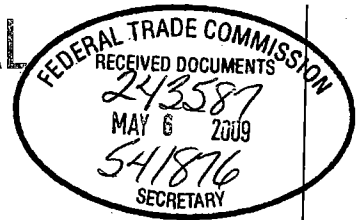


ORIGINAL



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

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

RESPONDENTS' STIPULATED MOTION TO INCLUDE EXHIBIT
IN HEARING RECORD

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.

Respectfully submitted,

Dated: May 6, 2009

Dated: May 6, 2009

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Counsel for Respondents

1
2
3 **[PROPOSED] ORDER**

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

6 IT IS ORDERED that

7 To the extent it is necessary to change the hearing record such that Exhibit 1 to Exhibit
8 R18 shall consist of THE JOURNAL OF THE AMERICAN BOTANICAL COUNCIL, "HerbalGram," No.
9 81 (Feb-Apr 2009), the hearing record shall be so changed.
10

11 **ORDERED:**

12
13 _____
14 D. Michael Chappell
15 Administrative Law Judge

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Dated: May ____, 2009

CERTIFICATE OF SERVICE

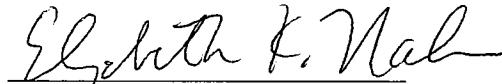
I HEREBY CERTIFY that on May 6, 2009, I served the attached **RESPONDENTS' STIPULATED MOTION TO INCLUDE EXHIBIT IN HEARING RECORD** upon the following:

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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HERBALGRAM

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-angiogenic 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 cicatrization (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 membranes¹² 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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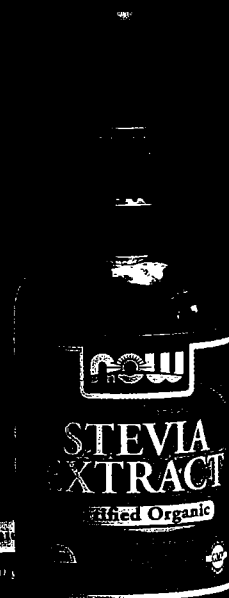
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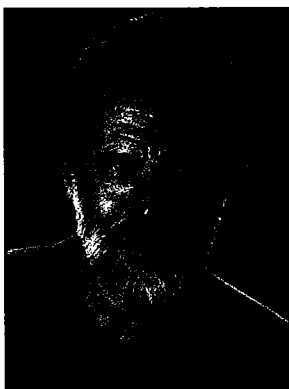
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dear reader



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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Number 81 • February – April 2009

features

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.

departments

10 ABC News

American Botanical Council Reaches 20th Birthday

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

Employee Profile: Tamarind Reaves

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

16 Organization News

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

CRN Appoints Duffy MacKay, ND, to Scientific Staff

New Naturex Foundation Assisting Local Communities in Morocco and Peru

20 World News

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

23 Research Reviews

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

Garlic Preparations Show Benefit in Reducing Blood Pressure

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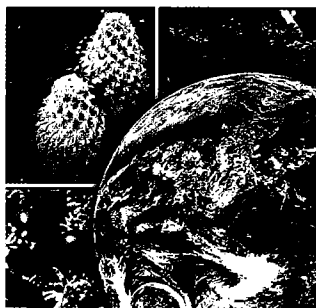
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Published by the American Botanical Council, P.O. Box 144345, Austin, TX 78714-4345.

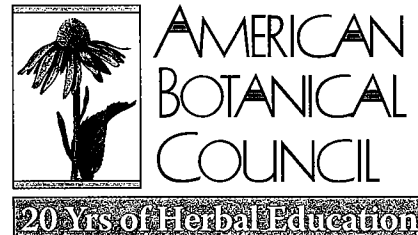
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American Botanical Council Reaches 20th Birthday

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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