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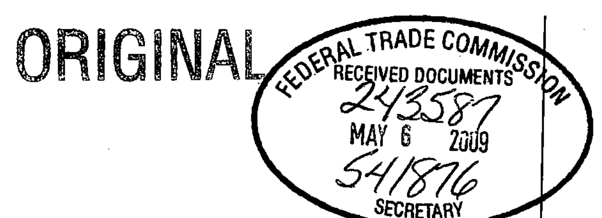

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IN THE UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION
OFFICE OF ADMINISTRATIVE LAW JUDGES

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In the Matter of **DANIEL CHAPTER ONE,** **a corporation, and** **JAMES FEIJO,** **individually, and as an officer of** **Daniel Chapter One**	**Docket No.: 9329** **PUBLIC DOCUMENT**

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RESPONDENTS' STIPULATED MOTION TO INCLUDE EXHIBIT IN HEARING RECORD

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On May 5, 2009, Complaint Counsel and Respondents' Counsel agreed – pending approval by the hearing officer – that the attached THE JOURNAL OF THE AMERICAN BOTANICAL COUNCIL, "HerbalGram," No. 81 (Feb-Apr 2009) constitutes the correct and complete Exhibit 1 to Exhibit R18 (Deposition Transcript of James A. Duke), which was provided to the reporter at the deposition but may not have been included in the final hearing record.

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Respectfully submitted,

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Dated: May 6, 2009	Dated: May 6, 2009
[signature]	[signature]
Leonard L. Gordon, Esq. Theodore Zang, Jr., Esq. Carole A. Paynter, Esq. David W. Dulabon, Esq. Elizabeth Nach, Esq. William H. Efron, Esq. Federal Trade Commission – Northeast Region One Bowling Green, Suite 318 New York, NY 10004	James S. Turner, Esq. Michael McCormack, Esq Betsy E. Lehrfeld, Esq. Christopher B. Turner, Esq. Swankin & Turner 1400 16th Street, NW, Suite 101 Washington, DC 20036
Complaint Counsel	Counsel for Respondents

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[PROPOSED] ORDER

The parties having agreed that Exhibit 1 to Exhibit R18 consists of THE JOURNAL OF THE AMERICAN BOTANICAL COUNCIL, "HerbalGram," No. 81 (Feb-Apr 2009),

IT IS ORDERED that

To the extent it is necessary to change the hearing record such that Exhibit 1 to Exhibit R18 shall consist of THE JOURNAL OF THE AMERICAN BOTANICAL COUNCIL, "HerbalGram," No. 81 (Feb-Apr 2009), the hearing record shall be so changed.

ORDERED:

____
D. Michael Chappell
Administrative Law Judge

Dated: May ____, 2009

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on May 6, 2009, I served the attached **RESPONDENTS' STIPULATED MOTION TO INCLUDE EXHIBIT IN HEARING RECORD** upon the following:

The original and two paper copies via hand delivery to:

Donald S. Clark, Secretary
Federal Trade Commission
600 Pennsylvania Ave., N.W., Room H-159
Washington, DC 20580

Two paper copies via hand delivery to:

The Honorable D. Michael Chappell
Administrative Law Judge
600 Pennsylvania Ave., N.W., Room H-528
Washington, DC 20580

Elizabeth K. Nach

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The Journal of the American Botanical Council

Number 81 | February – April 2009

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bilberry extracts to treat diabetic retinopathy, blindness, cataracts, glaucoma, and macular degeneration, with retinopathy showing the most promise.[13] In a meta-analysis of 30 clinical trials on bilberry extract for vision in reduced light, the 4 most recent randomized controlled trials (RCTs) had negative outcomes. However, one RCT and 7 non-randomized controlled trials reported positive effects on outcome measures relevant to night vision.[17] However, the use of bilberry extract for vision in reduced light has been based mainly on anecdotal experience during the Second World War and today is generally dismissed.

The primary application of anthocyanoside-enriched bilberry extracts in ophthalmology focuses on diabetic retinopathy, where bilberry can be used as an adjuvant in combination with conventional pharmaceutical therapies. Bilberry extract improves capillary fragility, reducing vessel proliferation through an anti-angiogenetic mechanism related to the high content of delphinidin. This appears to be a unique property of bilberry compared to most other anthocyanoside-containing, fruit-derived extracts. In diabetic patients bilberry extract improves cicatrisation (healing of a wound by producing scar tissue) of leg ulcers, combining a proteases inhibitory effect with anti-edema (anti-inflammatory) properties.

A recent uncontrolled trial found that a standardized bilberry extract (Myrtoselect®, Indena, Milan, Italy) combined with a patented French maritime pine bark extract (Pycnogenol®, Horphag Research, Geneva, Switzerland) called Mirtogenol® was able to lower ocular pressure in non-glaucoma patients with ocular hypertension.[18] Additional clinical trials have documented the benefits of bilberry extracts in treating venous insufficiency.[13] The concentrated extract also has been evaluated for its possible effects in treating inflamed oral and pharyngeal membranes[12] as well as on painful menstruation.[19]

FUTURE OUTLOOK

Bilberry is currently commercially harvested in several countries including the Russian Federation, Bulgaria, Romania, Sweden, Poland, Ukraine, Finland, Bosnia and Herzegovina, Croatia, Serbia and Montenegro, and Kosovo, among other eastern European countries.[20] Most bilberry (fruit and leaf) is still collected via wild harvest, much of it under organic wild certification (J. Brinckmann, e-mail to M. Blumenthal, November 21, 2008). Some attempts are being made to commercially cultivate the crop in the Northwestern United States; however, most have been unsuccessful thus far.[21] Large-scale efforts to grow bilberry are considered risky and are not recommended; small-scale agricultural trials are appropriate depending on the site.[21]

Owing to the relatively high commercial value of bilberry extracts, intentional adulteration has been detected, not only with anthocyanosides obtained from other plant sources, but even with synthetic dyes, e.g., amaranth dye, a synthetic dye used in foods (*not* related to what is often called "grain amaranth" [*Amaranthus* spp., Amaranthaceae], the increasingly popular food cultivated and marketed for its relatively high protein content.) Analytical methods have been developed to determine such adulteration for use by responsible manufacturers.[22]

—Gayle Engels

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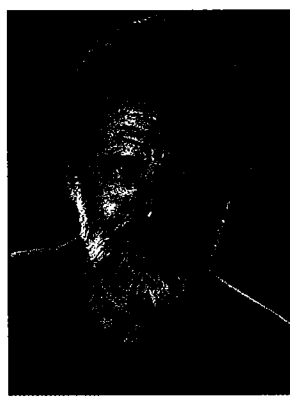

In recent years much has been written and said about the effects of climate change and global warming. Much of this discussion has been characterized by controversy, criticism, and denial. Despite the length and breadth of articles on this vitally significant subject, little has been written about the effects of climate change on the future sustainability of medicinal and aromatic plants. In our cover story, ABC's Courtney Cavaliere covers many geographic regions and consults numerous experts to present possibly the most cogent assessment of this situation to date.

On the clinical research front, there has been controversy in the past decade about the pros and cons of evidence-based medicine (EBM). While not wanting to get into the polemics of this issue (there's simply not space), it is worth noting that numerous systematic reviews and meta-analyses of randomized controlled clinical trials (RCTs) continue to support the safety and clinical benefits of select herbs and phytomedicines.

In our Research Review section, we present two summaries of recent meta-analyses supporting clinical uses of two perennial favorites: garlic for lowering blood pressure and Asian ginseng—in this case, Korean red ginseng—for treating erectile dysfunction. Unfortunately, there was not enough space to include our review of the latest meta-analysis of RCTs on St. John's wort for treating symptoms associated with mild-to-moderate depression. (An HerbClip covering this trial is accessible on the ABC Web site, www. herbalgram.org.) According to all 3 reviews, the bulk of the RCTs support the judicious use of preparations made from these herbs for the respective indications.

The November publication of the Ginkgo Evaluation of Memory trial in the *Journal of the American Medical Association* received predictably widespread media coverage. In this trial on over 3000 subjects (median age about 79 yrs), most of whom were cognitively intact, the administration of 240 mg per day of the world's leading ginkgo extract (EGb 761®, W. Schwabe, Karlsruhe, Germany) did not prevent the onset of dementia or Alzheimer's dementia after 6 years of use. Unfortunately, but predictably, much of the media overlooked the fact that *no* conventional pharmaceutical drug has shown efficacy in preventing these conditions, and that there *are* clinically documented benefits for using ginkgo extract, e.g., *treating* (not preventing) dementia (as well as treating peripheral arterial occlusive disease). In addition, the media did not report that controlled trials have shown that ginkgo extract has been as effective, and safer, as pharmaceutical drugs for such treatment.

This issue of *HerbalGram* also addresses big news on the regulatory front. In late December, the US Food and Drug Administration sent "no objection" letters regarding the GRAS (generally recognized as safe) affirmations of two proprietary stevia extracts produced by Cargill and Whole Earth Sweetener Co., respectively (the latter being a joint venture between Pepsi and Merisant, maker of Equal® brand aspartame). The result will be widespread availability of these, and eventually other, stevia-derived extracts as sweeteners in numerous consumer products. As discussed in the "Dear Reader" column of our previous issue, the safety of many sweeteners made from the South American stevia plant is impressive, and it was high time for the FDA to help millions of consumers gain further access to this safe, low-cost, natural, non-caloric sweetener by approving its use as a food additive. Stevia can become one of the best tools in the so-called war against obesity and its associated complications such as diabetes and related health problems.

Mark Blumenthal

American Botanical Council

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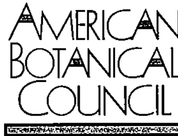

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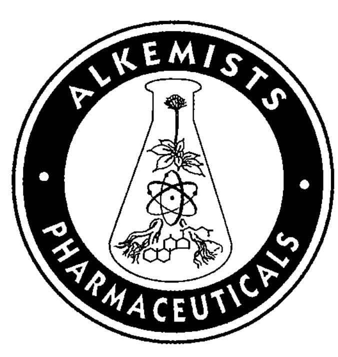

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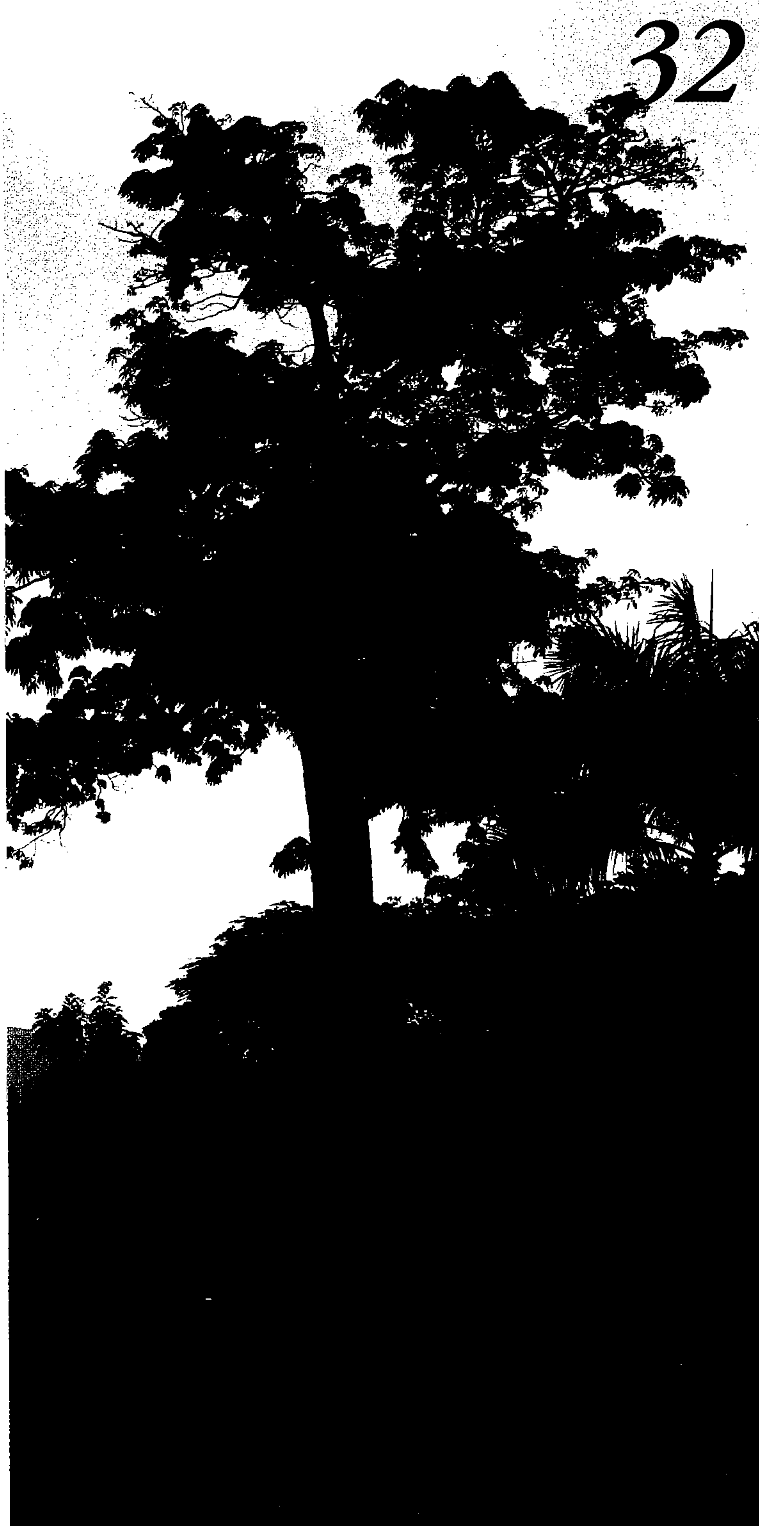

32 **Medicinal Trees of the US Virgin Islands and Neighboring Islands**
By Robert W. Nicholls, PhD

The US Virgin Islands are home to many useful trees, some of which are currently being affected by environmental degradation and a loss of local knowledge of traditional use. This pictorial essay describes 10 trees of the Virgin Islands that have been identified as having traditional medicinal uses. The author recounts some of the decoctions, poultices, and other medicinal treatments derived from the trees and used by inhabitants of the Virgin Islands and neighboring islands. Numerous photographs, meanwhile, illustrate these beautiful natural resources of the islands.

44 **The Effects of Climate Change on Medicinal and Aromatic Plants**
By Courtney Cavaliere

Like all other vegetation on Earth, medicinal and aromatic plants (MAPs) are being affected by climate change. This article explores potential threats that climate change may pose to MAPs of such vulnerable regions as Arctic ecosystems, alpine areas, rainforests, and islands. It further examines widespread effects of climate change that are impacting some MAPs throughout the world, such as changes in the timing of plants' life cycles, the ranges at which plants can thrive, and the frequency and severity of extreme weather events. The article points out that more research should be conducted on this topic, particularly since climate change may raise some significant concerns for the medicinal plant community.

58 **Comparison of Herbal Product Use in the Two Largest Border Communities between the US and Mexico**
By Armando González-Stuart, PhD, and José O. Rivera, PharmD

A recent survey of residents of El Paso, Texas, and Ciudad Juarez, Mexico, has indicated that herbal use by inhabitants of these border communities is particularly high. The authors of this article attempt to explain the possible reasons behind this high incidence of herbal use. They further discuss differences among herbal product providers, herbal products used, and safety concerns associated with herbal use within the 2 locations. An extensive table also identifies some of the principal herbal products sold within both cities.

Silk Cotton at St. George Village Botanical Garden, St. Croix Island.
Photo ©2009 Robert W. Nicholls

departments

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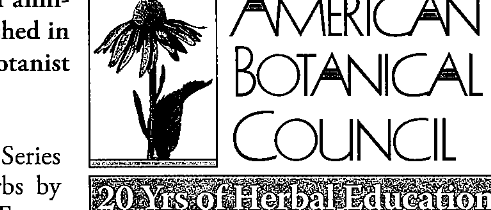
American Botanical Council Reaches 20th Birthday

On November 1, 2008, the American Botanical Council (ABC) observed its 20th anniversary. The independent nonprofit research and education organization was established in 1988 by Founder and Executive Director Mark Blumenthal, along with noted ethnobotanist James A. Duke, PhD, and renowned pharmacognosist Norman R. Farnsworth, PhD.



Dr. Duke is retired from a 30-year career at the United States Department of Agriculture, and Dr. Farnsworth is still research professor of pharmacognosy and senior university scholar at the College of Pharmacy at the University of Illinois at Chicago.

According to Dr. Duke, "Respect for herbal medicine has grown geometrically, thanks in large part to ABC and its peer-reviewed journal *HerbalGram*. Twenty years of ABC have markedly improved public perception of some of the world's best medicines—herbal medicines."

Prof. Farnsworth said, "ABC may be *the* primary force promoting a reasonable and responsible perspective on the emerging science on herbs and medicinal plants. There is no way to adequately measure the significant contribution ABC has made to the health of American consumers."

"ABC was initially created as a vehicle to take *HerbalGram*, then a newsletter, to another level of publication—a full-color magazine-journal format," noted ABC's Blumenthal.

Since those early days, ABC has been at the forefront of herbal educational publications and projects. Some of these include the publication of four volumes of "Classic Botanical Reprints"; the Botanical Booklet Series on individual herbs by botanist Steven Foster (with contributions from Alicia Goldberg and Roy Upton); routine publication of HerbClips, the twice-monthly summaries and critical reviews of recently published scientific and clinical literature; and hosting of the "Pharmacy from the Rainforest" ethnobotany ecotours to the Peruvian Amazon and Andes (with additional trips to Belize, Costa Rica, Kenya, and South Africa), which are continuing education accredited for pharmacists and other health professionals.

Additional projects have included the Ginseng Evaluation Program, the first-of-its-kind large-scale laboratory testing of commercial herbal products for proper identity; ABC's Media Education Program; ABC's Safety Assessment Program, providing safety evaluations of popular herbs for inclusion on commercial herb product labels; ABC's Herbal Information Course for retailers; and ABC's recent acquisition of HerbMedPro, one of the most powerful Internet-based databases on herbal research.

ABC has also published seminal reference books for health professionals and researchers that are often cited and considered highly reliable. These are the extensive, award-winning *The Complete German Commission E Monographs: Therapeutic Guide to Herbal Medicines* (Integrative Medicine Communications, 1998), *Herbal Medicines: Expanded Commission E Monographs* (Integrative Medicine Communications, 2000), *The ABC Clinical Guide to Herbs* (ABC, 2003), and ABC's contribution to enhanced quality control in the herb industry, *The Identification of Medicinal Plants: A Handbook of the Morphology of Botanicals in Commerce* (ABC, 2006; in cooperation with the Missouri Botanical Garden).

"We believe that ABC has reached many of its goals," said Blumenthal. "The use of herbs and botanical products for self-care and in alternative and conventional healthcare has increased tremendously in the past 20 years. We are grateful for the opportunity to have contributed to this growing public recognition and acceptance of herbs as part of everyone's birthright, part of our collective planetary heritage."

"At the same time," he added, "there is much more work to be done. There are many scientific and clinical studies that continue to underscore the traditional uses and health benefits of hundreds of herbs. And modern research and technology are finding new, previously unrecognized health benefits for many traditional herbal medicines."

Blumenthal is optimistic about the future of herbs and the future of ABC. "With the growth of public acceptance and use of herbs and other natural plant-based preparations, ABC will have a busy agenda and many more challenges for many years to come." HG

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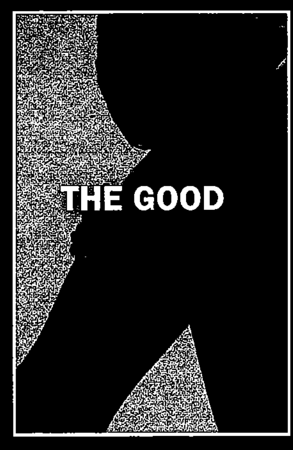

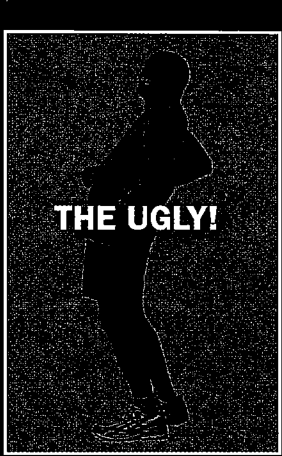

THE GOOD NEWS...
Inflammation is a wellness "buzz word" these days. Reducing inflammation not only can make you look and feel younger, but it also can significantly lower your risk for chronic disease.

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† Watson et al., (2007) Nutr Res, 27:692-697
†Belcaro et al., (2008) Redox Report,13(6): 271-276.
†Cisar et al., (2008) Phytother Res, 22(8): 1087-1092.
††For a complete list of scientific research and further information visit our website at **www.pycnogenol.com**

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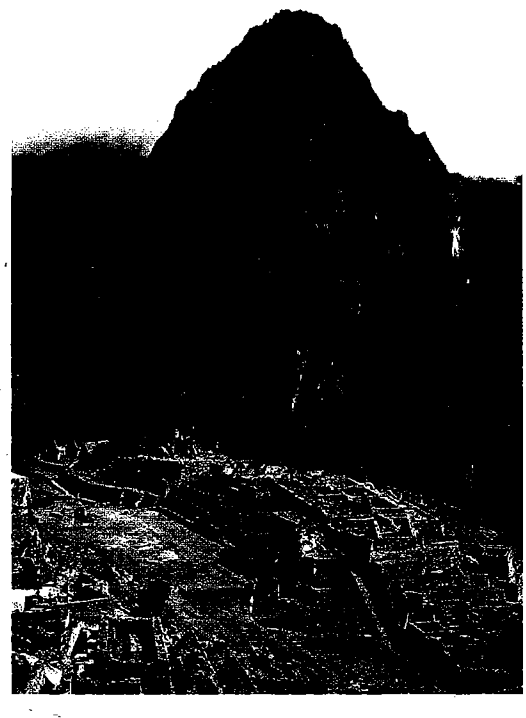
Date set for ABC's 2009 Peruvian Amazonia and Andes Botanical Medicine Trip

All photos ©2009 Steven Foster

By Steven Foster

Each year since 1994, the American Botanical Council (ABC) and the Amazon Center for Education and Environmental Research (ACEER) have co-sponsored ethnobotanical ecotours to the Peruvian Amazon and Andes, introducing hundreds of travelers to the medicinal plants and varied cultures of Peru. Now it's your turn. From October 1–10, 2009, join noted herbalists and authors Rosemary Gladstar, Mindy Green, and Steven Foster for an unforgettable Peruvian adventure. We begin in the southern Peru rainforest, near the Bolivian border—Inkaterra Reserva Amazonica, a 17,000-hectare (42,000 acre) private ecological research reserve adjacent to the lush Tambopata National Reserve. This remote, yet easily accessible venue on the Madre de Dios River, a large tributary of the Amazon, is where famed Harvard biologist E.O. Wilson conducted seminal research on ant ecology. Our "home" in Amazonia, Inkaterra Lodge, located on the banks of the Madre de Dios, is about a 45-minute boat trip from the southern Peruvian city of Puerto Maldonado. One might describe Inkaterra Lodge as a cross between a scout camp and a 4-star luxury hotel. Thirty private cabanas, modeled on traditional Amazon housing, feature low-impact electricity, kerosene lanterns, and hot showers. Any preconceived anxieties of "camping" in the Amazon rainforest are quickly dissipated after a complimentary pisco sour—the national drink of Peru—then slipping between crisp cotton sheets for a good night's rest. We will explore local markets, visit the Inkaterra Canopy Walkway (a series of 7 suspended walkways 100 feet above the forest floor, providing an unparalleled opportunity to view and study plants, birds, and primates in the forest canopy), hike to the oxbow Sandoval Lake with a chance to see the endangered Amazon giant otter, and explore medicinal plants at the Jardín de Plantas Medicinales with traditional Amazonian Shaman Antonio Montero Pisco. After 4 nights in Amazonia, we take a short 30-minute flight to the Andean city of Cusco, possibly the longest-inhabited city in the Western Hemisphere and the heart of the Inca Empire. From Cusco we head to the Urubamba Valley on the way to Machu Picchu. The must-see extraordinary ruins of plazas, palaces, and temples are nestled at 8,000 feet, surrounded by a wide diversity of flora and fauna. More than 1000 species of orchids are found within the Machu Picchu Sanctuary, as well as a wide variety of ferns, begonias, palms, and bromeliads. After several unforgettable days in the Sacred Valley at Aguas Calientes, we take the train back to Ollantaytambo to explore the traditional healing practice of the Andes, led by our guide and a *curandero* from the Sacred Valley. The Andes segment concludes with a day in Cusco, then back to the capital city Lima for the return home. The approximate cost is $3,309 plus airfare to Lima. For more information and a complete itinerary, contact: Mary Ann Robinson, ACEER program coordinator: MRobinson@WCUFoundation.org. HG



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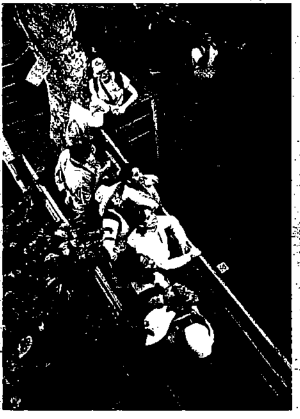

Employee Profile: Tamarind Reaves

Reaves

Tamarind Reaves, whose first name is derived from a beautiful tropical tree, is a welcome recent addition to the ABC staff. Tamarind is ABC's receptionist. Here at ABC, we could let our phones default to a voicemail system, like so many other nonprofits and businesses have done for over a decade. Not here. During our normal business hours we want a real, live person to answer calls from ABC's members—researchers, educators, healthcare providers, journalists, industry members—and many other members of the public who call ABC each day. Tamarind performs this function beautifully, with a genuinely friendly and inviting personality.

She further provides many other critically important services for ABC. While Tamarind spends most of her time answering the phone, fielding ABC member questions and problems, helping callers with information, and routing calls to other ABC staff members, she also spends her day opening incoming mail and distributing it to various ABC staff members, greeting visitors, processing membership benefits, mailing out membership packets to new and renewing ABC members, updating member contact information into ABC's databases, and maintaining ABC's extensive Web calendar of professional education and industry events around the world.

Tamarind also assists in the copy-editing of ABC's HerbClips, and she copies and scans articles from incoming magazines and scientific journals for HerbClip and ABC's literature database, among even more administrative duties. One of the "fun" aspects of her job is that she gets to digitally scan recently published cartoons for use in some of my forthcoming presentations!

Tamarind comes to ABC with a varied background. She has worked at a biotech company, a private investigation business, and a nonprofit organization. As a college student studying English, she assisted disabled students by taking notes for students in classes, helping them prepare for tests and exams, and assisting them in various extracurricular activities.

She notes the synchronicity of her profile's being published in this issue: "I am thrilled that ABC is publishing the employee profile on me in the same issue of *HerbalGram* that contains the article on trees of the Virgin Islands. I was born in St. Thomas, USVI, and that is where my mom fell in love with the tamarind trees and fruit." HG

—Mark Blumenthal

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Noted Herbal Author/Photographer Steven Foster Elected Chair of ABC Board of Trustees

Drs. Roberta Lee and Bernadette Marriott Named New Board Members

The Board of Trustees of the American Botanical Council (ABC) has elected Steven Foster as its new chair. Foster, a member of the ABC Board for 10 years, is the author of 15 herb-related books and hundreds of magazine articles, and he is widely known for his stunning botanical photography. The Board made its selection at a recent onsite meeting at the ABC headquarters in Austin, Texas. Foster succeeds former chair Peggy Brevoort, who is remaining on the ABC Board.

"Steven Foster has made many significant contributions to ABC, since the time of its founding 20 years ago," said ABC Founder and Executive Director Mark Blumenthal. In addition to acting as the associate editor of ABC's flagship publication *HerbalGram* for two decades, his articles and photography have helped to make it one of the leading publications on herbs in North America, and beyond. In addition, Steven was the editor of ABC's Classic Botanical Reprint series in its early years, as well as the author of more than a dozen titles in ABC's Botanical series, which consisted of in-depth profiles on many of the most popular herbs in the North American market. (An extensive profile on Foster was published in *HerbalGram* #80.)

"It's an honor to serve as the chair of the ABC Board of Trustees, especially given the high level of experience and diverse organizational, academic, and business expertise, represented by the Board's members," said Foster. "This is an exciting time for ABC, with the launch of our new Web site and recent staff additions of energetic and talented people who can enhance service to our most important constituency—the ABC membership. These changing and challenging times require a renewed focus in optimizing the success of herbs in contributing to healthcare, and bringing that message to the public, media, academia, and the greater herbal community."

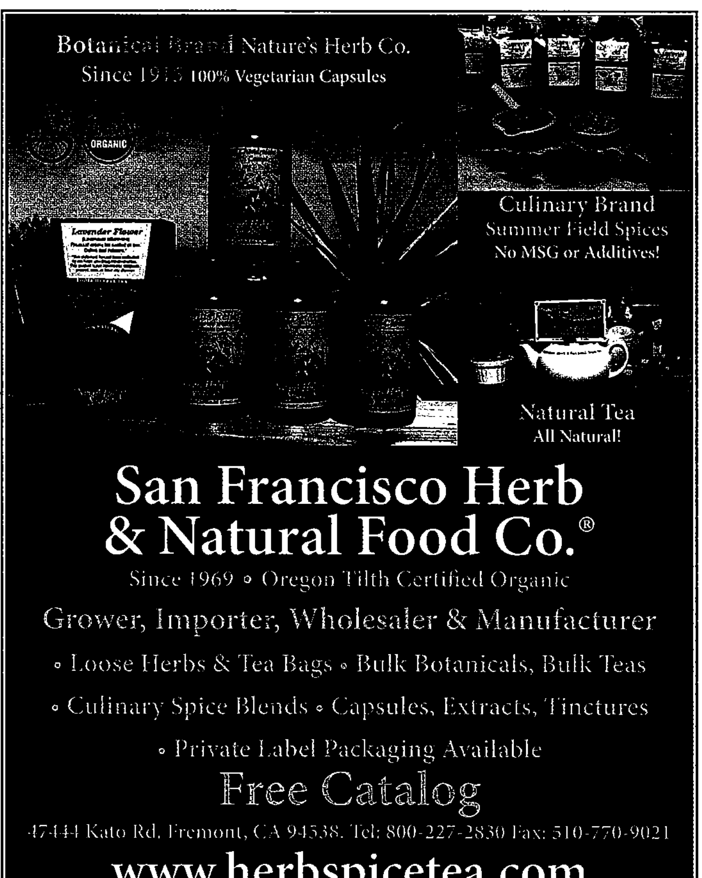
Steven Foster

The ABC Board also selected Roberta A. Lee, MD, and Bernadette M. Marriott, PhD, to serve as new Board members. Both have extensive experience with herbs and dietary supplements.

Dr. Lee is medical director for the Continuum Center for Health and Healing at the Beth Israel Medical Center in New York City. She was among the first 3 fellows at the University of Arizona Medical School's Program in Integrative Medicine under the direction of the famous author and integrative medicine expert, Andrew Weil, MD (who is also a member of the ABC Advisory Board). Dr. Lee has been interviewed in print and on the Internet and has appeared on the *Today* show, Fox news, CBS, and CNN.

In addition to her clinical experience, Dr. Lee has also been involved with ethnobotanical field work, particularly in the South Pacific islands of Micronesia with noted ethnobotanist Michael J. Balick, PhD, of the New York Botanical Garden (also a member of the ABC Board of Trustees). Drs. Lee and Balick have collaborated on numerous ethnobotanically-oriented articles for peer-reviewed journals (e.g., *Alternative Therapies* and *Explore!*). Dr. Lee is currently developing

Dr. Roberta Lee



new strategies for stress management that incorporate a unique blend of mind/body exercises, lifestyle changes, and botanical supplements. Her book, *The SuperStress Solution*, will be published by Random House in the fall of 2009.

"It's truly a privilege to join the ABC Board of Trustees," said Dr. Lee. "I am looking forward to contributing to ABC's mission of expanding awareness of botanical medicines. There are so many new scientific studies being released about botanical medicines, suggesting that plants can continue to serve as a great pharmaceutical reservoir for unanticipated diseases of the future and to provide new remedies for complex medical syndromes."

A nutritional biochemist and psychologist, Dr. Marriott was the first director of the Office of Dietary Supplements (ODS) at the National Institutes of Health, mandated under the Dietary Supplement Health and Education Act of 1994. As the first director of ODS, Dr. Marriott was responsible for surveying and collecting information on all US federal government-funded research on dietary supplements (vitamins, minerals, amino acids, herbs, and related substances), as well as coordinating and stimulating future research in this area. Prior to her work at the ODS, Dr. Marriott was deputy director of the Food and Nutrition Board at the Institute of Medicine, where she contributed to the initial development of the Dietary Reference Intakes for Americans.

Dr. Bernadette Marriott

Dr. Marriott is currently a principal scientist with Abt Associates Inc. in Durham, North Carolina, where she focuses on domestic health, developing an area of expertise for the company in nutrition, diet, and chronic disease. She serves on the boards of scientific advisors for several universities and is also an adjunct professor at the University of North Carolina at Chapel Hill Department of Nutrition. Dr. Marriott has published numerous articles in journals like the *American Journal of Clinical Nutrition* and *Advances in Experimental Medicine and Biology*, as well as written chapters in books like *Examining the Science Behind Nutraceuticals* (Springer, 2001) and *Dietary Supplements of Plant Origin: A Nutrition and Health Approach* (Taylor and Francis, 2003). "I am very honored and enthusiastic about the opportunity to work with Mark Blumenthal and the Board members," said Dr. Marriott. "The American Botanical Council has been an important educational leader in the United States for the last two decades and was instrumental in first awakening American scientists to the wealth of herbal research in other parts of the world. I look forward to the chance to support the excellent activities of ABC as a member of the Board." HG

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AHPA Issues New Trade Recommendation on the Definition of "Extract" and Guidance on Heavy Metal and Microbiological Limits

The American Herbal Products Association (AHPA) issued a new trade recommendation regarding the definition of "extract" in October 2008, as well as guidance on establishing heavy metal and microbiological limits for herbal products.[1]

"These measures were developed at the committee level and represent the community's commitment to self-regulation and the association's dedication to providing industry with tools to meet current good manufacturing practices and conduct responsible commerce in herbal products," said AHPA President Michael McGuffin, in an AHPA press release.[1] "We are proud to support industry with this good work."

According to the new trade recommendation, use of the word "extract" in the labeling of herbal ingredients should not be used to describe dehydrated plant materials that have not undergone additional processing (beyond size reduction). AHPA explained that an extract is the result of some processing of a raw agricultural commodity, such as maceration, distillation, or steeping.

This new recommendation, like all AHPA trade recommendations, is considered an amendment to AHPA's Code of Ethics and Business Conduct. All AHPA members are required to conform to the organization's Code in order to maintain their membership in good standing.

In addition to the new trade recommendation, AHPA has adopted an interim guidance with quantitative limits of certain heavy metals that may be present in herbal supplements. AHPA has recommended the following limits for botanical-containing finished products consumed at a total daily amount of 5 grams or less: 10 µg per day of inorganic arsenic, 4.1 µg per day of cadmium, 10 µg per day of lead, and 2 µg per day of methylmercury. If the highest labeled dose of a supplement is over 5 grams, heavy metal limits should be established at appropriate levels under current good manufacturing practices (cGMPs), according to AHPA.

AHPA further adopted as guidance a recommendation that manufacturers and marketers of non-liquid dietary supplements establish specifications under cGMPs for microbiological limits of certain substances, such as yeasts and molds, salmonella, *Escherichia coli*, and others. AHPA has provided a few suggested limits for these substances, although the organization has also stipulated some limitations and conditions that manufacturers can apply when referring to the guidance.

More information about the trade recommendation and guidance, as well as AHPA's Code of Ethics and Business Conduct, is available from AHPA's Web site. HG

—Courtney Cavaliere

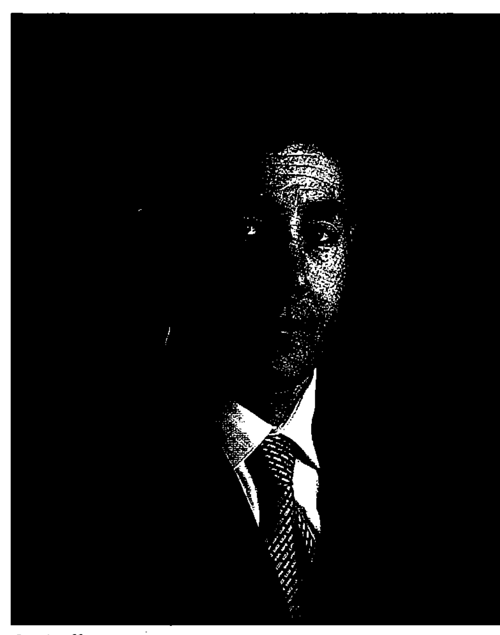
Reference

1. AHPA adopts new trade recommendation; guidance on heavy metal, microbiological limits [press release]. Silver Spring, MD: American Herbal Products Association; October 24, 2008.

CRN Appoints Duffy MacKay, ND, to Scientific Staff

The Council for Responsible Nutrition (CRN), a leading trade association for the dietary supplement industry, announced the addition of a new member to its team of scientists in September 2008.[1] Douglas (Duffy) MacKay, ND, now serves as a new vice president of regulatory and scientific affairs for CRN.

"We are extremely excited to welcome Dr. MacKay to our staff," said CRN President and CEO Steve Mister, according to a CRN press release.[1] "As a licensed naturopathic doctor, he adds an impressive combination of theoretical and practical expertise to our scientific team."



Dr. Duffy MacKay

Prior to joining CRN, Dr. MacKay served for 4 years as the vice president of clinical research at Nordic Naturals, a respected producer of fish oil-based dietary supplements. In that position, he was responsible for product formulation, coordinating clinical trial research, serving as a technical/medical advisor, and managing the company's Adverse Event Reporting (AER) system, among other duties. Other previous work experiences include serving as senior technical advisor for Thorne Research (a manufacturer of dietary supplements for health professionals) and senior editor of the journal *Alternative Medicine Review*. He also co-owned and practiced naturopathic medicine at the Makai Naturopathic Center in New Hampshire for 7 years. He has a bachelor's degree in marine sciences from the University of California at Santa Cruz and a degree in naturopathic medicine from the National College of Naturopathic Medicine in Portland, Oregon.

"My career path thus far has included facilitating research, formulating products, writing [Dietary Supplement Health and Education Act] compliant marketing material, and working with manufacturers," said Dr. MacKay (e-mail, September 29, 2008). "All of this was done at the same time I was working directly with patients and getting a first-hand perspective on how they are impacted by the dietary supplement industry. I have observed the whole spectrum of the industry on consumers. I have seen supplements dramatically improve the health and lives of hundreds, but also have observed consumers fall prey to false and misleading advertising claims."

He continued: "As a naturopathic doctor, I felt a duty to take my next career step and to attempt to influence the future of health as we know it. My role at CRN will allow me to indirectly support my many colleagues that practice integrative medicine, as well as the millions of Americans that take dietary supplements. In addition, my first hand experience within supplement companies and in patient care will bring a new perspective and energy to CRN."

Dr. MacKay is to serve as CRN's resident expert on botanicals. He will assist other key CRN staff members in interpreting and contributing to the science surrounding dietary supplements and nutrition, as well as advising, educating, and representing CRN's members on regulatory matters that impact the industry.

"I have many goals to accomplish while at CRN," said Dr. MacKay. "I have a particular interest in the area of botanical medicine. Herbs are complex entities and our scientific understanding of how they influence human health is in its infancy stage. My goal is to continue to promote and shape guidelines that facilitate the safety and efficacy of botanical products. At the same time, I would like to be a voice of reason that helps to preserve the many time-honored and widely varied approaches to using herbal products. There is danger in over-emphasizing randomized placebo-controlled trials as the only means to establishing efficacy. Herbs are far too complex to solely rely on the reductionist models and thinking of conventional medicine to validate efficacy."

He added that he would also like to help researchers establish more validated risk biomarkers. Dr. MacKay explained that the availability of additional risk biomarkers would eliminate the need to continue some research studies until a disease endpoint has been reached. For instance, if a study were to show that a product increases bone density, the researcher could profess that the product decreases the risk for osteoporosis. It would eliminate the need to continue the clinical trial until osteoporosis sets in. According to Dr. MacKay, this would significantly reduce research costs and could help to quickly expand understanding of natural products on human health.

"Medicine is clearly moving toward an integrated model that includes dietary supplements as a key tool to staying healthy," said Dr. MacKay. "Change is happening—the research and science supporting natural products is prolific, [complementary and alternative medicine] is being taught at most conventional medical schools, and the public is demanding more options. As a licensed naturopathic doctor with my unique and various experiences, I felt a duty to get involved on a deeper level. I was thrilled that CRN acknowledged my training and experience by extending me a job offer." HG

—**Courtney Cavaliere**

Reference

1. CRN welcomes new scientist to its team [press release]. Washington DC: Council for Responsible Nutrition; September 9, 2008.

New Naturex Foundation Assisting Local Communities in Morocco and Peru

The botanical extraction company Naturex, based in Avignon, France, announced the opening of its new corporate foundation in September 2008.[1] The Naturex Foundation, created in March 2008, will support projects in countries from which Naturex derives its plant materials.[2]

"Our corporate foundation is a long-term engagement and an extension of our long-standing commitment to responsible corporate citizenship and sustainable development," said Jacques Dikansky, president and CEO of Naturex and president of the Naturex Foundation, according to a Naturex press release.[1] "Although Naturex has already been involved in several sustainable initiatives since its creation, we upgrade to an upper level with the opening of our corporate foundation."

"For Naturex, the foundation is a line in the sand," said Chris Kilham, founder of Medicine Hunter Inc. and member of the foundation's consulting committee (e-mail, November 3, 2008). "It shows a real and practical commitment to communities from whom it derives botanicals and demonstrates real leadership in benefit sharing. Basically, Naturex is voluntarily upholding practices and principles outlined in the international Convention of Biological Diversity. I admire Naturex for stepping up and putting resources into this foundation."

> "Although Naturex has already been involved in several sustainable initiatives since its creation, we upgrade to an upper level with the opening of our corporate foundation."

The foundation has already made a commitment to support 2 community projects. In partnership with the France-based charitable association AgriSud International, it will help fund a project to set up farms to facilitate social and economic advancements for disabled young persons of the Moroccan countryside. The foundation has also partnered with the nonprofit Peruvian association Kalisayas Out Reach to upgrade and improve the dental office and school within the Peruvian town of Ninacaca, as well as provide the town with an Internet center.

"Morocco and the Peruvian

highlands are areas from which Naturex derives significant quantities of beneficial botanicals, and in which the company also has excellent community relations," said Kilham. "Starting out funding projects in these areas makes good practical sense and honors the contribution that these areas make to the global Naturex business."

Naturex sources several botanical extracts from Morocco, including such wild-harvested culinary and medicinal botanicals as rosemary (*Rosmarinus officinalis*, Lamiaceae), thyme (*Thymus vulgaris*, Lamiaceae), hawthorn (*Crataegus* spp., Rosaceae), and chasteberry (*Vitex agnus-castus*, Verbenaceae), and such cultivated botanicals as olive (*Olea europaea*, Oleaceae), artichoke (*Cynara scolymus*, Asteraceae), and pomegranate (*Punica granatum*, Punicaceae). "Naturex has a large extraction facility in Casablanca, on the main prolific plain of Morocco, which provides privileged access to abundant raw materials of great quality," said Antoine Dauby, secretary of the Naturex Foundation (e-mail, October 10, 2008). "This location has strengthened Naturex's relationship with the Berber and other people who harvest and prepare these herbs."

The main botanical that Naturex obtains from Peru is maca (*Lepidium meyenii*, Brassicaceae). "Naturex sources maca in the central Peruvian highlands, relying on partnerships with local growers," said Dauby. "Work conducted by Naturex over the past 10 years has helped to transform maca from an unknown herbal product to a well established herbal product in the United States and other countries. This has resulted in economic benefits to the people of the Peruvian highlands."

According to Dauby, Naturex has allocated a total budget of 150,000 euros (approximately $192,800 USD) to fund projects during the foundation's first 5 years. Kilham explained, "These projects and others will go on for 5 years. Then the foundation's activities will be formally scrutinized by government agencies. If Naturex has fulfilled its commitments by law, then the foundation will carry on." He added, "It will definitely carry on."

Persons who represent a project in line with the foundation's values and intervention fields are encouraged to fill out a project submission form from the foundation's Web site (www.foundation.naturex.com).[3] The foundation may choose to support submitted project proposals, pending approval by the executive board and subject to a partnership agreement.

"The Naturex Foundation is a good start," said Kilham. "It will be successful not only for its projects, but hopefully for influencing other profitable companies to do the right thing and share benefits with communities from which resources are derived. Benefit sharing is not gift-giving. It is an essential component of honest business."

Naturex was founded in 1992 in France, and it purchased the US botanical company PureWorld Inc., in 2005. More information about Naturex is available at www.naturex.com. HG

—**Courtney Cavaliere**

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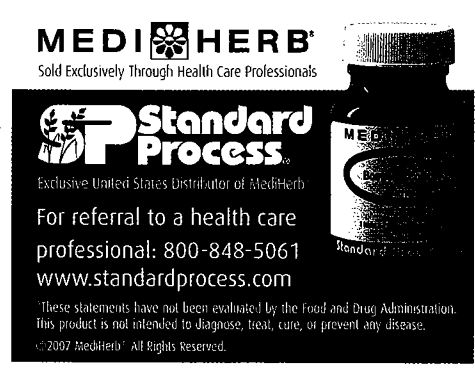

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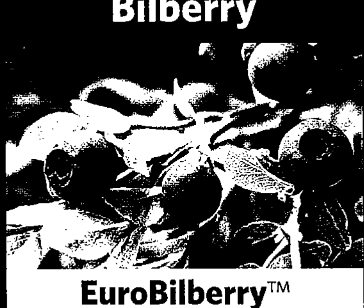
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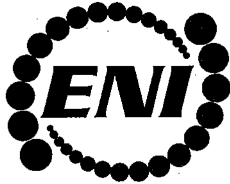

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A Century of Herbal Innovation: Indiana Botanic Gardens Celebrates 100 Years

By Deborah S. Ramstorf

The year was 1910. The first yellow cab rolled onto the street, a quart of milk cost only 8 cents, and the first live musical radio performance hit the airwaves. This was also the year that Joseph E. Meyer established Indiana Herb Gardens, now known as Indiana Botanic Gardens, Inc, in a small shed behind his home.

From Tragedy to Triumph

The seed that would later flower into the Indiana Botanic Gardens was planted early in Joseph's life. Born in Kenosha, Wisconsin, on September 5, 1878, Joseph used to accompany his father, a photographer, on excursions into the country. While his father took pictures, Joseph wandered the forests and fields, fascinated by the enormous variety of grasses, plants, trees, and flowers.

After a series of family tragedies, including the death of his father, Joseph landed in an orphanage. There he passed lonely hours reading and re-reading a single medical book, especially intrigued by the section on herbal remedies. He was surprised to learn that those plants that many people considered to be worthless weeds had been used throughout all of time for the treatment of various diseases. He soon dreamed of starting an herbal company. But it wasn't until decades later, after starting a family and spending years in the printing business, that the dream was able to come to fruition. Funding for the company was obtained through the sale of his first literary effort, *The Sealed Book,* an exposé on popular gambling schemes.

In time Joseph purchased land along the Little Calumet River in Hammond, Indiana. It was an herbalist's dream with a profusion of medicinal plants, native flowers, and virgin forests. It also appeared to have been an ancient Native American burial site, as several relics were found. This fact, coupled with Joseph's admiration of Native American natural remedies, directly influenced the company's early logos and artwork.

The Early Herb Market

Until the early 20th century, major drug companies (companies that would eventually evolve into some of today's large pharmaceutical companies) supplied roots, bark, flowers, or leaves of dried plants and trees, in cut or powdered forms, to be dispensed by doctors and pharmacists. After that point, many medicines from nature, once considered "official," began to be supplanted by drugs made with synthetic chemicals that could be produced under laboratory conditions and for increasingly specific uses and controlled dosages. Traditional botanical medicines, often more general in effect and taking longer to act, were steadily falling into disuse.

Joseph E. Meyer, Founder Indiana Botanic Gardens, 1878-1950. Image ©2009 Indiana Botanic Gardens

According to Tim Cleland, great-grandson of Joseph Meyer and current president of Indiana Botanic Gardens, from its very beginning the company carried over 400 different herbs—from alder (*Alnus serrulata*, Betulaceae) to yohimbe (*Pausinystalia johimbe*, Rubiaceae)—that were available in 25-cent boxes or sold in bulk.

Originally published in 1918, *The Herbalist* is now in its tenth reprinting. Image ©2009 Indiana Botanic Gardens

The herbs were listed according to their therapeutic properties under various general headings: "digestants, intestines, vermifuges, ulcers, diarrhea, liver, Bright's disease, hemorrhage, tonics," etc. Recipes were included for making shampoos, lotions, pomades, liniments, creams, ointments and salves. Any requested mixtures could be provided to resellers for orders "of not less than 10 pounds of any kind desired."

At first, the business barely made living expenses. Meyer's 7 sons and 1 daughter helped gather herbs, pack boxes, fill orders, feed the printing press, and fold circulars. Many evenings the family put catalogs together with needle and thread. With the publication of the over 400-page book *The Herbalist and Herb Doctor* in 1918, the business expanded.

The First-Ever *Herbalist* and *Almanac*

The Herbalist and Herb Doctor, which is now in its 10th reprinting, details plants from *Aloe vera* (Liliaceae) to zedoary (*Curcuma zedoaria*, Zingiberaceae), explaining their common names, botanical descriptions, medicinal parts, and uses and doses. It contains illustrations and color plates for many of the described plants. This popular herb book is largely based on Dr. O. Phelps Brown's *The Complete Herbalist; or, the People Their Own Physicians,* published by the author in Jersey City, New Jersey, in 1865 (with editions continuing to at least 1907).

In 1925 Indiana Botanic Gardens began producing an annual publication, *The Herbalist Almanac,* a condensed and updated version of *The Herbalist and Herb Doctor,* which also served as the first-ever product catalog. By this time, retail customers, more than agents, had become the heart of the business and the leading force behind the company's growth. In an age where medical expertise was not always readily available or affordable, *The Herbalist Almanac* offered the public valuable medical information on most of the common ailments of the day—including malaria, tape worms, rheumatism and more—along with herb descriptions, remedies, recipes, and customer testimonials.

Over the next few years, Joseph traveled to all parts of Europe and North America gathering samples and information on many types of medicinal plants, many from Native Americans. The *Herbalist Almanac* gained in popularity and mail poured in from all over the world, including from universities, libraries, botanists, and people from all walks of life, both contributing to and seeking information. Today Indiana Botanic Gardens, Inc. is still a source of information on herbal matters for thousands of people.

A Tradition of Loyal Customers

In 1910 self-treatment with herbs was commonly practiced and often necessary due to economic conditions and the scarcity of professional medical help. Indiana Botanic Gardens' early customers included a variety of ethnic minorities, including newly-arrived European and South American immigrants as well as African Americans, Amish, rural inhabitants who did not have easy access to medical doctors or clinics, and those who sought traditional ways of self-medication used by earlier generations. Today, some of the company's current customer base includes the sons and

Cover of *The Herbalist Almanac* first printed in 1925. Image ©2009 Indiana Botanic Gardens

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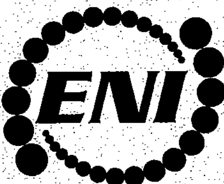

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grandsons, daughters and granddaughters of past customers. This is a significant reason why Indiana Botanic Gardens has reached the 100-year milestone.

The Legacy Continues

Very few businesses reach their 100-year anniversary. When asked about their key to success, Tim Cleland says, "Our family practices what we preach—we believe in a natural approach to health. We think this is the reason we have so many family members living actively and enjoying life well into their 80s and 90s."

Built in 1925 specifically for Indiana Botanic Gardens, this English-gabled structure known as the "Hammond building" was home to the company until 1990. Image ©2009 Indiana Botanic Gardens

The family's commitment to a natural lifestyle is one they share with the public as well. The Joseph E. Meyer Memorial Pavilion, located in the Taltree Arboretum & Gardens on the southern shores of Lake Michigan, was a gift from the Florence Melton family. Florence Melton was the sole daughter of Joseph E. Meyer. Dedicated in 2002, the Pavilion was the first building erected in Taltree. Its serene lakeside setting surrounded by native trees, plants, and herbs, is a popular site for summertime concerts, classroom field trips, seminars, retreats, weddings, and other events. The arboretum itself is a 300-acre preservation of wood plant collections, gardens, wetlands, woodlands, and prairies for education, research, and enjoyment.

While the herbal industry itself has changed in the past 100 years, some aspects of the business have not, nor does Tim Cleland expect them to change. He predicts, "Just like in 1910, we'll continue to focus developing state-of-the-art herbal remedies that improve the health and lives of those who seek a natural approach." HG

Deborah S. Ramstorf is the copywriter for Indiana Botanic Gardens, Inc., Hobart, Indiana, www.botanicchoice.com

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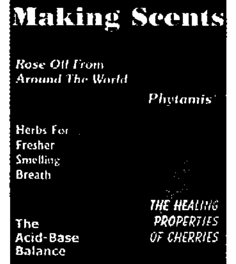
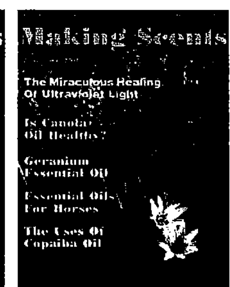
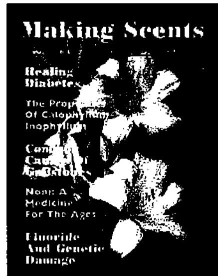
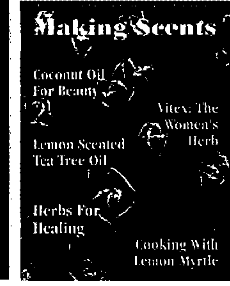
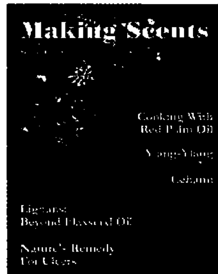
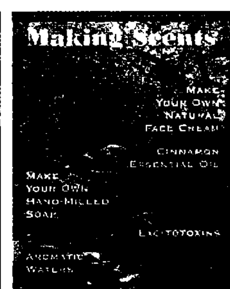












Biological Activity of Curcuminoids from Turmeric Assessed in Patients with Advanced Pancreatic Cancer

Reviewed: Dhillon N, Aggarwal BB, Newman RA, et al. Phase II trial of curcumin in patients with advanced pancreatic cancer. *Clin Cancer Res.* 2008;14(14):4491–4499.

Pancreatic cancer is almost always lethal, and most patients die within 1 year of diagnosis. The only drugs approved by the Food and Drug Administration that are currently available for treatment are gemcitabine and erlotinib. Both of these drugs elicit responses in only a small percentage of patients (less than 10%), and their effect on survival is measured in weeks. Thus, effective treatments are urgently needed. Many studies have shown that nuclear transcription factor-κB (NF-κB) is activated in patients with pancreatic cancer; therefore, an agent that targets NF-κB may prove effective in the treatment of this disease.

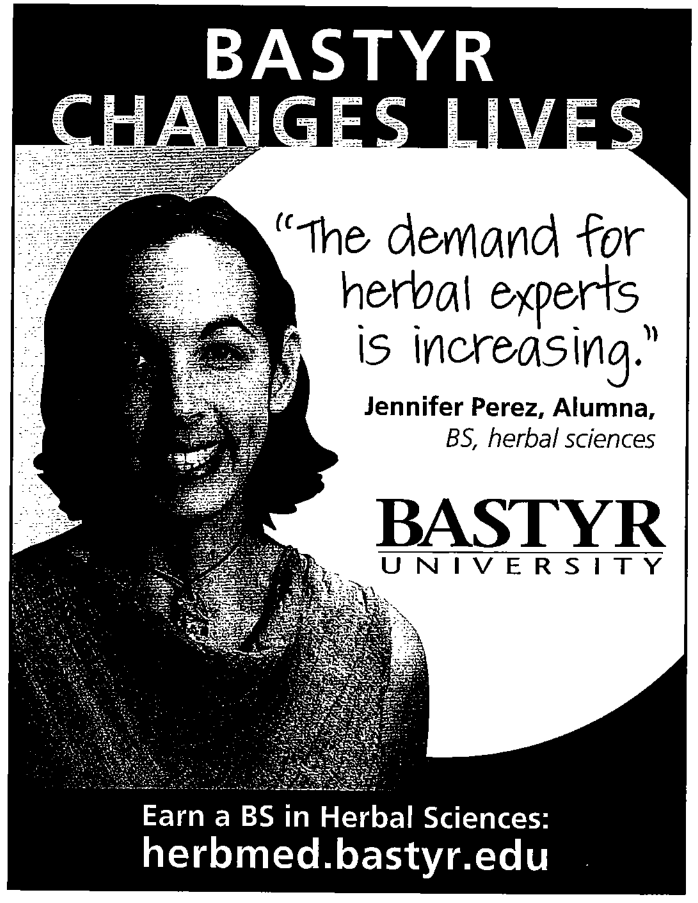
Previous laboratory research has shown that curcuminoids, a group of compounds derived from the traditional herb and spice turmeric (*Curcuma longa*, Zingiberaceae), suppress NF-κB activation, cell growth associated with apoptosis (programmed cell death), and the growth of human pancreatic cancer xenografts in mice. These curcumoinds are curcumin, desmethoxycurcumin, and bisdesmethoxycurcumin. Phase I human clinical trials of curcuminoids have shown that they are safe at doses up to 8 g/day but that their oral bioavailability may be poor. Thus, this phase II clinical trial was undertaken to determine whether orally administered curcuminoids have biological activity in patients with advanced pancreatic cancer.

Twenty-five patients (13 men, 12 women; aged 43-77) with histologically confirmed pancreatic cancer and a Karnofsky performance score greater than 60 were enrolled in this nonrandomized, open-label, phase II trial, which was conducted at the University of Texas M.D. Anderson Cancer Center in Houston, Texas. As controls, cytokine levels were measured in 48–62 healthy volunteers depending on the cytokine assessed. The patients ingested a daily dose of 8 g of curcuminoids in capsule form (1 capsule = 1 g curcuminoids [900 mg curcumin, 80 mg desmethoxycurcumin, and 20 mg bisdesmethoxycurcumin]; Sabinsa Corp., Piscataway, NJ). Concomitant chemotherapy or radiotherapy was prohibited, but supportive care was allowed. Disease staging, a physical examination, and blood sampling were performed at baseline and at 4 and 8 weeks. Blood samples were used to measure the following values: cytokine concentrations (interleukin-6, -8, -10, and interleukin-1 receptor antagonist), carcinoembryonic antigen concentrations, and peripheral blood mononuclear cell expression of NF-κB and cyclooxygenase-2 (COX-2). The adverse events were assessed on the basis of the National Cancer Institute Expanded Common Toxicity Criteria (http://ctep.cancer.gov/forms/CTCAEv3.pdf), and tumor response was evaluated on the basis of the Response Evaluation Criteria in Solid Tumors.

Twenty-four patients were available for the toxicity evaluation, and 21 patients were available for evaluation of the response to treatment with curcuminoids. Circulating concentrations of curcumin in blood serum were low, which indicated poor oral bioavailability. However, 2 patients exhibited a favorable response to curcuminoids. Pancreatic cancer remained stable in 1 of these patients for greater than 18 months. "Marked" tumor regression (73%) and significant ($P < 0.05$) increases in serum interleukin-6, -8, and -10 and in interleukin-1 receptor agonist were observed in the other patient. NF-κB activation decreased with curcuminoids treatment, but not significantly compared with the healthy controls. COX-2 expression decreased significantly ($P < 0.03$) with curcumin treatment. Blood concentrations of curcumin peaked at 22–41 ng/mL and remained relatively constant over the first 4 weeks of the study. Carcinoembryonic antigen concentrations decreased gradually over 1 year in 1 patient, which indicated an improvement in cancer status. No treatment-related toxicity was observed.

The results of this study indicate that orally administered curcuminoids are tolerated well at doses of 8 g/day for up to 18 months and have "biological activity in some patients with pancreatic cancer." Although curcumin was poorly absorbed, biological activity (i.e., tumor regression and increase in cytokine concentrations) was evident at steady-state. Because curcumin is hydrophobic (i.e., not water soluble), it cannot be administered intravenously unless encapsulated in a liposome, which would presumably result in higher circulating concentrations of curcumin in the blood. The authors intend to conduct clinical trials in pancreatic cancer patients with the use of liposomal curcuminoids, which they hope will result in more consistent blood concentrations of curcumin and a better pharmacologic effect. HG

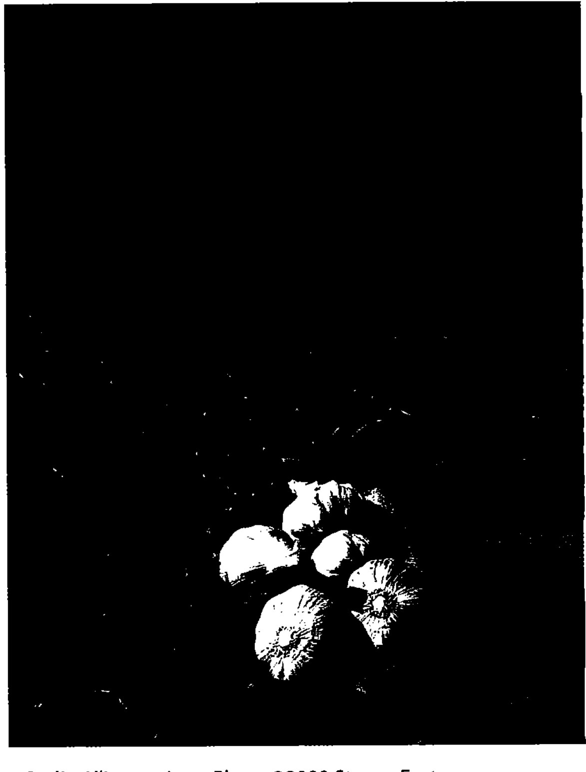
—**Brenda Milot, ELS**



Garlic Preparations Show Benefit in Reducing Blood Pressure

Reviewed: Ried K, Frank OR, Stocks NP, Fakler P, Sullivan T. Effect of garlic on blood pressure: a systematic review and meta-analysis. *BMC Cardiovasc Disord.* 2008;8:13. doi:10.1186/1471-2261-8-13.

Hypertension (high blood pressure) affects about 1 billion persons worldwide. Clinically, hypertension is defined as systolic blood pressure (SBP) equal to or greater than (≥) 140 mm Hg (millimeters of mercury) and diastolic blood pressure (DBP) ≥ 90 mm Hg. Recent guidelines extend the management of blood pressure to include prehypertensive persons with SBP of 120-139 mm Hg and DBP of 80-89 mm Hg. In research studies, animal results have suggested that garlic (*Allium sativum*, Liliaceae) preparations produce moderate reductions in blood pressure while primary studies in humans and nonsystematic reviews have reported mixed results. Because of the increased use of alternative and complementary therapies for hypertension, these authors, from the Discipline of General Practice, The University of Adelaide, Adelaide, South Australia, conducted a systematic review and meta-analysis of trials investigating the effect of garlic preparations on blood pressure.



Garlic *Allium sativum* Photo ©2009 Steven Foster

The authors searched the Medline, Embase, and Cochrane databases for studies published between 1955 and October 2007, and they checked reference lists of previously published systematic reviews and meta-analyses for more primary studies. For the systematic review, they included published intervention studies (including randomized controlled trials and non-placebo-controlled trials) in English and German that reported effects of garlic preparations on blood pressure. For the meta-analyses, they included only studies with placebo control groups, using garlic-only supplements, and reporting mean SBP and/or DBP and standard deviation (SD).

The number of subjects in intervention and control groups, mean SBP and DBP at start and end of intervention, and SD were collated from text, tables, or figures. Methodological quality was assessed independently by two of the investigators using guidelines of the Cochrane Collaboration.

The authors also conducted a subgroup meta-analysis by baseline blood pressure (hypertensive/normotensive) for the first time and a meta-regression analysis to test the associations between blood pressure outcomes and duration of treatment, dosage, and blood pressure at the start of treatment.

Eleven of 25 studies included in the systematic review and investigating the effect of garlic preparations on blood pressure met the inclusion criteria for meta-analysis. Fourteen studies were excluded from meta-analysis: 6 trials had no placebo control group, another 6 reported incomplete data for mean SBP, DBP, or SD, and 2 studies used garlic combination supplements containing other potentially hypotensive agents.

Nine studies compared garlic preparations to placebo, and 2 studies compared the effect of garlic on blood pressure in addition to a drug compared to drug plus placebo. Nine studies used garlic powder (the commercial standardized garlic product Kwai®, Lichtwer Pharma AG, Berlin, Germany), one study used aged garlic extract (Kyolic®, Wakunaga, Japan), and another used distilled garlic oil. Dosage of garlic powder ranged between 600 and 900 mg per day (providing potentially 3.6 to 5.4 mg of allicin, an active compound produced in fresh garlic but not in the aged garlic extract), and duration of intervention ranged from 12 to 23 weeks. A total of 252

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subjects allocated to a garlic intervention group and 251 subjects allocated to a control group were included in the meta-analysis on SBP from 10 studies, and 283 (garlic) versus 282 (control) on DBP. Mean blood pressure at start of intervention varied markedly, with 4 studies reporting mean SBP in the hypertensive range (≥140 mm Hg) and 3 studies reporting mean DBP in the hypertensive range (≥90 mm Hg) before treatment.

The authors report that their meta-analysis suggests that garlic supplements exert a hypotensive effect compared with placebo, particularly in subjects with high blood pressure. Meta-analysis of 10 studies of the effect of garlic on SBP showed a significant difference between garlic and control groups, with garlic having a greater effect in reducing SBP than placebo by 4.56 (95% CI, -7.36, -1.77) mm Hg compared with placebo (P<0.001). Subgroup analysis of studies with mean SBP in the hypertensive range at start of intervention revealed a greater SBP reduction in the garlic group than in the placebo group by 8.38 (95% CI, -11.13, -5.62) mm Hg (P<0.001). Subgroup analysis of the remaining studies with mean SBP in the normotensive range (<140 mm Hg) at start of intervention showed no significant difference between the garlic and placebo groups.

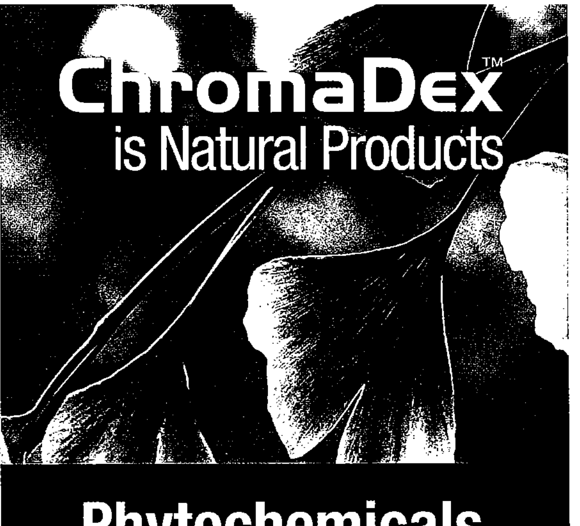
The meta-analysis of the effect of garlic on DBP did not show a significant difference between garlic and placebo groups (-2.44 [95% CI, -4.97, 0.09] mm Hg, P=0.06). However, subgroup analysis of studies with mean DBP in the hypertensive range at the start of treatment revealed a significant difference between garlic and control groups. The results indicate that garlic was more effective in reducing DBP than placebo in hypertensive subjects by 7.27 (95% CI, -8.77, -5.76) mm Hg (P<0.001). In contrast, subgroup meta-analysis of normotensive subjects was not significant.

Regression analysis revealed a significant association between blood pressure at the start of the intervention and the level of blood pressure reduction (SBP: R=0.057; P=0.03; DBP: R=0.351; P=0.02).

The authors report that their findings on the effects of garlic preparations on SBP/DBP are comparable to the hypotensive effects of commonly prescribed blood pressure drugs.

"This systematic review and meta-analysis suggest that garlic preparations are superior to placebo in reducing blood pressure in individuals with hypertension. Future large-scale long-term trials are needed to investigate whether standardized garlic preparations could provide a safe alternative or complementary treatment option for hypertension in clinical practice," say the authors. HG

—**Shari Henson**



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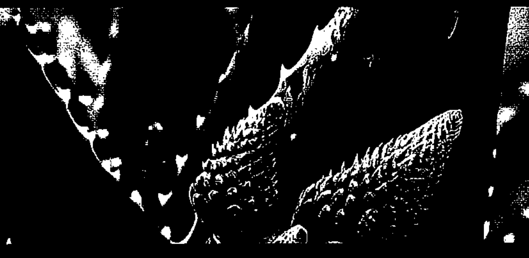

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Ginkgo Extract Does Not Prevent Dementia or Alzheimer's Disease in Large 6-year Clinical Trial—The GEM Study

Reviewed: DeKosky ST, Williamson JD, Fitzpatrick AL, et al. Ginkgo biloba for prevention of dementia. A randomized controlled trial. *JAMA*. 2008; 300(19):2253-2262.

Standardized extracts made from the leaves of the ginkgo (*Ginkgo biloba*, Ginkgoaceae) tree are used worldwide to enhance numerous cognitive and circulatory functions and to treat symptoms associated with cognitive decline and impaired circulation. Currently no medications—conventional or alternative—have been shown to be effective and thus approved by regulatory bodies for the primary prevention of dementia. And no studies have been published with an adequate design or power to sufficiently evaluate the efficacy and safety of ginkgo extracts for preventing dementia. During the past decade 2 well-powered long-term clinical trials have been initiated to assess the efficacy of ginkgo in preventing dementia. The results of one of these studies—the Ginkgo Evaluation of Memory (GEM) Study—is presented here. The Guidage trial is still underway and its results will not be known for another year or two.[1]

The GEM study is a randomized, double-blind, placebo-controlled study sponsored by the National Center for Complementary and Alternative Medicine and the National Institute on Aging of the National Institutes of Health (NIH). Volunteers (N = 3069) aged 75 years or older were recruited using voter registration and other purchased mailing lists from 4 US communities with academic medical centers: Hagerstown, Maryland (Johns Hopkins); Pittsburgh, Pennsylvania (University of Pittsburgh); Sacramento, California (University of California–Davis); and Winston-Salem and Greensboro, North Carolina (Wake Forest University). All participants had a proxy (representative) willing to be interviewed every 6 months.

Individuals with prevalent dementia (meeting *Diagnostic and Statistical Manual of Mental Disorders Fourth Edition* [DSM-IV] criteria for dementia or a score > 0.5 on the Clinical Dementia Rating scale) were excluded from the study. However, participants with mild cognitive impairment were not excluded. Participants were randomized to twice-daily doses of either 120 mg ginkgo (EGb 761®, W. Schwabe Pharmaceuticals, Karlsruhe, Germany; n = 1545) or an identically appearing placebo (n = 1524). The 240 mg per day dose of EGb 761 was chosen based on information from prior clinical studies. It is also the upward dose approved by the German Commission E and is a standard dosage used in more cognitively impaired adults.[2] The primary hypothesis was that 240 mg/day of ginkgo extract would decrease the incidence of all-cause dementia and specifically reduce the incidence of Alzheimer's disease (AD). The secondary objectives were to evaluate the effect of ginkgo extract on the following end points: overall cognitive decline, functional disability, total mortality, and incidence of cardiovascular disease. The primary efficacy endpoint was the diagnosis of dementia by DSM-IV criteria. When a participant's dementia scores declined by a pre-specified number of points from his or her study entry scores, or there was onset of new memory or other cognitive problems, the participant underwent the full GEM study neuropsychological battery, which included 12 tests.

The ginkgo and placebo groups were similar in their baseline characteristics. The mean age at entry was 79.1 years and 46% of the participants were women. The median follow-up time was 6.1 years (maximum 7.3 years). The dementia rate was extremely low (< 1%) during the first year in both groups. Approximately 61% of those taking placebo and 40% of those taking ginkgo guessed their actual drug assignment correctly. During the intervention period, 246 (16.1%) of the participants in the placebo group and 277 (17.9%) in the ginkgo group were diagnosed with dementia. The rate of total dementia did not differ between participants assigned to ginkgo or placebo (P = 0.21, 3.3/100 person-years and 2.9/100 person-years, respectively). The rate of Alzheimer-type dementia also did not differ between the 2 treatment groups (P = 0.11, 3.0/100

person-years and 2.6/100 person-years, respectively). The results were similar when the endpoint was AD only versus AD with evidence of vascular disease of the brain. The number of participants with cardiovascular disease, pure vascular dementia, myocardial infarction, or stroke was too small to draw any firm conclusions.

The adverse event (AE) profiles for ginkgo and placebo were similar. There were no statistically significant differences in the rate of serious AEs. The mortality rate was similar in the 2 treatment groups. There were no differences between treatment groups in the incidence of coronary heart disease or stroke. The rates of major bleeding did not differ between the treatment groups. Also, for participants taking aspirin, the bleeding incidence did not differ between treatment groups.

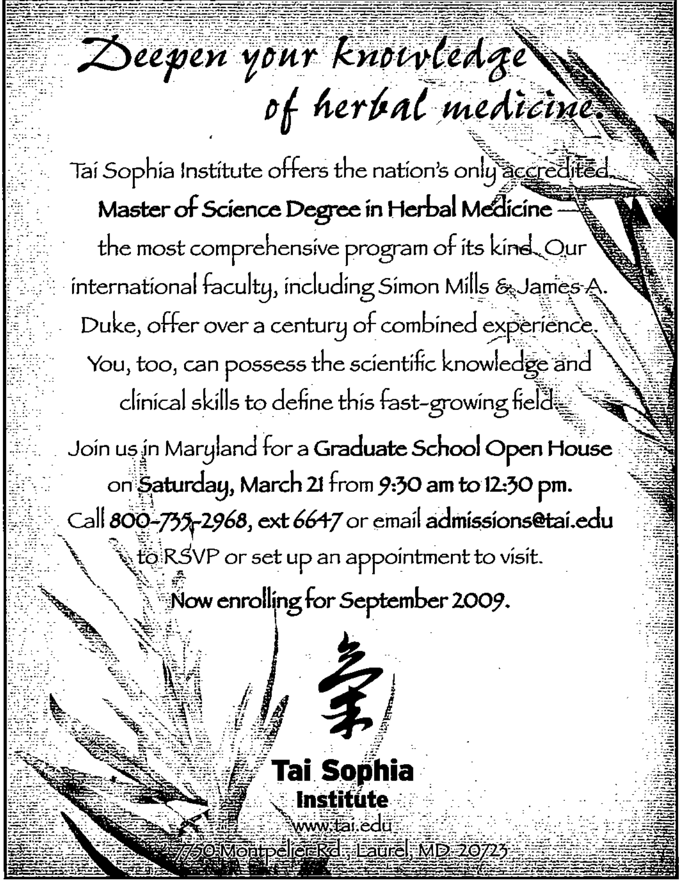
The authors conclude that in this study gingko was not effective in preventing or delaying the onset of all-cause dementia in participants older than 75 years. Also, ginkgo had no effect on the risk for developing AD in this population.

It should be noted that at study end, only 60.3% of the active participants were taking their assigned study medications. There is the possibility that this poor adherence to the assigned treatment might have had a negative effect on the trial's results. An NIH-sponsored study in the United States in 2008 demonstrated a beneficial effect of a standardized ginkgo extract on the risk of developing dementia in only the trial subjects taking the ginkgo on a regular basis.[3] In the present study it does not appear that any statistics were done on the population having good compliance (i.e., excluding the participants who were not in compliance). It would be interesting to see the results of the compliant population. Also, there is no conventional pharmaceutical drug that has the ability to prevent the onset of dementia or diminish its progression, so there is no drug to act as a positive control. Hence, it is unknown to what extent the particular population being tested would respond to any treatment.

According to Mark Blumenthal, the founder and executive director of the American Botanical Council, "Ginkgo's benefits must be viewed in the context of the entirety of the published clinical data. There is a significant body of scientific and clinical evidence supporting the safety and efficacy of ginkgo extract for both cognitive function and improved circulation."[4] In fact, a randomized controlled clinical trial (RCT) published in *JAMA* in 1997 demonstrated efficacy of EGb 761 versus placebo, producing positive results in treating symptoms associated with early stages of Alzheimer's dementia.[5] Numerous subsequent RCTs have also shown beneficial effects. In addition, an RCT comparing EGb 761 versus the pharmaceutical drug donepezil (Aricept®, Pfizer) showed the ginkgo extract to have similar efficacy in treating dementia symptoms with less AEs,[6] while a review article in 2000 showed that EGb 761 had a similar effect of 4 pharmaceutical cholinesterase-inhibiting drugs, with fewer adverse effects for ginkgo.[7]

A large (n=400) multicenter RCT in Russia using 240 mg/day of EGb 761 on patients with clinically evaluated mild to moderate dementia and moderate neuropsychiatric symptoms for 22 weeks resulted in improvement in the ginkgo patients with respect to the neuropsychiatric symptoms and activities of daily living.[8] In contrast, those who received

Ginkgo *Ginkgo biloba*
Photo ©2009 Steven Foster



placebo deteriorated slightly or remained unchanged. EGb 761 was significantly superior to placebo with respect to all efficacy variables ($P < 0.001$). And in a yet-to-be published RCT, one daily dose of 240mg EGb used in the treatment of dementia was significantly superior to placebo.[9] This trial was presented at the International Congress on Alzheimer's Disease in Chicago in July 2008.

In addition to being tested for cognitive impairment, at least 16 RCTs have evaluated various ginkgo extracts for healthy, non-cognitively impaired adults. A comprehensive review has shown that in 11 of these trials, the ginkgo extract increased short-term memory, concentration, and time to process mental tasks.[10] Finally, as noted by ABC in its press release, numerous RCTs demonstrate the efficacy of ginkgo extract in treating symptoms associated with peripheral arterial occlusive disease (a.k.a. intermittent claudication, a condition experienced by many elderly adults, characterized by pain and difficulty in walking, due to poor circulation).[11] HG

—Heather S. Oliff, PhD

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Korean Red Ginseng May Aid in Erectile Dysfunction According to Systematic Review

Reviewed: Jang D-J, Lee MS, Shin B-C, Lee Y-C, Ernst E. Red ginseng for treating erectile dysfunction: a systematic review. *Br J Clin Pharmacol.* October 2008;66(4):444-450.

Erectile dysfunction (ED) affects 30-50% of men over the age of 40. Current medical interventions for the management of ED include drugs, intrapenile therapies, and penile prosthetic implants. Korean red ginseng (*Panax ginseng*, Araliaceae) is the steamed and dried roots of plants that are harvested 6 years after planting. One of the popular traditional uses of red ginseng is the enhancement of sexual function. Few clinical trials have evaluated the effect of red ginseng on ED, and recent reviews of ED therapies did not include studies published in languages other than English. The purpose of this systematic review was to critically evaluate the evidence from all randomized controlled trials (RCTs) of red ginseng in men with ED.

Korean Ginseng *Panax ginseng*
Photo ©2009 Steven Foster

Researchers at the Korea Institute of Oriental Medicine searched electronic databases from their inception until January 2008. The databases included MEDLINE, AMED (Allied and Complementary Medicine Database), British Nursing Index, CINAHL (Cumulative Index to Nursing and Allied Health Literature), EMBASE (Excerpta Medica Database), PsycInfo, The Cochrane Library, 6 Korean medical databases, 4 Chinese medical databases, and 3 Japanese medical databases. The researchers also manually searched relevant journals and checked the references of all articles identified in the search. The analysis included all articles that reported on an RCT in which human subjects with any type of ED were treated with any type of red ginseng, regardless of language of publication. Three independent reviewers read, extracted, and rated each article.

The researchers identified 28 potentially relevant trials, and 7 of these trials met the criteria for inclusion in the analysis.[1-7] A total of 363 men, ranging in age from 24 to 70 years, were studied in these 7 trials. The duration of treatment with red ginseng ranged from 4 to 12 weeks. The doses of red ginseng ranged from a daily total of 1800 mg to 3000 mg. (Presumably, this dosage range refers to the dried root powder as extracts would probably be expressed in lower daily doses. The trade names of any commercial ginseng products that may have been used in the RCTS were not given.) Outcome measures included scores on the International Index of Erectile Function, the Watts sexual function questionnaire, global efficacy questions, and study-specific structured interview questionnaires related to ED.

Six of the trials reported an improvement in erectile function in subjects taking red ginseng compared to subjects taking placebo. A meta-analysis of data from the 7 trials suggests that red ginseng is superior to placebo in improving erectile function ($P < 0.0001$). The methodological quality of the trials was variable, ranging from scores of 1 to 5 on the Jadad scale. The majority of the articles failed to report the method of randomization, the method of double-blinding, and details about subject withdrawals and drop-outs. Other shortcomings included failure to report a power calculation for statistical analysis and failure to report approval of the study by a research ethics board. (The use of red ginseng in Korea particularly, as well as in China, is widespread, even ubiquitous; it is sold and consumed as a food, similar to coffee and tea in Western countries; thus the usual requirement to have an institutional review board approve the design of a proposed RCT may not have been seen as necessary.)

The authors explain that this is the first systematic review and meta-analysis of RCTs of the effectiveness of Korean red ginseng in men with ED. They conclude that these trials provide evidence suggesting such effectiveness. However, the number of trials that could be included in the analysis, the total sample size (363 men), and the typical methodological quality of the studies were too low to allow firm conclusions to be drawn. The authors recommend that additional studies with better methodological quality are needed to establish whether or not Korean red ginseng has a place in the treatment of ED. HG

—Heather S. Oliff, PhD

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COLD-fX® Special Extract from American Ginseng Root Shown Safe for Children with Upper Respiratory Tract Infections

Reviewed: Vohra S, Johnston BC, Laycock KL, et al. Safety and tolerability of North American ginseng extract in the treatment of pediatric upper respiratory tract infection: a phase II randomized, controlled trial of 2 dosing schedules. *Pediatrics.* Aug 2008;122(2): e402-e410.

Upper respiratory tract infections (URIs) are more common in children than in adults, and parents often treat their children's symptoms with herbs and other natural health products (NHPs, the regulatory term used in Canada for vitamins, minerals, herbs, homeopathic remedies, etc.). One of the most popular products used for enhancing immunity and preventing and treating URIs in Canada is a special, patented extract of American ginseng root (*Panax quinquefolius*, Araliaceae) called COLD-fX® (CV Technologies, Inc., Edmonton, Alberta, Canada) consisting of only the saccharide fraction of the root (i.e., furanyl-, oligo- and polysaccharides). Unlike conventional ginseng extracts, this preparation does not contain ginsenosides, the characteristic active triterpene glycosides in various species of the genus *Panax* that are the subject of most chemical and pharmacological research on this highly-researched genus.

In Canada, COLD-fX is approved by the Natural Health Products Directorate of Health Canada for the prevention and treatment of URIs related to cold and flu, based on a previous review of published clinical trials and laboratory research. Although the safety and efficacy of COLD-fX has been studied for the treatment and prevention of URIs in adults, the authors of this phase II randomized, double-blind, dose-finding, 3-arm clinical trial claim that it is the first to examine safety, dose, and efficacy in children.

There were 2 dosing arms and a placebo arm. The objectives were to document the safety and efficacy of weight-based dosing schedules and to determine the treatment effect of COLD-fX on the severity and duration of pediatric URIs. Children aged 3-12 years old were recruited between November 2005 and February 2006 from 2 teaching hospitals at the University of Alberta (Edmonton, Alberta, Canada). A computerized random number generator was used for randomization.

Parents of the subjects contacted the study nurse upon the onset of symptoms. If the study nurse determined that the symptoms were those of a URI, then the pharmacy was contacted and the study medications (COLD-fX or placebo) were dispensed and sent by courier. The weight-based COLD-fX standard dose (n=13) was 26 mg/kg on day 1, 17 mg/kg on day 2, and 9 mg/kg on day 3. Children who received the standard adult dose (600 mg on day 1, 400 mg on day 2, and 200 mg on day 3) weighed over 45 kg. The

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weight-based COLD-fX low-dose group (n=14) received 13 mg/kg on day 1, 8.5 mg/kg on day 2, and 4.5 mg/kg on day 3. Children in the low dose group also weighed less than 45 kg. The placebo group (n=15) received a liquid solution similar in appearance to the COLD-fX formulation. The placebo or COLD-fX formulations were dispensed into 3 equal portions to be taken 3 times daily for 3 days. The children received other medications and tests as determined by their physicians. The severity and duration of the URIs were measured using the Canadian Acute Respiratory Infection Flu Scale (CARIFS) score, a validated 18-item scale that covers 3 domains: symptoms, function, and parental impact. The severity and duration of the treatment effect was measured as the average length of time in days from treatment onset to resolution of symptoms, defined as a 25% decrease from the baseline CARIFS score.

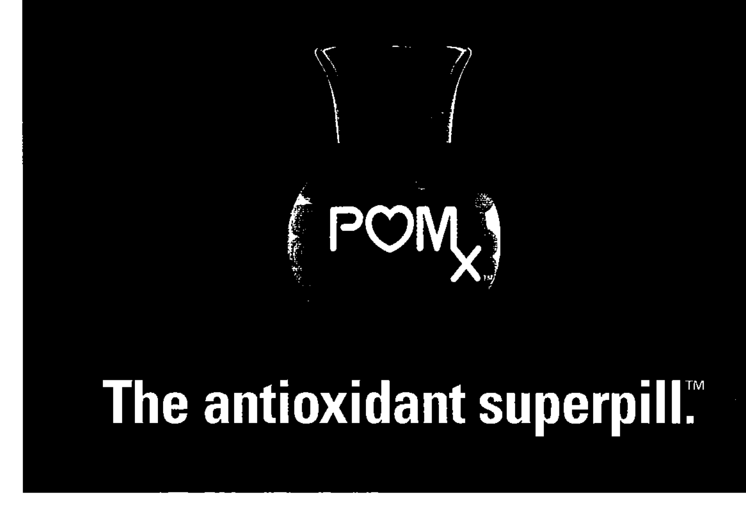
No serious adverse events were reported. A total of 31 subjects reported 51 adverse events. Out of these, 8 were classified as moderate: 2 in the low-dose group (fever and secondary bacterial throat infection), 6 in the placebo group, and none in the standard dose group. In addition, 11 adverse events were classified as possibly related to the intervention. Those receiving the standard dose had fewer of these adverse events than either those receiving low-dose or placebo, but there was no statistically significant between-group difference.

The severity and duration of treatment effect was 1.5 days for the standard dose group, 1.9 days for the low dose group, and 1.9 days for the placebo group. This is all-the-more impressive given that those in the standard dose group were the sickest group at the outset. Nevertheless, the study group was too small for this trend to reach statistical significance. From this information, however, the authors were able to calculate that repeating the study with 48 children in each treatment arm could confirm whether COLD-fX shortens the duration of colds in children. The use of antipyretics (fever-reducing medications) was highest in the low-dose group (P=0.48). Otherwise, there was no significant difference in the use of cold and flu remedies, antibiotics, or asthma medications among the groups.

The authors conclude that the standard weight-based dose of COLD-fX used in this study is safe and well-tolerated in children and appropriate for larger, phase III clinical trials. The difference in the use of NHPs and asthma medication was not significant among the treatment arms, but the authors recommend that future investigators caution subjects not to use other NHPs during the study and to include a specific measure of asthma status. The authors also recommend rigorous stepwise clinical trials from phase I to phase III on NHPs, which could help to avoid expensive negative phase III trials. Future research on the efficacy of COLD-fX in the treatment of pediatric URIs is warranted. In addition, the authors recommend studies evaluating daily use of COLD-fX in children for preventing URIs.

In February 2007 the American Botanical Council published an extensive clinical monograph on COLD-fX (also known by the name of its extract, CVT-E002), available on the ABC Web site at http://cms.herbalgram.org/herbclip/306/review44663.html. HG

—Marissa Oppel, MS



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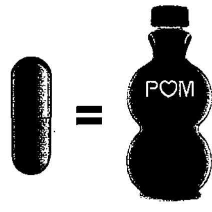

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Medicinal Trees of the US Virgin Islands and Neighboring Islands

By Robert W. Nicholls, PhD

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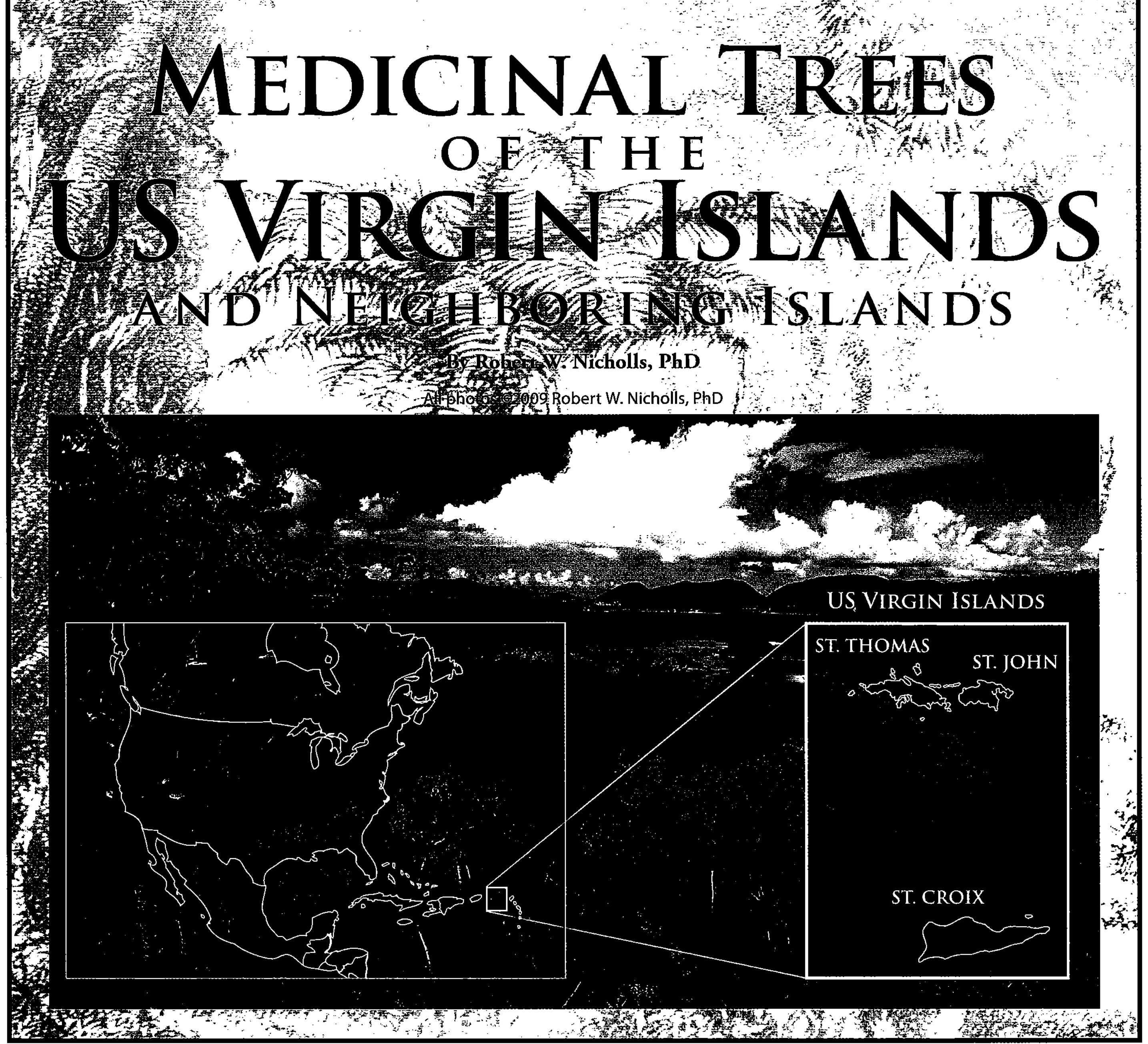


INTRODUCTION

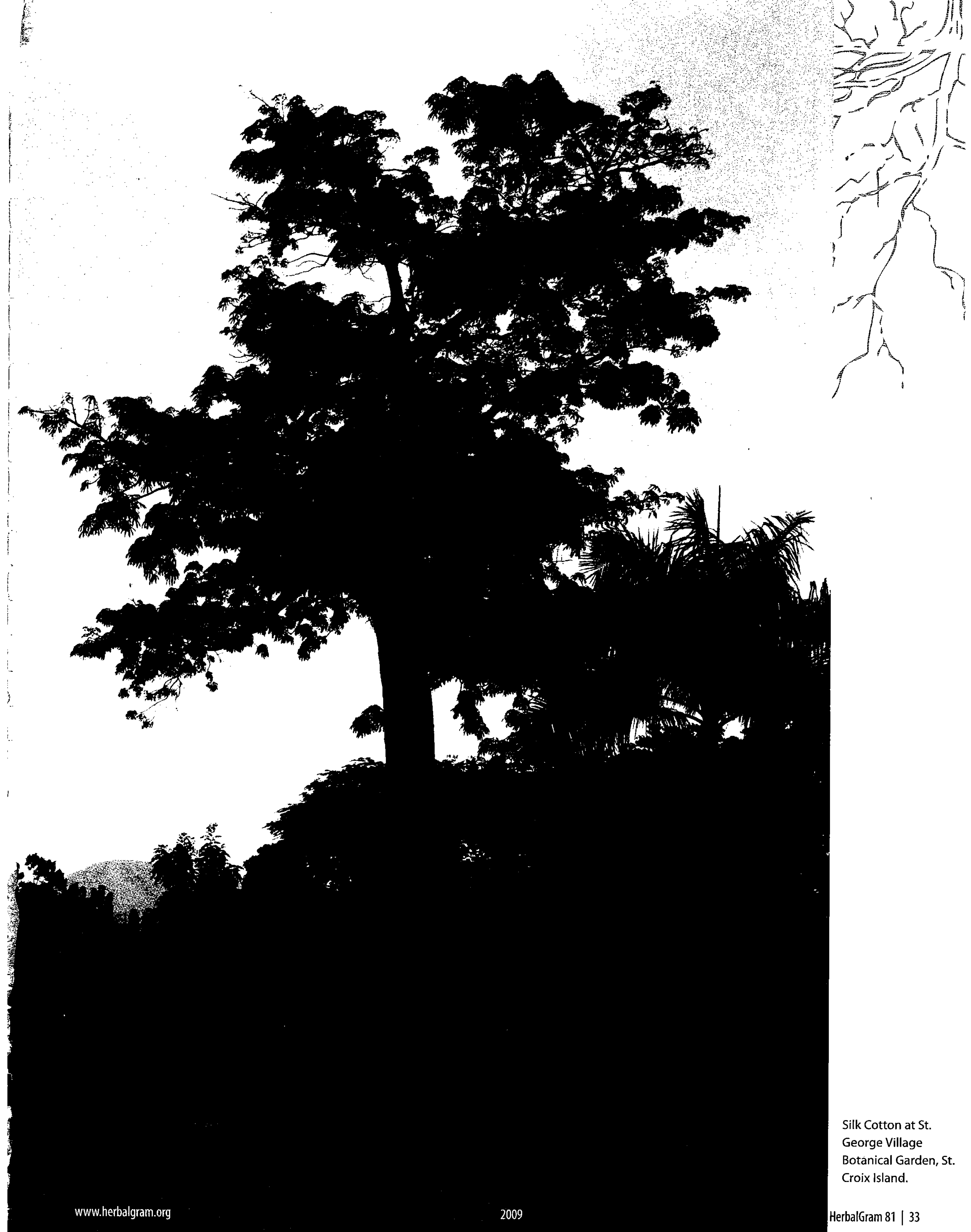
Trees of the US Virgin Islands (USVI) and neighboring islands have traditionally been used for their timber and fruit, as well as for their medicinal properties. Research shows that medicinal treatments in the form of gargles, poultices, compresses, teas, inhalants, and lotions have long been prepared from the roots, leaves, flowers, seeds, fruit, resin, and bark of native USVI trees and introduced species.

Local healers—variously described as medicine men and women, bush doctors, or weed people—have been an important fixture in the lives of common folk of the USVI, as in other agrarian societies. As is common with traditional folk healing elsewhere in the world, "cures" have often blended the sacred and the secular, wherein the "patient" has been required to seek spiritual well-being as a prelude to restoring physical health. Trees often have been viewed as mediators between human society and spiritual realms. Some trees have even served as sites of spiritual transactions, with offerings made at special tree shrines.

I acquired information about the medicinal functions of some of these trees during my research on the big trees* of the USVI from 2001 to 2006. Information about the medicinal uses of these trees was so extensive that I deliberately excluded much of it from the book I published in 2006, titled *Remarkable Big Trees in the US Virgin Islands*—feeling that a description of such myriad medicinal uses would have overwhelmed the publication.[1]

This pictorial essay introduces the reader to 10 trees of the USVI and neighboring islands by reporting on some of the traditional and current folk-medicinal uses that have been attributed to them, though I am not vouching for their efficacy from a scientific or clinical perspective.

* A "big tree" is typically defined as one that has at least a 3-feet diameter trunk and is over 60 feet tall. For the author's research, the definition of a "big tree" was more flexible. Some trees of the Virgin Islands were considered to be deserving of inclusion in the author's research due to their cultural significance but did not have sufficient size to technically meet the requirements of the "big tree" definition. Some medium-sized trees were therefore included, such as large specimens of the bay rum tree and lignum vitae.



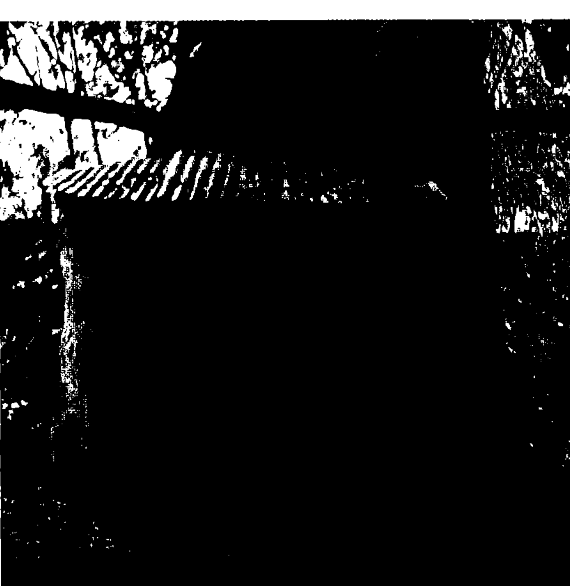
Silk Cotton at St. George Village Botanical Garden, St. Croix Island.

SILK COTTON

Ceiba pentandra, Malvaceae

The silk cotton tree is indigenous to tropical America and the West Indies and can grow extremely large—to over a hundred feet high with spreading buttress roots. It has many names in the Caribbean, including "jumbie tree." (A jumbie is a ghost in local parlance.) Some Crucians (i.e., people from the island of St. Croix) remember a silk cotton tree shrine at Estate Mount Victory that was tended by local medicine man John Dubois from the 1940s and 1950s. Dubois would dispense herbs and enact cures there. The shrine later fell into disrepair but was rehabilitated in the 1990s. Nowadays, it contains Christian and other elements, including a figurine of the Biblical character Lazarus (S. Rodrigues, personal communication, September 3, 2003).

The silk cotton tree has a multitude of medicinal uses. People in St. Croix and Trinidad have used silk cotton leaves in baths to relieve fatigue and as a poultice for sore or sprained feet.[2] In Trinidad, the leaves are also used as a poultice for erysipelas (a streptococcus infection of the skin). In Haiti, a leaf decoction administered through a bath or as a poultice is used to treat various skin maladies, including insect bites and boils. For dizziness, Haitians apply a fresh leaf compress or lotion, and for edema-like swellings they apply a boiled root decoction. For diabetes, Haitians use a root infusion, taken orally. For cough or hoarse throat a leaf infusion is taken orally, while the fruit rind is used for placenta expulsion.[3] Haitians also eat gum from the silk cotton tree for upset stomach and ingest a root infusion to relieve constipation.



Above photo: Bassin Triangle Silk Cotton, St. Croix Island.

Left photo: Silk Cotton shrine at Estate Mount Victory, St. Croix Island.

Lignum vitae is a slow-growing tree native to the USVI. Its name means "Wood of Life," and it is renowned for its medicinal qualities. The wood of this tree is among the densest in the world.

A lignum vitae leaf decoction has reportedly been used in the USVI and Curacao to treat diabetes and asthma.[4] The leaf juice has also been used to treat biliousness (digestive complaints) in the USVI. A poultice made from the leaves has sometimes been used to treat rheumatism in the USVI and Barbados.[4,5] Leaves are boiled and ingested as a diuretic tea on Middle Caicos in the West Indies, and a mash of the leaves is also used there for treating swollen areas or small wounds on the body.[6]

Decoctions of the tree's resin or bark, meanwhile, have been used to treat venereal diseases.[5] The tree achieved great recognition for this use in Puerto Rico. Lignum vitae resin has also been used to alleviate skin disorders and gout and to treat cuts and bruises in the USVI.[4,5] Haitians have sometimes applied the resin to toothaches.[3] A bark decoction has been taken orally for fish poisonings in the USVI and Puerto Rico.[4]

LIGNUM VITAE

Guaiacum officinale, Zygophyllaceae

Lignum vitae at Estate Eden, Coral Bay, St. John Island.

WEST INDIAN MAHOGANY

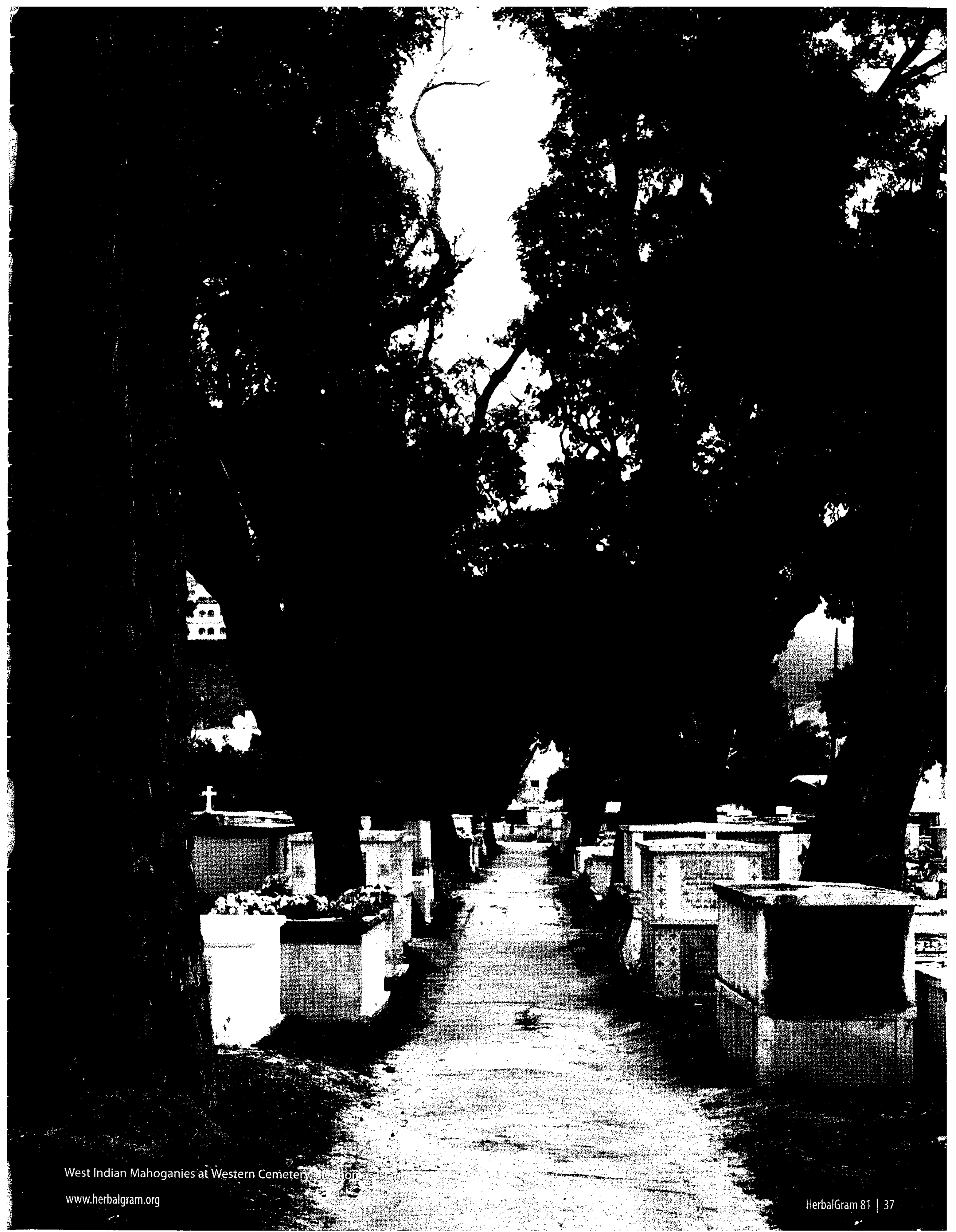
Swietenia mahagoni, Meliaceae

The West Indian mahogany is native to the Bahamas, southern Florida, Cuba, Jamaica, and Hispaniola. It was introduced into the USVI before or during the 17th century and became well established after that time. It is now considered borderline naturalized in the USVI.

In Haiti, West Indian mahogany bark, either macerated or in a decoction, is taken orally with salt to relieve fever.[3] The bark is similarly used to alleviate diarrhea and dysentery in Haiti, and steeped mahogany bark is drunk to combat loss of appetite. In cases of toothache, Haitians will sometimes apply the tree's resin, or a resin or bark decoction, as a treatment. Haitians have further ingested teas of steeped West Indian mahogany bark and roots to improve vitality (due to the tree's vitamin and iron content).

Jamaicans, meanwhile, use a leaf decoction of West Indian mahogany as a tea or bath to combat colds and fever.[5] Jamaicans have also used a mahogany bark decoction to halt diarrhea. In Cuba, a bark decoction is used to relieve catarrh.

Right photo: Mahogany tree, VI Legislature, St. Thomas Island.



West Indian Mahoganies at Western Cemetery

TAMARIND

Tamarindus indica, Fabaceae

The tamarind is an African tree that was introduced into the Caribbean in the 17th century. Although it is an introduced species in the USVI, it has been part of the islands' ecosystems for 3 ½ centuries and is today considered to be borderline naturalized.

The tamarind is used medicinally for multiple conditions throughout the Caribbean. In Haiti, a compress of young tamarind leaves is used for sprains, as well as for eye infections.[3] A decoction made from tamarind fruit has been used to treat malarial fever in Haiti, and macerated tamarind fruit mixed with water is sometimes drunk as a laxative in Haiti. Haitians also take a tamarind leaf, bark, or root decoction with salt for asthma and a tamarind leaf decoction with salt for throat infections.

Tamarind fruit and/or leaf decoctions are used to relieve colds and coughing in Curacao and Aruba.[5] Tamarind is also used to relieve fever and pain via a leaf decoction administered through baths in Jamaica, a leaf decoction that is drunk in the Bahamas, and by ingesting the ripe fruit in Curacao. In Jamaica, a tamarind leaf decoction is given as a remedy for measles. Tamarind leaf extracts have also exhibited antioxidant activity in the liver, and a tamarind root decoction is used as a remedy for jaundice in Cuba.

Jumbie Tamarind tree at St. Paul's Church, Frederiksted, St. Croix

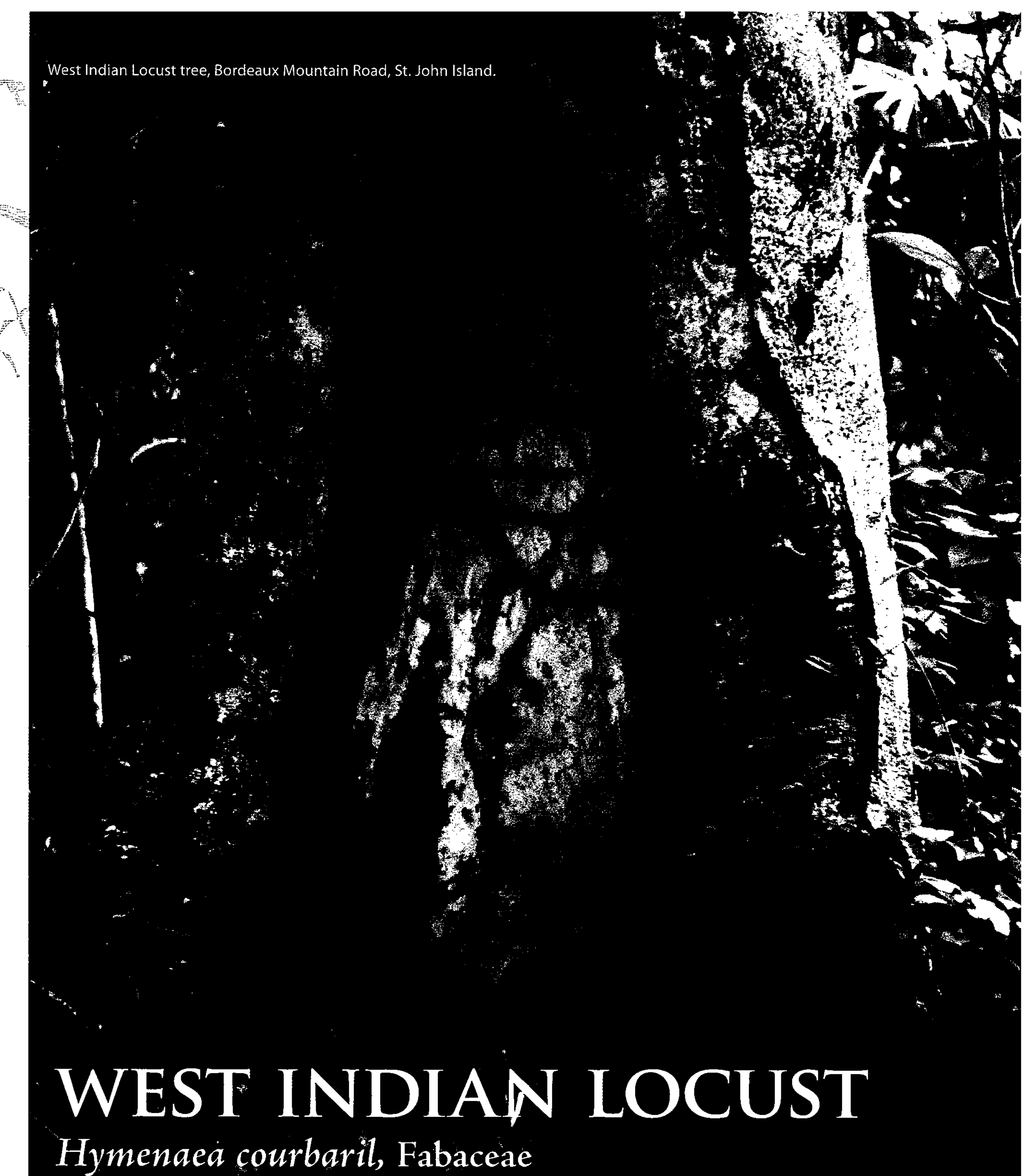
White Cedar at Caneel Bay, St. John Island.

WHITE CEDAR

Tabebuia heterophylla, Bignoniaceae

The white cedar is native to the USVI, and despite heavy logging, it is widely spread throughout the islands. It is a hardy and profusely blooming tree with masses of trumpet-shaped flowers. It has been used for multiple purposes throughout the Caribbean, including as a medicinal agent.

Tea made from the leaves has been used in the USVI and Bahamas to relieve gonorrhea.[2] It has been written that a decoction of the leaves can act as a diuretic and alleviate pain in urination.[5] Leaf decoctions of white cedar have also been used to treat fish poisoning in St. Croix and Curacao and to treat toothache in St. Croix and the Bahamas.[2,5]



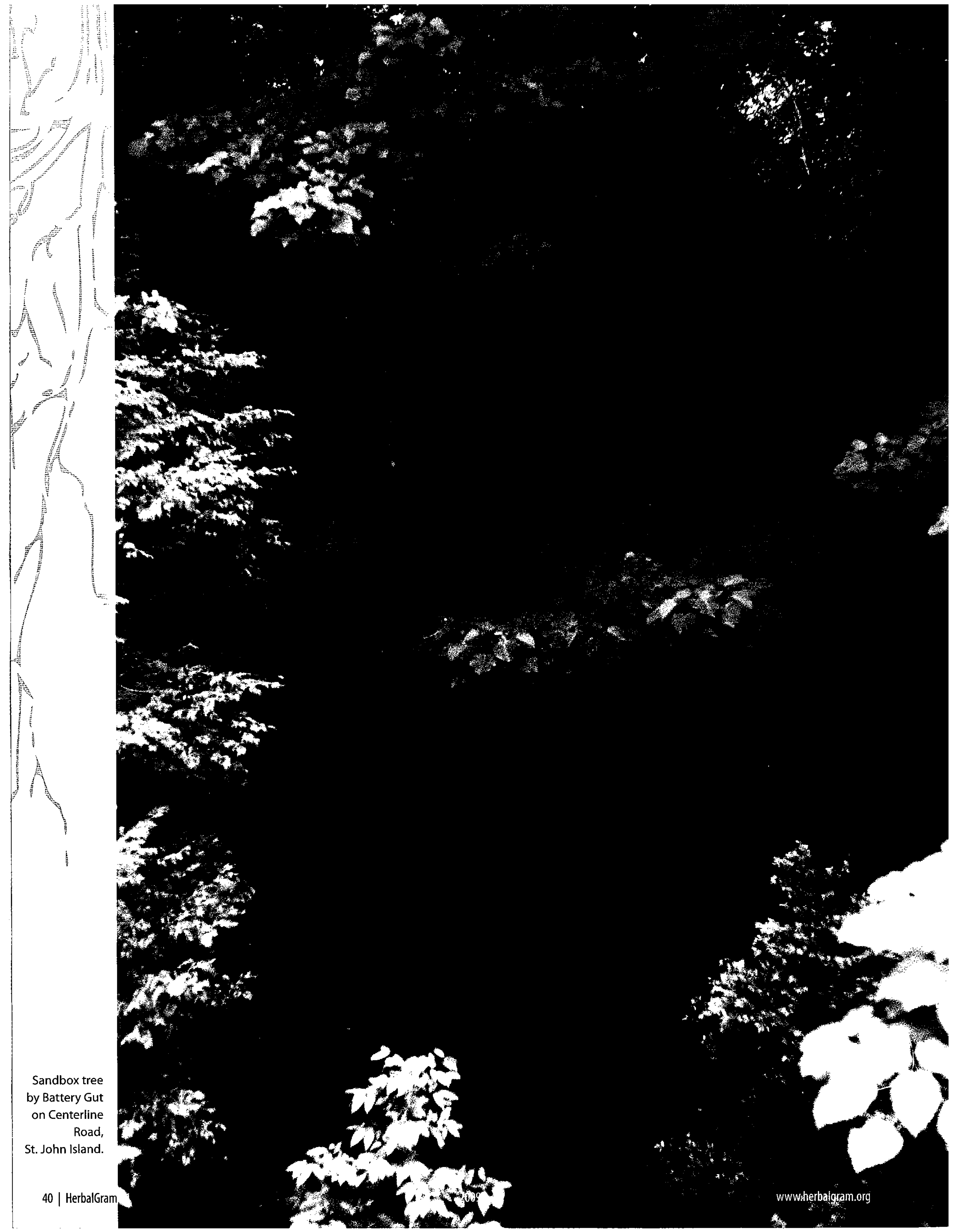
West Indian Locust tree, Bordeaux Mountain Road, St. John Island.

WEST INDIAN LOCUST

Hymenaea courbaril, Fabaceae

The West Indian locust, a native of the USVI, is sometimes referred to as "Stinking Toe Tree." It produces shiny, brown, thick-walled seed pods that contain a pale-yellow powdery pulp with a sweet taste but an unpleasant odor. The tree's bark and leaves are rich in tannin, which exhibits antibacterial properties. Because of their tannin content, locust leaves have shown activity against Lewis lung carcinoma in an experimental trial with mice.[5]

West Indian locust bark has sometimes been ingested to treat constipation and intestinal gas, while an inner bark decoction has sometimes been used to combat intestinal worms.[3] In Haiti, the scalded resin of West Indian locust has been used as an inhalant for emphysema, asthma, and coughs. Haitians have also applied powdered locust resin to wounds, sores, and ulcers, and they have used resin liniment to treat muscle cramps, rheumatism, arthritis, and bruises. Crucians have reportedly used West Indian locust bark in home remedies to purify the blood.[2]



Sandbox tree by Battery Gut on Centerline Road, St. John Island.

SANDBOX *Hura crepitans,* Euphorbiaceae

The sandbox tree, native to the USVI, is popularly known as "monkey-no-climb" due to the large protruding thorns that cover its trunk. Like the silk cotton, the sandbox is sometimes considered a jumbie tree. According to Crucian weed woman Veronica Gordon, "It provides housing for spirits, but they don't want people. That's why the tree has prickles; you can't touch it" (personal communication, August 6, 2001). Gordon has claimed that sandbox seeds can be used sparingly for constipation and that they taste like almonds. It has been written, however, that ingestion of raw sandbox seeds may cause violent vomiting and diarrhea.[5]

In some areas of the Caribbean, the leaves of sandbox are pressed and mixed with salt, then used as a poultice on boils and swellings.[2] In Cuba, a leaf decoction of sandbox has reportedly been used in baths, and fresh leaves have been placed on the temples to allay headaches or to other parts of the body to relieve pains.[5] A bark decoction, meanwhile, has been used to treat leprosy. In Haiti, boiled leaves are applied externally to treat abscesses.[3]

Bay Rum tree at residence near Hawksnest Bay, St. John Island.

BAY RUM

Pimenta racemosa, Myrtaceae

The bay rum tree, which is indigenous to the USVI, has an attractive pale, mottled bark with a cinnamon taste. The tree is especially prevalent on St. John, where the manufacture of bay rum represented a major historical industry. Bay rum trees have been traditionally used for aromatic, cosmetic, medicinal, and culinary purposes.

The tree has been used in many areas of the Caribbean to address digestive complaints. Virgin Islanders take bay rum leaves orally as a treatment for upset stomach and as an appetite stimulant.[4] People in Curacao take a decoction made from bay rum leaves to dispel flatulence, whereas in the Grenadines (and Haiti) a bay rum leaf decoction is drunk to remedy diarrhea.[5] Haitians also take bay rum oil with sugar to relieve nausea.[3] There has been some concern expressed, however, that internal use of bay rum might cause or irritate ulcers.[4]

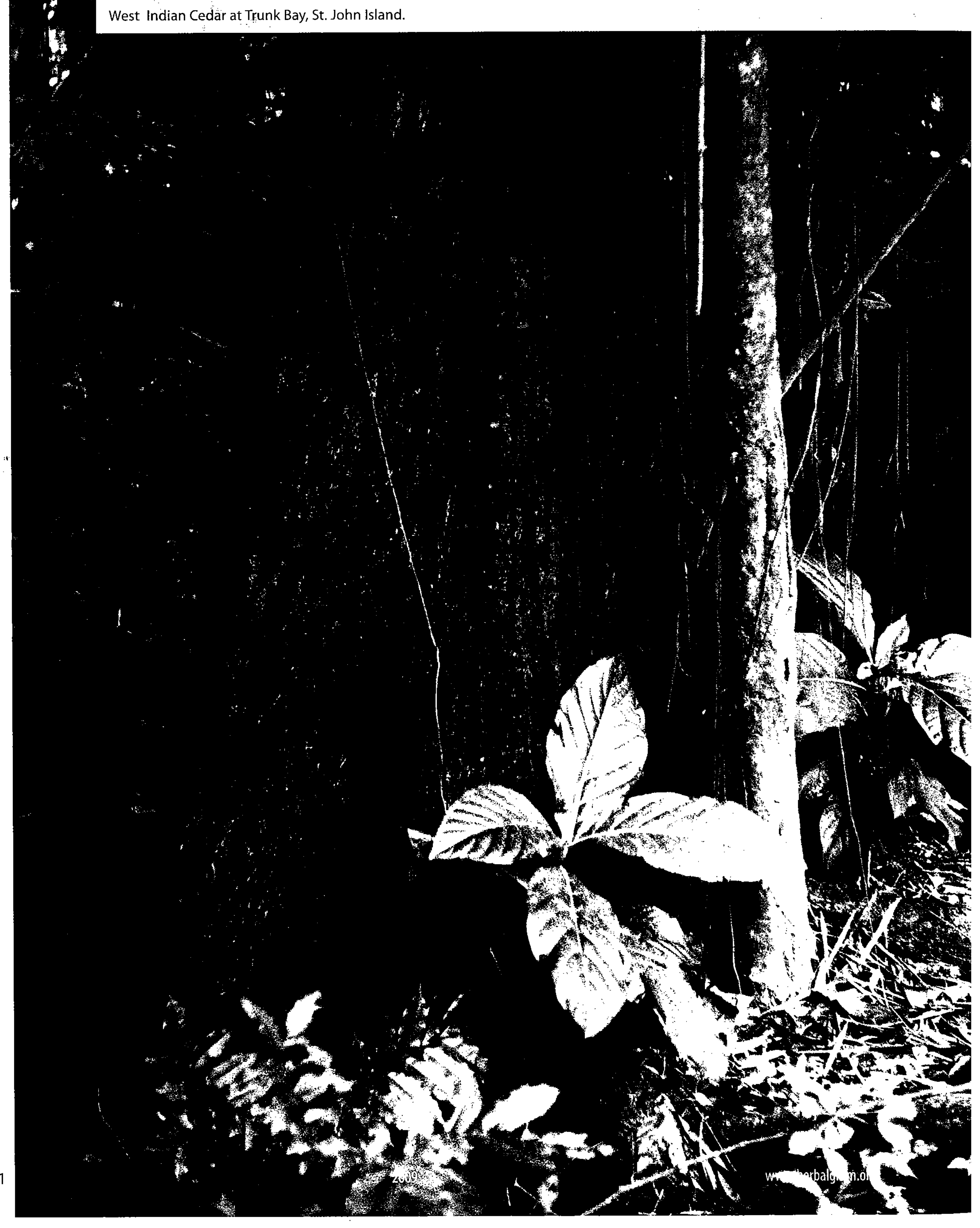
Bay rum leaves placed over the body or under the bed covers are used as a treatment for colds and fever in the USVI,[4] and a tea made from bay rum leaves has reportedly been used to overcome chills on St. Croix.[2] In Trinidad, a bay leaf decoction is taken as a remedy for chest colds, pneumonia, and influenza. People in Curacao also use it to relieve colds.[5]

The tree is popularly used to treat skin conditions and for pain relief. Virgin Islanders sometimes use bay rum leaves as a rubbing compound for the skin.[4] In the Bahamas parched bay leaves are rubbed on skin irritations, while Puerto Ricans use the leaves as an analgesic rub on the body to alleviate discomforts of grippe, rheumatism or muscular pains.[5] In Haiti, a leaf and seed decoction can be applied to insect bites, bruises, varicose veins, and edema swellings. A leaf bath is recommended for elephantiasis.[3]

WEST INDIAN CEDAR

Cedrela odorata, Meliaceae

West Indian Cedar at Trunk Bay, St. John Island.



The West Indian cedar, a native tree of the USVI, is sometimes also called "Cigar Box Cedar Tree." It can grow to 100 feet tall; however, it is rare to find large West Indian cedars in the USVI since their durable wood is considered one of the most valuable timbers in tropical America.

The leaves and twigs of the West Indian cedar have been used by Crucians and Jamaicans in baths for aches and fever.[2] The tree's root-bark, and a leaf or twig decoction, taken orally, have been used as a remedy for malarial fever in Haiti.[3] Haitians also use a bark decoction of West Indian cedar as a gargle for toothache. In some areas, an infusion of the bark can be taken to improve the appetite and dispel chronic headaches associated with menstrual periods.

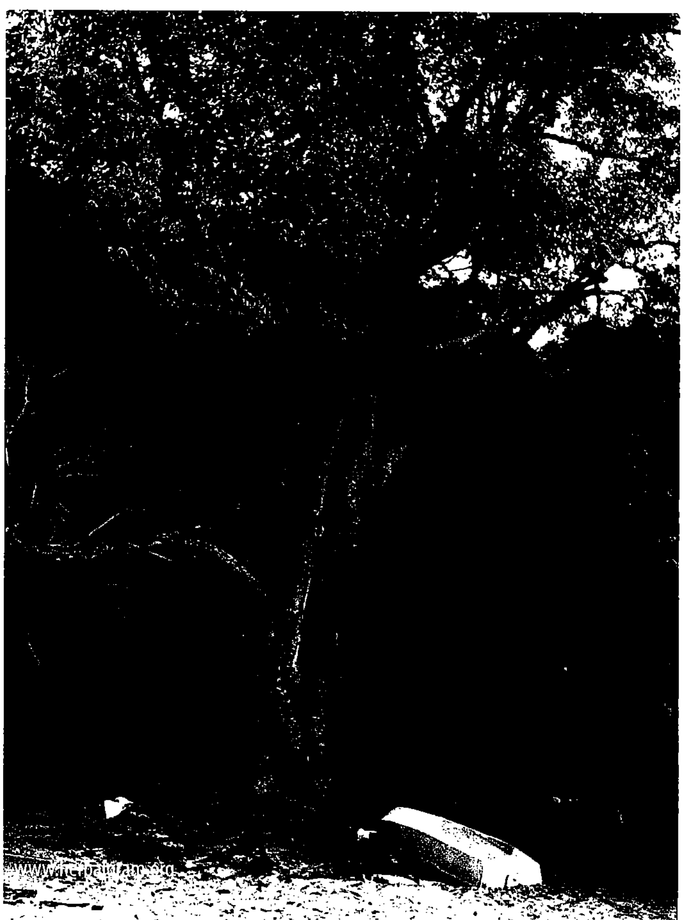
GENIP OR KENIP

Melicoccus bijugatus, Sapindaceae

The genip or kenip tree is native to Guyana, Venezuela, and Margarita Island. It was introduced to the USVI many years ago, later escaped, and is now naturalized and ubiquitous throughout the USVI. Its fruit, which contains a high level of carbohydrates, is borne in clusters that are easily accessible and popular to eat.

Virgin Islanders sometimes eat genip or kenip fruit to alleviate diarrhea,[4] and Haitians sometimes consume powdered roasted genip seed syrup or tea for the same purpose.[3] Virgin Islanders have also been known to take a decoction of genip leaves and stems orally for coughs and fever.[4] In Haiti, the macerated juice of genip leaves is gargled to relieve sore throat, thrush, and tonsillitis.[3] A decoction of genip leaves is also drunk in the Bahamas to lower blood pressure.[5]

Genip at Hull Bay, St. Thomas Island.



CONCLUSION

The 10 trees pictured and described in this essay are just a few of the many important trees endemic to or widespread throughout the USVI. Several other USVI trees are also known to have medicinal uses. Unfortunately, the lore and respect formerly attributed to many USVI trees has begun to fade, and the islands' trees are also increasingly threatened by environmental degradation. Better integration of both native and introduced ornamental trees is needed in the USVI's current urban environment.

To enhance attitudes toward conservation of these natural landmarks, the US Virgin Islands Remarkable Big Trees Project was recently initiated, sponsored jointly by the University of the Virgin Islands and the VI Department of Agriculture's Urban and Community Forestry Assistance Program, with assistance from the Virgin Islands Experimental Program to Stimulate Competitive Research. The project stresses the need for protective measures and strategic planning to preserve trees as a cultural resource and supports initiatives that encourage education and conservation of USVI trees. Because of their intrinsic historic value—and, in some cases, their economic, medicinal, and aesthetic values—remarkable trees of the USVI should be extolled, and it is of utmost importance that conservation and educational activities be implemented to rekindle an appreciation of trees within the USVI and surrounding islands. HG

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