexico. By the 1970s, herbalism was re-awakened. He was one of the most well-known herbalists in the country. During those early years he wandered and taught, selling herbs as he went. He wrote some of the very first herb articles in *Well-Being* magazine, possibly the first publication on alternative medicine. In the early '80s, he settled in New York City to open Chiron's Magic Minerals, where he practiced and taught energy work. The Taoist Arts Center was also graced with his wisdom. He continued his busy herbal practice, blending modalities of bodywork and incorporating herbs, energy work, and acupuncture. A perfectionist, William's book was constantly evolving. We hope to publish his works in the next few years.

Like so many people of genius, William led a life full of intensity we would expect from one who received formulas shared from the book of Pythagoras, in blasts of white light. Thus, the birth of the *Triad System of Formulation* 30 years ago, visually drawing one triangle within another, with the client's constitution/core condition in the center. Herbs on the apex representing the "king," the ruler/significant herb/neutral signified by a circle, a "minister" the herb that communicates to other plants and takes the message to the king, signified by a plus sign, and a "servant" the reciprocal part of the formula that acts upon/eliminates through the "doorways of the body." Measurement of herb was formulated by energetic strength, not weight. William's *Triad System of Formulation* continues to be taught from coast to coast.

Hanging in herb schools and practitioner's offices around the country are William's *Facial Diagnosis Charts*, which illustrate the five elements as they relate to general and specific characteristics including the shape of the face, temperament, tone of voice, and the myriad of fascinating descriptions that make up a "type" of person. The chart is based on a combination of traditional Chinese physiognomy and William's own interpretations. Clients are always curious to discover their "type."

William was exceptional and at the same time completely human in experiencing the extremes of life. Never one to moderate excess! A gifted man and blessed soul. So regular, so ordinary, so "no big deal" in his beige turtleneck and sweats with words falling out of his mouth in such profusion that one could easily forget that he was a brilliant genius and channeled the healing energy of the universe. The flow of knowledge while he taught was magical. Humor and lighter entertainment interspersed between the meatier portions of diagnostic tone and color, nails and tongues. He grasped each line of the face, each subtle marking, explained, and drew so beautifully. That smirk, his delightful wry comments sneaking in at just the right moment, to tickle the joy button of the whole experience. He was so gracious. How fortunate we were.

It was good to see he had come back into his own light these past few years. He returned to his herbal family. What impact can a single man make? The lineage of those directly influenced during his life journey walking our Earth includes a bounty of accomplished practitioners. I share Rosemary Gladstar's sentiment that William was "...sweet, rare and fairly complex. May our hearts feel peace as his heart does. He is close, even closer now than in life. That is the gift of those who pass over. Our gift is to remember them and to honor them."

Herbalist, acupuncturist, artist, teacher, husband, father, keeper of his beloved Virginian land — William was always a body worker. Matthew Wood so succinctly added, "William touched the four elements — earth, air, fire, water — and then the fifth element which changes everything, as in the twinkling of an eye, in a magical moment when no one sees. And then he was gone. We thought we could always learn from him, but suddenly the book was complete."

Spirit and *wind* are the same word in Greek. To inspire is to breathe in. We all share inspiration, our breath. To inspire is to excite with passion. William was my inspiration to be a better practitioner. He always liked an "Amen corner." I am not alone in that corner. So Amen, my friend, amen.

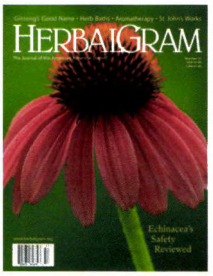
— Margi Flint

All are welcome to send stories or photographs or, better still, to arrive and share at the Memorial Gathering for William LeSassier scheduled for Saturday, September 13, 2003, 1 p.m. at The Breathing Project, 15 West 26th St., 10th Floor, New York City, New York.

letters

Clarification to EU Legislation

Thank you for your *HerbalGram* 57, which arrived this morning. It is as excellent as ever. One point I would like to make. The article headed "European Union passes Traditional Herbal Medicines Directive" is not entirely accurate.



A report on the Directive from a committee within the European Parliament was indeed voted upon last November but, in no way, did this represent the final agreement to the Traditional Herbal Medicinal Products Directive.

We estimate that it will be a year before the Directive is adopted by the EU — that is, mid-2004 — and then another year before it becomes law in the Member States. There will be a five-year transition period from adoption, which means products that need to comply will have until 2009 so to do.

Opinions vary as to whether this will help or hinder the herbals market in the EU and, in a sense, it will depend from what Member State you come.

Anthony Bush
European Regulatory Consultant
CAMedica
Henley on Thames, Oxfordshire,
United Kingdom

One Step Forward, One Step Back

I just finished reading the February 20, 2003 copy of *USA Today* and the various interview clips quoting Mark Blumenthal (happy to see that they went to him for information) by Nanci Hellmich. But I was disappointed that amidst all of the explanation, none was given for the intended herbal uses for ephedra/*ma huang*.

As an herbalist myself, I am grateful for the powers that *ma huang* can deliver in an asthmatic attack or acute episode of difficult breathing due to inflamation in the bronchial pathways. It seems to me Mark had the perfect opportunity to educate the public in the proper uses of ephedra and to point out that the first American cultural belief that searches for a quick fix to a discipline problem (dietary judiciousness) is what got ephedra into the wrong hands for the wrong reasons.

And let's not forget the second American cultural belief that if the recommended dose can do "x" amount of effect, then more must be better. Lost in all of the media frothy stirring around *ma huang* is that the toxicology report is still being developed, and until that happens, the question of banning *ma huang* should not really be entertained.

In the same paper in the same day, there appeared a report "College Blackout Drinkers Face More Risks" including death (by Kathleen Fackelmann), and there was a beer ad directly below the report entitled "FDA Awaits Ephedra Report After Baseball Player's Death." How ironic.

Maybe *ma huang* should be limited to purchase by herbalists who carry credentials and/or licenses, but if it is banned, then why not the same plight for all the substances that Americans use inappropriately?

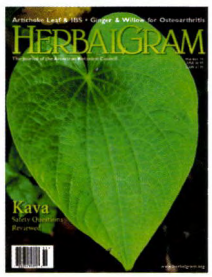
Thank you for being there as a voice we can count on to represent herbal medicine.

—Therese A. Walsh, L. Ac.
and Traditional Chinese Herbalist
Los Angeles, California

We appreciate Ms. Walsh's letter. Unfortunately, many of the points on ephedra that Mark discussed with the USA Today *reporter — including some of the potential and documented benefits of ephedra — were not included in the articles because of lack of space. This is a typical problem with the reportage of that particular publication, where conciseness has reached a new level, often leaving out important material information and nuance. — Editors*

Further on the Patterson Bundle

I wish to express my thanks to Merry Lycett Harrison for her fine work in researching the contents of the Patterson Bundle. I very much enjoyed the article published in *HerbalGram* 55, and can't resist making some comments.



The overall characteristics of the collection — the small quantities of common and uncommon plants, the variety of material, and the care with which they have been prepared — are familiar to anyone who goes into a traditional Chinese herbal pharmacy here in the U.S. and fills a prescription for an herbal formula. Ten to fifteen different ingredients for the formula, including minerals, bones and other animal parts as well as the plant parts, are standard. Each ingredient is harvested and prepared according to a traditional protocol.

There are intriguing hints that at least some of the native Americans migrated from Asia and brought their medicinal knowledge with them, and maybe even their plants. For instance, it's believed that certain of the languages, such as Navaho, are linguistic cousins of Asian languages. Botanists since the 17th century have noticed a close similarity in the flora (and fauna) of eastern North American and eastern Asia.

Duke and Ayensu include an interesting short essay at the beginning of their two-volume set, *Medicinal Plants of China* (1985, Reference Publications). In it, they list over a hundred genera of plants that are used similarly in traditional Chinese medicine and traditional North American Native medicine. Other medicinal practices such as the use of moxa [cones made of mugwort] are similar.

I believe that the study of traditional Oriental medicine offers us the opportunity to take the "royal road" toward re-creating an authentic native plant medicine on this continent. Fortunately, there are now more than 40 accredited, independent colleges in acupuncture and Oriental medicine and several professional organizations supporting this study.

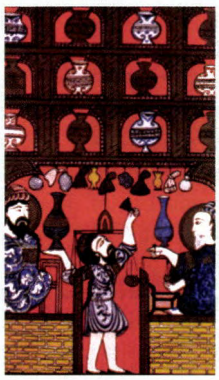
— Jean Giblette, Director
High Falls Gardens
Philmont, NY

Hawthorn Interaction Potential

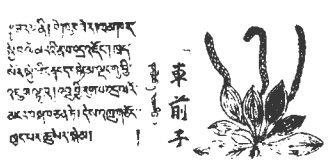
In Don Brown's review (High dose hawthorn extract for advanced congestive heart failure, in *HerbalGram* 57), he states that "there are no known interactions of hawthorn extracts with prescription cardiac drugs." Such interactions have "not been documented in any clinical trials to date nor has it been cited as a concern by either the German Commission E, the American Herbal Pharmacopoeia, or the American Botanical Council monographs on hawthorn."

He admits that some authors suggest the possibility of such interactions. The idea of an interaction actually arose in one of the very first published studies on hawthorn extracts. Semm (*Arzneimittel-Forschung* 1952;2:562) found that hawthorn flavonoids produced a distinct synergy

Aromatic Herbal Baths of the Ancients: Photo Captions



Two photo captions in the article Aromatic Herbal Baths of the Ancients, published in *HerbalGram* 57, were incorrect. The photo reproduced at left was described as a bath house, when it is actually a Middle-Eastern apothecary. And the photograph at right was described horsetail, but it is obviously plaintain (*Plantago*). The Chinese characters, *cheqianzi*, just to the left of the image mean "plantain seed." These errors occurred during the production of this issue and *HerbalGram* regrets any confusion they have caused. Our thanks to Wendy Applequist, Ph.D., of the Missouri Botanical Garden Applied Research Department, for spotting the plantain error and translating the Chinese.



with the classical cardiac glycosides from *Digitalis lanata*. Bersin, Mueller and Schwarz (*Arzneimittel-Forschung* 1955;5:490-1) noted during a routine pharmacological screening study, that in a frog heart preparation, a hawthorn glycoside fraction increased the toxicity of digitoxin in the frog. What they actually found was that heart tissue pretreated with either one becomes sensitized to the other, so that only about half the normal dose of the second is required to obtain the same result. Later on, Herbert Wolkerstorfer (*München Medizinischer Wochenscrift* 1966;8:438-41) found that he could reduce the dose of digoxin by a considerable amount if he combined it with hawthorn extract. If I read this study correctly, patients who were receiving doses of digoxin as high as 6–8 mg did well on the hawthorn/digoxin combination that contained just 0.25 mg of digoxin, a dose that is at the very low end of the dosage spectrum. The combination went by the name Crataelanat.

I have not examined recent hawthorn work to determine if interactions between hawthorn extracts and other cardioactive drugs have been ruled out. Would be curious to learn of such work.

— Daniel Mowrey, Ph.D.
Director of Scientific Affairs
Basic Research
Salt Lake City, Utah

[*Editor's note: We turned to Dr. Wilmar Schwabe GmbH, a German phytomedicine company that has researched hawthorn extensively, for expert input on this query and provide, after that response, the summary of interactions from* The ABC Clinical Guide to Herbs, *which is based on the most recent clinical research.*]

In the very old studies cited above, it is unfortunately impossible to determine which extracts were actually administered and how the experiments were exactly performed. The paper by Semm does not really show a synergistic effect with digitalis, for example, but describes in obsolete pharmacological (in fact, toxicological) studies that the pre-treatment of guinea pigs (about 500 g body weight) with 1000 microL hawthorn extract (with a content of 45 percent ethanol ≈ 450 mg pure ethanol) increases the lethal effect of digitalis. Indeed, it is a wonder that the animals did not die from the alcohol alone. Bersin *et al.* did not give an account of a glycoside fraction from hawthorn, but of an isolated glycoside. If frogs were injected with 175 mg/kg of this glycoside, only half the dose of digitoxin usually required was needed to kill the animals. However, the lethal dose for this isolated compound in rabbits was approx. 80–100 mg/kg i.v. Sensitization of heart tissue cannot be inferred from these experiments. Reciprocal sensitization, as described in the letter to the editor, was not reported at all in the paper cited. Unfortunately, the publication by Wolkerstorfer, who treated patients with a combined preparation of crataegus and strophanthin, is also misinterpreted. For 12 of his patients, he required 2.65 mg for oral saturation and he compared this value with data from the literature, which should supposedly be about 6–8 mg digoxin. The maintenance dose of 0.25 mg was apparently at the lower range of the literature findings (0.25–0.75 mg). However, it is impossible to interpret these data without a control group and accurate information about the severity of the heart failure.

In summary, it is impossible to deduce evidence for potential interactions from these early investigations. However, it is not only proof of pharmacodynamic interactions that is lacking. Results from a recent study as well rule out pharmacokinetic interactions between hawthorn and digoxin (Tankanow R, Tarner HR, Streetman DS et al. Interaction study between digoxin and a preparation of hawthorn (*Crataegus oxyacantha*). *J Clin Pharmacol* 2003;43:637-42.)

— Egon Koch, D.M.V.
Head of Pharmacology
Dr. Willmar Schwabe GmbH & Co.
Karlsruhe, Germany

Drug Interactions

HAWTHORN LEAF WITH FLOWER: No known documented interactions, according to the Commission E monograph of 1994 and later therapeutic reviews, including one by the European Scientific Cooperative on Phytotherapy.[1-3] Other references suggest that hawthorn preparations may potentiate drugs containing cardiac glycosides (e.g., digoxin) probably resulting from the positive inotropic and coronary vasodilating effects.[4] Earlier research suggested potentiation of digitalis glycosides with hawthorn,[5] and another study suggested that hawthorn preparations may potentiate the coronary artery dilating effects of theophylline, caffeine, papaverine, sodium nitrate, adenosine, and epinephrine.[6] Because of the similarity in actions, one reference suggests that hawthorn should not be used with any other heart medications without the advice of a healthcare provider.[7]

HAWTHORN FRUIT: None known.[8] Depending on dosage the same interactions for leaf and flower may be relevant.[9]

From: Blumenthal M, Hall T, Goldberg A, Kunz T, Dinda K, Brinckmann J, et al., editors. *The ABC Clinical Guide to Herbs.* Austin (TX): American Botanical Council; 2003. p. 240.

References:

1. Blumenthal M, Busse WR, Goldberg A, Gruenwald J, Hall T, Riggins CW, Rister RS (eds.). Klein S, Rister RS (trans.). *The Complete German Commission E Monographs—Therapeutic Guide to Herbal Medicines.* Austin, TX: American Botanical Council; Boston: Integrative Medicine Communication; 1998;142–4.
2. Braun R, Surmann P, Wendt R, Wichtl M, Ziegenmeyer J (eds.). *Standard Drug Approval for Prescription Drugs. Text and Commentary.* [in German]. Stuttgart: Deutscher Apotheker Verlag; 1996 Feb;Zulassungsnummer 1349.99.99.
3. European Scientific Cooperative on Phytotherapy. Crataegi Folium cum Flore. In: *Monographs On The Medicinal Uses of Plant Drugs.* Exeter, U.K.: European Scientific Cooperative on Phytotherapy; Oct 1999.
4. Brinker F. *Herb Contraindications and Drug Interactions,* 3rd ed. Sandy, OR: Eclectic Medical Publications; 2001.
5. Trunzler V, Schuler E. Comparative investigation of the effect of a *Crataegus* extract, digotoxin, digoxin and γ-strophanthin on isolated heart muscle. [in German]. *Arzneimittelforshung* 1962; 12:198. Cited in: Upton R (ed.). Hawthorn leaf with flower—*Crataegus* spp.: Analytical, quality control, and therapeutic monograph. In: Upton R (ed.). *American Herbal Pharmacopoeia and Therapeutic Compendium.* Santa Cruz, CA:AHP;1999.
6. Hahn F, Klinkhammer F, Oberdorf A. Description and pharmacological investigation of a new therapeutic active agent derived from *Crataegus oxyacantha.* [in German]. *Arzneimittelforshung* 1960;10:825–6. In: Upton R. (ed.). Hawthorn leaf with flower—*Crataegus* spp.: Analytical, quality control, and therapeutic monograph. In: Upton R (ed.). *American Herbal Pharmacopoeia and Therapeutic Compendium.* Santa Cruz, CA:AHP;1999.
7. Newall C, Anderson L, Phillipson J. *Herbal Medicines, A Guide for Health-Care Professionals.* London, U.K.: The Pharmaceutical Press; 1996;157–9.
8. Meyer-Buchtela E. *Tee-Rezepturen—Ein Handbuch für Apotheker und Ärzte.* Stuttgart, Germany: Deutscher Apotheker Verlag; 1999.
9. Upton R (ed.). Hawthorn berry—*Crataegus* spp.: Analytical, quality control, and therapeutic monograph. In: Upton R (ed.). *American Herbal Pharmacopoeia and Therapeutic Compendium.* Santa Cruz, CA:AHP;1999a.

HerbalGram welcomes letters to the editor as part of the ongoing dialog that makes science so vibrant, and as part of our efforts to learn as well as to educate. Please submit your letters to Karen Robin, managing editor, via email <KRobin@HerbalGram.org>, or by postal service in care of the American Botanical Council, P.O. Box 144345, Austin, TX 78714-4345, USA. Be sure to include your contact information so we may confirm.

The editors reserve the right to edit, clarify, or decline to publish.

calendar

2003

September 1–2: Latin American Herbal Medicines: Harmonization of Regulatory and Drug Development. Santiago, Chile. Sponsored by the Drug Information Association, this conference will analyze the regulatory status of herbal product manufacturers and distributors in Latin America and provide an open forum for discussing their potential for harmonization in a number of areas. Website: <www.diahome.org>.

September 4–7: Natural Products Expo East. Washington, DC. Contact: New Hope Natural Media/Penton Media. Ph: 303/939-8440. Website: <www.newhope.com>.

September 5–7: 18th Annual Breitenbush Herbal Conference. Portland, OR. "Herbal Passions" conference includes workshops, herb walks, hands-on experiences, most of intensive length. Beginner through advanced classes, professional CE credits. Ph: 503/236-2220. Website: <www.trilliumeducation.org>.

September 8–9: Hepatoxicity Assessment for Botanical Dietary Supplements Workshop. Four Points Sheraton, Bethesda, MD. "Hepatoxicity Assessment for Botanical Dietary Supplements," sponsored by the National Center for Natural Product Research, which is based at the University of Mississippi School's Pharmacy. Also supported by the FDA's Center for Food Safety and Applied Nutrition. Focus is on improved quality and safety of botanical dietary supplements. Contact: Walter Chambliss, Asso. Dir., NCNPR, the Cochran Research Center, Univ. of Mississippi. Ph: 662/915-1005. Fax: 662/915-1006. E-mail: <wchambli@olemiss.edu>. Website: <www.olemiss.edu/depts/ncnpr>.

September 8–12: XII Congresso Ítalo Latino Americano de Etnomedicina. Rio de Janeiro, Brazil. Sponsored by the Istituto Italo-Latino Americano (IILA), Roma Societa Italo-Latinoamericano di Etnomedicina, the Universade Federale do Rio de Janeiro, and the Pestana Rio Atlantica Hotel, this year's theme is "Nuno Álvares Pereira." Website: <http://www.farmacia.ufrj.br/silae>.

September 14–17: CRN 2003 Conference. Tucson, AZ. Council for Responsible Nutrition annual conference on dietary supplements. Network and hear experts in various aspects of the dietary supplements including science, regulation, and legislation. Contact: Verna Breland. Ph: 202/204-8001. E-mail: <vbreland@crnusa.org>. Website: <www.crnusa.org>.

September 16–19: China Association of Fragrance & Cosmetic Industry Exhibition. Guang Dong, China. See new cosmetics products while learning manufacturing and marketing techniques at technical exchanges and lectures. E-mail: <mail@fnfnet.com>.

September 19–20: 15th Annual Green Nations Gathering. Iroquois Springs at Camp Sequoia, Rock Hill, NY. Sponsored by Green Nations, the finest herbal teachers; alternative health practitioners; food, water and environmental activists; and spiritual ecologists will offer workshops, lectures, and plenary sessions. Ph: 802/293-5996. E-mail: <greenpam@aol.com>. Website: <www.greennations.org>.

September 20: 2nd Annual Ginseng Festival. Catskill, NY. Sponsored by the Catskill Kiwanis Club and the Cornell Co-op Extension, activities include workshops, lectures, ginseng products, crafts and refreshments. Ph: 518/622-9820.

September 20-21: Cultivating the Herbal Medicine Woman Within with Kami McBride. Vacaville, CA. This experiential herbal studies class is for women studying herbal medicine as a deepening relationship with the Earth and a way of life. One weekend a month, September 2003 through April 2004, and provides CEU credits for nurses. Ph: 707/446-1290. Website: <www.livingawareness.com>.

September 26–October 1: Global Summit on Medicinal Plants in Mauritius Island. Mauritius. "Recent Trends in Phytomedicine and Other Alternative Therapies for Human Welfare" conference will focus on the vital importance of medicinal plants and other therapies in health care via programs, plenary lectures, oral and poster presentations, round table discussions. Website: <www.cenfound.org/global/global.html>.

September 26–October 5: International Congress on Traditional and Natural Medicine. Havana, Cuba. A special U.S. delegation being organized to attend the conference; the theme is "All united in pursuit of one goal: a better quality of life through health." Includes an exchange of scientific papers and discussions among experts; poster exhibits; open debates with participation of researchers and practitioners; invited papers; and visits to research centers, universities, hospitals and clinics. Contact: Rachel Bruhnke, Natural Medicine Conference, c/o Global Exchange, 2017 Mission Street, Suite #303, San Francisco, CA 94708 Ph: 415/255-7296, ext 354. E-mail: <rachel@globalexchange.org>. Website: <http://www.globalexchange.org/tours/>.

September 27–October 6: Ayahuasca Healing Retreat. Bahia, Brazil. Ayahuasca ceremonies, aromatherapy, herbal remedies, full moon sessions with shamanic drums on the beach, massage and hydrotherapy, three optional days for *Salvia divinorum*, and excursions. Website: <www.ayahuasca-healing.net>. E-mail: <silviap@house.com.ar>.

September 27–October 5: BioNat 2003. Havana, Cuba. Learn how acupuncture and other alternative therapies have already been integrated into both the healthcare system and medical schools in Cuba at this international congress on natural and traditional medicine. Contact: Ana Perez. Ph: 415/255-7296. Email: <ana@globalexchange.org>.

September 28–October 1: Worldnutra 2003. Las Vegas, NV. Fourth Annual international conference and exhibition on nutraceuticals and functional foods. ABC Founder and Executive Director Mark Blumenthal will be speaking at this event. Website: <www.worldnutra.com>.

October 1–3: Virgo Publishing's SupplySide West. Las Vegas, NV. Share new science or research with industry professionals at the Venetian Hotel and Sands exhibition center. Contact: Ted Willis, Virgo Publishing. Ph: 480/990-1101 ext. 1526. Website: <www.supplysideshow.com>.

October 2–4: 3rd International Symposium on Natural Drugs. Naples, Italy. Sponsored by the International Council for Medicinal and Aromatic Plants, this symposium will focus on botanical, chemical, and pharmacological aspects of medicinal plants, also satellite symposia on cannabis and cannabinoids, chemical and pharmacological aspects of propolis and its components, green tea and cancer, and toxicity of anthraquinone drugs. Contact: Dr. F. Borelli or Dr. N. Milic, Dept. of Experimental Pharmacology, University of Naples, Federico II, Via D. Montesano, 80131 Naples, Italy. Ph: 0039 081 67 84 32 436/439. Fax: 0039 081 67 84 03. E-mail: <franborr@unina.it>.

October 9–12: Building Bridges of Integration for Traditional Chinese Medicine. East Rutherford, NJ. Join Eastern and Western experts for an unprecedented dialogue about the role of the full system of traditional Chinese medicine in contemporary healthcare at this conference on cancer, pain, immune system disorders and women's health. Contact: Elaine Katen. Ph: 888/TCM-6909 or 212/274-1079. E-mail: <info@tcmconference.org>. Website: <www.tcmconference.org>.

October 11: Women's Wisdom: Herb for Women's Health with Kami McBride. Vacaville, California. Explore the use of herbal medicine to support optimum health through all the female cycles of life at the Living Awareness Institute. Ph: 707/446-1290. Website: <www.livingawareness.com>.

October 13–15: Natural Products Expo Arabia. Dubai, Saudi Arabia. Organized under the patronage of the Ministries of Agriculture and Health, this conference will include speakers, workshops, and demonstrations from the natural products industry. E-mail: <info.np@apexmediafz.com>. Website: <www.apexmediafz.com>.

October 13–17: The Integration of Complementary Medicine into Cardiology. Kohala Coast, HI. Sponsored by the American College of Cardiology Foundation, this program will put this emerging area of treatment and investigation into focus and to enable physicians to provide better patient care in a meaningful and safe manner. Ph: 800/253-4636, ext. 694. Website: <www.acc.org>.

October 14–15: Industrial Leadership for the Preservation of Medicinal and Aromatic Plants. Philadelphia, PA. This symposium will explore supply, demand, and natural inventory issues facing the Medicinal and Aromatic Plants industry; lay the foundation for addressing sustainability, environmental and human rights issues on an industry-wide basis; and determine appropriate models. ABC Founder and Executive Director Mark Blumenthal will chair at this symposium. Website: <www.plantconservation.org/mpwgconference>.

October 17–19: American Herbalists Guild Symposium 2003, La Posada de Albuquerque, New Mexico. 40+ workshops by leading herbalists, CE credits for nurses, pharmacists, acupuncturists, and naturopathic physicians. Preconference intensives on Oct. 16. Contact: AHG, 1931 Gaddis Road, Canton, GA 30115. Ph: 770/751-6021. Fax: 770/751-7472 Email: <ahgoffice@earthlink.net>. Website: <www.americanherbalist.com>.

October 17–19: Bioneers Conference. San Rafael, CA. Local conferences will also be held in Traverse City, MI; Prescott College, Prescott, AZ; Toronto, Canada; Caspar, CA; Bloomington, IN; Houston, TX; Telluride, CA; Bozeman, MT; Fair-

field, IA; New York, NY; Boulder, CO; and at the University of New Hampshire. ABC's Mark Blumenthal will be speaking at the Houston conference. This conference is the preeminient gathering of visionaries with practical solutions for restoring the Earth. For both general and professional audiences, this three-day, annual event equips attendees with models, resources, and networks to encourage everyone to act as primary sources in the transformation towards a restorative future. Website: <www.bioneers.org/ conference_page/conferencehub.html>.

October 17–19: West Virginia Herb Association's 2003 Fall Conference. Jackson's Mill, WV. "Wisdom from the Herb Garden: An Introduction and Beyond" conference features workshops, presentation by James A. Duke. Ph:304/269-7681. Website: <www.wvherb.org>.

October 20–24: International Conference on Traditional, Alternative, and Complementary Medicines. Quito, Ecuador. Conceptual foundations of traditional medicines, natural resources and health, health legislation, international health policies related to CAM, and diagnostic therapeutic discoveries. Ph: (593-2) 258-7128. Fax: (593-2) 240-9698. Website: <www.convencionesquito.org>.

October 20–25: Clinical Herbal Medicine Training for Healthcare Professionals. Ashland, OR Intensive experiential training in case-taking, physical examination techniques, differential symptom analysis, case follow-up, formulating, prescribing and dispensing. Also assessing disease processes from a wholistic perspective, materia medica, case studies of natural therapies with cancer and other chronic illnesses. Contact: Andrea Luchese at Centre for Natural Healing, 300 N. Pioneer Street, Ashland, OR 97520. Ph: 541/488-3133. Fax 541/488-6949. E-mail: <cnhwest@centrehealing.com>. Website: <www.centrehealing.com>.

October 24–25: International Conference on Safety Evaluation of Complementary and Alternative Medicine. Empoli, Italy. Key themes include acupuncture, herbal medicine, homeopathy, vertebral manipulations, and other CAM therapies. Website: <www.naturamedica.net>.

November 2–6: IFEAT International Conference 2003. Sydney, Australia. This conference will focus on the production and marketing of essential oils and aroma chemicals in Australia and New Zealand. Website: <www.ifeat.org>.

November 5–8: Second International Congress on Tibetan Medicine: From Tradition to Evidence-Research and Practical Applications. Washington DC. This conference will focus on recent developments, findings, and emerging themes that directly affect the application and practice of Tibetan medicine in the West. One key track of the meeting will address issues of sustainability of medicinal plants in the Himalayan Region and South Asia. Ph: 866/547-3309. Website: <http://www.tibetmedicine.org/>.

November 10–15: First Annual Agarwood Conference. Ho Chi Minh City, Viet Nam. *Aquilaria* trees have been harvested to near extinction throughout Asia; this forum will present, explore, and discuss current Agarwood research and practices including formation, trade, legal frameworks and more. Contact: Agarwood Conference Coordinator, The Rainforest Project Viet Nam, 71 Lam San, Tan Binh District, Ho Chi Minh City, Vietnam. E-mail: <conference@agarwood.org.vn>. Website: <www.agarwood.org.vn>.

November 13–17: American Association of Oriental Medicine 2003 International Conference and Exposition. Orlando, FL. This year's theme is "Oriental Medicine: A New Era in Medicine, A New Hope for Humanity." Ph: 301/941-1064. E-mail: <info@aaom.org>. Website: <www.aaom.org>.

November 27–30: International Ginseng Conference: The Globalization of Ginseng. Melbourne, Australia. Organized by the Australian Ginseng Growers Association. Includes trade and poster displays, technical program, and post conference tours. Contact: Conference Secretary, IGC 2003, PO Box 250, Gembrook, Victoria 3783, Australia. Ph:+ 61 3 5968 1877. Fax: +61 3 5968 1119. E-mail: <agga@nex.net.au>.

access

In this department of *HerbalGram*, we list resources such as publications, organizations, seminars, and networking for our readers.
A listing in this section does not constitute any endorsement or approval by *HerbalGram*, ABC, or its Advisory Board.

Recent papers on plant toxicity. Jean Bruneton's website contains references on the main papers dealing with plant toxicity, adverse effects of herbal drugs, etc. that have been published since 2000. Website: <http://ead.univ-angers.fr/~pharma/bruneton/>.

Libraries announce digital versions of classic texts. The Missouri Botanical Garden Library has digitized William Woodville's classic *Medical Botany*, published 1790–1793. The text contains "systematic and general descriptions, with plates, of all the medicinal plants, indigenous and exotic, comprehended in the catalogues of the materia medica," and is "accompanied with a circumstantial detail of their medicinal effects, and of the diseases in which they have been most successfully employed." The Southwest School of Herbal Medicine also has some classics available as downloads at their website. University of Missouri's Woodville Website: <http://ridgwaydb.mobot.org/mobot/rarebooks/title.asp?relation=QK91C7431790V1>. Southwest School of Herbal Medicine's classic texts website: <www.swsbm.com/ManualsOther/ManOther.html>.

OTA Newsletter available in PDF format. The Organic Trade Association's newsletter, *What's News in Organic*, is now available in PDF form on OTA's web site. <www.ota.com>.

Organic Farming Research Foundation announces new grant application deadlines. The foundation, which has disbursed nearly $1.2 million in organic research grants since 1990, will accept grant applications by July 15 and December 15 of each year. Contact: Jane Sooby. Ph: 831-426-6606. E-mail: <jane@ofrf.org>.

State and Federal Clinical Trial Requirements are in a new online database. Published by Thompson Publishing Group, ClinLaw is a service to protect clinical trials from ever-changing state requirements and makes it fast and easy to find the clinical trial requirements to ensure clinical trials are fully compliant. Visit the ClinLaw website for a free trial. Website: <http://mailiwant.com/links.jsp?linkid=3681&subid=249968&campid=7188>.

New Medical Marijuana Website. Sponsored by the Drug Policy Alliance, the legal section of the site contains texts of laws of various jurisdictions which permit medical marijuana, court decisions addressing medical marijuana issues, legal briefs from important medical marijuana cases, and sworn testimony of patients and physicians. The medical section provides information about the historical uses of medical marijuana, leading scientific studies and research about medical marijuana, medical conditions for which cannabis is helpful, issues associated with Marinol, alternative delivery methods for THC and cannabinoids, and viewpoints of key medical associations. Website: <http://www.drugpolicy.org/marijuana/medical/challenges/litigators/>.

The Plant Press is the quarterly newsletter from the Smithsonian Institution's Department of Systematic Biology – Botany and the U.S. National Herbarium. Articles cover staff research and travel, visitors, new publications, and plant conservation highlights, in-depth insight in the world of botany, and artwork from resident artist Alice Tangerini. Website: <http://www.nmnh.si.edu/botany/plantpress/plantpress.html>.

Biostar Nutraceuticals Educational Resource. The Nutrient Network Library (NNL) was established to expedite the development of better health products and has become a source for nutriceutical scientists who want to educate and promote good nutrition and health throughout the world. The NNL features scientific information and real-time research is available to anyone wanting to learn how they can improve their health through proper nutrition or for companies wishing to develop effective products supported by solid science. Website: <www.nutrientlibrary.com>.

classified

Correspondence Courses And Seminars

Aromatherapy and Herbal Studies Course by Jeanne Rose. Correspondence, certification, in-person intensives. 160 CEU provided, California Board of RN Provider #CEP11659. Info: 219 Carl St., San Francisco, CA 94117 or FAX 415/564-6799.

Publications

American Herb Association Quarterly Newsletter — $20/yr. AHA, P.O. Box 1673, Nevada City, CA 95959.

Australian Journal of Medical Herbalism — quarterly publication of the National Herbalists Association of Australia (founded in 1920). Deals with all aspects of Medical Herbalism, including latest medicinal plant research findings. Regular features include Australian medicinal plants, conferences, conference reports, book reviews, rare books, case study and medicinal plant review. AUD/$95 plus AUD/$15 if required by airmail. National Herbalists Association of Australia, 33 Reserve Street, Annandale, NSW 2038, Australia.

HerbalGram — Quarterly journal published by the American Botanical Council. A benefit at all levels of membership in ABC. See page 3 for membership information or join online at <www.herbalgram.org>. P.O. Box 144345, Austin, TX 78714. 800/373-7105 or fax 512/926-2345. Email <abc@herbalgram.org>.

Medical Herbalism — Subtitled "A Clinical Newsletter for the Herbal Practitioner." Edited by Paul Bergner. $36/yr, $60/2 yrs. Canada $39/yr. Overseas $45/yr. Sample/$6. Medical Herbalism, P. O. Box 20512, Boulder, CO 80308.

Schools

Distance Learning Master Herbalist, Master Aromatherapist. Australasian College of Herbal Studies, USA. Accredited member DETC. Oregon State Licensed. CEU's for Registered Nurses, Pharmacists, Veterinarians, Naturopaths and Licensed Massage Therapists. NCBTMB (Category A), ABMP, AMTA, Florida and Louisiana Board of Massage approved. Student Loans, Liability Insurance. Call 800.487.8839. <achs@herbed.com>, www.herbed.com

Australian College of Phytotherapy – founded in 1998 by Kerry Bone, offers innovative, clinically-oriented, post-graduate courses by distance education. Courses are open to health care professionals world-wide and train in the clinical applications of Western Herbal Medicine. "Practical Herbal Therapy" is a 180-hour course on CD-ROM; the "Master of Health Science (Herbal Medicine)" is a course in association with the University of New England, Australia. Visit: <ww.herbaleducation.com.au>

Travel

Hawaiian Herbal Education — Go beyond traditional herbalism to learn Hawaiian plant medicine secrets. 3-day hands-on workshops at Hi'iaka's Healing Hawaiian Herb Garden near Hilo. Scheduled for January, April, July, October 2003. Individual retreats also designed, scheduled upon request. $110/day includes lodging on-site. Details and images at <www.hiiakas.com>. Phone 808/966-6126, email <goddess@hiiakas.com>.

Dear Reader

Continued from page 5

this bill, and NNFA has begun to arm retailers with instore promotion packets to elicit consumer opposition of the bill.

In this issue, we also highlight rooibos, the South African herb with a delightful flavor and a relatively high antioxidant effect. Rooibos was first introduced into the U.S. market in the early 1980s by herbal tea leader Celestial Seasonings, but the product was avoided by many human rights-conscious health food consumers who did not want to support a product from the then-apartheid South Africa. Ironically, sales of rooibos would have benefited the very African people whom the consumers would have wanted to support. Rooibos is back, with numerous companies beginning to market the product as a tea or dietary supplement.

We also offer some new insight into the current kava controversy. Ethnobotanist Paul Cox and colleagues provide a survey of traditional native healers and biomedically trained healthcare professionals in Samoa. Despite concerns by some public health officials of the alleged hepatotoxicity of kava, the traditional and Western healers surveyed have not observed liver disease among native kava users.

And, finally, a *mea culpa*. *HerbalGram* 55 included an article on an herbalist's quest to determine the botanical contents of the Patterson Bundle, an Indian medicine bag found in Utah. The author felt it important to determine the identity of the herbs, and their known medicinal and/or sacerdotal properties. One of our loyal readers, herbalist Cindy Bloom, herself half Native American, was horrified to see what she considered the defiling of a sacred site and its contents. She contacted us, we invited to share her concerns with us, and we now print her letter in its entirety. We sincerely apologize for any insensitivity we may have exhibited in this matter.

Mark Blumenthal

GMPs

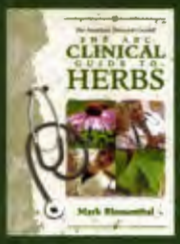
Continued from page 58

3. CGMP Review Update: Regional Meetings Completed – Additional Input Requested. AHPA Update. Silver Spring, MD: American Herbal Products Assn., Jun 19, 2003.
4. Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Supplements: Proposed Rule. Federal Register Volume 62, No. 25, Docket No. 5700-9. Washington, DC: Food and Drug Administration. February 6, 1997.
5. GMP Comparison. Washington, D.C.: Council for Responsible Nutrition. Accessed Jun 26, 2003 online at <www.crnusa.org>.
6. Current good manufacturing practice in manufacturing, packing, or holding human food. 21 CFR, part 110.
7. Current good manufacturing practice in manufacturing, processing, packing or holding of drugs: General. 21 CFR, part 210.
8. Current good manufacturing practice for finished pharmaceuticals. 21 CFR, part 211.
9. Israelsen LD. DSHEA Ten Years Later: What Happened? Presentation at National Nutritional Foods Association., Las Vegas, Nevada, June 28, 2003.

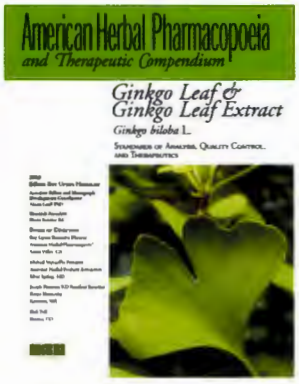
Herbal Education Catalog

ABC Members now receive a 10% discount on all orders!

Inside This Catalog

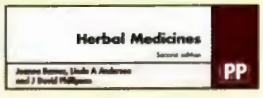


New Items



Ginkgo Leaf & Ginkgo Leaf Extract: *Ginkgo biloba L.* Standards of Analysis, Quality Control, and Therapeutics.
2003. Editor: Roy Upton. The latest monograph from the American Herbal Pharmacopoeia. Comprehensive review of therapeutic uses; complete safety and toxicology data, and more. Fully referenced and peer reviewed. 14 pages. $24.95. Item 446.

(Information on the complete series of AHP monographs is on page 3.)



Herbal Medicines. Second ed.
By Barnes, Anderson and Phillipson. 2002. Provides information on mediciannl herbs sold in UK pharmacies. Seven new monographs have been added to the second edition, 10 have been extensively revised and rewritten, and a further 33 have been updated. It new includes a total of 148 herbs. Includes references for each monograph as well as an index. 530 pp. $59.95. Item B198

Special Offer

HerbalGram BackPacks

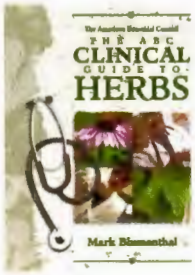
Don't leave any gaps in your library. *HerbalGram* back issues provide a comprehensive store of information on herbs, book reviews, research, and conference reports, legal and regulatory developments.

BackPacks are a set of *HerbalGrams* from 1989, except the most current issue, and include a complete Cumulative Index.

Order a complete set of BackPacks, Volumes II, III and IV for $95 and you'll receive 2 slipcases at no extra charge to protect and store those back issues. That's a $19 value.

To order, use the order form on the inside back cover or, for secure online ordering, please visit the Herbal Education Catalog section of our website:

www.herbalgram.org

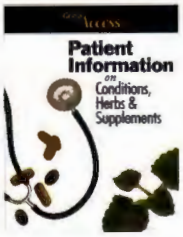


The ABC Clinical Guide to Herbs

Ed. by Mark Blumenthal et al., American Botanical Council, 2003. How does the healthcare professional effectively respond to patient inquiries on the use of herbal supplements? What clinical research has been conducted? How is safety evaluated? This science-based educational course answers these and other questions for healthcare professionals, pharmaceutical companies, health management companies, policy makers, the dietary supplement industry and consumers. Hardcover, 512 pp. $49.95. #905

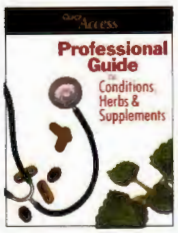
Quick Access Guide to Conditions, Herbs & Supplements

by Integrative Medicine Communications, 2000. This book has three broad categories for quick answers to consumer questions. The largest section deals with conditions and covers various treatment options including herbs, supplements, drugs, and other complementary and alternative therapies. Only alternative treatments that are considered safe and effective when used with conventional medicine are included. Additional sections on herbs and supplements cover basic information, precautions, and dosage information. The Quick Reference Guide found at the end of the book shows at a glance all the herbs and supplements that are useful in treating that condition. Softcover. 430 pp. $29.95. #B521. Special offer $24.00!



Quick Access Patient Information on Conditions, Herbs & Supplements

by Integrative Medicine Communications. Consists of three types of monographs. Condition monographs provide patients with information on standard medical care with additional information on nutritional support and the use of alternative and complementary therapies. Herb monographs provide important information on their use in maintaining health or treating conditions. Supplement monographs provide information on the use of dietary supplements. Thirteen Quick Reference Guide lists allow easy and targeted access to information by symptom, use, precautions, etc. Spiral bound. 266 pp. $49.95. #B522. Special offer $40.00!



Quick Access Professional Guide to Conditions, Herbs & Supplements

by Integrative Medicine Communications. Contains Condition, Herb, and Supplement Monographs with extensive information geared toward medical practitioners. Thirteen Quick References allow easy and targeted access to the information. 472 pp. Hardcover. $49.95. #B523. Special offer $40.00!

Quick Access Professional Reference to Conditions, Herbs & Supplements CD-ROM

by Integrative Medicine Communications. Monographs address numerous medical conditions, provide information on a range of treatment options, outline uses, dosages and interactions for over 115 herbs and supplements, and present nutrition depletions associated with the most popular drugs. PC compatible. $49.95. #C001. Special offer $40.00!

Steven Foster Photography

Medicinal Plants - Volume 1 CD-ROM

This royalty-free CD ROM contains 102 photos of some of the most popular medicinal plants in use today. Medicinal Plants - Volume I is designed for both Macintosh™ and Windows™ operating systems. The images are high resolution: 8x12 inches at 300 dpi (20.3x30.5 cm at 118 dpcm) and have excellent highlight and shadow detail.

$495*

Item #C008

* For products produced in quantities of less than 100,000 units.

For a complete listing of the plants in this collection, visit: http://www.herbalgram.org/default.asp?c=sfg_images

ESCOP Monographs

Prepared by the European Scientific Cooperative on Phytotherapy (ESCOP), a group of herbal experts from academia and industry in the European Union. These monographs contain indications, contraindications, side effects, dosage, interactions, and many other important therapeutic parameters of 60 leading herbs and phytomedicines in Europe. Well referenced. A must for physicians, pharmacists, naturopaths, herbalists, industry, and researchers.

ESCOP monographs are published in looseleaf form, for insertion into a dedicated ring binder. ESCOP employs the traditional pharmacopeial name of the herb as the title of each monograph.

For a complete listing of monographed herbs and fascicule divisions, visit our website: www.herbalgram.org/monographs.html

for all 6 fascicules Item #421 **$225**

WHO Monographs on Selected Medicinal Plants, Vol. 1

by the World Health Organization. 1999. Collection of 28 monographs covering the quality control and traditional and clinical uses of medicinal plants selected for inclusion on the basis of their widespread use, particularly in countries that rely heavily on medicinal plants to meet primary health care needs. Aims to encourage standardized scientific approaches to ensuring the safety, quality, and efficacy of medicinal plants and their products. Softcover, 287 pp. Item #428

$82.80

WHO Monographs on Selected Medicinal Plants, Vol. 2

By the World Health Organization. 2002. Provides an additional collection of 30 monographs covering quality control and traditional and clinical uses of selected medicinal plants reviewed by 120 experts in more than 50 countries, as well as by experts through a network of relevant NGOs. Also included are two cumulative indexes to both volumes. Softcover, 362 pp. Item #428A.

$90.00

Fitoterapia

Extensive monographs and literature reviews from *Fitoterapia*, a leading international botanical research journal, founded by Indena, the leading European supplier of botanical derivatives.

Bilberry	*Vaccinium myrtillus*	26 pp.	Item #425A
Ginkgo	*Ginkgo biloba*	48 pp.	#425B
Grape	*Vitis vinifera*	25 pp.	#425C
Horse Chestnut	*Aesculus hippocastanum*	28 pp.	#425D
Milk Thistle	*Silybum marianum*	39 pp.	#425E
Pumpkin	*Cucurbita pepo*	11 pp.	#425F
Pygeum	*Prunus africana*	14 pp.	#425G
Saw Palmetto	*Serenoa repens*	14 pp.	#425H
St. John's Wort	*Hypericum perforatum*	25 pp.	#425I
Valerian	*Valeriana officinalis*	13 pp.	#425J
Stinging Nettle	*Urtica dioica*	16 pp.	#425L

$10 each **$98** for all 11 Item #425K

Chinese Herb Monographs

Chinese Drug Monographs and Analysis by H. Wagner, R. Bauer et al. Monographs range from 8 to 17 pp. and include such information as: pharmacopeias found in, publication first cited in, official drugs, substitute drugs, description of official drugs, falsification drugs, pretreatment of the raw drug, medicinal use, main constituents, pharmacology, toxicology, TLC fingerprint analysis, evaluation, HPLC fingerprint analysis, and references.

Radix Astragali (Huang Qi) Astragalus	Item #0424A
Fructus Schisandrae (Wuweizi) Schisandra	#0424B
Radix Rehmanniae (Dihuang) Rehmannia	#0424C
Radix Bupleuri (Chaihu) Bupleurum	#0424D
Bulbus Fritillariae (Beimu) Fritillariae	#0424E
Rhizoma Pinelliae (Banxia) Pinellia	#0424F
Herbe Houttuyniae Cordatae (Xuxingcao) Houttuynia	#0424G
Herba Asari (Xixin) Asarum	#0424H
Radix Angelicae Pubenscentis (Duhuo) Angelica	#0424J
Rhizoma Atractylodes Macrocephalae (Baizhu) Atractalodes	#0242K
Rhizoma Belamcandae Sinensis (Shegan) Belamcanda	#0424L
Herba Lycopi Lucidi (Zelan) Lycopus	#0424M
Rhizoma Seu Radix Notopterygii (Qianghuo) Notopterygium	#0424N
Radix Angelicai (Danggui)	#0424P
Radix Angelicai Dahuricae (Baizhi)	#0424Q
Radix Ligustici Chuanxiong (Chuanxiong)	#0424R
Pericarpium Zanthoxyli (Huajiao)	#0424S

$12 each All 17 monographs **$185** (Save over 10%) #0424I

American Herbal Pharmacopoeia Monographs

- Comprehensive review of the therapeutic uses
- Complete safety and toxicology data
- Critical information on side effects, contraindications, all aspects of quality control, historical use and more
- Astragalus, Reishi and Schisandra also include Traditional Chinese Medicine supplement section
- Ashwagandha includes Ayurvedic supplement section
- Fully referenced and peer reviewed by international authorities

St. John's Wort	#5420
Hawthorn Leaf with Flower	#426
Astragalus Root	#431
Hawthorn Berry	#430
Valerian Root	#427
Schisandra Berry	#434
Willow Bark	#433
Ashwagandha Root	#435
Black Haw Bark	#436
Chaste Tree Fruit	#437
Cramp Bark	#438
Reishi Mushroom	#439
Goldenseal	#440
Bilberry	#441
Black Cohosh Rhizome	#442
Cranberry Fruit	#443
Dang Gui	#445
Ginkgo	#446

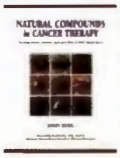
$19.95 each

St. John's Wort
$9.95 each

Ginkgo
$24.95 each

All 18 monographs
$328.00
(10% discoount)
Item #450

Cancer Research



Natural Compounds In Cancer Therapy: Promising Nontoxic Anti-tumor Agents from Plants and Other Natural Sources by John Boik. 2001. Presents a solid scientific basis for the use of natural compounds in cancer treatment. Includes in-depth discussions of cancer at the cellular level and the level of the organism, as well as clinical considerations covering trace metals, vitamin C and antioxidants, polysaccharides, lipids, amino acids and related compounds, flavonoids, nonflavonoid phenolic compounds, terpenes, lipid-soluble vitamins, and the effects of natural compounds on chemotherapy and radiation therapy. Softcover, 521 pp. $32. #B494

Clinical/Therapeutic

The Clinician's Handbook of Natural Medicine by Joseph Pizzorno Jr., Michael Murray, and Herb Joiner-Bey. 2002. Provides an easily accessed set of decision-making flowcharts and summary information based on the best available evidence on natural medicine options, including herbs, supplements and dietary advice. Covers 74 common diseases and includes scientifically verified therapies. Softcover, 522 pp. $39.95. #B506

The Desktop Guide to Complementary and Alternative Medicine: an Evidence-Based Approach Ed. by Edzard Ernst, Max Pittler, Clare Stevinson, and Adrian White. 2001. Offers concise information on 64 popular CAM diagnostic methods and treatments; summarizes clinical trial data on the effectiveness of CAM for 38 specific conditions; weighs the benefits and risks of each CAM treatment; and includes a CD-ROM of the book that links to Medline. Softcover, 444 pp. $36.95. #B501

NEW LOW PRICE

The Complete German Commission E Monographs—Therapeutic Guide to Herbal Medicines Ed. by M. Blumenthal, W. Busse, A. Goldberg, J. Gruenwald, T. Hall, C. Riggins, and R. Rister. 1998. The official English translation of the monographs resulting from the German Federal Health Agency's expert committee. The 2nd-ranked medical book of 1998 (Doody Publishing). Contains 380 monographs, 190 herbs and fixed combinations approved for therapeutic use, 150 indications, and more. Hardcover, 685 pp. $89. #B181. CD-ROM $49. #C181

NEW LOW PRICE

Herbal Medicine: Expanded Commission E Monographs Ed. by M. Blumenthal, A. Goldberg, and J. Brinckmann. 2000. Expanded content on the Commission E herb monographs for the most widely used herbs in the U.S. Includes updated, detailed information on their botany, history, chemistry, pharmacology, safety, efficacy, and therapeutic use. Extensive list of published references. Hardcover, 519 pp. $39.95. #B181E. CD-ROM $39.95. #C181E

SPECIAL OFFER Purchase both Commission E books for **$96.76**. #B181S

Evidence-Based Herbal Medicine by Michael Rotblatt, MD, and Irwin Ziment, MD. 2002. Analyzes a large quantity of the primary literature on controlled clinical trials and provides reliable and practical information on the uses, pharmacology, efficacy, and adverse effects of approximately 65 herbal medicines and a few non-herbal dietary supplements. Softcover, 464 pp. $29. #B516

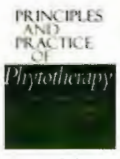
NEW EDITION

Herbal Medicine by Rudolf Fritz Weiss, M.D. 2000. 2nd Edition. The now-classic text used by M.D.s in Germany. An indispensable modern text in medical herbalism. Many herbs are illustrated. Plant drugs are arranged by clinical diagnoses relating to particular systems. Softcover, 362 pp. $59. #B006

Herbal Medicine - Classic Edition by Rudolf Fritz Weiss, M.D. 2000.This is a key text in the field of phytotherapy, used by both herbalists and medical professionals. Arranged by clinical diagnoses related to organ systems, with guidelines for prescribing herbal remedies, sections on dosage, application and precautionary measures. Proprietary formulations, full references, and a comprehensive subject index of almost 2,000 entries round out the coverage. Softcover, 362 pp. $49. #B006A

Herbal Medicine: A Concise Overview for Professionals Ed. by Edzard Ernst. 2000. Evidence-based look at herbal medicine that will serve as a useful, fully-referenced guide for physicians, medical herbalists and other healthcare professionals with an interest in plant-based therapy. Addresses regulation in the UK and EU, safety issues, efficacy of herbal drugs, quality and standardization, synergy and more. Softcover, 120 pp. $39.95. #B509

Natural Medicine Comprehensive Database compiled by the editors of Pharmacist's Letter and Prescriber's Letter. 2000. 2nd edition. Contains a listing for almost every natural medicine sold in the U.S. and Canada and a listing for every product discussed in any reputable reference. Information covered includes name of product, also known as, scientific names, uses, safety, effectiveness, possible mechanisms of action and active ingredients, adverse reactions including known allergies, possible interactions, typical dosages and common modes of administration, and other comments. Softcover, 1,310 pp. $92. #B463 Access to web version for 1 year, updated daily. $92. #D008 Both book and web access. $132. #B463C



Principles and Practice of Phytotherapy by Simon Mills and Kerry Bone. 2000. Detailed, practical, and research-based approach to the use of herbal treatments in a wide variety of clinical conditions and problems. Includes a clear description of the principles and foundations for the practice of phytotherapy; in-depth and detailed profiles of over 45 herbs, reviewing pharmacology, research, and traditional use; therapeutics for actual disease states, supported by case histories; and coverage of challenging issues such as dosage, safety, and drug-herb interactions. Fully referenced with more than 4,000 citations. Hardcover, 643 pp. $82.95. #B441

Tyler's Herbs of Choice: The Therapeutic Use of Phytomedicinals James Robbers and Varro Tyler. 1999. 2nd edition. Up-to-date legal data about herb use in the U.S., clinical studies and advances in determining mechanism of action, information essential for understanding any medicinal agent and its rational use in therapeutics, easy-to-follow breakdown of how herbal remedies are used to treat various conditions and systems, and an expanded introduction to phytomedicines and their respective applications. 287 pp. Softcover, $19.95. #B079S

Consumer Education

Herbs For Your Health by Steven Foster. 1996. Designed as a quick reference guide to the 50 most commonly used herbs available in the U.S. as dietary supplements. Profiles include common and botanical name, brief history of traditional uses, summary of credible scientific reports, brief descriptions of conditions and symptoms the herb treats, forms in which it is available in the U.S., actions, dosage, cautions or contraindications, and photograph. Softcover, 121 pp. $6.00. #B232

Making Plant Medicine by Richo Cech. 2000. The medicine making section includes: drying and processing herbs; making tinctures the easy way; the mathematics of tincturing and solubility factors; basic formulas for fresh and dry extraction, including dosages; vinegar extracts, glycerites, herbal succi and syrups; teas, decoctions, herbal oils, salves and creams; poultices, compresses and soaks; and a section with more than 100 herbs that are readily cultivated in North America. The listings include conservation status, parts used, specific formulas, practical uses, dosages, contraindications and an overview of alternate species. Softcover, 282 pp. $14.95. #B490

General Herbals

New Encyclopedia of Herbs and Their Uses by Deni Bown. 2001. 2nd edition. The Royal Horticultural Society's new edition of the most comprehensive illustrated encyclopedia of herbs. More than 1,000 species, varieties, hybrids, and cultivars listed alphabetically by genus. Addresses culinary, medicinal, and economic properties of each herb along with cultivation information. More than 1500 color photographs by the author. Hardcover, 456 pp. $40. #B156

Legal/Regulatory

Herbs of Commerce Ed. by M. McGuffin, J. Kartesz, A. Leung, and A. Tucker. 2nd edition. 2000. Destined to be the "de facto standard by which all plant common and scientific names will be determined on all products containing herbs" (Christopher Hobbs), this edition lists Latin binomials, Standardized Common Names, Ayurvedic, Chinese (pinyin), and other common names for 2048 species, including 25 fungi and 23 seaweeds. A must-have for anyone who writes about or manufactures herbal products. Hardcover, 421 pp. $95. #B475

Regional

A Field Guide to Medicinal and Useful Plants of the Upper Amazon by J. L. Castner, S. L. Timme and J. A. Duke. 1998. Practical guide to approximately 100 of the most important and representative plants of the region. Includes a fascinating discussion and beautiful color photos of each plant. Softcover, 151 pp. $35. #B358

Jamaica's Ethnomedicine: Its Potential In The Healthcare System by Henry Lowe, Arvilla Payne-Jackson, Steven Beckstrom-Sternberg, and James Duke. 2001. Provides a historical overview of Jamaica's healthcare system from ethnomedical and biomedical perspectives; explores the potential role of ethnomedical practices in public healthcare; examines the potential benefits of developing Jamaica's herbal medicines as a possible pharmaceutical resource; proposes an organizational structure for an indigenous drug industry; and presents an extensive listing of Jamaican plants with their potential medicinal uses, along with the bioactivities related to these plants. Softcover, 250 pp. $37 #B497

Plant Resources of South-East Asia 12 (1) Medicinal and Poisonous Plants 1 Ed. by L.S. de Padua, N. Bunyapraphatsara, and R.H.M.J. Lemmens. 1999. Medicinal and poisonous plants are a rich source of promising chemical compounds. Thus, the best way to find new applications of plant-derived drugs would seem to be to combine local knowledge with the results of modern research on the properties of plant-derived medicines. This book provides the latest information on the botanical, agricultural, chemical, and medicinal aspect of 92 genera and species. Also sections on phytochemistry, biological and pharmacological activity and therapeutical applications, botany, ecology, agronomy, harvesting and handling after harvest, processing, utilization and quality control, genetic resources and breeding, and research and development. Hardcover, 711 pp. $175. #B432

Plant Resources of South-East Asia: Spices Edited by C.C. de Guzman and J.S. Siemonsma. 1999. Addresses 61 important spices in 50 papers, including origin and geographic distribution, historical aspects, main product forms and uses, economic aspects, biology, chemistry, botany, growth and development, ecology, agronomy, harvesting, and processing. 65 species of minor importance are described briefly and another 150 species secondarily used as spices are listed. Hardcover, 400 pp. $112. #B453

Research/Technical

Medicinal Plants: Culture, Utilization and Phytopharmacology by Thomas S. C. Li. 2000. Presents data for more than 400 species in tables arranged in alphabetical order by Latin binomial. Includes current information on major constituents and medicinal values, toxicity or hazards, essential oil and their fractions, value-added products and their possible uses, cultivation and harvesting, and infectious diseases and insects. Three appendices cross reference major active ingredients and their sources, essential oils and their derivations, and the common and scientific names of the plants cited in the tables. Hardcover, 517 pp. $149.95. #B510

Pharmacodynamic Basis of Herbal Medicine by Manuchair Ebadi. 2002. Demonstrates the beneficial effects and adverse side effects of a large number of herbal drugs, showing their actions and effects on organ, tissue, cellular, and subcellular levels. Includes herbal medications whose pharmacodynamic parameters have been delineated at the molecular level. Discusses the potential interactions of dietary supplements with prescription medications. Hardcover, 726 pp. $139.95. #B517

Quality Control Methods for Medicinal Plant Materials by the World Health Organization. 1998. A collection of recommended test procedures for assessing the identity, purity, and content of medicinal plant materials intended to support development of national standards based on local market conditions. Includes macroscopic and microscopic examination, thin-layer chromatography, and tests for determination of many factors. Softcover, 115 pp. $31.50. #B406

Quality Management of Nutraceuticals Ed. By Chi-Tang Ho and Qun Yi Zheng. 2002. 21 symposium papers that examine the chemical and biological quality management of nutraceuticals. Reviews several important classes of compounds, flavonoids, anthocyanins, and marine nutraceuticals. Discusses the chemical analysis of some products on the market such as goldenseal, saw palmetto, green tea, cocoa, and black cohosh. Addresses the bioactivity of several nutraceutical products such as ginger and gum guggal. Hardcover, 327 pp. $135. #B520

Safety/Toxicology

Botanical Safety Handbook: Guide for Safe Use and Labeling for Herbs in Commerce Ed. by M. McGuffin, C. Hobbs, R. Upton, and A. Goldberg. 1997. Provides safety data on more than 550 herbs as guidelines for product labels, including contraindications, side effects, and special warnings. Each herb is classed as can be safely consumed when used appropriately, herbs with the following restrictions, for external use only, or not to be used during pregnancy. Hardcover, 256 pp. $44.95. #B275

Essential Oil Safety by Robert Tisserand and Tony Balacs. 1995. Up-to-date research findings. Practical, comprehensive guide. Detailed profiles of 95 essential oils, including constituents, hazards, dosage, toxicity data and contraindications; brief safety profiles of 311 essential oils and 135 essential oil components; safety guidelines, details of essential oil absorption, metabolism and excretion; oils which may react adversely with certain drugs; and extensive references. Hardcover, 279 pp. $55. #B169

Herb Contraindications and Drug Interactions by Francis Brinker, N.D. 2001, 3rd edition. Information on 240 traditional therapeutic herbs explaining documented contraindications and drug interactions. Appendices identify even more herbs as they affect certain conditions and medicines. Softcover, 432 pp. $25.95 #B282

The Toxicology of Botanical Medicines by Francis Brinker. 2000. 3rd edition. Provides essential information for a basic knowledge of human reactions to certain plant toxins. A concise compilation of traditional knowledge and up-to-date information on the toxic effects of plants and plant extracts that may be used medicinally. Reviews the toxicology of medicinal plants as noted in American pharmacology, pharmacognosy and botanical medicine texts and is updated with recent publication and articles from medical journals. Softcover, 296 pp. $35. #B491

Special Savings

Sixty Medicinal Plants from the Peruvian Amazon. $25.00. B465

Ginseng: A Concise Handbook. $30.00. B047

Illustrated Chinese Materia Medica. $67.95. B158

Encyclopedia of Herbal Medicine. $34.00. B213

American Ginseng: The Root of North America's Medicinal Herb Trade. $10.00. B347

Medicinal Herbal Therapy: A Pharmacist's Viewpoint. $7.50. B372

Ginkgo Biloba Extract (EGb 761): From Chemistry to the Clinic. $16.00. B378

Straight Path of the Spirit. $12.00. B409

Canadian Medicinal Crops. $20.00. B429

Ayahuasca Reader: Encounters with the Amazon's Sacred Vine. $18.00. B473

Medicine Quest. $13.95. B481

to see the complete Herbal Education Catalog and to see special offers, visit us onlne at:
www.herbalgram.org/bookcatalog

PDR for Nutritional Supplements, 1st edition. 2001. Provides detailed information on each nutritional supplement including clinical research summary; scientific and common names; chemical and physical attributes; indications and usage; pharmacology and pharmacokinetics; precautions, adverse reactions and contraindications; potential interactions with drugs, food, alcohol, and herbs; and dosage and administration. Hardcover, 575 pp. $59.95. #B500

PDR for Herbal Medicines 2nd edition. 2000. Updated to include the latest scientific findings, clinical trials (including abstracts), case reports, and meta-analysis results. More detailed monograph sections on herb/drug interaction side effects, contraindications, precautions, adverse reactions, and dosage. Hardcover, 858 pp. $59.95. #B474

One of the great benefits of Membership in the American Botanical Council

HERBALGRAM

The Journal of the American Botanical Council

"In my opinion, HerbalGram *is the best source available on all aspects of phytomedicine, clinical data, historical information, legal and regulatory status, market reports, and more."*

— Michael Flannery,
Associate Director for Historical Collections,
Lister Hill Library for the Health Sciences,
University of Alabama at Birmingham

At all levels of membership, you will receive a new issue of *HerbalGram* four times each year. See application on page 2 of this issue of *HerbalGram*.

Slipcases

Protect and store valuable back issues!

One slipcase holds one BackPack Volume.
Item # 550C

$9.50

HerbalGram Sample

The current issue of the highly-acclaimed peer-reviewed journal. Item #CURR

$6.95

BackPacks

HerbalGram back issues enhance your library of information on herbal issues, books, research, conferences, laws, and related topics. The BackPacks are a set of *HerbalGrams* from 1989 through the second most current issue.

Volume II

HerbalGram issues
#18/19-33
(1989-1995)
Item #550B
$40.00

Volume III

HerbalGram issues
#34-49
(1995 to 2000)
Item #550D
$40.00

Volume IV

HerbalGram issues
#50-58
(2000 to 2003)
Item #550E
$27.00

Special Offer All three back packs, 2 slipcases and index. ($123 value) Item #5505 **$95.00**

ORDER FORM

QTY	Item(s) #	Description	Price	Total
		Deduct 10% from merchandise total if you are already a member or joining at this time.		
			Shipping	
			Please add $20 for rush orders	
			Texas residents only add 8.25% **Sales tax**	
HG59 08/03			Minimum order - $9 **TOTAL**	

Sales Total	**U.S.**	**Canada**
up to $20	$ 5.75	$ 8.75
$21-50	8.50	12.50
$51-100	11.50	17.25
$101-300	15.75	23.50
$301-500	21.00	31.25

Rush orders, special shipping, foreign and orders over $500, call 1-800-373-7105 or email <custserv@herbalgram.org> for rates.

Credit Card holders call toll-free
800/373-7105
FAX this form: 512/926-2345
E-Mail: custserv@herbalgram.org

Payment:

❑ I have enclosed my check or money order
(U.S. funds only, must be drawn on a U.S. bank)
❑ Visa ❑ MC Expiration date_____
Account # _____
(Please include the 3-digit number following the account # on signature line on back of card.) _____

Shipping address

_____
name

_____
company profession

_____
phone fax

_____
address

_____

_____
city state/province

_____
zip/postal code

_____
country

_____
email

Make checks payable to the American Botanical Council, P.O. Box 144345, Austin, TX 78714-4345. Phone 512/926-4900

UPS is our preferred courier, as they ensure safe, accurate, and quick arrival of your goods.

We accept returns for books only if they are returned within 30 days. Videos and CD-ROMs are non-refundable. Sale items may not be returned. Refunds or credits are given for the cost of the book if it is returned in good condition. Shipping and handling costs are not refunded or credited unless it was our error. Returns after 30 days are subject to a 30% restocking fee. Please include an explanation of the reason for the return and a copy of the original invoice if possible. **Please pack the items carefully, so that damage will not occur in the return shipment.**

Summer 2003 price list. Prices subject to change. We occasionally make our mailing list available to organizations that promote education events and conferences or provide a service that promotes ABC. We do not make it available to supplement companies to promote products. We respect your privacy. If you prefer not to be included, you may request that your name be removed from special promotion lists. Write to ABC Customer Service, P.O. Box 144345, Austin, TX 78714-4345.

P.O. Box 144345
Austin, TX 78714-4345
512/926-4900
www.herbalgram.org

Non-Profit Org.
U.S. Postage
Paid
Ft. Worth, TX
Permit no.
1467

CHANGE SERVICE REQUESTED

POSTMASTER: TIME SENSITIVE MATERIAL. PLEASE EXPEDITE DELIVERY.