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HERBALGRAM

The Journal of the American Botanical Council

Number 106 | May — July 2015

Schisandra:
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Schisandra

Schisandra chinensis, S. sphenanthera

Family: Schisandraceae

INTRODUCTION

The plant genus *Schisandra* contains 19 species; of the 12 that are endemic in China,¹ there are two main species – *Schisandra chinensis* and *S. sphenanthera*. These are used interchangeably in traditional Chinese medicine (TCM) for the same indications at the same dosage.² Both are deciduous climbers with a medium rate of growth, with *S. chinensis* growing to about 29 feet (9 meters) and *S. sphenanthera* growing to 23 feet (7 meters).^{3,4} Both have clusters of small white flowers in April through May, followed by red berries. *S. sphenanthera* fruit ripens July through September, while *S. chinensis* fruit ripens a little later, August through October.^{3,4} Both species are exported and traded under the genus and standardized common name schisandra.⁵

The Chinese common name for schisandra is *wu wei zi*, which refers to the five flavors of the fruits – *wu* (五, “five”) *wei* (味, “flavor”) *zi* (子, “fruit and seed”).¹ Depending on the species, the common name *wu wei zi* is preceded by a qualifying prefix. For example, *S. chinensis*, or northern schisandra, is differentiated as *bei wu wei zi* (*bei* means northern), and *S. sphenanthera*, or southern schisandra, is differentiated as *nan wu wei zi* (*nan* means southern).¹

Southern schisandra is dioecious (individual flowers are either male or female, and only one sex is found on any given plant) and mainly grows in broad-leaved forests in temperate and subtropical regions of central and southern China at altitudes of 2300–6560 feet (700–2000 meters).¹ Northern schisandra is monoecious (both male and female flowers are borne on the same plant) and commonly occurs in deciduous and coniferous forests of northeastern China at altitudes of 3937–5577 feet (1200–1700 meters), as well as in parts of North Korea, far northern Japan, and the Russian Far East (RFE).¹

Most of the commercial supply of southern schisandra is wild-collected in the Chinese provinces of Sichuan, Shaanxi, and Gansu, while the supply of northern schisandra comes from both wild collection and wild-simulated cultivation mainly from the northeastern provinces of Liaoning, Jilin, and Heilongjiang. Schisandra marketed with a protected geographical indication (PGI) designation is generally perceived to be of the highest quality and fetches the highest prices. Some wild collection also occurs in parts

of neighboring North Korea and Siberia, mainly for domestic consumption, although a small amount is exported to China.

HISTORY AND CULTURAL SIGNIFICANCE

Since the two species of *Schisandra* discussed in this article are used interchangeably in TCM, attributed uses apply to both species unless stated otherwise.

The first recorded use of schisandra is in the early Chinese herbal medicine text *Shen Nong Ben Cao Jing*, the *Divine Husbandman's Classic Materia Medica*.⁶ It was believed to



Schisandra *Schisandra chinensis*
Photo ©2015 Steven Foster

be one of the superior medicines that would “prolong life without aging” and was said to increase energy, treat cough and fatigue, and serve as a male sexual tonic.

The dried fruit of schisandra is said to be completely balanced because it exhibits all five classically recognized flavors in Chinese herbalism, hence its Chinese name meaning five-flavored fruit.⁶ The skin and pulp are both sweet and sour; the seed is pungent and bitter; and the fruit overall is salty.⁷ It is used as a tonic and sedative, and for the treatment of anxiety, asthma and chronic cough, diarrhea, dream-disturbed sleep, frequent urination, insomnia, night sweats, and palpitations.⁸⁻¹¹ Conditions displaying the following symptoms are treated with schisandra: dry cough, dull complexion, fatigue, labored breathing or shortness of breath, and weakness.⁹ It is also used in combination with other herbs to inhibit sweating, relieve wasting and thirst, and to treat spermatorrhea (involuntary discharge of semen), nocturnal emissions, and urinary incontinence.⁹ In TCM, schisandra is said to have warm properties, to act on the heart, lung, and kidney channels, and to have the following actions: antibacterial, analgesic, antitussive and expectorant, cardiogenic, central nervous system and uterine stimulant, bile secretion promotion, and gastric secretion inhibition.^{10,11}

Different qualities and values are assigned to schisandra fruits of different geographical origins. One of the more famous is “Fushun Liao Schisandra,” produced only in certain ecoregions of Liaoning province.¹² For schisandra to be labeled and marketed with a PGI designation, the berries must be produced in compliance with technical requirements and quality specifications established by China’s General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ).¹³

This is one example of “geoherbalism,” an important concept in TCM that correlates the use of “geo-authentic” (referred to as *daodi*) medicinal materials with the highest clinical efficacy.¹⁴ *Daodi* herbs account for the highest volume and economic value of botanicals used in TCM; of the 500 most commonly used Chinese medicinal plants, about 200 are classified as materials of *daodi* origin, which account for about 80% of total medicinal plant usage in terms of volume.¹⁵ In China, there is a relationship between the practice of geoherbalism and intellectual property laws governing products of “geographical indication” (GI).¹⁶ As such, geoherbalism can be protected as “traditional Chinese medical knowledge” under the GI regulatory framework.¹⁷

Furthermore, for use of schisandra fruit as an active ingredient in medicines, quality standards monographs for both species have been published in the *Hong Kong Chinese Materia Medica Standards*, Vol. 4 (HKCMMS, 2012)¹⁸ and in *The Pharmacopoeia of the People’s Republic of China* (PPRC, 2010).² Additionally, for northern schisandra only, quality monographs are available in the current editions of the *European Pharmacopoeia* (Ph. Eur. 8.0),¹⁹ *Japanese Pharmacopoeia* (JP XVI),²⁰ *Korean Pharmacopoeia* (KP X),²¹ *United States Pharmacopoeia Herbal Medicines Compendium* (USP-HMC Version 1.0, 2015),²² and *WHO Monographs*

on Selected Medicinal Plants, Vol. 3 (2007).²³ The unofficial American Herbal Pharmacopoeia also provides quality standards and analytical methods.⁶

CURRENT AUTHORIZED USES IN COSMETICS, FOODS, AND MEDICINES

In China and other Asian regions where TCM is recognized and practiced, as well as in some Western countries, both species are used as active substances indicated for treating conditions including chronic cough and dyspnea (shortness of breath), nocturnal emission and spermatorrhea, enuresis (urinary incontinence) and frequent urination, chronic diarrhea, spontaneous sweating and night sweating, thirst caused by fluid consumption and interior heat-wasting thirst,* palpitations, and insomnia.²

In the United States, schisandra is permitted as a component of dietary supplement products, requiring Food and Drug Administration (FDA) notification within 30 days of marketing (if a “structure-function” claim is made) and product manufacturing according to dietary supplement current Good Manufacturing Practices (cGMPs).²⁴ The USP has developed draft dietary supplement quality standards monographs for “Northern Schisandra Fruit” and “Northern Schisandra Fruit Powder,” which are scheduled to become official in the first supplement to the 38th revision of the USP in August 2015.²⁵ Certain licensed healthcare practitioners, such as licensed acupuncturists (LAc) and naturopathic doctors (ND), may also dispense schisandra-containing preparations to their patients.

In Canada, both species are classified as medicinal ingredients listed in Table 1 (General Medicinal Ingredients) of the Natural Health Product (NHP) Traditional Chinese Medicinal Ingredients monograph.²⁶ Schisandra is also listed in the draft Cognitive Function Products monograph as an adaptogenic active ingredient “to help increase energy and resistance to stress (e.g., in case of mental and physical fatigue related to stress).”²⁷ At the time of this writing, there were 622 licensed NHPs containing schisandra as a medicinal ingredient.²⁸

In the European Union (EU), although the use of schisandra berries as food or a food ingredient is established — due to evidence of significant human consumption prior to May 15, 1997²⁹ — when claim statements are made, schisandra is regulated as an active ingredient of herbal medicinal products that require pre-marketing authorization and product registration (EPCEU 2004).³⁰ There are no known schisandra mono-preparations with marketing authorization for sale in the EU, although there are some poly-preparations. For example, in 2013, Sweden’s Medical Products Agency granted Bringwell AB (Stockholm, Sweden) traditional herbal registrations for two schisandra-containing products manufactured by the Swedish Herbal Institute (Vallberga, Sweden) called “Chisandra” (coated tablets) and “Chisan” (an oral suspension). The liquid form contains, per mL, 10 mg northern schisandra fruit soft extract (2.0-5.0:1), 2.6 mg eleuthero (*Eleutherococcus senticosus*, Araliaceae) root soft extract (17-30:1), and 3 mg of rhodiola (*Rhodiola rosea*,

Crassulaceae) root and rhizome soft extract (2.5-5.0:1). Both products are labeled with the same indication of “traditionally used as an adaptogen in case of reduced performance ability such as tiredness and fatigue.”^{31,32}

A few *S. chinensis* ingredients are also authorized for use in cosmetic products, including callus extracts (grown in culture), essential oil of the fruit, extracts of the fruit and of the seed (usually supercritical CO₂ soft extracts), fruit powder, and fruit water (aqueous solution of the steam distillates obtained from the fruit). Extracts of *S. sphenanthera* are also listed for functions including antioxidant, antiseborrheic (oil-production regulating), skin conditioning, and skin protecting.³³

MODERN RESEARCH

Pharmacological, animal, and clinical studies have shown schisandra to have adaptogenic, antioxidant, anti-inflammatory, anti-stress, astringent, cardiogenic, energy-enhancing, hepatoprotective, and immune-enhancing properties.³⁴

In the former Soviet Union, interest in schisandra was stimulated by the Nanai (Siberian) hunters who used the herb to improve stamina and night vision and to reduce hunger and thirst. Research conducted in the USSR between 1940 and 1960 supports many of the modern uses of schisandra, specifically for improved mental performance and increased work capacity.³⁴

Most of the modern clinical trials have used fixed combination products containing schisandra. Many of these studies were performed in China and, unfortunately, are of questionable design.

In a 2013 randomized, parallel, placebo-controlled study investigating the effect of a combination product containing schisandra and sesame (*Sesamum indicum*, Pedaliaceae) seed extracts on liver function, 40 patients with borderline liver dysfunction were randomly assigned to experimental or placebo groups (n=20 for each group).³⁵ The subjects were given 34.4 mg/kg per day of *S. chinensis* fruit extract with sesamin (BRAND’S® SCH; containing 0.06-0.12 mg schisandrin B plus 2.25-2.95 mg sesamin, extraction method not specified; Cerebos International Health Ltd.; Taipei, Taiwan) or placebo for five months. Blood samples were taken and assayed at pre-intake and each month for six months post-intake. After five months of SCH administration, liver function and fatty liver were improved, antioxidant capacity was increased, and oxidative stress was greatly reduced. The authors recommended further study of SCH’s detailed mechanisms of action.

A number of clinical studies have been conducted using a Chinese prescription herbal drug called Wuzhi or Wu-Zhi (registration number in China: Z20025766) in combination with other drugs to test their efficacy in addressing liver function.³⁶ It is difficult to determine if all Wuzhi

tablets are made by the same company because the information is not provided in study reports. However, it is probable that, since it is a prescription drug, all of the tablets are made to the same specifications (i.e., an ethanolic extract of *S. sphenanthera* containing 7.5 mg schisandrin A per tablet).

In a 2011 letter to the editor of the *European Journal of Clinical Pharmacology*, one researcher described a study in which 64 renal transplant patients were randomly assigned to receive either tacrolimus (Tac) and mycophenolic acid (immunosuppressive drugs used after organ transplant) plus the anti-inflammatory drug prednisone, or Wuzhi tablets in addition to Tac, mycophenolic acid, and prednisone (n=32 in each group).³⁷ The results indicated that the addition of *S. sphenanthera* extract in the form of Wuzhi tablets increased the bioavailability of Tac. In a 2010 study, researchers investigated the effects of co-administration of Wuzhi and Tac on liver transplant patients.³⁸ During the first phase, all 46 patients received the same dose of Tac. In



Schisandra *Schisandra chinensis*
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*Internal heat in TCM is (1) a heat syndrome caused by consumption of *yin* or body fluid, usually manifested by fever in the afternoon or at night; heat sensation in the chest, palms, and soles; night sweating; thirst; constipation; reddened tongue with scanty coating; and thready, rapid pulse; or (2) invasion of exogenous pathogenic heat into the interior of the body.

the second phase, 21 patients (group A) received the same dose of Tac while 25 patients (group B) received a lower dose; both groups also received Wuzhi. Subsequently, all patients experienced increased Tac concentration in the blood (339% in group A and 262% in group B), improved liver function, and reduced incidence of Tac-associated side effects.

Several clinical trials have been conducted using a multi-herb combination formula called ADAPT-232[®] (containing 27.6% *R. rosea* root extracted with 70% ethanol, 51% *S. chinensis* berry extracted with 95% ethanol, and 24.4% *E. senticosus* root extracted with 70% ethanol; standardized to 0.32% rhodioloside, 0.5% rosavin, 0.05% tyrosol, 0.37% schisandrin, 0.24% schisandrin B, and 0.15% eleutherosides B and E; Swedish Herbal Institute), but the results cannot be attributed solely to the presence of schisandra.

In 2010, a randomized, double-blind, placebo-controlled study investigated the effects of a single dose of this fixed combination product on cognition.³⁹ Forty healthy females who claimed to have felt stressed over a long period of time were randomly assigned to receive a single tablet of ADAPT-232 or placebo. The ADAPT-232 group experienced significantly improved scores with regard to ability to focus, processing speed, and accuracy of task performance. A 2005 randomized, double-blind, placebo-controlled, pilot (phase III) study investigated the efficacy of ADAPT-232 in treating acute non-specific pneumonia.⁴⁰ Two parallel groups of patients (n=60) received bromhexine (an expectorant), cephazoline (an antibiotic), and theophylline (a bronchodilator), in addition to either 20 mL ADAPT-232 or placebo, twice daily for 10-15 days as required. The group receiving ADAPT-232 in addition to the standard treatment required a shorter duration of therapy than those receiving placebo with standard treatment (5.67 days vs. 7.53 days, respectively). In a quality-of-life test, patients who received ADAPT-232 scored significantly higher than the placebo group.

A 2003 randomized, placebo-controlled, pilot study assessed the usefulness of treating Familial Mediterranean Fever (FMF) with ImmunoGuard[®] (a 370 mg fixed combination product containing 50 mg *Andrographis paniculata* [Acanthaceae] extract standardized to 4 mg andrographolide, 10 mg *E. senticosus* extract standardized to > 0.8 mg eleutheroside E, 100 mg *S. chinensis* extract standardized to > 0.8 mg schisandrins, and 10 mg *Glycyrrhiza glabra* [Fabaceae] extract standardized to > 0.6 mg glycyrrhizin; Swedish Herbal Institute).⁴¹ Patients with FMF (n=24) were randomly assigned into two groups; 14 were treated with ImmunoGuard three times over the course of one month with four tablets per day, and the other 10 patients with placebo at the same rate. After one month, the ImmunoGuard group experienced significantly fewer and less-severe FMF attacks.

FUTURE OUTLOOK

The current (April 2015) average market price for dried northern schisandra berries of Liaoning origin (autumn 2014 harvest) is 45.00 Chinese yuan (CNY)/kg (approximately \$7.34/kg) at both the Chengdu TCM Market (Sichuan province) and Anguo TCM Market (Hebei province).⁴²

Southern schisandra berries are trading at 25.00 CNY/kg (\$4.08/kg) at the Chengdu TCM Market.⁴³

A January 2015 market research report involved a survey of 41 Chinese businesses trading in schisandra fruit at the Chengdu TCM Market, of which 35 questionnaires were evaluated (six were invalidated).⁴⁴ Of the 35 respondents, 3% believed that the current market for schisandra was better than had been expected, 37% rated the current market as worse than expected, and 60% thought it was just as expected. Regarding market outlook, 23% of the traders expected upward price movement, 3% expected downward price movement, and 74% of the surveyed companies expected no change.

Since the mid-2000s, the sustainable wild collection of schisandra berries has become an issue within broader natural resource management projects and priorities of conservation-focused non-governmental organizations (NGOs) such as the Wildlife Conservation Society (WCS), World Wide Fund for Nature (WWF), and TRAFFIC, often in collaboration with governmental and inter-governmental agencies charged with biodiversity conservation responsibilities. This has been the case particularly in ecoregions with special conservation status where schisandra berries are harvested for commercial trade by local, rural, and indigenous communities. Examples of such protected regions include the “Ussurisky taiga” and forests of the RFE, which provide habitats for the 400-500 remaining Amur (Siberian) tigers (*Panthera tigris* ssp. *altaica*, Felidae), and the Upper Yangtze ecoregion of Sichuan, Gansu, and Shaanxi provinces that is home to an estimated 1,864 giant pandas (*Ailuropoda melanoleuca*, Ursidae). In such cases, standards have been developed and tests have been implemented for sustainable resource management of the entire ecoregion in consideration of the people, plants, and animals.

In 2004, WCS Russia began working with traditional hunting associations throughout Primorskiy and southern Khabarovskiy Krai in the RFE to develop resource management tools, including a “Tiger Friendly Standard” for the certification of non-timber forest products (NTFPs) such as northern schisandra berries.⁴⁵ The following year, WCS, in partnership with the Far Eastern Association of Non-Timber Forest Producers (FEANTFP), implemented a project “Linking Economic Development and Biodiversity Conservation in the Russian Far East through Tiger Friendly Certification.” The objective of the project was to provide economic incentives for local communities to conserve tigers and their habitats by recognizing sustainably harvested products, including schisandra, marketed with Tiger Friendly Certification.⁴⁶

Starting in 2008, WWF began a three-year project in the Amur tiger habitat. The project — which aimed to “Mitigate Impacts of Climate Change through the Protection of Large Scale Virgin Forests in the Bikin River Valley” — was financed by the German Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety (BMU) and Development Bank of Germany (KfW Entwicklungsbank).⁴⁷ It enabled WWF and its local partners to lease the largest remaining massifs of Korean pine-broadleaf-coniferous forests and collaborate with the indigenous Udege and Nanai communities for sustainable

wild collection of prioritized NTFPs, including northern schisandra berries, eleuthero root, Chaga mushrooms (*Inonotus obliquus*, Hymenochaeta-ceae), and Korean pine (*Pinus koraiensis*, Pinaceae) nuts, among others.

Concerning southern schisandra, the EU-China Biodiversity Programme established a five-year (2007-2011) project for the “Sustainable Management of Traditional Medicinal Plants in the High-Biodiversity Landscapes of Upper Yangtze Eco-region.” The project was funded by the EU and implemented by the United Nations Development Programme in cooperation with China’s Ministry of Environmental Protection.⁴⁸ As a result of the project, a 22-village cooperative was established to sell certified organic wild schisandra berries, and, in 2009, the Chengdu University of TCM, TRAFFIC, and WWF China collaborated to produce a Chinese-language book on sustainable wild-harvesting practices for southern schisandra berries. The collaboration also resulted in draft “Standards for Giant Panda Friendly Products,” which specifically apply to the management of three products — honey, southern schisandra berries, and bamboo (including leaves and shoots) — in the giant panda distribution areas of the Sichuan province.⁴⁹

In 2013, government officials in Jilin province estimated the annual market demand for schisandra fruit to be approximately 3-3.5 million kg (dry weight) and increasing.⁵⁰ Their report also stated that the reserve of wild schisandra was steadily declining due to habitat destruction (development) and non-sustainable harvesting practices. The annual yield of wild-harvested schisandra is beginning to fall significantly below annual market demand. Based on these data, large schisandra cultivation projects have been in the works with provincial and national governmental support. One such project is ongoing in the Yanbian Korean Autonomous Prefecture area of eastern Jilin province, adjacent to North Korea and the RFE.

Schisandra vines tend to climb trees in biodiverse forests of eastern Asia that are also inhabited by threatened and endangered large mammals. This has led to innovative approaches in nature conservation that aim to incentivize and empower local, rural, or indigenous communities, who earn some or all of their household income from wild collection of NTFPs, to become stewards of the ecosystems that they themselves are a part of — and benefit economically by offering sustainably harvested schisandra (and other forest products) at a premium price while help-



Schisandra *Schisandra chinensis*
Photo ©2015 Steven Foster

ing to ensure the long-term survival of endangered animal and plant species. Schisandra has become a beneficiary of the considerable support from national and international governmental agencies and NGOs to effectively protect certain sensitive ecoregions. One of the authors of this article (JB) has been involved with sustainable schisandra projects in both China and the RFE, and has observed sustainable wild-collection operations in several provinces as well as wild-simulated cultivation of both northern and southern schisandra.

With these projects in place, even with the increasing global demand for schisandra, a sustainable supply should be possible in view of the new plantation projects for northern schisandra starting up within the species’ geographical origin. The future market will offer choices of wild-collected, geo-authentic berries and increasingly wild-simulated cultivated berries, which can also, in principle, be produced according to the requirements for PGI products. HG

—Gayle Engels and Josef Brinckmann

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dear reader

DNA and Identity of Botanical Ingredients — More Perspectives

Let's be clear about DNA testing and herb identity. As we have stated in these pages in extensive articles in 2010 and 2013, DNA barcoding and related genetic testing methods are excellent means to determine the identity of plant raw materials, and DNA testing should be considered by the herb industry as another viable analytical tool to add to the existing "toolbox" of scientifically valid analytical methods. However, we have never suggested that DNA barcoding

alone is appropriate for such testing (e.g., it cannot distinguish plant parts of the same plant, a Good Manufacturing Practices requirement in the US). In addition, as the recent case with the New York Attorney General's misuse of DNA barcode testing has made abundantly clear, DNA testing is not appropriate for most herbal *extracts*, again, especially without corroboration and confirmation with other valid testing methods.

As reported in Tyler Smith's extensively detailed overview of the NY AG's actions thus far, the NY AG and retailer GNC have agreed that GNC will begin to employ DNA barcoding in its quality control regimens within 18 months. Per the deal, the NY AG has allowed GNC to resume sales in New York state of the six herbal *extract* supplements that, only a few weeks before, the NY AG had claimed were mislabeled, fraudulent, possibly "contaminated," and posing a public health problem — all based on the NY AG's sole reliance on DNA testing by a university lab with no apparent prior experience in this type of analysis.

The NY AG's staff members have told industry representatives that they no longer care about the DNA issue — i.e., whether the method was appropriate or adequate — and thus presumably about the accuracy of the results. The NY AG has moved on to the bigger political issue of pushing the herb regulation agenda to the front pages and to Congress. In other words, the ends justify the means. However, as we went to press, the NY AG issued a statement with a trade organization suggesting his partial acknowledgement of the limitations of DNA testing, albeit three months after starting his campaign.

While we welcome a robust discussion of quality control related to herbal supplements, particularly with respect to their identity and authenticity — after all, ABC is the founding and managing partner in the four-year-old ABC-AHP-NCNPR Botanical Adulterants Program wherein we are attempting to educate industry and other interested stakeholders on issues related to accidental and intentional adulteration of botanical raw materials and extracts — we prefer to have such a discussion based on appropriate use of scientifically valid and validated analytical methodology. Accordingly, ABC will continue to press the issue regarding the NY AG's entire case being built on probably faulty evidence — an analytical "house of cards" (or perhaps an even less-stable construction). As we stated previously in *HerbalGram*, we are attempting to defend *appropriate scientific methodology* and *accuracy* as a basis for legal action and public discourse.

This issue contains several articles related to botanical quality control. In addition to Tyler's article on the NY AG DNA affair — probably one of the most extensively detailed on this subject — we also provide our Chief Science Officer Stefan Gafner's review of two white papers released in March by experts on the capabilities and limitations of DNA analysis for herbal supplements — one by experts in analysis of botanical dietary supplements and the other by two former officials of the Food and Drug Administration. Although some critics might tend to dismiss the papers since they were commissioned and released by supplement industry trade associations, the content and results are scientifically and technologically sound and would most likely be generally accepted by most medicinal plant analytical experts.

Another article on "Botanical Integrity" is submitted by our good friends at the College of Pharmacy at the University of Illinois at Chicago, an internationally recognized center for medicinal plant research. New ABC Advisory Board member Professor Guido Pauli and UIC colleagues have written the first part of a proposed series on botanical integrity, i.e., the use of scientific techniques to assess botany (including DNA testing), chemistry, and biological activity (including safety), all of which are required to adequately determine the "integrity" of the botanical material.

In this issue we also warmly welcome 13 new members to our Advisory Board, including medicinal plant experts from Australia, Canada, Germany, the United Kingdom, and United States. The growing and increasingly international ABC Advisory Board provides a broad range of volunteer expert services to ABC, including peer review of ABC publications, advice on ABC policy, and more.

Finally, this issue contains six obituaries of persons who have contributed significantly to the botanical and medicinal plant community, some of whom have passed at relatively young ages — a reminder to all of us to make every day, and every breath, count. HG

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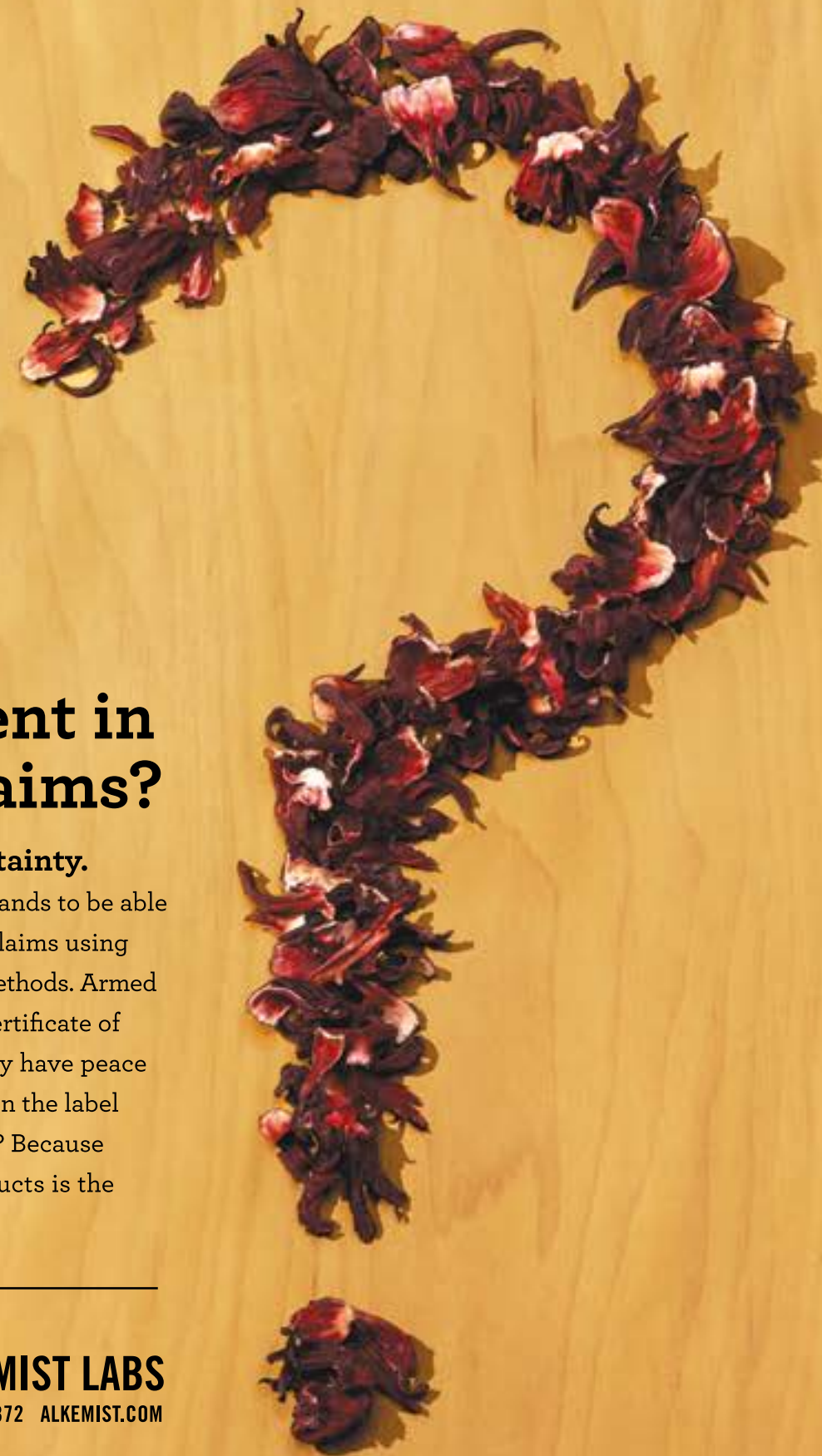
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The Supplement Saga: A Review of the New York Attorney General's Herbal Supplement Investigation

By Tyler Smith

The New York Attorney General's (NY AG's) crusade against herbal supplements, which began unexpectedly on February 3, 2015, has been a source of much frustration, confusion, and concern for the dietary supplements industry and herbal community. Over the past three-plus months, NY AG Eric T. Schneiderman has taken multiple significant and unprecedented actions against herbal products, companies, and manufacturers. In February, he ordered GNC, Walgreens, Walmart, Target to stop sales of certain store-brand herbal supplements; in March, Schneiderman announced a "landmark" deal with GNC, in which the company agreed to test its raw herbal materials using DNA barcoding; and, in April, his coalition of state attorneys general asked Congress to launch an inquiry into the supplements industry. Each of these developments stemmed from the results of the NY AG's DNA barcoding of 78 herbal supplements from the four retailers, which indicated a lack of the labeled herbs' DNA, or the presence of unlisted ingredients, in roughly 80% of the products. Although members of the natural products industry initially fixated on the shortcomings of DNA-based analyses for botanical extracts — which remains a scientifically sound argument — as Schneiderman widened the scope of his investigation, the community's message evolved to focus on education, transparency, and authenticity — and signs of compromise have emerged from both sides.

St. John's Wort *Hypericum perforatum*. Photo ©2015 Steven Foster



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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 Publishes 6,000th HerbClip™ Research Summary

The American Botanical Council (ABC) published its 6,000th HerbClip™ on April 15, 2015. An essential resource for scientists, researchers, health professionals, and others, HerbClips are two- to three-page summaries and critical reviews of scientific journal articles covering medicinal plant-related human clinical research, analytical methods, regulatory data, market information, ethnobotanical reviews, conservation and sustainability studies, and much more.

HerbClip summaries and reviews are typically focused on the growing body of human clinical trials for herbs and phytomedicinal products, including systematic reviews and meta-analyses of such clinical trials. These articles are drawn from a wide variety of peer-reviewed scientific and medical journals, as well as occasional monographs, government documents, special reports, trade journals, and news articles. In addition to summarizing the original article, HerbClips often include insights, perspectives, criticisms, and links to other articles or resources.

Per ABC style, HerbClip reviews always provide the trade name of the medicinal product on which the study is based — including the name of the company that produced the tested material or product — as well as a description of the product, extract, or material so that the reader is able to have a better understanding of the potential significance of the study's results. HerbClip summaries and reviews are vetted by editors and peer reviewers before they are published to help ensure their accuracy.

"In this era of ever-expanding information, it becomes increasingly difficult to remain apprised of such varied content without some assistance that provides an overview of pertinent material. HerbClips have served that need for me," said Francis Brinker, ND, HerbClip consulting editor, clinical assistant professor in the Department of Medicine at the University of Arizona College of Medicine, and an ABC Advisory Board member. "HerbClips have been a steady and wide-ranging supply of information on botanicals that otherwise would have often passed me by."

HerbClip's roots stretch back to 1993, just five years after ABC was founded. At the time, ABC Founder and Executive Director Mark Blumenthal would often photocopy and share relevant news articles with numerous friends and professional colleagues. When the cost of toner for ABC's copier became prohibitively expensive, inspiration struck. Blumenthal called two close friends in the herb industry and asked if they would be willing to pay for a service to send them summaries of the latest herb research and related developments. The friends agreed, and HerbClip was born.

In the beginning, HerbClip involved mailing summa-



ries and reviews of herbal literature to ABC colleagues in the academic and scientific communities, as well as key members of industry. At the time, no such service existed in the natural medicine and herbal supplement industry. The groundbreaking HerbClips offered not only summaries and reviews, but also the original articles on which they were based when such permissions were granted by the articles' publishers. In 2005, ABC started to include HerbClip News with each mailing — a column of commentary from HerbClip Managing Editor Lori Glenn. Two years later, the first electronic HerbClips were sent to ABC members, dramatically expanding readership. By 2009, all HerbClips were delivered electronically, which further solidified the organization's commitment to environmental sustainability.

"There has been a virtual explosion of scientific and clinical publications on herbs, medicinal plants, phytomedicines, essential oils, so-called 'functional foods,' and medicinal fungi in the past several decades," noted Blumenthal. "HerbClip is probably one of the most robust databases available anywhere that provides researchers and other interested parties a much deeper dive into the herbal science and clinical literature than merely reading a study's abstract."

"I would like to take this opportunity to formally thank HerbClip Managing Editor Lori Glenn for her long-time service to ABC and the herbal community for her stewardship of HerbClip for over 11 years," added Blumenthal. "ABC also gratefully acknowledges HerbClip writers Heather Oliff, PhD, who has written over 1,120 HerbClips since 1999, and Mariann Garner-Wizard, who has written more than 1,000 HerbClips since 1999."

"HerbClip has an amazing group of writers and consulting editors," said Glenn. "The peer reviewers, who provide their expertise to the various subjects covered

in HerbClip, are an integral part of the process, and their input is vital to the quality of the summaries and critical reviews produced. Tamarind Reaves, the assistant editor, consistently and thoroughly examines each HerbClip prior to the production process. I am most appreciative of all the time and effort from those who are part of the HerbClip educational service."

"Wow, 6,000 HerbClips!" exclaimed Dr. Oliff, of California-based Science Consulting Group, LLC. "Reading HerbClip is an easy way to keep abreast of the latest research in the industry. I appreciate that the HerbClip writers critique the reports so that readers can quickly see the value of a study. I am so proud to have written more than one-sixth of the total HerbClips."

HerbClip summaries and reviews are available

online through the ABC website, www.herbalgram.org. The entire database of 6,000 articles is searchable by common and Latin names of herbs, author names, journal and article titles, pharmacological actions, clinical endpoints, conditions, and more.

Fifteen new HerbClips and an HerbClip News article are produced twice monthly. At least four HerbClips from each installment are available to the public for free; ABC members at the Academic level and above can access the entire HerbClip database. Sponsor members also receive HerbClips and, when available, the PDF versions of the original articles on which they are based. HG

"HerbClip is probably one of the most robust databases available anywhere that provides researchers and other interested parties a much deeper dive into the herbal science and clinical literature than merely reading a study's abstract."

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Expand Your Herbal Library. It's as easy as ABC!

These are just a few of the recent additions to the ABC catalog of expert books.

Ancient Pathways, Ancestral Knowledge: Ethnobotany and Ecological Wisdom of Indigenous Peoples of Northwestern North America by Nancy J. Turner, 2014. Turner, the preeminent ethnobotanist studying the First Nations of Canada, weaves together a complex understanding of the traditions of use and management of plant resources in this vast region. She follows Indigenous inhabitants over time and through space, showing how they actively participated in their environments, managed and cultivated valued plant resources, and maintained key habitats that supported their dynamic cultures for thousands of years, as well as how knowledge was passed on from generation to generation and from one community to another. To understand the values and perspectives that have guided Indigenous ethnobotanical knowledge and practices, Turner looks beyond the details of individual plant species and their uses to determine the overall patterns and processes of their development, application, and adaptation. Hardcover, Two volumes, 1056 pages. **\$100.00 (\$90.00 ABC Member Price)**

Botanicals: Methods and Techniques for Quality and Authenticity by Kurt Reynertson and Khalid Mahmood, 2015. Insight compiled from expert contributors addresses the challenge of identifying a botanical extract or preparation on the basis of its chemical content and includes a range of methods and techniques that can be used to help guide quality and authenticity determinations. Topics include metabolic profiling, authentication via morphology, and genetic methods of authentication; NMR, NIR, and HPTLC methods; and tools for building models for the authentication of materials. Hardcover, 332 pages. **\$125.96 (\$113.36 ABC Member Price)**

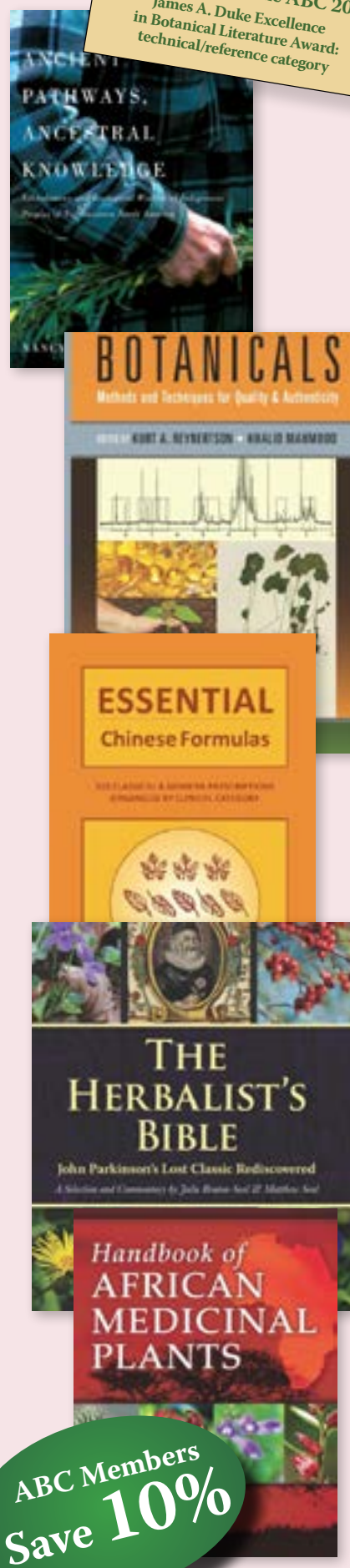
Essential Chinese Formulas: 225 Classical and Modern Prescriptions Organized by Clinical Category by Jake Paul Fratkin, 2014. Calling on the author's 35 years of clinical experience with Chinese herbal medicine, this book concisely summarizes existing information on 133 classical Chinese formulas, 83 modern formulas, and nine single herbs. It provides ingredient percentages, historical origins, TCM indications, commentary with clinical applications, and contraindications and cautions. Hardcover, 650 pages. **\$65.00 (\$58.50 ABC Member Price)**

The Herbalist's Bible: John Parkinson's Lost Classic Rediscovered by Julie Bruton-Seal and Matthew Seal, 2014. John Parkinson (1567-1650) was a practicing London apothecary, herbalist to the royal family, renowned gardener, and author. *The Herbalist's Bible* is a gorgeous presentation of 50 of the herbs addressed in Parkinson's *Theatrum Botanicum* of 1640, the main medical text of its day. Each reproduced page from Parkinson's herbal is set opposite a modern translation which includes therapeutic applications illustrated with color photographs. Hardcover, 256 pages. **\$37.94 (\$33.97 ABC Member Price)**

Handbook of African Medicinal Plants, 2nd ed. by Maurice M. Iwu, 2014. An overview of 2000 species of plants available in Africa as medicinal agents, with information about botany, chemistry, pharmacology, and usage, including traditional healing methods. Provides a pharmacognosy-based profile of 170 of the major herbs, with a brief description of the diagnostic features of the leaves, flowers, and fruits and monographs with botanical names, common names, synonyms, African names, habitat and distribution, ethnomedicinal uses, chemical constituents, and reported pharmacological activity. Hardcover, 506 pages. **\$125.96 (\$113.36 ABC Member Price)**



RECIPIENT of the ABC 2014
James A. Duke Excellence
in Botanical Literature Award:
technical/reference category



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ABC Welcomes 13 New Advisory Board Members

The American Botanical Council (ABC) welcomes 13 new expert members to its Advisory Board. The addition of these distinguished individuals, six of whom are from outside the United States, represents ABC's continued goal of expanding its international relationships and educational impact. They join 127 existing members, including 32 international experts. The new members will bring their perspectives and experiences from numerous scientific fields related to the study of medicinal plants, including ethnobotany, pharmacognosy, phytotherapy, pharmacy, organic chemistry, biochemistry, natural products research, and more.

"We are deeply grateful to these highly qualified new members of the ABC Advisory Board for their willingness to engage formally with ABC and help us promote our nonprofit educational mission," said Mark Blumenthal, founder and executive director of ABC. "These people constitute some of the leading experts in their respective fields, and their active association with ABC will help ensure the high-quality, accurate, and reliable educational information for which ABC is known."

ABC Advisory Board members generously volunteer their time to peer review articles that appear in *HerbalGram*, *HerbalEGram*, *HerbClips*, and various other peer-reviewed ABC publications. Additionally, ABC management and *HerbalGram* editors seek feedback and advice from Advisory Board members on research questions, article ideas, ABC policies, and book reviews, among many other topics.

"One of the most exciting aspects of the work at ABC is to have this unique network of experts in the many aspects of botanical medicine available," noted Stefan Gafner, PhD, ABC's chief science officer. "The breadth of knowledge that the new members will bring to ABC is extraordinary, and I am looking forward to a closer interaction with this talented group of individuals with expertise in traditional use, clinical studies, molecular biology, formulation, chemical analysis, and regulatory aspects of medicinal plants."

The newest ABC Advisory Board members are the following:

Valerie Assinewe, PhD, has consulted on projects for the Aboriginal Traditional Knowledge Subcommittee, a branch of the Committee on the Status of Endangered Wildlife in Canada. Fluent in English, French, and Ojibwa, Dr. Assinewe conducts research on indigenous plants with traditional uses in Canada, including cherry birch (*Betula lenta*, Betulaceae), American ginseng (*Panax quinquefolius*, Araliaceae), and eleuthero (*Eleutherococcus senticosus*, Araliaceae). She previously worked at Health Canada's Natural Health Products Directorate for 10 years, developing monographs and labeling standards for natural health products and reviewing product license applications to determine safety and efficacy. She has given many presentations about the role of First Nation traditional knowledge in pharmacology and biology, and her articles have been published in a number of journals including

Phytochemistry, *Biodiversity*, and the *American Journal of Clinical Nutrition*. Dr. Assinewe is a member of the Sagamok Anishnawbek First Nation.



Alan Bensoussan, PhD, DipAc, is the director of the University of Western Sydney's Australian National Institute of Complementary Medicine. From 2008 to 2011, he was a member of the National Medicines Policy Committee, and from 2012 to 2014 he served as chair of the Australian Therapeutic Goods Administration's Advisory Committee for Complementary Medicines. Dr. Bensoussan's

awards and accolades include the Complementary Medicines Australia's (formerly the Complementary Healthcare Council of Australia) Lady Cilento Award (2014) and the International Award for Contribution to Chinese Medicine (2013), which is awarded by the Chinese government. An expert in traditional Chinese medicine, Dr. Bensoussan's research and publications helped to establish Australia's regulation of Chinese medicine practitioners. He is the author of two books, and his work has appeared in a number of respected journals, including the *Journal of the American Medical Association*.

Chantal Bergeron, PhD, is the manager of research and development for home and personal care products at Seventh Generation. Previously, Dr. Bergeron spent 13 years as director of research at Tom's of Maine, where she developed novel plant-based materials for oral, body care, and self-care products. Her innovative work has led to the development of hops (*Humulus lupulus*, Cannabaceae) and olive (*Olea europaea*, Oleaceae) leaf extract as deodorant and antiperspirant ingredients. Dr. Bergeron attended graduate school at Laval University in Quebec City, Canada, and the University of Lausanne in Switzerland; her post-doctorate work was completed at the University of Ottawa. She has received four Technology Innovation Fund grants from Colgate-Palmolive, holds numerous patents, and has authored or co-authored 25 scientific papers. Bergeron is a member of American Society of Pharmacognosy and the Society for Medicinal Plant and Natural Product Research (GA).





Nadja Cech, PhD, is an associate professor of chemistry at the University of North Carolina (UNC) Greensboro. In 2001, Dr. Cech completed her PhD in analytical chemistry at the University of New Mexico, where she studied electrospray ionization mass spectrometry. Her research at UNC Greensboro over the past 13 years has focused on the synergistic biological activities of components of botanical

extracts and the development of analytical methods to address such complex interactions. These research efforts have been funded in part by the National Center for Complementary and Integrative Health (NCCIH; formerly the National Center for Complementary and Alternative Medicine). Dr. Cech received the Jack L. Beal Award for Best Paper in the *Journal of Natural Products* by a Young Investigator in 2011, the UNC Greensboro Junior Research Excellence Award in 2010, and the UNC Greensboro College Teaching Award in 2008. To date, Dr. Cech has published more than 30 peer-reviewed scientific papers.

Zoë Gardner has served as the research and development manager for the herbal wellness tea company Traditional Medicinals since 2012. She completed a master's degree and is finishing a doctoral program in plant and soil sciences — focusing on the cultivation, conservation, and quality of medicinal plants — at the University of Massachusetts at Amherst. Gardner served as the program coordinator and a research fellow for the University's medicinal plant program from 2000 to 2006 and from 2007 to 2010, respectively. She has co-authored more than a dozen scientific journal articles and is the research editor of the *American Herbal Products Association's Botanical Safety Handbook*, 2nd ed., probably the most current and comprehensive review of the safety issues related to herbs and medicinal plants that are available in commerce in the United States.



Gabriel Giancaspro, PhD, is vice president of the Foods, Dietary Supplements, and Herbal Medicines Division of the United States Pharmacopeia (USP). He earned his pharmacy degree and doctorate in medicinal chemistry from the University of Buenos Aires and spent 17 years teaching and researching medicinal chemistry, drug stability, and drug analysis at the University's School of Pharmacy. Dr. Giancaspro has served in leadership positions for several companies — including Rigecon, Schwabe-Argentina, and Kampel-Martian — where he was responsible

for regulatory affairs, analytical research and development, and quality control of herbal medicines. He joined USP in 1995 as a visiting scientist and later became the director for dietary supplements in USP's Documentary Standards Division, the division charged with developing monographs for herbal dietary supplements. Dr. Giancaspro is a member of AOAC International and was an editorial board member of the *Journal of AOAC International*.

Joerg Gruenwald, PhD, is the founder and chief scientific advisor of Analyze & Realize GmbH in Berlin, Germany, a specialized research and consulting company for natural health products, phyto-medicines, functional foods, dietary supplements, and other natural medicinal items. Previously, he served as co-founder and board member of InQpharm and chief scientific officer of Biotropics Malaysia. He has authored and edited 13 books, including *Physician's Desk Reference for Herbal Medicines*, *Plant-Based Ingredients for Functional Foods*, and acted as a co-editor of the American Botanical Council's *The Complete German Commission E Monographs*, as well as over 300 scientific articles. He has worked as advisor to the Office of Dietary Supplements at the US National Institutes of Health, is on the International Advisory Board of the Research Council for Complementary Medicine, was chairman of the American Herbal Products Association's International Committee, and is a member of the Council for Responsible Nutrition's Botanical/Quality Standards Committee and the USP's Ad Hoc Group on Botanicals.



Pierre Selim Haddad, PhD, is director of the Natural Health Products and Metabolic Diseases Laboratory and director of the Research Team in Aboriginal Antidiabetic Medicines in the pharmacology department at the Université de Montréal in Quebec, Canada. He received his PhD in pharmacology from the Université de Montréal in 1986, after earning his bachelor's degree in physiology from McGill University in 1981. In 1992, Dr. Haddad was the recipient of the Young Physiologist Award from the Association des Physiologistes. In 2014, he received the Natural Health Products Research Society's Neil Towers "Pride of Burma" Award. He served as an expert policy advisor for Health Canada's Natural Health Products Directorate, as a research consultant and coordinator for the Lucie and André Chagnon Foundation, and as an expert policy advisor for Environment Canada's Office of Biodiversity. He has been a scientific advisory board member of the Institute of Aboriginal Peoples' Health of the Canadian Institutes of Health Research since 2009.



James Harnly, PhD, is an analytical chemist with expertise in atomic and molecular spectroscopy and more than 40 years of experience with industry and government organizations. Since 1997, he has served as the research leader for the Food Composition and Methods Development Laboratory at the Beltsville Human Nutrition Research Center — a division of the US Department of Agriculture's Agricultural Research Service — where he is developing new analytical methods for the identification of compounds in botanical products. To date, Dr. Harnly has authored more than 130 peer-reviewed papers, 18 technical reports and book chapters, and holds two patents. He was the editor of the *Journal of Analytical Atomic Spectrometry* for 22 years, and is a member of the Society for Applied Spectroscopy, American Society for Nutrition, American Society for Mass Spectrometry, and AOAC International, for which he served as board president from 2013 to 2014.



Michael Heinrich, Dr. rer. nat. habil, MA, Dipl. Biol, FLS, is a pharmaceutical biologist/pharmacognosist and anthropologist with multidisciplinary research interests including medicinal and food plant research, particularly bioactive natural products, as well as the interface of cultural and natural sciences on the traditional use of food and medicinal plants, primarily in Mexico and the Mediterranean. He currently is the head of the

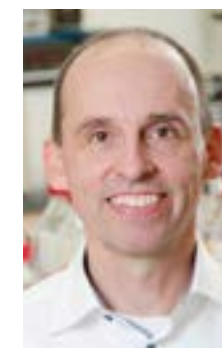
Biodiversity and Medicines research cluster and professor at the University College London's School of Pharmacy in the United Kingdom. He is also the editor-in-chief of *Frontiers in Ethnopharmacology*, reviews editor for the *Journal of Ethnopharmacology*, and a member of the editorial board for a wide range of journals in the area of medicinal plant research. Previously, he was the founding director of the Southern Cross Plant Science Program at Southern Cross University in Lismore, Australia. He is also the co-author or editor of six books, including the second edition of *Fundamentals of Pharmacognosy and Phytotherapy* and *Phytotherapy: An Evidence-Based Guide to Herbal Medicinal Products* (April 2015).

Andrea Ottesen, PhD, is the research area coordinator for metagenomics in the Molecular Methods and Subtyping Branch of the Division of Microbiology at the US Food and Drug Administration's Center for Food Safety and Applied Nutrition, focusing on microbial ecology and metagenomics of high-risk crops. She



is also an adjunct assistant professor in the Department of Plant Science and Landscape Architecture at the University of Maryland and spent many years as a botanical research technician at the Jim Duke Green Farmacy Gardens doing medicinal plant research. In her position as adjunct assistant professor, she co-taught "Medicinal Plants of the Amazon" with Dr. Jim Duke in the Peruvian Amazon. She currently mentors graduate and undergraduate research teams. Dr. Ottesen has given many presentations regarding her work and research around the world.

Guido Pauli, PhD, FAPA, has belonged to the College of Pharmacy at the University of Illinois at Chicago since 2001, when he joined the faculty as a research professor for the Institute for Tuberculosis Research. He became a member in full standing of the graduate faculty in 2002 as an assistant professor at the Department of Medicinal Chemistry and Pharmacognosy, advanced to the rank of professor in 2012, and was named University Scholar in 2014. He teaches pharmacognosy and pharmaceutical biology in addition to advising graduate students and postdoctoral fellows. He has served as a member for panels and work groups for the NCCIH, part of the National Institutes of Health, since 2006, and the USP, since 2010. He is the associate editor of *Chinese Herbal Medicines* and has served on the editorial boards and as peer reviewer for several English- and Spanish-language phytomedicine publications.



Alain Touwaide, PhD, is an expert in ancient Mediterranean botany with a focus on medicinal plants. He has served as scientific director of the Institute for the Preservation of Medical Traditions since 2007 and has been a Smithsonian Institution research associate since 2011. Dr. Touwaide earned his bachelor's, master's, and doctoral degrees from the University of Louvain in Belgium. Over the course of his career, he has been a fellow at the Dumbarton Oaks Center for Byzantine Studies, a Rockefeller Foundation Fellow at the University of Oklahoma, a scholar-in-residence at the National Library of Medicine, and a visiting professor at universities around the world. He is the author or co-author of eight books and numerous book chapters, essays, and scholarly papers. In 2014, he received a prize from the International Society for the History of Medicine honoring his outstanding contribution to the history of medicine, and was elected fellow of the International Academy of the History of Science for his life-long dedication to the discipline. HG



American Botanical Council Presents Annual Botanical Excellence Awards

The American Botanical Council (ABC) hosted its 10th annual ABC Botanical Celebration and Awards ceremony on March 5, 2015, at the Hilton Anaheim in Anaheim, California. This event honors the support of ABC's Sponsor Members and the contributions to the herbal community by the recipients of ABC's Botanical Excellence Awards. As in previous years, it was held in conjunction with the Natural Products Expo West trade show and NEXT Innovation Summit.

The annual Celebration brought together a diverse group of approximately 350 ABC supporters — ABC Sponsor Members; Small Business Members; members of the ABC Board of Trustees, Advisory Board, and Director's Circle; and others — for a lively evening of conversation, cocktails, hors d'oeuvres, and an engaging awards ceremony. Highlights of the evening included ABC Founder and Executive Director Mark Blumenthal's always-anticipated cartoon slideshow, and a special and timely presentation by United Natural Products Alliance (UNPA) President Loren Israelsen, titled "The Herb Industry at the Crossroads: The Impact of the New York Attorney General's DNA Test on Herbal Supplements."

The night also marked the announcement of Terry Lemerond, founder and president of EuroPharma, Inc., as the recipient of the first-ever ABC Champion Award. Blumenthal made the announcement as he kicked off the awards portion of the program, lauding Lemerond for his decades of commitment to ABC's mission and programs, as well as his 40 years of activity and contributions within the herbal community.

ABC Board Chair, Thomas Newmark, announced the recipient of the James A. Duke Excellence in Botanical Literature Award — Nancy J. Turner, PhD, for her two-volume work, *Ancient Pathways, Ancestral Knowledge*. Dr. Turner accepted the award and conveyed her deep gratitude for the honor via a short video shown at the ceremony.

Joseph Betz, PhD, director of the Analytical Methods & Reference Materials Program at the Office of Dietary Supplements, presented the Norman R. Farnsworth Excellence in Botanical Research Award to Harry H.S. Fong, PhD. Daniel Fabricant, PhD, CEO and executive director of the Natural Products Association (NPA) and a former student of Drs. Farnsworth and Fong, accepted the award in Dr. Fong's stead.

The Varro E. Tyler Commercial Investment in Phytomedicinal Research Award was presented by ABC Chief Science Officer Stefan Gafner, PhD, to Soho Flordis International (SFI). Nigel Pollard, CEO of SFI, accepted the award on behalf of his Australian-based company.

Finally, Blumenthal presented the third annual Herbal Community Builder Award — the recipient of which was not announced prior to the Celebration — to Loren Israelsen. Israelsen accepted the award and expressed his gratitude



for the collaboration with ABC over the years working toward the common good within the herbal community.

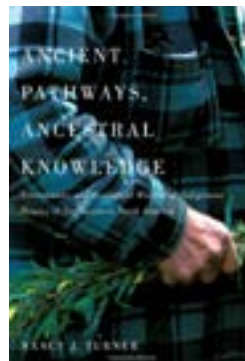
Additional details about the ABC Awards and recipients are as follows:

Book Documenting Northwest Native American Uses of Medicinal Plants Is Recipient of ABC James A. Duke Excellence in Botanical Literature Award

Dr. Nancy Turner received the Duke award for her two-volume work — *Ancient Pathways, Ancestral Knowledge: Ethnobotany and Ecological Wisdom of Indigenous Peoples of Northwestern North America* (McGill-Queen's University Press, 2014) — which is based on her research concerning the plants, practices, and ecology of native tribes. Dr. Turner is an ethnobotanist and Distinguished Professor and Hakai Professor in Ethnoecology at the University of Victoria in British Columbia, Canada.

The ABC James A. Duke Excellence in Botanical Literature Award was created in 2006 in honor of noted economic botanist and author, James A. Duke, PhD. It is awarded annually to books that provide a significant contribution to the literature in the fields of botany, taxonomy, ethnobotany, phytomedicine, or other disciplines related to the vast field of medicinal plants. Along with his expansive and prestigious career achievements in economic botany and ethnobotany and decades of work at the United States Department of Agriculture (USDA), Dr. Duke has authored more than 30 reference and consumer books. He is also a co-founding member of ABC's Board of Trustees and currently serves as Director Emeritus.

Ancient Pathways, Ancestral Knowledge represents four years of research and writing, drawing from Dr. Turner's previous work and publications. She compiled a database of plant names from approximately 50 Indigenous languages and major dialects of the First Peoples, whose territories extend through most of the area covered in the book — from central Alaska to the Columbia River and east to the Rocky Mountains in western North America. "That showed some



amazing connections, in some cases across long distances, that must have resulted from communication and linkages going way back into the past," said Dr. Turner.

"I tried to write the book in an accessible way," Dr. Turner continued, "so that it would be useful and of interest to a large and diverse group, from undergraduate university and college students to interested members of the general public. Most especially, I wanted to honor the elders and knowledge holders from Indigenous communities, and hope that younger generations will find the information in the book relevant and important as a part of their own cultural heritage."

As Dr. Duke noted in his review of *Ancient Pathways, Ancestral Knowledge* in issue 105 of ABC's peer-reviewed journal *HerbalGram*, "I have long admired Dr. Turner's great work. As I skim pleasantly through her books, I can see interesting parallels between the late, great [Harvard ethnobotanist] R.E. Schultes, PhD, and his students assembling anthropological and ethnobotanical data on the First Amazonian Americans into a solid framework. Nancy and her students have done the same for approximately 500 ethnobotanical species of the First Americans in Northwest America."

Dr. Turner, who has been studying ethnobotany and the cultures of Indigenous American peoples since 1967, has taught full-time at the University of Victoria since 1991. She has written more than 20 books and numerous articles, and also has an impressive array of awards, grants, and honors to her name, including Distinguished Economic Botanist of the Year from the Society for Economic Botany in 2011 and appointment as a Member of the Order of Canada in 2009. ABC has proudly included her on its Advisory Board since 1996. *Ancient Pathways, Ancestral Knowledge* represents the culmination of a career of almost 50 years.

"I was always interested in plants and people," said Dr. Turner. "Once I learned that this study was called ethnobotany ... that's what I wanted to study. It's in my high school yearbook (1965). I remember [that] in grade four, I was already serving dandelion and wild greens salad to my friends, much to their parents' concern." Thanks to her continued dedication to teaching through experience, Dr. Turner's students absorb much more than names and places, and it is this idea that permeates her text. "[The students] learn that humans can live within Nature without destroying it, working with natural processes and Nature's wonderful abilities to regenerate and restore itself," she said.

"Dr. Nancy J. Turner collects, preserves, and explores biological information for (not from) Indigenous cultures, primarily First Nation groups in British Columbia," said Steven Foster, noted author, photog-

rapher, and former president of the ABC Board of Trustees. "Her five decades of shared wisdom challenge how we think about people as a part of, rather than apart from, ecosystems. *Ancient Pathways, Ancestral Knowledge* is a magnum opus of timeless value that will define ethnobotany and ethnoecology for generations forward."

"Ethnobotany is a key foundation of modern herbal medicine," said Blumenthal. "Much of the herbal knowledge we have today is based on the traditional uses of plants by people in Indigenous cultures. Nancy Turner's documentation of the plant use in northwestern North America is a true treasure."

Prof. Harry H.S. Fong Receives ABC's Norman R. Farnsworth Excellence in Botanical Research Award

Professor Fong received the ABC Norman R. Farnsworth Excellence in Botanical Research Award for 2014. Dr. Fong — a close friend and collaborator of Prof. Farnsworth for almost 60 years — is professor emeritus of pharmacognosy in the Department of Medicinal Chemistry and Pharmacognosy at the University of Illinois at Chicago (UIC). ABC presents this award each year to a person who or an institution that has made significant contributions to ethnobotanical and/or pharmacognostic research (i.e., research on drugs of natural origin, usually from plants).

Throughout his long career in academia, Dr. Fong has focused his research efforts on collaborative drug discovery from plants, particularly those with active antitumor, cancer chemopreventative, antimalarial, and anti-tuberculosis activities. Dr. Fong also has been dedicated to the quality, analysis, and standardization of herbal medicines and botanical dietary supplements worldwide, collaborating with the World Health Organization's (WHO) Traditional and Complementary Medicine Programme for 30 years and "working with the Hong Kong Health Department for the past 13 years on its ongoing setting of pharmacopeial quality standards for Chinese herbal materials commercially available in Hong Kong."

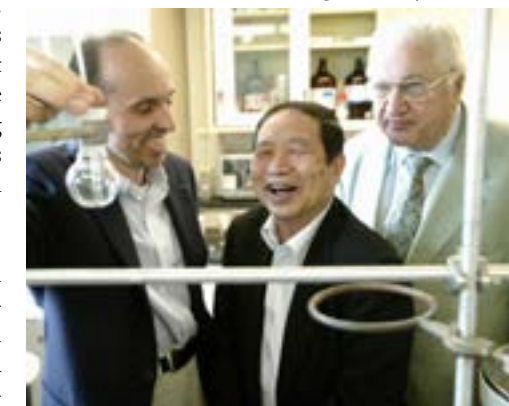
To date, Dr. Fong has authored more than 270 scientific journal articles, co-authored nine book chapters, and edited

16 scientific publications, including multiple WHO medicinal plant monographs.

"Being named the recipient of the ABC Norman R. Farnsworth Excellence in Botanical Research Award for 2014 is a unique honor," stated Dr. Fong. "To be invited to join the company of a small, select group of internationally recognized botanical medicine researchers is very humbling."

Dr. Fong first met Prof. Farnsworth in 1955 at the University of Pittsburgh's School of Pharmacy, where Dr. Fong was a first-year pharmacy student and Prof. Farnsworth was an instructor and

Guido F. Pauli, UIC Botanical Center Co-Director, with Professor Emeritus Harry H.S. Fong and the late Professor Norman R. Farnsworth (right), Founding Director of the UIC/NIH Botanical Center. Image courtesy of UIC.



PhD student of pharmacognosy. “Subsequently, I became his first graduate student in 1959,” noted Dr. Fong. After Dr. Fong completed his own PhD in pharmacognosy at Ohio State University in 1965, he returned to the University of Pittsburgh, where he worked with Prof. Farnsworth as a research assistant professor.

The late Professor Farnsworth — the Excellence in Botanical Research Award’s namesake — was one of ABC’s co-founding Board of Trustees members, a research professor of pharmacognosy, and a senior university scholar in the College of Pharmacy at UIC. When Professor Farnsworth died in 2011 at the age of 81, the global medicinal plant community lost one of its greatest champions.

“Norman Farnsworth and I were best friends on the personal level, and were research and academic collaborators/partners professionally,” explained Dr. Fong. “To say that Norm had impacted my career and my life is an understatement. ... Norman convinced me that my life would be more fulfilling as an underpaid academic, rather than a rich pharmacist. The rest, as they say, is history.”

“Harry Fong has made many significant contributions in the fields of drug discovery from botanical materials, the quality control of botanical dietary supplements and traditional herbal medicines, and in setting standards for herbal medicines worldwide,” said ABC Chief Science Officer, Stefan Gafner, PhD, who did post-doctoral research at UIC from 1998 to 1999. “He is internationally recognized as an expert in herbal medicine and one of the most highly regarded pharmacognosists of our time.”

“Dr. Fong’s ability to encourage and inspire collaborative research from world-renowned scientists is second to no one’s,” noted NPA’s Dr. Fabricant. Dr. Fabricant received his PhD from Prof. Farnsworth at UIC and Prof. Fong was a member of his thesis committee. “Professor

Fong played a huge role in expanding the program at UIC into the best in the world, leaving no details to chance, then repeated that success with the WHO program and countless others. What makes this amazing is that in addition to growing those programs, Dr. Fong was also responsible for the students in the Medicinal Chemistry/Pharmacognosy program at UIC, often serving as an advisor on every-



Daniel Fabricant, CEO & Executive Director of Natural Products Association accepting the 2014 Norman R. Farnsworth Excellence in Botanical Research Award on behalf of recipient Harry H.S. Fong.

thing outside of the dissertation. [H]ow he was able to balance those roles and so many others, is a wonder to this day.”

Dr. Fong has received numerous awards and has served the botanical research community through a number of leadership positions. In the late 1970s, Dr. Fong was the president of the American Society of Pharmacognosy, after which he became president of the Society for Economic Botany from 1981 to 1982. He was the recipient of the Ohio State University College of Pharmacy’s 1997 Jack L. Beal Post-Baccalaureate Alumnae Award as well as the NPA’s 2008 Burton Kallman Scientific Award. Dr. Fong also is a charter and honorary member of the

American Society of Pharmacognosy, a member of the WHO Expert Panel on Traditional Medicine since 1997, and serves on multiple scientific advisory boards for universities around the world.

“Harry has been a key member of major collaborative research programs aimed at the discovery of compounds from terrestrial plants having potential as leads for the development of novel agents for the treatment of a range of serious diseases such as cancer, malaria, and tuberculosis,” noted Gordon M. Cragg, PhD, former chief of the Natural Products Branch of the National Cancer Institute and 2013 recipient of the ABC Farnsworth Award. “Added to this important research, he has also had a major impact on botanical research through the application of his extensive knowledge and expertise to the standardization and quality control of herbal medicines and botanical dietary supplements.”

“Harry Fong and Norman Farnsworth collaborated closely for many decades in advancing botanical research,” added Dr. Cragg, “and it is most fitting that Dr. Fong’s outstanding achievements be recognized with this award named in honor of his longtime colleague and friend.”

“Harry is a dynamic researcher and advocate for natural product research and the responsible use of quality medicinal plant materials,” said Blumenthal. “He and Prof. Farnsworth were almost inseparable, and it is highly fitting that ABC acknowledge and honor not only his loyal friendship and academic relationship with Norm, but also his many excellent contributions to the medicinal plant research community.”

“Being named the recipient of the ABC Norman R. Farnsworth Excellence in Botanical Research Award for 2014 is a unique honor,” stated Dr. Fong. “To be invited to join the company of a small, select group of internationally recognized botanical medicine researchers is very humbling.”

SFI Receives ABC Varro E. Tyler Award for Phytomedicinal Research

Australia-based Soho Flordis International (SFI) received ABC’s Varro E. Tyler Commercial Investment in Phytomedicinal Research Award. SFI is a global natural medicine company committed to identifying and developing natural medicines with high levels of evidence of quality, safety, and effectiveness, and marketing them around the world.

The late Professor Tyler — who has been described as one of the most respected men in late-20th century herbal medicine and pharmacognosy — was an early trustee of ABC, dean of the College of Pharmacy and Pharmaceutical Sciences at Purdue University for 20 years, and vice president of academic affairs at Purdue. He was the senior author of six editions of the leading textbook in the field, formerly used in every college of pharmacy in the United States, as well as numerous other professional and popular books and many articles in the academic literature. Prof. Tyler encouraged scientific and product integrity, and envisioned a rational phytomedicinal (plant-based medicines) healthcare sector that valued the proper evaluation of products’ quality, safety, and efficacy.

SFI was established in 2010 as a collaboration between Flordis Pty. Ltd. and SOHO Group. The company’s brands now include Flordis, Ginsana®, ProThera®, Klaire Labs®, and Complementary Prescriptions™.

“Today, Soho Flordis International operates in over 35 countries and has 68 clinical trials published on our own products,” said Nigel Pollard, CEO of SFI. “Through our research company, SFI Research, we have eight ongoing clinical trials on our own products and those of our partners. Our partners in research and marketing are other pioneers of clinically proven natural medicines, such as Zeller’s, Madaus/Rottapharm (Meda), Steigerwald (Bayer), Bionorica, Ilhwa, and Pharmatoka.”

“SFI has established itself as one of the leading herbal dietary supplement companies with a portfolio of products that are well-characterized not only with regard to the phytochemical composition but also their research regarding safety and efficacy,” said Dr. Gafner. “The number of current and past clinical studies is a testament to their commitment to high-quality products. I congratulate SFI for their outstanding work and for their well-deserved recognition in the form of the 2014 ABC Varro E. Tyler Award for Commercial Investment in Phytomedicinal Research.”

Ginsana, which contains the standardized extract of Asian ginseng (*Panax ginseng*, Araliaceae) root, G115®, has a 35-year history of scientific investigation and clinical use for increasing physical endurance and improving immune function. (Ginsana and G115 are trademarks of Pharmaton SA of Lugano, Switzerland; SFI acquired Ginsana in July 2013.) Initially patented in 1960, Ginsana is the world’s first chemi-



Recipients of the 2014 Varro E. Tyler Commercial Investment in Phytomedicinal Research Award, Soho Flordis International (SFI), and the 2014 Mark Blumenthal Herbal Community Builder Award, Loren Israelsen, display their awards. Shown L-R: Wolfgang Kuchen, GM Americas, SFI; Nigel Pollard, CEO, SFI; Mark Blumenthal, Founder and Executive Director, ABC; and Loren Israelsen, President, UNPA.

cally standardized botanical extract.

Flordis also produces KeenMind®, which contains the standardized extract of a traditional Ayurvedic plant from India known as brahmi (*Bacopa monnieri*, Plantaginaceae). SFI’s bacopa extract, CDRI08®, has been shown to promote memory retention and recall, concentration, and focus in five human clinical trials. Like G115, CDRI08 has decades of research behind it and is currently undergoing multiple clinical trials to measure its efficacy in a number of different populations. These trials are a testament to SFI’s commitment to furthering product development and clinical evidence of the quality and potency of its products.

“We are really delighted to receive the American Botanical Council’s Varro E. Tyler Award,” said Pollard. “In fact, our company’s vision was inspired by Professor Tyler and Mr. Blumenthal at a conference 16 years ago in Australia. Prof. Tyler’s principles of rational phytotherapy underpin these investments and our vision for natural products in mainstream medicine.”

“SFI is a company built on the research-based values that Professor Tyler promoted regarding developing and marketing clinically tested phytomedicinal products,” said Blumenthal. “As a research- and science-based organization, ABC is pleased to be able to recognize SFI for its many clinical trials and related research achievements.”

Herbal Advocate Loren Israelsen Receives ABC Mark Blumenthal Herbal Community Builder Award

Loren D. Israelsen, president of UNPA, was selected as the recipient of ABC’s 2014 Mark Blumenthal Herbal Community Builder Award.

This is the third award of its kind to be presented by ABC. The Herbal Community Builder Award is granted annually to an individual in the herbal medicine community who has

played a significant role in creating a sense of community among herbalists, researchers, members of the herb and natural products communities, and related groups who work in the area of medicinal plants.

Among his many noteworthy accomplishments, since 1991, Israelsen has served as the president of UNPA (formerly the Utah Natural Products Alliance), a global industry trade association dedicated to supporting companies and consumers committed to high-quality natural health products.

It is especially apt that he is the recipient of the Mark Blumenthal Herbal Community Builder Award for 2014, the year in which the herbal and dietary supplements community observed the 20-year anniversary of the passage of the Dietary Supplement Health and Education Act of 1994 (DSHEA), for which Israelsen was integral to framing and seeing through into law.

Israelsen earned his bachelor's degree in political science from Utah State University, after which he studied at Oxford University's Queen's College Jurisprudence Program in the United Kingdom. He received his Juris Doctor from Brigham Young University in Provo, Utah.

Mr. Israelsen is an expert on the regulation of herbs and dietary supplements in the United States and internationally. He has served as an advisor to or officer in numerous industry and nonprofit organizations, as well as government agencies.

Over the course of his venerable career, Israelsen has served as vice president and general counsel for the American Herbal Products Association, and he co-founded and provided general counsel for the European American Phytomedicine Coalition. Israelsen also has acted as an advisor to the National Institutes of Health's Office of Dietary Supplements, as an industry liaison to the Food and Drug Administration's expert advisory committee on ephedra (*Ephedra sinica*, Ephedraceae), and as an advisory board member for the Office of Technology Assessment's Working Group on Dietary Supplement Regulation. Further, he was an expert panel member for both the Institute of Food Technologists' 2005 Functional Food Report and the Department of Defense/RAND study concerning regulation of dietary supplements in the US military.



Loren Israelsen with his 2014 Mark Blumenthal Community Builder Award. Shown L-R: Frank Lampe, VP of Communications and Industry Relations, United Natural Products Alliance (UNPA); Loren Israelsen, President, UNPA; and Kira Olsen, Director of Operations & Member Services, UNPA.

“Loren is a widely respected source of rational perspectives and insights into the regulation of herbs and dietary supplements in the United States,” said Blumenthal. “He is a close friend and trusted advisor to numerous people in and outside the American herb industry, including many researchers and integrative healthcare practitioners. I am deeply grateful for his long-term friendship and for the support he has given to so many people over the past three decades. He has really been instrumental in helping to build a sense of community among many responsible elements of the herb community.”

“To receive an award named after one of my great mentors for contributing to the betterment of the herbal community is as great an honor as I can imagine,” said Israelsen. “We all follow in the footsteps and on the shoulders of so many who devoted their hearts and minds to the protection and advancement of botanical medicine and its traditions and culture.”

“Being honored as one who has tried to carry on that tradition, in the hope of building the herbal community, warms my heart beyond words,” he continued. “My thanks to the American Botanical Council for being a strong and clear voice of our community and for extending the hand of friendship and recognition through this award.”

“Loren is one of those rare jewels that this industry is highly fortunate to have in its midst. His measured, thoughtful, and insightful approaches to the issues and challenges we face on a daily basis reinforce not only his value — but also his values — to the greater community. The UNPA staff and all of its members laud this award and look forward to many more years of his wisdom and leadership,” said Frank Lampe, vice president of communications and industry relations for UNPA, who has known and been a colleague to Israelsen for more than 27 years.

Supplement Pioneer Terry Lemerond Receives First ABC Champion Award

The inaugural American Botanical Council Champion Award was granted to Terry Lemerond, founder and president of EuroPharma, Inc., of Green Bay, Wisconsin.

The ABC Champion Award was created to recognize

an individual or individuals who have been outstanding supporters of ABC, helping significantly to promote the achievement of ABC's nonprofit educational mission. The award was given to Lemerond by Blumenthal just prior to the 10th Annual ABC Botanical Celebration and Awards Ceremony in Anaheim, California.

Lemerond's contributions to the natural health sphere over the course of his more than 40-year career are manifold. His self-proclaimed mission is to “improve the health of America.”

Preceding his founding of EuroPharma, a botanical and dietary supplement manufacturer and distributor to natural food stores, and its sister company, EuroMedica, a manufacturer of dietary supplements for health professionals, Terry founded and owned both Enzymatic Therapy, Inc. and PhytoPharmica, Inc. before he sold the companies in 2000. Enzymatic Therapy was instrumental in being one of the first companies in North America to offer a retail line of standardized herbal extracts (e.g., ginkgo [*Ginkgo biloba*, Ginkgoaceae], milk thistle [*Silybum marianum*, Asteraceae], et al.) for which he partnered with the respected global extract manufacturer Indena of Milan, Italy.

A veteran of the natural foods industry, Terry started in the natural products business in 1969 when he purchased Bay Natural Foods, an independent natural food store in

Green Bay. He sold the store along with Enzymatic Therapy in 2000, and then started EuroPharma and his new health food store Terry Naturally in 2007.

Lemerond has developed more than 400 natural products, empowers health education through his various *Terry Talks Nutrition* outlets, and has authored two books — *Seven Keys to Vibrant Health* (1995) and *Seven Keys to Unlimited Personal Achievement* (1997). Among the various *Terry Talks Nutrition* programs is a live radio show, which Terry hosts weekly.

“Terry has been a good friend and great ABC supporter for over 25 years, since the earliest days of ABC,” said Blumenthal. “He is a strong believer in the value of education to help consumers and health professionals learn about the beneficial roles that herbs and other dietary supplements play in a healthy lifestyle. Throughout the years, Terry has been one of ABC's most consistent supporters — of the organization in general and of many of our publications and programs. In addition to providing ongoing support of ABC's programs, Terry is often one of the first to support, or even help launch, a new ABC educational initiative.”

“I am deeply honored to receive the Herbal Champion Award from ABC,” said Lemerond. “I find it extremely gratifying to be able to support the herbal community as well as ABC.” He continued, “ABC assures fair and honest reporting on herbal medicine to the media and to researchers and

Thanks to the Sponsors of the 10th Annual American Botanical Celebration and Awards Ceremony



“To receive an award named after one of my great mentors for contributing to the betterment of the herbal community is as great an honor as I can imagine,” said Israelsen. “We all follow in the footsteps and on the shoulders of so many who devoted their hearts and minds to the protection and advancement of botanical medicine and its traditions and culture.”



Mark Blumenthal announcing Terry Lemerond, Founder & President of EuroPharma, Inc., as the recipient of the first-ever ABC Champion Award.

health professionals worldwide. This organization takes herbal medicine to a whole new level of professionalism. I encourage everyone who is dedicated to protecting our rights and choice of complementary medicine to support ABC.”

“ABC is always grateful for the many hundreds of industry and community leaders who support our nonprofit educational mission,” added Blumenthal. “Everyone who supports us often has their special way(s) of doing so. However, Terry stands out,” he noted. “His generosity and strong belief in ABC’s unique role as an agent of social and cultural change have been top notch. It’s people like Terry Lemerond that have been instrumental in ABC’s growth and long-term successes for almost 27 years.”

Acknowledging his generous support of the natural foods and dietary supplements industry and natural health communities, Terry has been the recipient of such honors as the NPA’s 2008 Industry Champion Award, the Southeast Natural Products Association’s 2013 President’s Award, and the Natural Products Association Southwest’s 2010 President’s Award.

“One of the most rewarding aspects of being a part of the herb and natural health community for over 45 years,” said Blumenthal, “is the quality of interesting, highly independent, and accomplished people I’ve met over the years. I am profoundly grateful for the many amazing, intelligent, sincere, and deeply committed people I’ve met in this community who are helping to raise the consciousness of Americans about the value of good nutrition and natural health. Many of these people become close friends, not only professionally, but personally. Terry is one of those people.” HG

Previous ABC Awards Recipients

James A. Duke Excellence in Botanical Literature Award

- 2013:** *Principles and Practice of Phytotherapy: Modern Herbal Medicine*, 2nd ed (Churchill Livingstone) by Kerry Bone and Simon Mills
- 2012:** Reference/Technical: *Medicinal Plants and the Legacy of Richard E. Schultes* (Missouri Botanical Garden) by Bruce E. Ponman and Rainer W. Bussmann, PhD; Consumer/Popular: *Smoke Signals* (Scribner) by Martin A. Lee
- 2011:** Reference/Technical: *American Herbal Pharmacopoeia’s Botanical Pharmacognosy* (CRC Press); Consumer/Popular: *Healing Spices* (Sterling Publishing) by Bharat B. Aggarwal, PhD
- 2010:** *Botanical Medicine for Women’s Health* (Churchill Livingstone) by Aviva Romm, MD
- 2009:** *An Oak Spring Herbaria* (Oak Spring Garden Library) by Lucia Tongiorgi Tomasi and Tony Willis
- 2008:** *Mabberley’s Plant-Book*, 3rd ed. (Cambridge University Press) by David J. Mabberley, PhD
- 2007:** Google Book Search
- 2006:** *Medicinal Spices* (MedPharm Scientific Publishers) by Eberhard Teuscher, PhD
- 2005:** *The Essential Guide to Herbal Safety* (Churchill Livingstone) by Simon Mills and Kerry Bone

Norman R. Farnsworth Excellence in Botanical Research Award

- 2013:** Gordon M. Cragg, PhD, former chief of the Natural Products Branch of the US National Cancer Institute
- 2012:** De-An Guo, PhD, director of the State Engineering Laboratory for Traditional Chinese Medicine Standardization Technology and director of the Shanghai Research Center for TCM Modernization at the Shanghai Institute of Materia Medica of the Chinese Academy of Sciences
- 2011:** Djaja D. Soejarto, PhD, professor of pharmacognosy at the College of Pharmacy at UIC
- 2010:** A. Douglas Kinghorn, PhD, chair of the Department of Medicinal Chemistry and Pharmacognosy in the College of Pharmacy at Ohio State University
- 2009:** Rudolf Bauer, PhD, head of the Institute of Pharmaceutical Sciences at the Karl-Franzens University of Graz in Austria
- 2008:** Ikhlas Khan, PhD, of the University of Mississippi’s National Center for Natural Products Research
- 2007:** Hildebert Wagner, PhD, of the Institute for Pharmaceutical Biology in Munich, Germany
- 2006:** Edzard Ernst, MD, PhD, formerly of the Peninsula Medical School at the University of Exeter in the United Kingdom
- 2005:** Joseph M. Betz, PhD, of the NIH Office of Dietary Supplements

Varro E. Tyler Commercial Investment in Phytomedicinal Research Award

- 2013:** Wakunaga Pharmaceutical Company, Ltd., of Japan
- 2012:** Horphag Research of Switzerland
- 2011:** Bioforce AG of Switzerland
- 2010:** New Chapter, Inc., of the United States
- 2009:** Bionorica AG of Germany
- 2008:** Indena SpA of Italy
- 2007:** Dr. Willmar Schwabe Pharmaceuticals of Germany

Mark Blumenthal Herbal Community Builder Award

- 2013:** Sara Katz, co-founder of Herb Pharm
- 2012:** Rosemary Gladstar, renowned herbalist and author

ABC Lifetime Achievement Award

- 2007:** Dr. Shiu-ying Hu, Chinese botanist

International Health Professional Groups Endorse ABC-AHP-NCNPR Botanical Adulterants Program

Academy of Integrative Health and Medicine, Integrative Healthcare Policy Consortium, American Herbalists Guild, and Irish Register of Herbalists Join Botanical Authenticity Consortium

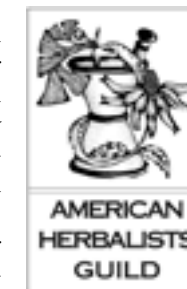
Four health practitioner groups have offered their endorsement and support to the ABC-AHP-NCNPR Botanical Adulterants Program. The Program is an international consortium of nonprofit organizations, analytical laboratories, professional scientists, healthcare practitioners, industry members, and others that educates and provides advice about the various challenges related to adulterated herbs, botanical extracts, and botanical ingredients in commerce.

The Academy of Integrative Health and Medicine (AIHM), the American Herbalists Guild (AHG), the Integrative Healthcare Policy Consortium (IHPC), and the Irish Register of Herbalists (IRH) collectively represent hundreds of thousands of integrative health practitioners across the United States and Ireland.

The ABC-AHP-NCNPR Botanical Adulterants Program is a coalition of three American nonprofit groups: the American Botanical Council (ABC), the American Herbal Pharmacopoeia (AHP), and the University of Mississippi’s National Center for Natural Products Research (NCNPR), with more than 140 other American and international parties supporting and cooperating with the Program. Adulteration refers to the accidental or intentional substitution or dilution of a material with an undisclosed, usually lower-cost ingredient, thereby giving the consumer a false sense of the value or quality of an ingredient or product containing such an adulterated ingredient.

AIHM is a professional group that brings together many different licensed integrative health practitioners, including family doctors, acupuncturists, nurses, psychologists, and doctors of Oriental medicine, and advocates for affordability and accessibility for patients. The Academy also offers courses for continuing education in integrative medicine and healthcare strategies. In a letter dated January 21, 2015, AIHM Executive Director Nancy Sudak, MD, wrote, “We support [the Program’s] mission to preserve botanical purity, and thank you for the effort that the [Program] has made to expose the challenges associated with adulterated herbs in commerce around the world. We will be proud to add our name to [the] growing list of underwriters, endorsers, and supporters.”

Founded in 2003, IHPC advocates for an integrative healthcare system with equal access to a full range of health-oriented, person-centered, regulated healthcare professionals. IHPC represents more than 400,000 licensed professionals



and, by extension, millions of patients, regarding the advancement of integrative health in the United States.

The 25-year-old AHG promotes the profession of clinical herbalism and access to herbal medicine. The Guild celebrates the diversity of the practice and encourages the development of

high education standards for its members. AHG members range from those who practice traditional and indigenous herbalism to modern clinical phytotherapy. AHG Executive Director Mimi Hernandez, MS, RH(AHG), confirming the endorsement, wrote, “The adulteration of herbal medicines throughout history has had a deep impact on the integrity of professional herbalists, and I am certain that our membership will benefit from the important educational aspects of the Program as well as the confidence attributed to a high-quality supply chain of herbal medicines.”

The IRH is a professional association for traditional herbalists in Ireland. “The IRH [supports] the Botanical Adulterants Program because we strongly believe in the safety and efficacy of the herbs we use in clinical practice,” wrote IRH Vice President Danny O’Rawe, ND. “As an accountable professional organization for herbalists in Ireland of all traditions, part of our role is to promote best practice throughout the herbal sector, and we have no hesitation in supporting this important initiative to keep the herb chain free of adulteration and contamination for the good of ourselves and future generations.”

“We are most grateful to these organizations of healthcare providers for their expression of support for the Botanical Adulterants Program,” said ABC Founder and Executive Director Mark Blumenthal. “Although much of the Program is focused on educating members of industry about the confirmed cases of adulteration of herbs, extracts, and other botanical materials, we are also attempting to help educate other stakeholders in the domain of herbal medicine, partic-

ularly healthcare providers who recommend and/or utilize botanical preparations in their clinical practice.”

The Botanical Adulterants Program was previously endorsed by the National Institute of Medical Herbalists, a 150-year-old organization representing herbal medicine practitioners in the United Kingdom, and the British Herbal Medicine Association. Other endorsing organizations of healthcare professionals include the American Association of Naturopathic Physicians, the Council of Colleges of Acupuncture and Oriental Medicine, and the Personalized Lifestyle Medicine Institute.

The Program has also been endorsed by leading organizations of medicinal plant research scientists, including the American Society of Pharmacognosy, the Society for Medicinal Plant and Natural Product Research (GA), and the Natural Health Products Research Society of Canada.

The ABC-AHP-NCNPR Botanical Adulterants Program has published extensively peer-reviewed and referenced arti-

cles on the history of adulteration, adulteration of the herbs black cohosh (*Actaea racemosa*, Ranunculaceae) and skullcap (*Scutellaria lateriflora*, Lamiaceae), and adulteration of bilberry (*Vaccinium myrtillus*, Ericaceae) fruit extract and so-called “grapefruit [*Citrus x paradisi*, Rutaceae] seed extract.” These open-access articles are available on the Program’s webpage: www.herbalgram.org/adulterants.

The Program recently released its first publication in a series of Laboratory Guidance Documents to help industry and third-party analytical laboratories determine the most effective analytical methods for detecting adulteration and authenticating botanical raw materials and extracts. The first of these documents is on skullcap, an herb subject to documented adulteration. Additional publications from the Program, including Laboratory Guidance Documents on bilberry extract and black cohosh, are scheduled for release in the coming months. HG

ABC-AHP-NCNPR Botanical Adulterants Program Publishes Third Issue of “Botanical Adulterants Monitor”

Newsletter Contains Summaries of New Authentication Methods and Research on Adulteration of Grape Seed Extract, Cranberry, and Traditional Indian Medicines

In March, the ABC-AHP-NCNPR Botanical Adulterants Program released its third issue of the Botanical Adulterants Monitor, an e-newsletter intended to provide relevant stakeholders with the latest news and information regarding the adulteration, identity, and quality of botanical raw materials, extracts, essential oils, and related plant-based materials used in consumer products.

The new edition of the Monitor contains the latest news from the ABC-AHP-NCNPR Botanical Adulterants Program, updates and commentaries on the regulatory activities of the New York Attorney General, plus summaries of recently published scientific papers about tests conducted on botanical materials to determine the presence of adulterants.

The Science Update section in the Monitor’s third issue focuses on the authentication of proanthocyanidin-containing botanical ingredients, such as grape (*Vitis vinifera*, Vitaceae) seed extract and cranberry (*Vaccinium macrocarpon*, Ericaceae).

Also included are discussions of new papers on methods to determine the authenticity of true cinnamon (*Cinnamomum verum*, Lauraceae), the morphological identification of Moldavian dragonhead (*Dracocephalum moldavica*, Lamiaceae), and suspected adulteration of plants used in traditional Ayurveda, Siddha, and Unani medicine, among others.

The newsletter is compiled and edited by Stefan Gafner, PhD, chief science officer of

ABC and technical director of the Botanical Adulterants Program.

The Botanical Adulterants Monitor contains timely information and updates that persons with responsibilities in regulatory, quality control, purchasing, and related departments of commercial businesses, as well as other colleagues in academia, health professions, and/or government agencies will find both interesting and useful. Articles are freely available from the Botanical Adulterants Program

homepage on the American Botanical Council’s website for all registered users. Registration information is available on ABC’s website, www.herbalgram.org.

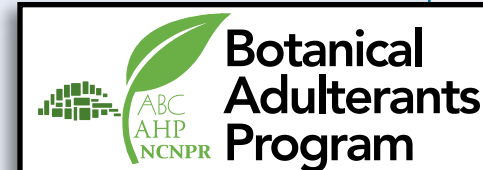
The third issue (March 2015) of the Monitor is available at <http://cms.herbalgram.org/BAP/BAM/issue3.html>.

The second issue (November 2014) is available at <http://cms.herbalgram.org/BAP/BAM/issue2.html>.

The first issue (June 2014) is available at cms.herbalgram.org/BAP/BAM/index.html. HG



Join more than 160 responsible companies, laboratories, nonprofits, trade associations, media outlets, and others in the international herb and natural products/natural medicine community.



Become a valued underwriter of the ABC-AHP-NCNPR Botanical Adulterants Program, a multi-year, supply chain integrity program providing education about accidental and intentional adulteration of botanical materials and extracts on an international scale.

For more details on joining the program, and access to the free publications produced to date, please see www.herbalgram.org/adulterants or contact Denise Meikel at denise@herbalgram.org.

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Cranberry *Vaccinium macrocarpon*. Photo ©2015 Steven Foster



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	Black Cohosh <i>Actaea racemosa</i>		Turmeric <i>Curcuma longa</i>
	Ginkgo <i>Ginkgo biloba</i>		Sceletium <i>Sceletium tortuosum</i>
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Safety and Quality Marks Are the Goal after UK Cracks Down on St. John's Wort Products

The recent removal of St. John's wort (*Hypericum perforatum*, Hypericaceae) products from the Amazon.co.uk website is prompting debate in the United Kingdom herbal industry on what to do about unlicensed herbal products and how to protect UK consumers from products that may be unsafe or of deficient or otherwise unacceptable quality, while not placing an undue regulatory burden on companies.

The debate surfaced in March after 107 products were removed from the site by the UK's Medicines and Healthcare Products Regulatory Agency (MHRA) for making unauthorized claims or being inappropriately labeled. While some industry groups believe that the agency overstepped by pulling products that were not making medicinal claims, herbal industry leaders agree the primary concern was one of safety.

The general position, according to MHRA Media Officer James McCreadie, is that the agency acted in accordance with procedures set out in its guidance, which requires that medicinal products hold a product license based on standards for safety, quality, and efficacy (email, March 27, 2015). While MHRA would not comment on specific products, McCreadie noted that consideration of claims being made "goes well beyond the information that is put on the packaging and can also extend to information on webpages and personal testimonies."

The Traditional Herbal Registration (THR) scheme is a simplified procedure, he added, which enables certain medicinal products to be registered based on quality, safety, and evidence of their traditional use. "Products registered under the THR scheme are intended for minor conditions suitable for self-medication," McCreadie said.

Under the European Traditional Herbal Medicinal Products Directive, products with this designation must meet quality and safety specifications and are required to include comprehensive safety and drug interaction information with the product. The registration process takes time and can cost as much as \$200,000 per product,¹ depending on how much existing data a company has on its product. Unlicensed products do not adhere to these requirements.

"I think the only reason that the St. John's wort was targeted was on the grounds of consumer safety," said Dick Middleton, PhD, MPhC, chairman of the British Herbal Medicine Association (BHMA), the UK's leading trade association for the medicinal herb industry (email, March 20, 2015). "St John's wort is a very useful herb for treating mood disorders and has a wide clinical research base," he explained. "I believe that MHRA was concerned that consumers were not being empowered safely to choose to take St. John's wort because of a lack of reliable consumer information and lack of quality assurance. This is clear because MHRA has registered many St. John's wort prod-



ucts as traditional herbal medicines."

Several St. John's wort extracts have been well-studied for the primary use of addressing mild-to-moderate depression;² a 2008 meta-analysis of randomized, controlled clinical trials documented their general efficacy and safety, reporting no serious adverse side effects.³ Drug

interactions have been a dominant area of concern, although some experts suggest that clinical evidence does not support this conclusion. That said, there is general agreement among clinicians and scientists that St. John's wort extracts with a high hyperforin content have an herb-drug interaction profile that needs to be considered before use. Such extracts have been shown to influence drug metabolizing enzymes and drug transporter proteins that may lead to reduced therapeutic activity for certain drugs, including antidepressants, immunosuppressants, anti-coagulants, statins, oral contraceptives, and anti-cancer agents.⁴

Finding a Middle Ground

The current cause of confusion in the UK comes from the two different market classifications for herbal products. Registered herbal medicines are used to treat, prevent, or cure specific medical conditions, while "botanicals" (as they are referred to in the UK) are used for general health and wellness and may not be advertised as medical treatments. Middleton agrees that there needs to be a place for both categories on the market. However, he said, the difficulty is that there is "no adequate control over the quality of botanicals, and this is illustrated time and again by studies that demonstrate lack of provenance and quality of these products."

A case in point, Middleton noted, was the recent study of 40 rhodiola (*Rhodiola rosea*, Crassulaceae) root products purchased from UK websites and tested for ingredient identification. Eight products were found to contain the wrong species (*R. crenulata*) or adulterated with other species. "The traditional herbal medicines tested were all correct and had the highest rosavin content of all the samples," he said. Rosavins are thought to be primary active constituents in *R. rosea*, but they are absent in *R. crenulata*, which makes them an ideal chemical marker to distinguish between the authentic species and the adulterant. "So this is extremely relevant to the consumer and whether the product would work for them," Middleton emphasized.

In Europe, he continued, "the EU through EFSA [the European Food Safety Authority] needs to assess and issue health claims for botanicals, whilst at the same time putting a scheme in place that ensures appropriate quality standards for such products. Easy words—very difficult to implement!"

These same concerns were echoed by Simon Mills, secretary of the European Scientific Cooperative on Phytotherapy (ESCAP), a consortium of European medicinal plant research experts and related parties with expertise in medicinal plant research. "Botanicals are not yet generally recommendable as their quality is found to be so variable," Mills said (email, March 23, 2015). "We hope that standards we have worked so hard to establish for Traditional Herbal Medicinal Products can be a mark for the food supplement sector to emulate. We see initiatives like [the ABC-AHP-NCNPR] Botanical Adulterants Program, and indeed the FDA GMPs [Good Manufacturing Practices], as significant examples of what could be possible for the botanical sector over here."

Although it may be too early to say, there has been little, if any, backlash in the herbal products market since the St. John's wort products were removed. "The sector is always concerned about bad publicity," Middleton said, "particularly as the majority of the sector is striving to manufacture high-quality products."

The other ongoing issue is that UK consumers can still purchase unlicensed herbal products on websites other than Amazon.co.uk. For MHRA, the effort will continue, according to McCreadie, who said the MHRA took action last year to close down more than 1,600 websites illegally advertising and selling medicines in the UK. "We continually look at sites selling inappropriately and will also take action where sites are brought to our attention," he said.

There is also some speculation as to which, if any, other herbal products might be on MHRA's radar. Black cohosh (*Actaea racemosa*, Ranunculaceae) could be of concern, noted Middleton, due to previous quality issues and isolated hepatotoxicity reports. "There is ongoing, unresolved debate as to whether hepatotoxicity reports have been related to black cohosh, or could even possibly be related to adulteration with similar species," he said.

Although manufacturers are not lining up to do battle over the regulatory classifications, it is clear, according to Mills, that THR is too demand-

ing for some companies' bottom lines. But, he noted, those companies "are pragmatically adapting their product ranges to the new horizons of EFSA—wherever they may be," he said. "Some of us believe that much is being lost here, but actually our main common goal is to get a clear quality mark in the market. And this is where [groups] like BHMA can lead." HG

—Karen Raterman

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St. John's Wort *Hypericum perforatum*
Photo ©2015 Steven Foster



Meta-Analysis Demonstrates Safety and Efficacy of Defined Ginkgo Extract for Treating Dementia in Elderly

Reviewed: Gauthier S, Schlaefke S. Efficacy and tolerability of *Ginkgo biloba* extract EGb 761® in dementia: a systematic review and meta-analysis of randomized placebo-controlled trials. *Clin Interv Aging*. 2014;9:2065-2077.

Many older adults suffer from Alzheimer's disease (AD) or other cerebrovascular diseases. The leading clinically tested proprietary ginkgo (*Ginkgo biloba*, Ginkgoaceae) leaf extract EGb 761® has shown a variety of mechanisms related to treating AD in vivo, including repairing mitochondrial function, modulating neuroplasticity, and increasing dopamine concentrations in only frontal brain areas.

EGb 761 is an acetic (60% per weight) dry extract of ginkgo leaves standardized to contain 22-27% ginkgo flavonglycosides, 5-7% terpene lactones (2.8-3.4% ginkgolides A, B, and C, and 2.6-3.2% bilobalide), and less than 5 parts per million ginkgolic acids. It is produced by Dr. Willmar Schwabe GmbH & Co. KG of Karlsruhe, Germany.

Processing methods and bioactive compound content are integral to establishing the efficacy and safety of botanicals and may greatly differ among products. This systematic review and meta-analysis investigates clinical trials using the standardized product EGb 761 for the treatment of AD and/or vascular dementia (VaD). The statistical analysis performed in this study was funded by Schwabe; one of the authors (Schlaefke) is an employee of the company.

This study searched the databases PubMed (to December 2012), EMBASE (2006-2011), and PASCAL (to December 2011). Included clinical trials were randomized, placebo-controlled, and double-blind, with a duration of 20 weeks or more. The included trials used EGb 761 for the treat-

ment of AD, VaD, or a combination of the two conditions, according to diagnostic requirements from a variety of internationally recognized sources of criteria. Also, trials must have used two of the three following outcome measures: cognition, activities of daily living (ADL), and clinical global impression. Trials with patients having other mental deficiencies or that incorporated EGb 761 in conjunction with cholinesterase inhibitors (e.g., donepezil [Aricept®] and tacrine [Cognex®]) were excluded.

The study authors located 15 randomized, placebo-controlled, clinical trials of EGb 761; of these, eight were excluded due to failure to meet the inclusion criteria listed above. Patients from the seven included trials were prescribed a dosage of 120 mg (two trials) or 240 mg (six trials) of EGb 761 for 22-26 weeks (one trial tested both dosages). The Jadad Scale, used to evaluate the trial quality (scores range from 1 to 5, with 5 indicating the highest trial robustness), indicated "appropriate" quality, with scores of 3 for two trials and 5 for five trials. From the trials, 2,625 patients were evaluated, with 1,396 taking EGb 761 and 1,229 taking placebo. Females comprised 50% to 86% of the patient population in the studies, and patients ranged from 63 to 79 years old. Physical metrics such as height, weight, body mass index, and cognitive metrics were not different at baseline between treatment and placebo groups.

The seven included trials used two different but overlapping validated cognitive assessment tools. Five of the trials

reported significant beneficial effects on cognition for those taking EGb 761 as compared to those in the placebo group (P=0.03). These effects were found to be dose dependent, and those taking 240 mg of EGb 761 had significantly better cognitive performance than those in the placebo group (P=0.04). ADL was measured by four different scales. Those taking EGb 761 scored significantly better as compared to those in the placebo group (P<0.001), and those taking 240 mg had a significantly greater improvement in ADL than those in the placebo group (P=0.001).

In clinical global impression assessments using three different rating scales, those taking EGb 761 rated significantly better than those taking placebo (P=0.01); this was also observed in those taking 240 mg of EGb 761 as compared to those in the placebo group (P=0.007). In general, the odds ratio for cognitive improvement in those taking EGb 761 as compared to placebo was 2.48 (95% confidence intervals [CI]: 1.17, 5.28; P=0.02). The odds ratio for improvement in clinical global impression for EGb 761 treatment as compared to placebo was 3.18 (95% CI: 1.78, 5.67; P<0.0001).

In two of the studies, slightly more patients taking EGb 761 experienced adverse side effects (ASEs) than those

taking the placebo; however, in the other five trials, those with ASEs were equally distributed between groups. The relative risk ratio for ASEs with EGb 761 was 0.96 (95% CI: 0.90, 1.01). Likewise, "serious" ASEs were comparable in all trials across the treatment groups. In both treatment and placebo groups, ASEs included headache, dizziness, hypertension, tinnitus, angina pectoris, and respiratory tract infection. The ASEs causing early termination of patient participation in either group were symptoms typical of dementia, including agitation, anxiety, insomnia, or unspecific symptoms such as constipation, nausea, headache, and dizziness.

Overall, the results of this meta-analysis suggest that 240 mg daily intake of EGb 761 is effective in improving cognition, ADL, and clinical global impression in those suffering from AD and/or VaD, with minimal adverse side effects. This phytomedicinal formulation may be a useful adjuvant therapy in those suffering from cognitive decline. HG

—Amy C. Keller, PhD

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Ginkgo *Ginkgo biloba*
Photo ©2015 Steven Foster

Valerian and Lemon Balm Combination Improves Symptoms of ADHD in Children

Reviewed: Gromball J, Beschoner F, Wantzen C, Paulsen U, Burkart M. Hyperactivity, concentration difficulties and impulsiveness improve during seven weeks' treatment with valerian root and lemon balm extracts in primary school children. *Phytomed.* 2014;21(8-9):1098-1103.

Children with mild or fluctuating levels of intensity in attention deficits, hyperactivity, or impulsiveness may not meet the diagnostic criteria for attention deficit hyperactivity disorder (ADHD). These children do not qualify for prescription pharmaceuticals to treat their symptoms; however, there remains an urgent need to reduce the burden of care presented by these challenging conditions. In clinical trials, it has been demonstrated that valerian (*Valeriana officinalis*, Caprifoliaceae) root extract and lemon balm (*Melissa officinalis*, Lamiaceae) aerial extract can help alleviate insomnia and restlessness. The purpose of this prospective, multi-center, open-label study was to evaluate the effectiveness of a valerian and lemon balm preparation in treating children who exhibit symptoms of ADHD but who do not fulfill the diagnostic criteria for ADHD.

Primary school children aged six to 11 years with hyperactivity and concentration difficulties — but who did not meet the ADHD criteria listed in the *Diagnostic and Statistical Manual of Mental Disorders*, 4th ed. (DSM-IV), or the *International Statistical Classification of Diseases and Related Health Problems*, 10th ed. (ICD-10), and not taking

stimulating drugs (e.g., methylphenidate) — participated in this study conducted in 27 pediatric practices throughout Germany. Patients took two coated tablets of Sandrin® (Dr. Willmar Schwabe GmbH & Co. KG; Karlsruhe, Germany) twice daily for seven weeks. Those with any of the contraindications listed in the product monograph were excluded from the study. The daily dosage of the fixed combination, as analyzed according to official *European Pharmacopoeia* monographs, supplied 640 mg per day of the quantified dry extract WS*1014 from valerian root (drug/extract ratio 3-6:1, 62% ethanol m/m) and 320 mg per day of the quantified lemon balm dry extract WS*1303 (drug/extract ratio 4-6:1, 30% ethanol m/m).

At baseline, two weeks, and seven weeks, both parents and physicians rated the child's behavior over the preceding seven days with regard to the following symptoms: concentration problems, hyperactivity, impulsiveness, impaired social behavior, difficulties falling asleep or sleeping through the night, morning fatigue, attention deficits, nervousness, anxiety, and behavior apart from school and family environments. There were also questions concerning the burden of the child's symptoms on the family

members. The enrolled patients had displayed symptoms for a mean of 24.3 months (with a range of one month to four years). Prior to the study, 16.6% of the patients had been prescribed other treatments. The physicians rated compliance as “very good” or “good” in 74.9% of patients.

According to the authors, 169 patients were evaluated, 152 patients were completely documented, and “treatment was terminated prematurely in 16 patients, mainly because of insufficient compliance (6), low efficacy (5), problems with intake (3) and/or other reasons (multiple responses allowed). 77 patients terminated therapy after the final examination (29 because symptoms had improved or vanished, 29 because of insufficient efficacy, 10 for poor compliance).” The authors do not account for the discrepancy (n=11) between the number of enrolled patients and their report of post-treatment terminations and continuations.

After seven weeks of treatment, the physician ratings indicated a significant improvement in ability to concentrate, hyperactivity, impulsiveness, social behavior, difficulty falling asleep, difficulty sleeping through the night, and morning fatigue compared with baseline ($P < 0.0001$ for all). The parent ratings of symptom severity decreased from a mean overall score of 3.2 at baseline to 2.7 at the end of the study. Specifically, there was a significant improvement compared with baseline in the following areas: problems in leisure time, problems with friends, difficulties in everyday life, burden on child, burden on parents/family, and problems in school ($P < 0.0001$ for all).

At baseline, 58% of parents perceived their child's behavior as a “heavy” or “very heavy” burden, which decreased to 18% after seven weeks of treatment. The symptom with the highest severity score at baseline was distractibility, which significantly decreased after seven weeks of treatment ($P < 0.0001$). Treatment satisfaction was rated as “very good” or “good” by 62% of the physicians and 58% of the parents. Treatment tolerability was rated as “very good” or “good” by 96.9% of the physicians and 95.1% of the parents. There were three adverse side effects (ASEs) reported (eye blinking tics, moderate tiredness, and irritability) in two patients. All of these ASEs were judged by the physicians to be “unlikely” related to treatment.

The authors conclude that the Sandrin preparation is a safe and effective treatment for primary school children with hyperactivity and concentration difficulties but who do not meet ADHD diagnostic criteria. An important limitation of this study is that there was no control group; the reported benefits may have been due to a placebo effect. However, the results support the safety of this herbal combination for children. Another limitation is that the seven-week study duration is relatively short; it is unknown if any of the reported benefits would persist with chronic treatment. The study was sponsored by the manufacturer of the extracts, Dr. Willmar Schwabe GmbH & Co. KG; two of the authors (Paulsen and Burkart) are employees of the company. HG

—Heather S. Oliff, PhD

Valerian *Valeriana officinalis*
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Lemon Balm *Melissa officinalis*
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Cinnamon Extract Reduces Postprandial Blood Sugar Levels in Humans and Rats

Reviewed: Beejmohun V, Peytavy-Izard M, Mignon C, et al. **Acute effect of Ceylon cinnamon extract on postprandial glycemia: alpha-amylase inhibition, starch tolerance test in rats, and randomized crossover clinical trial in healthy volunteers.** *BMC Complement Altern Med.* 2014;14(1):351. doi: 10.1186/1472-6882-14-351.

Hyperglycemia, or high blood sugar, is central to the etiology of type 2 diabetes. Controlling postprandial (after-meal) hyperglycemia is important to maintaining overall health and reducing the risk of both type 2 diabetes and cardiovascular diseases. "Ceylon" or "true" cinnamon (*Cinnamomum verum* syn. *C. zeylanicum*, Lauraceae) has been used traditionally for gastrointestinal problems and continues to be used for respiratory infections. Although clinical trials have addressed the potential hypoglycemic activity of various types and preparations of cinnamon, studies conflict as to its efficacy. This in vitro, in vivo, and randomized, placebo-controlled, crossover human clinical trial investigated the starch tolerance of rats and healthy humans supplemented with Ceylon cinnamon bark extract.

Ceylon cinnamon bark extract (CCE; MealShape™; Dialpha; Montferrier sur Lez, France) is a 10:1 concentrate extracted with water and ethanol (50:50), which is then filtered and dried. [Note: Four of the seven study authors are Dialpha employees.] The resultant powder is standardized to contain at least 40% polyphenols, primarily oligomeric procyanidins composed of catechin and epicatechin. As a comparison for using the alcoholic solvent, an aqueous extract also was made. An enzymatic plate assay was used to gauge the inhibition of α -amylase (an enzyme that breaks down starches into sugars) activity, with acarbose (an anti-diabetic drug sold as Precose® in North America; Bayer; Whippany, New Jersey) as a positive control.



Cinnamon *Cinnamomum verum*
Photo ©2015 Steven Foster

Animal studies

The authors used male Wistar rats for the in vivo experiments. Various groups comprising eight to 20 animals were tested to determine effects of CCE on glucose and insulin at 50 mg/kg body weight; dose-effects of CCE on glucose response at 6.25, 12.5, 25, 50, or 100 mg/kg body weight; and comparative responses between CCE and aqueous extracts

at 50 mg/kg body weight. Fasted rats underwent a starch tolerance test (STT) and were fed wheat (*Triticum aestivum*, Poaceae) starch alone at 1.5 g/kg body weight as a control, or wheat starch with cinnamon extract at 20 mL/kg body weight. Blood glucose levels were measured at baseline, 15, 30, 60, 90, and 120 minutes.

During the STT, rats administered CCE and starch at 50 mg/kg body weight experienced a significant 20.4% decrease in glucose area under the curve (AUC; a calculation used to estimate a compound's bioavailability and clearance from the body) from 0-120 minutes, as compared to the control group ($P < 0.05$). At the same dose, insulin AUC was significantly less after 60 minutes compared to control ($P < 0.05$), with an insulin peak reduction of 40.6%. Glucose AUC from 0-120 minutes also was significantly less in rats given CCE at 12.5, 25, 50, and 100 mg/kg body weight ($P < 0.05$ for all). Compared to the aqueous cinnamon extract, CCE consumption in rats resulted in a significantly greater reduction in glucose AUC from 0-15 ($P < 0.05$), 0-30 ($P < 0.01$), and 0-60 minutes ($P < 0.05$).

In vitro analysis

In the pancreatic α -amylase activity assay, CCE had an inhibitory concentration of 50% (IC_{50} ; a measure of how much a substance inhibits a biological process) of 25 μ g/mL, while the acarbose control had an IC_{50} of 18 μ g/mL. When comparing the aqueous and alcoholic cinnamon extracts, the CCE had an IC_{50} of 30 μ g/mL while the water extract had an IC_{50} of 40 μ g/mL.

Human study

The clinical trial took place at the Clinic Nutrition Center at Hôpital Saint Vincent de Paul in Lille, France, and was administered by Naturalpha, a contract research company based in Lille, France. The study's primary endpoint was glucose AUC from 0-120 minutes following consumption of a standard white bread meal. Secondary endpoints included



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glucose AUC from 0-60 minutes, insulin AUC from 0-60 and 0-120 minutes, maximum concentrations of glucose and insulin, and concentrations of both at each time point. Adverse side effects (ASEs) were recorded and classified as mild, moderate, or severe.

Included subjects (aged 18 to 45 years) had a body mass index between 18.5 and 25 kg/m² and less than a 5% variation in body weight for the three months prior to the study. Those with fasting glucose concentrations greater than 110 mg/dL, a history of diabetes, a smoking habit, or who took any supplements or pharmaceuticals that could impact glucose or insulin were excluded. Subjects who had two-hour postprandial capillary blood glucose concentrations greater than 140 mg/dl were excluded as well.

Subjects were instructed to maintain their current lifestyle and were randomly assigned to receive either CCE followed by placebo or placebo followed by CCE. Treatment consisted of two capsules of CCE (500 mg each) or placebo (500 mg; containing 20% microcrystalline cellulose and 80% dicalcium phosphate). After an overnight fast, participants had blood drawn 35 minutes prior to the test and were given CCE or placebo five minutes later with 125 mL water. At baseline, a standardized meal was consumed with 250 mL water within eight minutes (103 g of white bread containing 52.2% carbohydrates [3.6% of which were sugars], 7.4% protein, 0.1% lipids, and 3.3% fiber). Fasting glucose concentrations were calculated as an average of measurements taken five and 10 minutes before the meal; fasting insulin was determined five minutes before the meal; and glucose and insulin were measured at 15, 30, 45, 60, 90, and 120 minutes following the meal.

Of the 22 subjects initially screened, 18 were randomly assigned to CCE (n=9) or placebo (n=9). Two subjects were not included in the per-protocol analysis due to protocol

deviations, leaving 16 subjects in the final analysis. Upon supplementation with CCE, there was a significantly lower glucose AUC from 0-60 minutes compared to placebo (P<0.05). No other significant effects were noted, and no ASEs were observed.

Conclusions

In summary, CCE consumption in rats decreased both glucose and insulin concentrations during a starch tolerance test, and doses of 12.5 mg/kg body weight and above resulted in decreased glucose concentrations. Comparable IC₅₀ levels for CCE and acarbose in the α -amylase activity assay suggest that enzyme inhibition is a likely mechanism of action for the alcoholic cinnamon extract. Although CCE significantly lowered glucose concentrations in healthy subjects, no effects were seen on insulin concentrations, which points to mechanisms independent of increased insulin in humans.

The authors mention that Ceylon cinnamon contains much less coumarin (a potentially toxic compound) than cassia (*Cinnamomum aromaticum* syn. *C. cassia*), although alcohol extraction can increase an extract's coumarin content due to its solubility. The CCE used in the study exposed participants to less than 0.2 mg coumarin per day (per one gram dose), well below the European Food Safety Authority's tolerable daily intake guideline of seven mg/day for a 70-kg (154-lb) person. This study reports more robust bioactivity with the alcoholic extract than the aqueous extract, which deserves further investigation. Future clinical trials of hyperglycemic individuals should continue to examine the use of Ceylon cinnamon extract in managing this condition. HG

—Amy C. Keller, PhD

Systematic Review of Ashwagandha for the Treatment of Anxiety

Reviewed: Pratte MA, Nanavati KB, Young V, Morley CP. An alternative treatment for anxiety: a systematic review of human trial results reported for the Ayurvedic herb ashwagandha (*Withania somnifera*). *J Altern Complement Med.* 2014;20(12):901-908.

Ashwagandha (*Withania somnifera*, Solanaceae; WS) root is used in Ayurvedic medicine as a broad-spectrum remedy or tonic, and has been shown to have anti-inflammatory, antioxidant, and anxiolytic properties. The purpose of this systematic review was to evaluate human studies of WS as a treatment for anxiety.

The PubMed, SCOPUS, CINAHL, Google Scholar, Google, and AYUSH Research Portal databases were searched using the key words ashwagandha or withania in combination with mental health terms such as anxiety, behavior, mood, and stress. The searches were limited to English language reports of randomized, controlled clinical trials evaluating WS as a treatment for anxiety. Studies investigating herbal combination formulas containing WS, review articles, and duplicate publications were excluded.

A total of 215 articles were located, and five studies met the inclusion criteria. Validity and risk of bias for each study was evaluated using the Cochrane Collaboration's risk-of-bias tool. A meta-analysis could not be conducted because of the lack of homogeneity in the trials; they had different primary outcome measures and durations (six to 12 weeks), evaluated different doses (12,000 mg/day raw herb, 125-2,500 mg/day extract) and dosage schedules (one to three times daily), and contained different formulations (raw root, ethanol extracts, or water extracts containing 1.5%, 5%, or 12% withanolides).

One study evaluated 39 patients who were treated with 500 mg twice daily (1000 mg/day) of placebo or WS root ethanol extract (manufacturer and composition not reported) for six weeks.¹ The dose was increased every two weeks as necessary, up to a maximum of 2,500 mg/day. There was a significant improvement on the Hamilton Anxiety Scale (HAM-A) in the WS group compared with the placebo group (P=0.026). The risk of bias was rated as high. Limitations of the study were the relatively small sample size and short study duration, inconsis-



Ashwagandha *Withania somnifera*
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Cinnamon *Cinnamomum* spp.
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tent dosing (500-2,500 mg/day), and 48.7% dropout rate.

The second study included 130 patients who were treated with 125 mg/day or 250 mg/day Sensoril® (Natreon, Inc; New Brunswick, New Jersey); 500 mg/day Essentra® (NutraGenesis LLC; Brattleboro, Vermont); or placebo for 60 days.² The Sensoril and Essentra products contained root and leaf material derived from a withaferin A- and withanolide glycoside-predominant, genetically uniform ashwagandha chemotype and extracted using a water-based protocol. The product composition cited in the review (minimum of 8% withanolide glycosides and 32% oligosaccharides) is not consistent with the data reported in the original article (11.9% withanolide glycosides, 1.05% withaferin A, and 40.25% oligosaccharides). There was a significant WS dose-dependent increase on the modified HAM-A ($P < 0.001$) compared to placebo. The risk of bias was rated as unclear.

One limitation of the study was the 24.6% dropout rate. (A total of 32 patients dropped out of the study, including ten who were lost to follow-up, six due to protocol violations, and four due to a physician's decision; the other 12 withdrew due to lack of efficacy — nine of which were in the placebo group.) There was also potential reporting bias (two authors were employed by the company funding the trial).

The third study included 81 patients who were treated with naturopathic counseling plus 300 mg twice daily

(600 mg/day) WS root extract standardized to 1.5% withanolides (manufacturer not reported) or psychotherapy plus placebo for 12 weeks.³ Beck Anxiety Inventory scores significantly improved in the WS group compared with the placebo group ($P < 0.0001$). The risk of bias was rated as high. Limitations of the study were the 21% dropout rate, the lack of a true control group, and potential performance bias because the therapists could not be blinded.

The fourth study included 64 patients who were treated with 300 mg twice daily (600 mg/day) WS root extract containing at least 5% withanolides (KSM-66®; Ixoreal Biomed; Hyderabad, Telangana, India) or placebo for 60 days.⁴ KSM-66 is produced using an alcohol-free and synthetic solvent-free “green chemistry” extraction process. There was significant improvement on the Perceived Stress Scale and in cortisol levels in the WS group compared with the placebo group ($P < 0.0001$ and $P = 0.0006$, respectively). The risk of bias was rated as unclear. A limitation of the study was the relatively small sample size.

The fifth study included 86 patients who took 4 g WS root (source not provided) with milk or placebo three times daily (12,000 mg/day) for 60 days.⁵ To prepare the WS treatment, dried root was pulverized, combined with equal quantities of sugar syrup, sieved, and dried to create granules (chemical composition/standardization not reported). Changes in HAM-A scores were not significant compared with placebo, except for the anxious mood

domain ($P < 0.001$). The risk of bias was rated as unclear.

All five studies concluded that WS was safe. Adverse events in the WS groups were mild and did not differ in frequency or duration compared with the control groups.

In summary, the ashwagandha preparations used in these clinical trials significantly improved measures of anxiety compared to the control in most trials. However, most of the studies were methodologically flawed and underpowered, and none attained a low risk-of-bias rating. In addition, the primary outcomes for all of these studies were patient-reported measures. The authors of the systematic review suggest that the addition of objective data obtained from blinded diagnostic interviews and the assessment of biomarkers would strengthen future studies. They also point out several limitations of their review, including the exclusion of studies published in other languages and trials evaluating the traditional use of WS (Ayurvedic formulas containing WS).

The authors conclude that while these “somewhat promising but early, and possibly biased, results” suggest that WS may significantly improve symptoms of stress, “additional research in larger samples and in more clinical contexts is essential to validate its therapeutic capabilities for widespread use.” In addition, the optimal WS preparation form, chemical composition, dose, and dosage schedule for the treatment of anxiety remain to be determined. HG

—Heather S. Oliff, PhD

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THE SUPPLEMENT SAGA: A Review of the New York Attorney General's Herbal Supplement Investigation

By Tyler Smith

Photos from left to right:
St. John's Wort *Hypericum perforatum*
Saw Palmetto *Serenoa repens*
Echinacea *Echinacea purpurea*
Asian Ginseng *Panax ginseng*
Garlic *Allium sativum*
Photos ©2015 Steven Foster

Editor's note: This is a revised and updated version of an article that originally appeared in the March 2015 issue of *HerbalGram*.

Introduction

In early February 2015, New York Attorney General (NY AG) Eric T. Schneiderman initiated an unprecedented legal and public relations campaign against the American herb industry. Details about his first attack on herbal dietary supplements from major retailers GNC, Walgreens, Walmart, and Target emerged at midnight on February 3, when the *New York Times* reported that Schneiderman sent cease-and-desist letters to the retailers demanding that they remove certain store-brand botanical dietary supplement products from their New York stores.¹ The move marked “the first time a state law enforcement agency has taken direct action against major supplement retailers for alleged fraud.”²

Schneiderman claimed that the supplements were adulterated based solely on the results of a DNA barcoding testing method, which reportedly found unlisted ingredients — or a complete lack of the labeled herbs' DNA — in 79% of the tested products.¹ The attorney general-sanctioned test method detected traces of DNA from alleged adulterants, including plants from the *Allium* (Amaryllidaceae) and *Dracaena* (Asparagaceae) genera, and potential allergens such as rice (*Oryza sativa*, Poaceae) and wheat (*Triticum aestivum*, Poaceae), instead of finding only echinacea (*Echinacea* spp., Asteraceae), garlic (*Allium sativum*), ginkgo (*Ginkgo biloba*, Ginkgoaceae), “ginseng” (*Panax* spp., Araliaceae), saw palmetto (*Serenoa repens*, Arecaceae), St. John's wort (*Hypericum perforatum*, Hypericaceae), or valerian (*Valeriana officinalis*, Caprifoliaceae). In a large number of the tested products, according to Schneiderman's office, there was no detectable plant DNA whatsoever.¹

The herbal community's response was swift and critical; trade associations, nonprofits, and others lambasted Schneiderman's use of DNA barcoding,³⁻⁶ which many experts say is unsuitable for ingredient authentication in finished botanical products, particularly those containing extracts.^{7,8} The

NY AG's herbal supplements investigation, however, was just beginning. Over the next few months, Schneiderman's office targeted quality control measures and product manufacturers, formed a coalition of attorneys general in support of his cause, and successfully forced a major supplement company to incorporate DNA barcoding into its standard ingredient testing procedures.⁹⁻¹¹ Schneiderman later asked Congress to launch an inquiry into what his office has called “a largely unregulated industry.”¹²

As Schneiderman's investigation switched focus, so too did the herbal community's arguments. Emphasizing issues with DNA barcoding, the robustness of current dietary supplement regulations, and numerous industry self-monitoring measures, members of the community referred to the NY AG's actions as “an unfounded witch hunt,”¹³ “a political grandstand,”¹⁴ and “harassment based on science fiction.”¹⁵ Although the community's highly critical reaction may seem familiar to some, it quickly became clear that this situation was different. “Not since DSHEA [the Dietary Supplement Health and Education Act of 1994] has there been a single event with the potential to affect how the botanical industry goes about its business,” noted Loren Israelsen, president of the United Natural Products Alliance (UNPA), a trade group, in an article from *Nutrition Business Journal*.¹⁴



Eric T. Schneiderman.
Image courtesy of NY
State Office of the
Attorney General.

Schneiderman's investigation was turning into the "biggest challenge to the industry's credibility since the days of ephedra [*Ephedra sinica*, Ephedraceae],"¹⁶⁻¹⁸ and the herbal community was concerned about the potential for significant, long-term damage to its reputation in the minds of legislators, health professionals, and the public.

Initial Reactions to Schneiderman's Supplement Investigation

The media frenzy commenced shortly after Mr. Schneiderman's announcement. Over the following week, the *New York Times* featured four articles with familiar supplement-industry criticisms from staff writer Anahad O'Connor,¹⁹⁻²² in addition to unfavorable editorials ("Herbal Supplements Without Herbs"²³) and opinion pieces ("The Politics of Fraudulent Dietary Supplements"²⁴). Herbal supplements were labeled "stupid pills" that likely contained more dust than active ingredients.

"This is ultimately a matter of public health," stated an NY AG spokesperson,²⁵ "and when public health is at stake the burden is on [the dietary supplements] industry to prove what's in its products."

The same day the *New York Times* broke the news, the nonprofit American Botanical Council (ABC) issued a press release stating that the NY AG had misused the DNA barcoding technology, particularly if the supplements contained botanical extracts — later confirmed to be the case — and that his results were "premature."⁵ At the same time, natural products industry trade organizations^{3,4,6} issued press releases and email advisories alerting their members to the situation. A telling headline from a February 3 NutraIngredients-USA article,²⁶ which included industry and natural health community leaders' first reactions to the news, referred to Schneiderman's actions as "uninformed" and "inappropriate."

AG Schneiderman's actions against GNC, Walgreens,

Walmart, and Target in early February are not the first example of DNA barcoding results being used against herbal supplements. According to the NY AG's February 3 press release,¹ he first became interested in the contents, quality, and regulation of herbal dietary supplements after a study on DNA barcoding-based identification of dietary supplement ingredients appeared in the October 2013 issue of *BMC Medicine*. The paper by lead author Steven Newmaster, PhD, an associate professor of biodiversity genomics at the University of Guelph — titled "DNA Barcoding Detects Contamination and Substitution in North American Herbal Products"²⁸ — was one of the first cases of highly publicized negative results based on DNA barcoding of commercial herbal products.

Numerous errors and methodological oversights in the paper by Newmaster et al. brought its results into question and led some organizations, including ABC, to call for its retraction from *BMC Medicine*.²⁹ ABC, working in conjunction with experts in DNA barcoding and analysis from the University of Mississippi's National Center for Natural Products Research (NCNPR) and AuthenTechnologies, published a comprehensive initial critique of the Newmaster et al. paper in the November 2013 issue of *HerbalEgram*.²⁹

Despite describing an entirely different set of analyses, the authors of the 2013 *HerbalEgram* article could very well have been writing about the natural product community's current dilemma with the NY AG. Schneiderman's office, citing protocol for ongoing investigations, has refused to release additional details of the recent DNA barcoding results,³⁰ which makes direct comparisons to the Newmaster et al. paper difficult. However, in both cases, DNA barcoding technology was the only analytical method utilized to attempt to determine the identity of the herbal ingredients in the commercial herbal products tested. Questions surrounding the test results have led some, like Council for Responsible Nutrition (CRN) President Steve Mister, to dig deeper into the available data.

"[W]e may have overlooked a more fundamental flaw with the test method: the internal inconsistency of the test results that make the very method scientifically unreliable and invalid," wrote Mister in an April 14 article in *Natural Products Insider*.³¹ According to Schneiderman's letter to GNC, just "[t]wenty-two percent of the tests yielded DNA matching the product label." Thus, out of the 120 individual DNA tests performed on the GNC herbal products — i.e., one bottle each of the six herbal products purchased from four different stores in New York — 26 tests were positive for the DNA of the herb in question, including six positive tests for saw palmetto. Since each product was tested five times, one sample of saw palmetto must have returned both positive and negative results. Mister refers to this calculation as "The Rule of Five."³¹

"Can you imagine submitting a study for peer review where a test performed five times sometimes produces a positive response and sometimes not, but claiming that the tests are a definitive measure of the identity of the ingredients?" asked Mister.³¹ "[A] reasonable scientist would acknowledge the methodology is unreliable for the purpose it is being used."

On February 11, as the novelty of the NY AG's herbal supplements investigation was beginning to fade and articles on the topic had lost page-one status, the NY AG sent a new round of letters to the same four retailers.³² This time, Schneiderman — a Harvard Law School-educated Democrat and the state's highest-ranking law enforcement officer³³ — issued subpoenas for any and all data supporting the structure-function claims of the retailers' herbal products — "a move that some say is a clear overstep of authority."² Although the companies had already complied with the NY AG's first request and removed the affected supplements from New York stores — with Target and Walgreens going further and removing the supplements from stores nationwide³⁴ — Schneiderman's crusade was not yet finished.

Thus, it was perhaps less surprising when, on February 24, he sent letters to four additional supplement manufacturers (i.e., Nature's Way of Lehi, Utah; NBTY of Ronkonkoma, New York; Nutraceutical Corp. of Park City, Utah; and Pharmavite of Mission Hills, California) requiring nine points of detailed information regarding their herbal supplement products.³⁵ The companies were given a deadline of less than a month to comply, and members of the industry were left wondering what might come next. Although the manufacturers were not implicated in the NY AG's initial letters to the four major retailers, the actions against them created a false appearance of wrongdoing nonetheless.

In early March, the *New York Times* reported that attorneys general from Connecticut, Indiana, and Puerto Rico had pledged their support for NY AG Schneiderman's ongoing investigation into herbal supplements.³⁶ Although details were scarce, Schneiderman explained the general goals of the new coalition in a statement: "The initiative seeks to enhance transparency and ensure that the herbal supplements industry is taking the steps necessary to validate their marketing claims, including [those related] to authenticity and purity," he said.¹⁰ "By joining together, and building on the long track record of state attorneys general upholding the rights of consumers, we can go further in investigating this industry and, as needed, in achieving reform."

The day after the AG coalition was reported, a group of four expert scientists published a white paper on DNA barcoding commissioned by four trade associations representing the dietary supplements industry (i.e., the American Herbal Products Association [AHPA], the Consumer Healthcare Products Association [CHPA], CRN, and UNPA). The objective of the paper, according to the authors, is "to provide an expert assessment of the capabilities and limitations of DNA barcoding for botanical dietary supplement authentica-

tion to inform assessments of the applicability and accuracy of DNA test results."⁷

On March 17, the Natural Products Association (NPA), another industry trade association, published a separate white paper on DNA barcoding methods for botanical authentication by its CEO, Daniel Fabricant, PhD, and senior vice president of scientific and regulatory affairs, Corey Hilmas, MD, PhD.⁸ Drs. Fabricant and Hilmas — the former director of the US Food and Drug Administration (FDA) Division of Dietary Supplement Programs and the former chief of the FDA Dietary Supplement Regulation Implementation Branch, respectively — address some of the specific analytical concerns raised by Schneiderman's investigation, as ABC Chief Science Officer Stefan Gafner, PhD, describes in more detail on pages 59-61 of this issue.

Schneiderman and GNC Come to Terms to End Investigation

After two weeks of relative national media silence, the NY AG's investigation of herbal supplements once again made front-page headlines. On March 30, Schneiderman's office issued a press release announcing that GNC had agreed to "landmark reforms" pertaining to its Herbal Plus[®] product line.¹¹

According to the press release, the terms of the agreement with the NY AG require that GNC "perform DNA barcoding on the 'active' plant ingredients used in its products; implement testing for contamination with allergens, both before and after production; and post prominent signage advising consumers of the processed, chemical nature of extracts."¹¹

As Schneiderman's office noted, its agreement with GNC is "the first in the nation to require testing standards for herbal supplements that exceed current FDA requirements."¹¹

Provided GNC complies with the new standards, the NY AG agreed to stop the investigation into its Herbal Plus supplements and allow the full line of products back in New York stores. However, the specific product lots tested by Schneiderman's office remain off store shelves, despite the subsequent testing performed by GNC and acknowledgment by the NY AG that the products were compliant with federal regulations.³⁸ As Schneiderman admitted in his letter to GNC outlining the terms of the agreement, "NYAG found no evidence in the course of its investigation that GNC deviated from the federal [FDA] 'Current Good Manufacturing Practices' rules or standard industry practice in the production of the tested supplements."³⁷

GNC explained their decision-making process in a letter to stakeholders.³⁹ "Our assessment was quite simple. A

"Our assessment was quite simple. A protracted battle to establish what we already knew and what the NYAG has now confirmed — that our products are pure, safe and fully compliant with applicable regulatory requirements — would have been, at best, counterproductive."

Table 1. The Main Problems with NY AG's DNA Barcoding Study²⁷

1. Apparently unqualified laboratory and researchers
2. Use of only one method
3. No verification of results via scientifically valid methods
4. Apparent lack of method validation
5. Lack of result confirmation in second lab
6. Lack of applicability/reliability of DNA barcoding to/for botanical extracts
7. Inability of DNA methods to distinguish different parts from same plant
8. Apparent lack of knowledge of botanical identification issues by NY AG & staff
9. Refusal of NY AG to release test protocols to affected companies, scientific experts, media, Congress, et al. for independent verification
10. NY AG insistence on staying with its findings, resulting in potential policy implications



protracted battle to establish what we already knew and what the NYAG has now confirmed — that our products are pure, safe and fully compliant with applicable regulatory requirements — would have been, at best, counterproductive.”

In an email to *HerbalGram*, GNC CEO Mike Archbold noted that the terms of the agreement were in line with the company’s history of exceeding current standards in order to ensure high-quality products. “The initiatives we have agreed to in the context of this agreement are consistent with that effort, and with the direction in which the industry is moving,” he wrote (email, April 30, 2015), “and [it] will further expand and strengthen our testing deeper into our supply chain by leading industry efforts to integrate source material traceability standards including DNA barcoding where appropriate (prior to extraction processes) and provide consumers with even greater confidence in our products.”

Although the agreement applies only to GNC and its Herbal Plus products, both the NY AG and GNC have expressed a hope that other companies will follow suit — an outcome Archbold describes as a win-win situation.^{38,39}

“As an industry leader, and as part of our commitment to continuous improvement, we will lead the efforts for higher standards, and if our actions lead to broader implementation of more robust practices across the industry, that’s good for consumers, good for the industry, and good for GNC,” wrote Archbold (email, April 30, 2015).

Supplements Community Responds to GNC Agreement

Members of the natural products community, however, did not describe GNC’s deal with the NY AG in such positive terms. In press releases issued the same day as the announcement, industry organizations such as CRN and NPA called the decision a “mistake” and a “180 degree turn” for Schneiderman, respectively.^{13,40} Others have expressed concerns about the potential repercussions of GNC’s adoption of new ingredient testing standards, suggesting that the company’s decision may have consequences for the herbal community at large.

“The announcement further entrenches a state attorney general’s office in a regulatory matter in which it has no expertise and substitutes face-saving requirements for meaningful advancement of the industry,” said Steve Mister in a CRN press release after the agreement was publicized.⁴⁰ “Moreover, the agreement gives credence to the New York AG’s misguided allegations based on its own DNA barcode testing that legitimate quality concerns existed about the products marketed by four retailers, when there were none.”

More consequential, however, is the agreement’s potential to lead to a “patchwork” of separate quality standards and requirements for dietary supplements. In a press release, NPA voiced the concern “that these actions could lead to each state instituting its own identity testing standards, preempting federal authorities already in place.”¹³ Natural products organizations have repeatedly stressed that existing regulations — when adequately enforced by the FDA — are sufficient to ensure high-quality dietary supplement products, which therefore makes GNC’s new standards redundant.

“The New York Attorney General’s investigation and today’s agreement with GNC provide clear evidence that current federal regulation of dietary supplement manufacturing is effective,” said AHPA President Michael McGuffin on March 30, emphasizing that the investigation found GNC’s products to be fully compliant with current Good Manufacturing Practices (cGMPs), which include identity testing.⁴¹ “DNA testing will add no additional assurance of the correct identification of any herbal ingredient that has already been verified by one or more of the other long-established analytical tools now used by responsible herbal manufacturers. Regulations, requirements and best practices for botanical identification and supplement manufacturing should be based on valid science coupled with qualified expertise and experience.”

Although the adoption of specific testing methods by dietary supplement manufacturers is voluntary per the 2007 dietary supplements final rule for cGMPs,⁴² the regulation requires manufacturers to “perform identity testing on every dietary ingredient, every time it is used.” The manufacturer has the flexibility to choose which particular type of identity test(s) to use for authentication of each dietary ingredient.⁴³ “Companies are supposed to choose reasonable, scientifically valid tests,” noted Tod Cooperman, CEO of ConsumerLab.com, in an article from *NutraIngredients-USA*.⁴⁴ “[N]ot defining these things ... leave[s] it open for an herbal company, or even the New York AG, to decide for itself in each case what is a reasonable test.”

Perhaps what is most concerning, some members of the herbal community have suggested, is that the agreement exalts DNA barcoding — a nascent and evolving analytical method — over other well-established, scientifically sound analytical methods such as chemical fingerprinting for botanical ingredient testing.

As John Bradley, editor-in-chief of *Nutrition Business Journal*, explained in an April 2 article, consumers may view the agreement as “a vindication for Schneiderman and a legitimization of DNA barcoding as an airtight testing standard. That could have damaging implications for the industry and consumers, because it suggests that things have been fixed now. They haven’t.”⁴⁵

Reverberations of the agreement are already being felt in the analytical community. “In fact, it’s already begun to cause problems,” said Alkemist Labs’ Elan Sudberg, writing for *New Hope 360*.⁴⁶ “Suddenly we are receiving requests to perform DNA analysis for our customers. Some are asking if every single reference sample in our herbarium of over 10,000 specimens has been DNA barcoded. Overnight, DNA barcode testing has [the appearance of becoming] the gold standard.”

“It’s the ‘CSI effect’ I was worried about, where the uninformed quickly flock to the shiniest and newest technique on the block,” wrote Sudberg in an email to *HerbalGram* (May 8, 2015), referring to the popular American television show in which forensic DNA testing frequently helps solve crimes. “Yet the average consumer may not realize that, while DNA barcoding has its place in this industry, it cannot assess plant parts (which is legally mandated by the FDA’s cGMPs) or quality — it can only identify the species. DNA barcoding is not a gold standard; rather, it is just another tool in the orthogonal approach to quality.”

GNC Agreement Reignites DNA Barcoding Conversation

Despite the industry backlash against GNC’s agreement, the company did not intend to disrupt the landscape of supplement ingredient testing in the United States. As with any compromise, the terms of the agreement were designed to be mutually beneficial and to help resolve an issue. However, from the start, GNC — along with many, perhaps most, natural products organizations — did not believe there was a problem with the products.

“Where NYAG and GNC disagree,” Schneiderman wrote in his letter to GNC that outlined the new procedure,³⁷ “is on the sufficiency of federal rules and testing requirements and their relationship to state consumer protections laws. The FDA does not mandate the use of DNA-based technologies, like barcoding, to authenticate herbal supplements. Instead, the FDA allows companies to support their claims through other methodologies, including chemical analysis methods, like those employed by GNC,” he continued. “Given the existence of chemically-similar natural or synthetic substitutes, NYAG is concerned that standard chemical approaches provide inadequate assurance of the authenticity of herbal supplements.”

If the “inadequacy” of standard testing procedures is the problem, then DNA barcoding, Schneiderman suggests, is the solution. Thus, one obvious question remains: does the addition of DNA-based analytical methods guarantee the authenticity of herbal dietary supplements? The answer seems to be a resounding “no.”

Importantly, DNA barcoding is not currently referenced in any official United States Pharmacopeia (USP) monograph, nor is it used or endorsed by the FDA for botanical ingredient verification.^{47,48} According to a widely distributed statement from FDA’s Center for Food Safety and Applied Nutrition (CFSAN), the Administration is, however, exploring the technology for such purposes. “The FDA does not currently use DNA sequencing for dietary supplement ingredient verification, but is actively working toward developing

Table 2. GNC Requirements for Herbal Plus® Products per NY AG Agreement³⁷

DNA Barcoding	
Within 18 months, GNC will use DNA barcoding to “confirm the authenticity of the ‘active’ herbal/botanical ingredients prior to extraction, if any.”	Details: GNC will require that suppliers test all botanical ingredients by DNA barcode method prior to their extraction. GNC will implement these procedures for ingredients for which DNA barcodes are not currently available as soon as they become available.
GNC will develop DNA barcodes for botanical species without DNA barcodes available “either through a public domain source or through a license with a third-party vendor” within 24 months.	GNC will add the barcodes to a public database along with the scientific methods used to identify them.
Allergen Testing	
GNC suppliers will randomly test all <i>raw ingredients</i> for the eight most common allergens defined by FDA (i.e., milk, eggs, fish, crustacean/shellfish, tree nuts, peanuts [<i>Arachis hypogaea</i> , Fabaceae], wheat, and soybeans [<i>Glycine max</i> , Fabaceae]).	Details: Using polymerase chain reaction-enzyme-linked immunosorbent assay (PCR-ELISA).
GNC will randomly allergen test <i>finished products</i> on an annual basis.	Using “a scientifically-validated” technique.
Signage & Labeling	
GNC will display in-store signs explaining the difference between whole herbs and extracts (see required text in opposite column) and give the template to all other retailers selling Herbal Plus products.	Details: “Whole herbs are usually dried, chopped or ground into powder, and may be processed with water or alcohol for encapsulation. Standardized herbal extracts are made by dissolving herbs in a solvent like water, alcohol or liquid carbon dioxide, resulting in a chemical extract. The goal of standardization is to provide uniformity of a specific, constituent that may be biologically active.”
GNC will include the signage text and an explanation of GNC’s extraction processes in online product descriptions for all extracted products.	
Product labels will confirm the absence of allergens in finished products.	Labels will list all ingredients and excipients “per existing FDA rules.”
Manufacturing Facilities	
All ingredients will be manufactured in current Good Manufacturing Practice (cGMP)-compliant facilities certified by a third party.	Details: Examples of third-party accreditation bodies include the International Organization for Standardization (ISO), the United States Pharmacopeial Convention (USP), and NSF International.



validated methods for plant identification, for use by both industry and the agency,” CFSAN stated.^{48,49} In addition, they noted that the FDA is “working on building a library of DNA sequences for plants, but this project is not complete. The agency currently uses chemical markers or fingerprints when it performs ingredient verification.”

Standards-setting bodies such as the USP are also considering adopting DNA-based testing methods, but, as they have stated, more work is needed.⁵⁰ “With the appropriate validation, USP may incorporate DNA tests into specific product quality standards, but even then it is envisioned not as stand-alone procedure, but as a complement [a different approach to measure the same outcome — otherwise known as an ‘orthogonal’ method] to existing chromatographic, spectroscopic, and botanical morphological (microscopic/macroscopic) analytical procedures.”

“DNA testing is a comparatively new technology,” explained Sudberg.⁵¹ “It has the potential to become an important tool in identity testing, particularly when used knowledgeably. However, like any test method, in the hands of a technician who does not have a working knowledge of the materials he is dealing with, the results have the potential to be inaccurate.”⁵¹

For Schneiderman’s original tests, his office commissioned Clarkson University professor James A. Schulte II, PhD — an expert in reptilian biology — to test the selected herbal dietary supplements. The DNA barcode analyses were conducted at Beckman Coulter Genomics, a DNA sequencing lab based in Massachusetts.⁵² Schulte’s assignment as investigator, however, was met immediately with criticism due to his apparent lack of experience in botanical identity testing.^{2,5,52} To date, no scientific papers can be found that are authored or co-authored by Prof. Schulte on the subject of genetic testing of plant material or finished botanical dietary supplements.⁵³

However, even if there were a plethora of experts trained in DNA barcoding of botanical ingredients, the analysts would still be lacking an essential tool — a complete database of DNA barcodes for herbal ingredients sold in dietary supplements.

“Most of the species under investigation by the NY AG cannot be accurately identified without a proprietary database of reference standards, as several of the species under investigation—including St. John’s wort and *Echinacea*—do not have publically available reference sequences from the genes necessary to identify them,” explained the authors of the Reynaud et al. white paper⁷ in a *Nutritional Outlook* article from April 2.⁵⁴ The story detailed Danica Harbaugh Reynaud’s, PhD, mostly favorable opinion of DNA barcoding. Dr. Reynaud is the CEO of AuthenTechnologies LLC, a contract laboratory that specializes in DNA-based analyses of natural products.⁵⁵

“Reynaud says she is skeptical of how thorough or effective this database could really be in order to achieve complete DNA sequencing data for most commercially used herb species,” the article noted.⁵⁴ “She says it would take years and millions of dollars to construct one—something that’s likely well beyond the scope of what GNC has agreed to do.”

In other words, as American Herbal Pharmacopoeia (AHP) President Roy Upton told *Nutrition Business Journal*

the same day, “The AG can’t realistically hold someone to a standard that does not exist.”¹⁴

Given its intricacies and relative infancy, DNA barcoding is not considered a universally appropriate method for identity testing of finished herbal products, especially without corroboration with at least one other widely recognized scientifically valid method. In particular, the technology is not ideal for detecting plant DNA in dry, liquid, or powdered herbal extracts, as such processes can “denature, degrade and destroy DNA.”⁵⁰ Pieter Cohen, MD of Harvard Medical School — known as a vocal critic of the supplements industry — has acknowledged this point as well.

“DNA barcoding looks for a specific fragment of DNA, but the ingredients in herbal supplements are often highly processed — crushed, dissolved, filtered and dried — so that they may no longer contain the particular fragment of DNA that researchers are searching for, making the supplement appear to be mislabeled,” Dr. Cohen was quoted as saying in the *New York Observer*.^{56,57} “The biological compounds extracted from the plant—the parts that supposedly have healing powers—would be in the supplement without the DNA sought in the tests.”

Understanding the shortcomings of DNA barcoding for botanical extracts makes the fact that up to 74% of the products tested by Schneiderman’s office were extracts even more troubling.^{13,26} GNC also has stated that all six of its herbal supplement products were extracts and are thus susceptible to inaccurate identification by DNA barcoding.²⁶

However, it seems that this point was not entirely lost on the NY AG’s office. The terms of the NY AG’s agreement with GNC specify that DNA barcoding will be performed on ingredients *prior to extraction*. In a subsequent press release, Schneiderman’s office even adopted new phrasing when referring to the extracts in the dietary supplements his office commissioned to Dr. Schulte for testing. “Some products were so thoroughly processed that the genetic material of the original natural plant source was unrecognizable,” the release stated.^{12,37} The fact that such processing is the intentional, established way to produce botanical extracts was not mentioned.

In addition to its limited utility for identifying materials in finished extracts, DNA barcoding has another significant shortcoming. “While DNA barcoding is a valid and useful technology, it is qualitative in nature (i.e., it can confirm whether DNA is present or not, but it does not indicate in what quantity the plant material is present),” explained USP Director of Dietary Supplements Nandakumara Sarma, PhD, in a USP blog post about the topic.⁴⁷ “Thus, chemical analysis tests should be used to determine the strength of a supplement in a quantitative manner.”

However, even when applied to raw herbal materials, DNA barcoding is not enough to satisfy cGMP rules, which require the plant part of each ingredient to be verified and labeled on products.⁴⁶ “It’s important to note here that dietary supplements containing botanical ingredients must list the part of the plant used in the final product,” Dr. Fabricant explained in a press release from NPA.¹³ “DNA barcoding will not provide useful information as to whether roots, stems, leaves or flowers are used in the supply of the raw material.”

Still, many experts and organizations — including the most

vocal critics of AG Schneiderman’s actions and members of the natural products community — agree that DNA barcoding may eventually become a useful and appropriate analytical tool.

“DNA testing poses some unique benefits,” USP noted recently.⁵⁰ “Its sensitivity and specificity helps in accurate identification of the botanical species as well as adulterants and contaminants — especially in material where the macro-botanical characteristics are no longer present, such as powdered or ground material. However, this same sensitivity can lead to false results and that calls for careful interpretation of the data.”

Dr. Reynaud, whose lab currently offers DNA barcoding for certain herbal extracts, has mostly positive things to say about GNC’s new testing requirements. “I think it’s a great idea,” she told *Nutritional Outlook*.⁵⁴ “We’ve been pushing for that for all of our clients for years. ... Typically chemical tests are limited in that they are looking for either target molecules or target species and aren’t as equipped for identifying unexpected adulterants or differentiating between closely related species.”

However, as ABC’s Blumenthal explained in an ABC press release about GNC’s agreement,⁵⁸ the DNA barcoding of raw plant materials is not enough to guarantee the authenticity of finished herbal products. Since the technology is unable to determine quantities, DNA barcoding conceivably would confirm the presence of the labeled herb even if only a pinch of the genuine substance were added to the tested material. “A potentially unscrupulous extractor could still subsequently manipulate the extract in such a way as to create a false sense of value, i.e., adulterate it with other extracts and/or additional unlabeled chemical compounds, natural or synthetic, from other sources,” Blumenthal explained.⁵⁸ “DNA testing will not be able to detect such changes in the chemical composition.”

Together, the shortcomings of DNA barcoding of botanicals bring into question the utility of the NY AG’s “landmark reforms” for ingredient testing. As Steve Mister concluded in CRN’s press release on the subject,⁴⁰ “DNA barcode testing remains a flawed method for across-the-board testing for analyzing the quality of botanical ingredients and finished products.”

AG Coalition Asks Congress to Investigate Supplements Industry

Just three days after Schneiderman announced his agreement with GNC, the NY AG issued yet another press release regarding herbal supplements.¹² By this time, Schneiderman’s coalition of state attorneys general had grown to 14 members from just four individuals in mid-March. With the backing of 13 of his colleagues (some experts have questioned whether the NY

AG may have been unable to attract more AGs to his group), the NY AG asked Congress to open an investigation into the herbal supplements industry and to consider a “more robust oversight role” for the FDA.

The letter began with an explanation of some of the concerns “reaffirmed” by Schneiderman’s investigation: “Many of the products tested were [allegedly] contaminated with allergens, plant species left off the label, or other potentially dangerous substances, or so thoroughly ‘processed’ that the genetic material of the original ‘natural’ plant source was unrecognizable or not present at all.”^{12,59}

In the letter addressed to chairmen and ranking members of Congressional subcommittees on health and consumer protection, the coalition asked Congress to address issues outlined in five bullet points (see Table 3).

After mentioning a number of examples from journal articles and media reports of adulterated supplements — including those found to contain “high levels of heavy metals” or prescription drugs, as well as supplements labeled as containing “black cohosh” (*Actaea racemosa*, Ranunculaceae) that have been associated with cases of liver damage — Schneiderman took to criticizing the current regulatory framework.

“In FY 2013, FDA inspectors cited two out of every three supplement manufacturers for allegedly violating ... ‘cGMPs.’ More than one in five of those citations—called Form 483s—observed that the manufacturer failed to verify that a finished supplements batch met product specifications as to identity, purity, strength, or composition,” he noted in the letter to Congress.⁵⁹ “A similar proportion was cited for failing to employ an appropriate test or examination to verify the identity of a dietary ingredient before incorporating it in the final product.”

Speaking to Capital New York, an online news site owned by Politico.com, a few days later, Schneiderman added that the Administration “was able to inspect less than three percent of the manufacturers of herbal supplements” according to the most recent data available.⁶⁰ In the same article, however, he acknowledged that the FDA is understaffed and lacking in

Table 3. Items for Congress to Address, per AG Coalition Request^{12,59}

1.	The adequacy and effectiveness of existing quality assurance measures for verifying the source, identity, purity, potency, and quality of ingredients and fillers;
2.	The adequacy and effectiveness of existing regimes for verifying the identity, composition, purity, potency, and quality of the finished products sold by domestic manufacturers and retailers;
3.	The degree to which product labels and marketing, including the use of the terms ‘natural,’ ‘herbal,’ and ‘extract,’ mislead consumers about the contents of herbal and dietary supplements, and whether the FDA should develop standards and restrictions governing their use;
4.	The extent to which Congress should mandate, or direct the FDA to develop enhanced, uniform, industry-wide quality assurance and verification regimes to guarantee the source, identity, purity, and potency of materials incorporated into herbal and dietary supplements; and,
5.	The extent to which Congress should mandate, or direct the FDA to develop, enhanced manufacturing and supply chain management requirements for the industry to guarantee the safety and efficacy of the finished herbal and dietary supplements.

resources.

Threatened with a Congressional inquiry of the industry they represent, herbal supplement trade associations responded, immediately dismissing the proposed investigation as unnecessary and a waste of taxpayer money.

“As the former head of the FDA’s Division of Dietary Supplement Programs, I have seen first-hand how the agency may take swift and forceful action when dietary supplement companies violate federal regulations,” noted NPA’s Fabricant in a press release.¹⁵ “The FDA is properly equipped to identify and go after firms that pose a threat to public health. Attorney General Schneiderman’s claims that the FDA doesn’t have ample authority in this area show a complete misunderstanding of the regulatory structure in place to protect consumers and remove products from the market.”

GMPs are just one facet of the regulations currently in place to help prevent adulterated products from entering the marketplace. “The FDA has an arsenal of options available to ensure compliance: a 483, a Warning Letter, and even injunctive relief,” *Natural Products Insider* noted in an article from late February.⁶¹

CRN’s Mister, in a press release, noted that the “concerns raised ... about alleged widespread safety issues are not true, based on [the] government’s post-market surveillance system which demonstrates relatively few safety issues for these products.”⁶² He added that CRN supports additional FDA resources to promote “stronger and swifter enforcement of these existing regulations.”

Extending cGMPs to the Botanical Supply Chain

On April 15, the recently formed Organic & Natural Health Association (Organic & Natural), a trade group, met with the NY AG’s office to discuss the herbal supplements investigation.⁶³ Karen Howard, CEO and executive director of Organic & Natural, called the meeting “encouraging,” and the organization presented a regulatory proposal for raw herbal ingredients in a press release the following day.⁶³

“Ensuring supply chain integrity must start at the earliest possible point,” said Todd Harrison, president of Organic & Natural and an attorney at Venable LLP.⁶³ “It would make sense to apply the FDA’s current cGMPs (code 21 CFR Part 111) to raw material manufacturers. Not only does it provide flexibility but would also be welcomed by branded ingredient manufacturers that are already following cGMPs but are forced to compete with lower quality ingredient manufacturers that have minimal, if any, cGMPs.”

21 CFR Part 111 — the cGMP statute — describes the federal requirements for dietary supplement manufacturing, packaging, labeling, and holding processes. Currently, the regulation does not apply to manufacturers of raw ingredients, extracts, or related materials destined for dietary supplements.⁴³ Organic & Natural hopes to extend the reach of

Part 111 to these manufacturers and says it is in the process of submitting an FDA citizens’ petition to that end.

Based on their conversations with the NY AG’s office, Howard and Harrison came away from the meeting with added perspective on the industry’s response to the investigation. In an article from *Natural Products Insider*, Harrison said that the NY AG’s staff “made it clear they were surprised everybody believes this is about testing rather than ... the quality of the supply chain.”⁶⁴

Members of the natural products community have voiced concerns about the potential drawbacks of focusing primarily on DNA barcoding in the weeks before Organic & Natural and other trade associations, such as NPA and CRN,⁶⁵ met with the NY AG’s staff. The scientific and technical minutiae of the DNA testing argument — despite the argument’s scientific validity — is likely lost on the average consumer, and, apparently, the NY AG as well.

“[The NY AG’s office] didn’t seem to be terribly concerned about the fact that the [DNA barcoding] tests are inconsistent because they got what they wanted,” Mister told *Natural Products Insider*,⁶⁵ “which was a lot of media attention for the Attorney General out of this investigation.”

Herbal Community Shifts Focus

When it started to become apparent that the herbal community’s DNA barcoding message was not going to shut down Schneiderman’s investigation overnight — or erase three months of negative media coverage from consumers’ minds — the natural products industry and herbal community were left to decide what to do next. Many believed that a uniform message was essential, but it was unclear as to what that message would be and for whom it would be intended.

“The bottom line is that this investigation ultimately raised serious questions about the quality of dietary supplements,” explained Frank Jaksch, Jr. in a guest article for *San Jose Mercury News*.⁶⁶ “In order to regain consumer trust and provide top quality products as promised, the industry must use an attack such as the Attorney General’s as a catalyst for change. The debate should lie in how. What should that change be?”

Two notions have received somewhat broad support from members of the herbal supplements community: the need for increased transparency in the supply chain and more robust education efforts for the public and policymakers alike.^{67,68}

“Both sides want to ensure consumers are provided the highest quality products possible, and the only way to do that in our opinion is to ensure the integrity of your supply chain,” said Harrison.⁶⁴ “We think focusing on testing methodology is missing the point. It is only a tool. It is not the be-all end-all.”

But ABC’s Mark Blumenthal believes that focusing on both issues is warranted. “As the managing organization of

“In order to regain consumer trust and provide top quality products as promised, the industry must use an attack such as the Attorney General’s as a catalyst for change. The debate should lie in how. What should that change be?”

the ABC-AHP-NCNPR Botanical Adulterants Program, ABC has been educating and promoting the proposition for over four years that industry members and others must become more aware of the level of adulteration of raw materials and extracts in the botanical supply chain,” he said.²⁷ “However, as science-based organizations, ABC and its Program partners cannot accept the misuse of DNA barcoding as the *sole* method to test botanical dietary supplements for their identity and authenticity, particularly when they are made with extracts. Although we consider DNA testing to be another valuable tool in the analytical toolbox, it has its limitations, as others have artfully demonstrated.”

“Establishing a legal or regulatory agenda, and a public media campaign, based on unreliable and probably inaccurate results from inadequate testing is not scientific and ultimately is not in the public interest,” continued Blumenthal. “Inasmuch as we want to see improvements where needed in detecting adulterated botanical materials, this should be conducted in a scientifically valid and technically defensible manner.”

The trade associations’ meetings with the NY AG in mid-April signaled that the natural products community’s message was evolving. The focus was “moving beyond the science of supplements ... to politics, seeking to influence state officials who have the clout to not only take enforcement actions against an industry currently under assault but severely damage its credibility.”⁶⁹

Although spreading the word about existing supplement regulations and the benefits of natural products may not shift the balance in favor of the herbal community overnight, organizations such as NPA, CRN, and others believe that they are conversations worth having. “Over the past month, CRN has met with a number of state AGs around the country,” Mister said in press release,⁶² “and we are gratified that the concerns go away once we’re given the opportunity to fully explain the issue.”

Fighting Back and Looking Forward

It has been more than three months since AG Schneiderman began his herbal supplement investigation. In that time, his office issued five press releases on the topic, and industry and community groups have responded with many more of their own. Although the natural products community is well acquainted with negative media coverage surrounding allegedly adulterated supplements, there seems to be a general consensus that these events are industry changing.

“In my experience over 41 years in the herbal community, this is the biggest issue that has been on the table,” Blumenthal told *Nutritional Outlook*.⁷⁰ In the same article, Mister shared a similar concern: “This is a paradigm-changing moment in terms of the way consumers [feel] about the industry,” he said.

For almost three months, NY AG Schneiderman was unrelenting in his actions against members of the herbal supplements community. Each time Schneiderman switched his focus — from herbal supplement quality and structure-function claims to the “misleading” nature of extracts and the federal regulatory framework — the industry fought

back. In the end, the natural products community and AG Schneiderman may share a common goal — the assurance of safe, high-quality, and authentic botanical supplements for consumers. The difference lies in the best way to achieve that goal.

“Every time something happens, the industry wants to fight or rebut,” Jaksch noted in a recent *Natural Products Insider* article.⁶⁵ “Maybe it is time to consider a different tactic, as whatever is being done now does not seem to be working. I am not saying that I support the NY AG’s actions, but perhaps it might [be] better to join him, and try and figure out a way to compromise.”

Already, there have been hints of compromise. Schneiderman agreed to stop its investigation into GNC’s products in exchange for the company’s adopting a new — albeit controversial — DNA-based testing standard for raw ingredients. In April, multiple trade associations met separately with the NY AG’s office to discuss the investigation, which led to frank conversations and at least one quality control proposal. Additionally, industry groups and others have made it clear that they support increased resources for the FDA to enhance its ability to enforce existing regulations.

More recently, the NY AG’s office issued a joint statement with NPA in perhaps what is the clearest sign of compromise yet.⁷¹ In a May 11 press release about the development, the NY AG’s office acknowledged its shared goals with NPA to provide “authentic, pure,” and fully compliant herbal supplements for consumers; Schneiderman also acknowledged one of the industry’s main criticisms about using DNA barcoding as the sole test method to authenticate botanical ingredients.

“While no single test or technology alone can provide complete confidence to consumers, we support the application of DNA barcoding technology as part of a multifaceted approach to assuring authenticity and identifying substitution,” Fabricant and Schneiderman noted in the joint statement.⁷¹ “This includes testing herbal/botanical ingredients prior to extraction in circumstances where [a] DNA Barcode is available for the relevant species. ... We view this dialogue as a positive step in resolving our differences and we are hopeful that we can work in collaboration to enhance confidence and safe access for consumers.”

In the meantime, the herbal community has adopted a mantra of transparency, integrity, and education — a message that is more likely to resonate with consumers than debating the intricacies of botanical genetic analyses. There are still many unknowns in the NY AG’s unexpected and aggressive investigation into herbal supplements, but one thing is clear — the natural products community has been dealt a serious blow.

“However this shakes out,” wrote Sudberg in an article for *NewHope360*⁵¹ just two days after Schneiderman’s original announcement, “and even if the results of this well-publicized testing are ultimately discredited, the damage is done in the minds of consumers, and quite possibly in the minds of Congress.” HG

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Botanical Integrity: The Importance of the Integration of Chemical, Biological, and Botanical Analyses, and the Role of DNA Barcoding

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Editor's note: This article was originally published in the April 2015 issue of *HerbalEgram*.

What are Botanicals?

Raw materials, ingredients, and products derived from plants are commonly referred to as herbs or botanicals in both the biomedical literature and the natural products health industry. This overarching term includes the breadth of crude herbs, plant parts, and the ingredients made from them, and also covers finished products such as botanical dietary supplements. Botanical dietary supplements are intended to supplement the human diet and are comprised primarily of powdered plant parts, their extracts, or other preparations derived from crude herbal material; some formulations include other ingredients such as vitamins, minerals, and amino acids. Botanical dietary supplements are highly complex mixtures reflecting the diverse chemical constituents that compose the source plant's raw material. Botanical analysis is an intricate analytical challenge requiring specialized skills and instrumentation that is different from those required for quality control of chemically simpler pharmaceuticals, or for the safety assessment of many conventional foods or other products that are generally recognized as safe (GRAS).

What is Botanical Integrity?

The concept of Botanical Integrity evolved from an initiative by the National Center for Complementary and Integrative Health (NCCIH, formerly the National Center for Complementary and Alternative Medicine [NCCAM]) and the Office of Dietary Supplements (ODS), both at the US National Institutes of Health (NIH). The initiative led to the implementation of the NIH natural products integrity policy,¹ which addresses botanical study materials by outlining special requirements for their characterization. Going beyond just "quality control," Botanical Integrity combines disparate aspects of defining and assessing plant-derived materials and products for human consumption: identity (correct plant species and plant part), homogeneity (absence of contamination by other species and chemicals; often called "purity" but different than the regulatory use of that term), biological potency (the presence of bioactive principles in desired amounts; a prerequisite for in vivo efficacy), and safety (an adequate toxicological profile).

How can Botanical Integrity be assessed?

The assessment of Botanical Integrity requires a multidisciplinary approach that combines three major domains of expertise, with each providing a variety of tools and analytical methodologies (See Fig. 1): botanical examination (botany), phytochemical analysis (chemistry),

and biological and safety assessment (bioactivity). Botanical examination is performed on the source material and involves operations typically performed in plant taxonomy, morphology, and genetics. Phytochemical analysis can be carried out with crude plant material, extracts, and finished products. These analyses encompass a wide array of chemical analytical tests with major domains in chromatography (e.g., liquid chromatography [LC], gas chromatography [GC], thin-layer chromatography [TLC]) and spectroscopy/spectrometry (e.g., ultraviolet [UV], infrared [IR], near-infrared [NIR], mass spectrometry [MS], nuclear magnetic resonance [NMR]). Operations for the assessment of bioactivity and safety, which are typically performed with botanical extracts, comprise in vitro and sometimes in vivo assays for endpoints related to the health benefit and/or safety of the herb. Investigations in the UIC/NIH Center for Botanical Dietary Supplements Research have integrated various aspects of all three of these fundamental domains (botany, chemistry, and bioactivity) since 1999. The UIC/NIH Center has pioneered new methodologies for the assessment of Botanical Integrity and produced insights into the safety and efficacy of botanical dietary supplements that are widely used for women's health. We have also implemented *Botanical Integrity Dossiers* as a means of documenting comprehensively the Botanical Integrity of our study materials, including crude herbal material, extracts, and purified phytochemicals.

How does Botanical Integrity help ensure safety and efficacy?

Under the governance of the Dietary Supplement Health and Education Act of 1994 (DSHEA), botanical products may be marketed as dietary supplements as long as they meet the appropriate regulatory requirements within that category of food, not drug, regulations. Category-specific current Good Manufacturing Practices (cGMP) and labeling requirements are in place for botanical dietary supplement manufacturers and have fostered the development of a marketplace with a broad range of high-integrity products. However, adulteration and other issues affecting the Botanical Integrity of products can still occur, and the combination of botanical, chemical, and biological standardization is a viable approach for ensuring safe and effective botanical products.

What is DNA barcoding?

The authentication of botanical raw materials (unextracted fresh and dried plant parts) has benefitted from the implementation of a variety of molecular biology methods based on the analysis of DNA sequences, and it was originally employed for plant systematics (i.e., the classification and naming of plants).²⁻⁴ Among these methods, DNA barcoding relies on the amplification and sequencing of short (400-800 base pairs) nucleotide sequences localized to standardized regions of the genome (plastid and nuclear loci for plants). Species are identified according to the nucleotide variations in these short standardized gene regions, which give them unique DNA identification tags.^{2,3,5} During the last decade, DNA barcoding has emerged as a method for the authentication of plant parts and herbal materials.⁶⁻¹⁰

Recently, a DNA-based authentication method was employed to evaluate the identities of 78 samples from commercial botanical dietary supplement products sold in New York, allegedly to expose potential cases of fraud.¹¹⁻¹³ The study generated much discussion after finding that only 21% of products contained DNA of the claimed plant species, thereby concluding that the other 79% of the products were not in compliance with their labels. This report also raised the question as to whether DNA barcoding and DNA-based authentication methods are sufficient and/or conclusive for the determination of botanical identity, and to what level DNA methodology addresses Botanical Integrity.

What is the role of plant DNA authentication in Botanical Integrity?

DNA-based methods such as DNA barcoding are one of the many available tools that can be used in botanical examination ("botany," See Fig. 1). The key outcome of botanical examination is the positive identification of the plant or plant-derived material by a scientifically valid method; the effectiveness of botanical assays based solely on DNA authentication depends on the presence of tissue

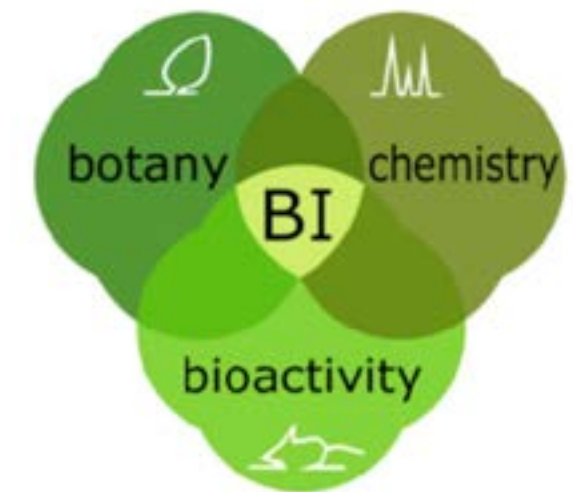


Figure 1. Botanical Integrity Requires Integration: Chemistry x Botany x Bioactivity = Integrity.

The three main components of the Botanical Integrity (BI) model used for research in the UIC/NIH Botanical Center are: botanical examination (botany), phytochemical analysis (chemistry), and biological and safety assessment (bioactivity). The concerted use of multiple methodologies from all three components is required to obtain a comprehensive representation of a botanical material.

and/or DNA from the target plant. In addition to DNA barcoding, there are other useful methods of botanical examination, such as morphology with the use of taxonomic keys, microscopy, and organoleptic analysis. In addition, a myriad of well-established methods are available to perform phytochemical analyses (e.g., high-performance TLC [HP-TLC], liquid chromatography [ultra-HP or HP]LC-UV, LC-MS), NIR spectroscopy, MS, tandem MS [MS/MS], and NMR) and bioactivity assessments (e.g., in vitro and in vivo assays for a variety of biological activities such as estrogenicity,¹⁴ chemopreventive,^{15,16} and anti-inflammatory activities¹⁷). Importantly, chemical and biological assays can provide strong evidence about Botanical Integrity even when original plant tissue or DNA is absent, such as in botanical extracts or final products containing them, or when the test materials contain other constituents such as excipients that may confound the analytical challenge. All three types of methodologies together (botany, chemistry, bioactivity) establish Botanical Integrity, and it is incomplete unless adequate phytochemical analyses have been performed. The complex chemical composition of botanicals requires parallel bioanalytical approaches for adequate description, especially when considering that the bioactive constituents in botanicals are (phyto)chemicals.

Conclusions

The assurance of Botanical Integrity is of paramount importance to ensure safe and efficacious botanical-

derived ingredients that can support both high-quality products and scientific excellence. Claims made about the quality, or lack thereof, of botanicals can be valid only if they rest on a variety of established and validated analytical methods (botany, chemistry, bioactivity) that are sufficient to address Botanical Integrity (See Fig. 1). In our experience, the employed methods have to be complementary to each other and cover at least two (botany and chemistry) — if not all three — of the major domains of expertise, leading to botanically, chemically, and biologically standardized materials.¹⁸ Notably, this process can be quite demanding, considering that several different (orthogonal) methods should be used to cover each domain of expertise.

In our scientific judgment, performing just one form of analysis (e.g., DNA barcoding) is insufficient to fully assess Botanical Integrity. Single-track approaches generally lack the rigor essential for authenticating the identity and adequately describing the biomedical integrity of the test material. DNA-based methods can be valuable tools for botanical evaluation in the early stages of the botanical supply chain. However, for the analysis of commercial botanical extracts and finished dietary supplement products, the numerous other methods belonging to the domains of phytochemical analysis and bioactivity assessment are much more meaningful and practical. HG

Acknowledgement

The authors acknowledge support by grant P50 AT000155 from the Office of Dietary Supplements and the NCCIH of the US National Institutes of Health. The contents are solely the responsibility of the authors and do not necessarily represent the views of the funding agencies.

About the UIC/NIH Center for Botanical Dietary Supplements Research

Established in 1999, the UIC/NIH Center for Botanical Dietary Supplements Research addresses issues of standardization, quality, safety, and efficacy of botanical dietary supplements used for women's health. Founded by the late Norman Farnsworth, PhD, and directed by Dr. Richard van Breemen, the Center's leaders, including Drs. Judy Bolton and Guido Pauli, take an integrated, collaborative approach to botanical research. Based on extensive preclinical studies involving botany, chemistry, and biology, the Center has completed clinical studies with black cohosh (*Actaea racemosa*, *Ranunculaceae*), red clover (*Trifolium pratense*, *Fabaceae*), and hops (*Humulus lupulus*, *Cannabaceae*), specifically addressing botanical safety and efficacy. Educating the next generation of pharmacognosists remains a primary goal of the Center, which has trained more than 60 pre- and post-doctoral researchers.

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Understanding DNA Barcoding: A Review and Summary of Recent White Papers on DNA Barcoding for the Authentication of Herbal Dietary Supplements

Separate Reports Commissioned by Industry Trade Group Coalition and Natural Products Association Emphasize Current Limitations of Barcoding Technology for Botanical Products, Particularly Extracts

By Stefan Gafner, PhD, ABC Chief Science Officer

Editor's note: Less than 24 hours after the New York Times broke the news of New York Attorney General Eric T. Schneiderman's investigation of herbal supplements on February 3, 2015, herbal science experts, natural products industry trade associations, analytical experts, and others issued press releases, member advisories, and letters to the editor questioning the NY AG-commissioned scientist's use of DNA barcoding to authenticate several store-brand herbal supplements from major US retailers. According to Schneiderman's office, the analysis revealed a lack of the labeled herbs or the presence of unlisted ingredients in a majority of the products. However, as numerous analytical and regulatory experts have noted in the weeks since the announcement, DNA barcoding is a developing technology that is neither appropriate for the authentication of botanical extracts nor approved by the US Food and Drug Administration (FDA) for such purposes. In the weeks following the NY AG's press release, two white papers from expert authors were published outlining the limitations of DNA-barcoding for botanicals. ABC Chief Science Officer Stefan Gafner, PhD — whose doctorate is in the field of pharmacognosy and natural products chemistry — summarizes and explains these documents below.

White Paper by Four Analytical Experts Evaluates Capabilities and Limitations of DNA Barcoding for Testing of Botanical Dietary Supplements

On March 11, 2015, a white paper was published on the capabilities and limitations of DNA barcode testing for the identification of botanical dietary supplement ingredients in finished products.¹ The document indicates that the conclusions from the DNA barcoding tests commissioned by the NY AG are not justified.

The white paper is authored by four highly respected experts in the fields of DNA and other analytical methods for botanical dietary supplements: Danica T. Harbaugh Reynaud, PhD, CEO of AuthenTechnologies LLC, in Berkeley, California, a leading laboratory in DNA authentication of botanicals; Brent D. Mishler, PhD, professor in the Department of Integrative Biology at the University of California at Berkeley; James Neal-Kababick, CEO of Flora Research in Eugene, Oregon, a leading laboratory for botanical dietary supplement analysis; and Paula N. Brown, PhD, director of the Natural Health and Food Products Research Group at the British Columbia Institute of Technology in Burnaby, British Columbia. The document was underwritten by four dietary supplement trade organizations: the American Herbal Products Association (AHPA), the Consumer Healthcare Products Association (CHPA), the Council for Responsible Nutrition (CRN), and the United Natural Products Alliance (UNPA).

As stated on the first page of the document, the purpose of the paper is to provide an “expert assessment of the capabilities and limitations of DNA barcoding for botanical dietary supplement authentication to inform assessments of

the applicability and accuracy of DNA test results.”

The focus of the white paper — clearly written as a critique of Schneiderman's test results² — is less on the capabilities of DNA barcoding, but it does provide a good overview of the limitations and possible pitfalls, which are often overlooked in papers published in the scientific literature (e.g., the now largely discredited report from 2013 on the authentication of herbal ingredients in dietary supplements authored by Steven Newmaster, PhD, et al. at the University of Guelph,³ which prompted the NY AG to look into the quality of botanical dietary supplements). It is important to understand that DNA barcoding is only one of many DNA-based methods for identification of herbal ingredients, and as such, the comments made in the paper are applicable only to DNA barcoding and not to other, more specific genetic methods used for identification of plant materials.

The white paper first explains the principles underlying DNA barcoding and the main experimental steps involved in the technique. One of the crucial steps in using genetic methods for identification of plant species is to find the gene region(s) that contain enough variation to allow the species of interest to be distinguished from other species. The choice of the best regions for DNA barcoding is still a matter of debate, and, according to a recent review of the peer-reviewed literature, a total of 17 different regions are reportedly used by scientists for authentication of plant material.⁴ After extraction from the sample, the DNA is amplified, which means that a large number of copies of the chosen gene regions are obtained using polymerase chain reaction (PCR). The resulting genes are sequenced — a

process that determines the order in which the four components of DNA (adenine, cytosine, guanine, and thymine) are aligned — and compared to reference sequences from authentic botanical material, or to sequences in publicly available databases like GenBank.

The authors stress that the applicability of DNA barcoding has to be evaluated on a case-by-case basis and comment that “failure to appreciate the effects of extraction on botanical materials indicates the general lack of understanding by scientists performing DNA testing on finished products and the importance of the distinction between raw material and processed materials, especially extracts.”

There is a relationship between the level of processing of herbal dietary supplements and the length of the DNA fragments; the more processed the ingredients are, the more fragmented the original DNA becomes. As a result, DNA barcoding of highly processed botanical materials often results in findings indicating the absence of any DNA, or the presence of DNA from excipients or fillers.

The paper continues with a number of key aspects to be looked at when considering DNA-based methods for herbal ingredient identification. The identification of the appropriate genes to be amplified has to be carefully evaluated. Also important is the inclusion of control samples: appropriate positive and negative controls must be used for each of the steps in the testing process to avoid false positive or false negative results. Another key aspect is the use of authentic reference materials. Ideally, the resulting DNA sequences should be compared to sequences of authenticated fresh or dried whole plant material. Comparison with publicly available databases, particularly GenBank, carries the risk of identification errors due to potentially erroneous or missing entries in the databases. Finally, the choice of the right algorithm for the analysis of the DNA sequence is crucial. The most reliable results are obtained when specific algorithms are used that consider species-specific DNA features rather than those that are based on the similarity of the match with sequences from public databases. As with any other analytical method, an appropriate validation of the DNA barcoding method needs to be performed.

A few pages in the document are devoted to answering questions with regard to the analysis performed by James A. Schulte II, PhD, on the samples collected by the NY AG. Since the NY AG has not released any details on the testing method, most of the questions raised cannot be answered with certainty, but based on the little information that is available, the authors conclude that the results of the NY AG's investigations are invalid. It remains to be seen if the results obtained from chemical testing by independent analytical laboratories will confirm the authors' suspicions that the cease-and-desist letters were based on erroneous results.

While it is impossible to give a comprehensive overview on such a complex topic as genetic authentication of botanical ingredients in a short paper, the authors have been able to explain many of the caveats of using DNA barcoding in a way that is accessible to the reader, and they have given

ample evidence as to why DNA barcoding is generally not appropriate for highly processed botanical ingredients such as herbal extracts. When in doubt, researchers may prefer to rely on well-established, appropriate, and scientifically valid analytical methods, e.g., those provided in official pharmacopeias and other authoritative compendia and/or scientific journals.

NPA White Paper by Former FDA Regulators Stresses Importance of Validation by Chemical Analyses and Highlights Issues with the Detection of Processed Plant DNA

The Natural Products Association released a white paper on March 17, 2015, questioning DNA barcoding as a valid method to determine the identity of herbal dietary supplement ingredients.⁵

The document was written by Daniel Fabricant, PhD, CEO of NPA, and Corey Hilmas, MD, PhD, NPA's senior vice president of scientific and regulatory affairs. Dr. Fabricant is the former director of the FDA's Division of Dietary Supplement Programs and Dr. Hilmas served as chief of the FDA's Dietary Supplement Regulation Implementation Branch.

The NPA publication came less than a week after the publication of the previously described white paper commissioned by AHPA, CHPA, CRN, and UNPA.

Drs. Fabricant and Hilmas start with a brief summary of the investigation into herbal dietary supplements by the NY AG and a call for increased transparency and the release of more details on the testing used as a basis for the cease-and-desist letters sent to GNC, Target, Walgreens, and Walmart. This is followed by an executive summary listing a number of key limitations of the DNA barcoding technology: e.g., the lack of high-quality DNA in many botanical extracts, which may prevent the ingredients listed on the dietary supplement labels to be detected; the inability to quantify the amounts of the alleged contaminants; the possibility for cross-contamination; and the absence of a large library with DNA sequences from properly authenticated and vouchered plant material.

The white paper then goes into the details of DNA barcoding and the various steps involved along the process. The authors stress the importance of removing certain secondary plant metabolites ahead of the gene amplification, since these metabolites can interfere with the PCR used to amplify the DNA. One paragraph is devoted to the selection of the gene regions (loci) that are best suited to distinguish the various plant species from each other. The authors provide some historical background about the loci selection process, and they conclude that the combination of two loci suggested by the Consortium for the Barcode of Life (CBOL) discriminates only to species level at a probability of 72%. They also note that the species delimitation (i.e., the process by which boundaries among species are determined) for plants is not always very straightforward due to hybridization within many plant genera, which is not the case for the animal kingdom.

A particular concern with DNA barcoding methods is the use of publicly available DNA sequence databases, due in part to the lack of vouchered specimens linking the DNA sequence

In the opinion of the authors, chromatographic methods are the gold standard for the identification of botanicals — in particular the approach where chemical fingerprints are obtained by high-performance liquid chromatography combined with mass spectrometric detection (HPLC-MS) — and they suggest that DNA barcoding should never be used without a chemical fingerprint method for botanical ingredient authentication.

to the specimen. (Other shortcomings of public DNA databases not mentioned in the paper include the occurrence of errors in specimen records and missing sequences from loci that prevent the use of the two-loci system proposed by CBOL.) Based on the data released by the NY AG, the authors write that “all we can conclude at this point is that [Dr. Schulte] used publicly available DNA sequences that did not involve voucher specimen, leading to erroneous results.”

A short paragraph is dedicated to the impact of processing on the plant DNA, explaining that the process of extraction, as well as the solvents used in the process, impact the quality and amount of DNA that can be detected. Other processes that impact DNA quality are excessive heat treatments, or submission of the material to UV light, often leading to only small DNA fragments remaining. These fragments are shorter in length than what is required to generate a useful barcode. Finally, the authors question the expertise of Dr. Schulte and the accreditation of his laboratory.

The NPA white paper ends with a discussion of appropriate test methods for botanical dietary supplements. In the opinion of the authors, chromatographic methods are the gold standard for the identification of botanicals — in particular the approach where chemical fingerprints are obtained by high-performance liquid chromatography combined with mass spectrometric detection (HPLC-MS) — and they suggest that DNA barcoding should never be used without a chemical fingerprint method for botanical ingredient authentication.

The white paper raises the same questions about the applicability of DNA barcoding to herbal extracts as the white paper written by Harbaugh Reynaud et al., but there is some additional information in the NPA paper, e.g., the potential for interference of secondary metabolites with the PCR and the historical perspective on the development of DNA barcoding. Some of the details are quite technical, which may make it difficult to follow for readers who are unfamiliar with DNA-based

methods. In addition, there are a few statements that are either unclear or potentially confusing, e.g., “moreover, if the study actually was scientifically valid and fit for purpose, the science would appear to be inconsistent with the dietary supplement current Good Manufacturing Practices,” or “chromatographic methods are the gold standard as stand-alone methods for the identification of botanicals in diverse matrices such as finished dietary supplement products. These tests produce a chemical fingerprint, corresponding to masses, which are characteristic of the phytochemical profile for a particular species.”

Overall, the authors conclude that DNA barcoding is not an appropriate choice to determine the identity of herbal extracts in dietary supplements. Or, as they put it, “in the end, if the method is unable to detect DNA, all it can conclude is that it was unable to detect a DNA barcode for a particular botanical extract.” HG

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Critical Approaches to the History of Western Herbal Medicine: From Classical Antiquity to the Early Modern Period by Susan Francia and Anne Stobart, eds. New York, New York: Bloomsbury Publishing; 2014. Hardcover; 368 pages. ISBN: 978-1-4411-8418-4. \$120.00.

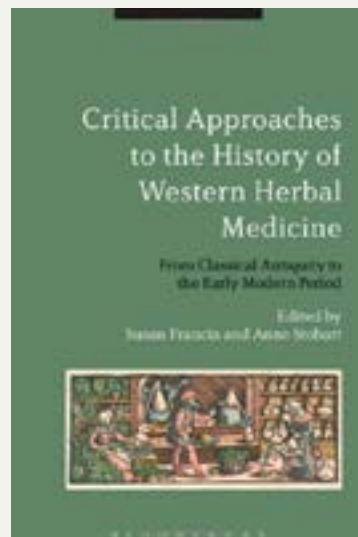
This book grew out of seminars on the history of herbal medicine held in London in 2010 and 2011. Both of its editors, Susan Francia and Anne Stobart, PhD, are qualified medical herbalists, as are six of the other 13 contributors; Dr. Stobart also is a founder-member of the recently established Herbal History Research Network, which has done much to promote interest in this field.

The 16 chapters cover a wide range of research topics, which are grouped into four main parts. The authors come from a variety of backgrounds, including: “social, medical and other historians, medical scientists, herbal practitioners, language experts, anthropologists, ethnobotanists, and even an archaeoethnopharmacologist,” as Elizabeth Williamson, PhD, distinguished professor of pharmacy at the University of Reading in England, points out in her foreword. Throughout, each chapter has its own section of reference notes; there is a useful glossary for names and terms that might be unfamiliar to readers, an impressive 33-page bibliography, and an index. Pleasingly, the publisher offers a generous eight pages at the back of the book for the reader’s own notes.

The book opens with an overview by its editors, titled “The Fragmentation of Herbal History: The Way Forward,” in which they express their wish “to support and stimulate those interested in pursuing further research studies.” They also indicate the giddy range of sources that may be mined for nuggets of information, among them “papers relating to estates and gardens, ... seed catalogues, ... merchant records, customs and import books, ... diaries, letters, ... domestic recipe collections, household accounts, probate records, ... prescriptions, individual case histories, printed medical advice books and pharmacopoeias, ... apothecary bills and notebooks and institutional, professional and legal records.”

Each of the four parts is prefaced with an introduction by the editors.

Part One, devoted to original texts, contains chapters on “Early Greek Medicine,” a discussion of the philosophy concerning the medicine of ancient Greek physicians, by medical herbalist Vicki Pitman, MPhil; the interpretation of medieval herbals, by Anne Van Arsdall, PhD; “Early-modern Midwifery Manuals and Herbal Practice” by Elaine Hobby, professor of seventeenth-century studies at Loughborough University in the United Kingdom; and an exploration of Culpeper’s *The English Physitian*, by medical herbalist Graeme Tobyn.



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Part Two concentrates on archival sources: Francia examines a variety of documentary sources to explore the importance of cumin (*Cuminum cyminum*, Apiaceae) in medieval England; Nicky Wesson assesses the evidence for the use of herbs in childbirth and perinatal care; and Richard Aspin, PhD, head of research at the Wellcome Library, searches for clues to the practice of herbal medicine in testamentary documents from the 16th to 18th centuries.

Part Three focuses on four household names from herbal history, with chapters on Galen, by John Wilkins, PhD, professor of Greek culture at the University of Exeter; Dioscorides, by two experienced British medical herbalists, Alison Denham and Midge Whitelegg, PhD; William Turner, by Marie Addyman; and John Parkinson, by Jill Francis, PhD.

Part Four addresses the multi-disciplinary nature of the history of herbal medicine, with a case study of St. John’s

wort (*Hypericum perforatum*, Hypericaceae) and valerian (*Valeriana officinalis*, Caprifoliaceae) at Soutra hospital, by Brian Moffat, PhD, director of the Soutra Hospital Archaeoethnopharmacological Research Project (SHARP); and a consideration of how ethnobotany can contribute to herbal history, with special references to the Aztec empire and Spanish colonial medicine, by Anna Waldstein, PhD.

In the conclusion, Francia and Dr. Stobart consider the proliferating avenues of research opened up by studies such as those presented in this book, and they discuss the ways such research could benefit both scholars and practitioners.

This is a broad investigation of sources for the history of herbal medicine. Some chapters significantly add to our knowledge of how medicinal herbs have been used in the past. Dr. Moffat’s chapter, “Archaeological Sources for the History of Herbal Medicine Practice,” is of exceptional interest: It tells the story of SHARP, which was established in the early ’80s to study clues to medieval medical practice found at the site of the Soutra medieval hospital. This site formed part of a once-impressive Augustinian monastery in southeast Scotland, and researchers have identified remains of 360 different plant species at the site, suggesting a well-stocked physic garden. The drains have yielded further treasures of information in the form of well-preserved caches of medicinal plant seeds, indicating that a combination of St. John’s wort and valerian was a common remedy, and that both herbs may have been used to treat depression as early as the 14th century.

The section dealing with four individual giants from the history of herbal medicine — Galen, Dioscorides, William Turner, and John Parkinson — will appeal particularly to those like me who view history in terms of people. It was perhaps unfortunate that the study of Parkinson was written by Francis, a specialist in the history of gardening; while she

considers Parkinson’s magisterial *Theatrum Botanicum* to be “the last in the genre of great herbals and as such ... the end of an era,” she devotes most of her attention to his book on gardening, *Paradisi in Sole Paradisus Terrestris*, which she finds new, exciting, and “revolutionary in its approach.”

Research is deeply addictive, but it can lure its practitioners into byways well away from the beaten track: Dr. Aspin’s “Testamentary Records of the Sixteenth to Eighteenth Centuries as a Source for the History of Herbal Medicine in England” is a neat example. He has examined “one potentially rich source” — wills and inventories of domestic goods. From an impressive display of vast research, one fact emerges: that stills and sets of pestle and mortar appear quite often, though the latter usually outnumbered the former. Does this prove that the family members in question were regular practitioners of herbal medicine? Not necessarily. As any kitchenware store will confirm, a pestle and mortar is a run-of-the-mill buy for any homemaker; distilling has been a fashionable occupation for ladies of the manor from the late-16th century onwards. Possession of this gadget doesn’t necessarily mean that it was used to make herbal remedies any more than ownership today of a state-of-the-art food processor proves that its owner is a dedicated cook.

In her chapter on cumin, Francia offers a delightful example of how rewarding research in the history of herbal

medicine can be: she has drawn on records of monastic and household accounts, rent payments, and port-tax documents, among others, to paint a vivid picture of the popularity and affordability of cumin in medieval England, as well as its uses both culinary and medicinal.

The two separate chapters devoted to midwifery illustrate the range as well as the limitations of research. In Elaine Hobby’s chapter on midwifery manuals, the reader can learn much about the spectrum and diversity of the manuals themselves, but not much about how or by whom they were actually put to use. Nicky Wesson, studying the use of herbs in childbirth in early modern times, found that although there was plenty of information about which herbs were recommended for use in childbirth, there was virtually no evidence as to which ones midwives actually employed. Her discussion of herbs used as analgesics and antimicrobials, however, is both surprising and intriguing.

All in all, this is perhaps not a book for the general reader, but it certainly will inform and delight researchers in this very broad field of study. HG

—Barbara Griggs, FLS

Author, *Green Pharmacy: The History and Evolution of Western Herbal Medicine*
Brighton, England

The New American Herbal by Stephen Orr. New York, New York: Clarkson Potter Publishers; 2014. Softcover; 384 pages. ISBN: 978-0-4498-1993-7. \$27.50.

The New American Herbal is an exceptionally misleading title for what really should have been called *Another Herb Garden Book* or *Herb Gardening Lite*. It seems that publishers, editors, and book designers all have taken the same online short course called “how to make all herb gardening books look identical.” The book has hundreds of color photographs of varying quality, with the obligatory cursory introduction to herbs, plus an “A-Z” section covering about 125 plants. It would have been a nice little food-and-gardening title if the book stuck to gardening, food, plus parsley, sage, rosemary, and thyme, but it ventures into other herbal realms where the author’s obvious lack of expertise invites a raised eyebrow. Still, for those new to the subject, *The New American Herbal* offers an enticing invitation to delve deeper into the limitless herbal universe.

The book begins with the predictable chapters on flavor, harvesting, propagating, and drying techniques, along



with a rudimentary discussion of extraction, essential oils, and do-it-yourself projects for herbal vinegars and oils, and even how to make herbal tea. There is a nice two-page spread that includes five recipes for making dried spice blends that are increasingly available (if you live in major metropolitan areas such as New York or Los Angeles). Another two-page spread is devoted to salad herbs, which sparks new culinary possibilities.

Additional short chapters cover “specialty herbs” such as native American herbs, Chinese medicinal herbs, trees and shrubs used as herbs, “herbs from older traditions” (whatever that means), “controversial herbs” (poisonous and psychoactive plants), and

“tropical herbs.” Nearly 200 herbs are included in the “specialty herbs” section, most of which receive a very brief treatment. For example, in “herbs from older traditions,” plantain (*Plantago major*, Plantaginaceae) is covered thus:

“**Plantain, common** (*Plantago major*)—an effective treatment for bleeding.”

The number of herbs treated in the “specialty herbs” section provides marketing folks an opportunity to tout

the book as containing “information on hundreds of herbs.” Dozens of photographs accompany the mostly one-line entries, which, if you are brand new to the subject, furnish a glimpse of uses past and present. Here it becomes glaringly evident that the book attempts to be too many things to too many people.

At the heart of the book is the treatment of 125 plants in the “A-Z” section. *The New American Herbal* reflects North America as a melting pot of cultures and cuisines as only six of the 125 plants (or generic groups) covered are indigenous American plants. Most of the herbs in these expanded entries are treated in two-page spreads unless a recipe is included, in which case the information can stretch to four pages, usually including two full-page photos. The book’s 45 recipes are original and worth the price of the book.

Those knowledgeable in medicinal herb topics will get a strong sense that the author strays far beyond his area of expertise with statements such as “Ginseng’s [*Panax* spp., Araliaceae] intricate chemical cocktail of triterpenoid saponins, which are thought to enhance its adaptogenic properties, is combined with ginsenosides, a complex class of steroidal glycosides that are being studied as active components of ginseng....” In reality, ginsenosides

are triterpene glycosides generally classified as saponins. We also learn that black cohosh “has estrogen-containing hormonal compounds.” Really? Further, the statement “Black cohosh is frequently used with another unrelated American herb called blue cohosh” may apply to use of the herbs’ names in the same sentence, but not to the use of the herbs by those seeking their respective health benefits.

Like the photographs, the information in this text is presented in broad impressionistic brush-strokes that lack clarity. The author has an obvious passion for herbs and sharing information on the diversity of human interaction and use of herbs in a modern context. If you do not own any other herb books and have no knowledge of the subject matter, this herb book was meant for you. For those new to the vast herbal field, the book will fulfill the author’s hope that it “...will inspire you to travel further down whatever herbal path you find most enticing....” HG

—Steven Foster
Author, Photographer, Herbalist
Eureka Springs, Arkansas

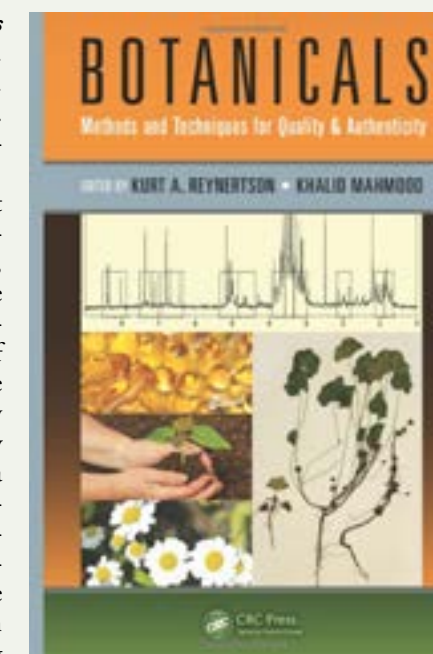
Botanicals: Methods and Techniques for Quality & Authenticity by Kurt A. Reynertson and Khalid Mahmood, eds. Boca Raton, Florida: CRC Press. 2015. Hardcover; 332 pages. ISBN: 978-1-4665-9841-6. \$139.95.

The editors of this book — Kurt Reynertson, associate manager of product stewardship at Johnson & Johnson, and Khalid Mahmood, manager of the naturals platform at Johnson & Johnson — set out to provide an overview of methods that can be used to determine the identity and quality of botanical raw materials and finished products. They purposefully have chosen to include a wide variety of methods, including classical methods such as taxonomic identification, organoleptic evaluation, or thin-layer chromatography, as well as more recent analytical tools for ingredients in herbal dietary supplements, including DNA-based methods or nuclear magnetic resonance (NMR).

After a brief chapter on the importance of ingredient authenticity and quality for botanical research and development by the two editors, the book continues with a discussion of one of the most crucial aspects of the analysis, which is the proper selection of botanical ingredient specifications. The authors of this chapter, Paula Brown, PhD, Michael Chan, PhD, and Joseph Betz, PhD, provide a number of examples in which method specifications were inadequate, with focus on instances when methods were not specific enough to distinguish between authentic and adulterated material. Another emphasized point is the relationship between the relative standard deviation and the concentration of the analyte in the sample. The consideration of this relationship is important for the verification of accuracy (for higher analyte concentrations, the permissible deviation from the actual value has to be smaller) and precision (higher analyte concentrations should result in lower relative standard deviation values).

The chapters that follow describe organoleptic analysis, botanical taxonomy, DNA-based methods, high-performance liquid chromatography (HPLC)-fingerprinting methods, multivariate statistics, analysis using stable isotopes, NMR, Fourier transform-near infrared (FT-NIR) spectroscopy, high-performance thin-layer chromatography (HPTLC), and sensory fingerprinting using an electronic nose. Chapter 17 addresses the influence of growing conditions and different processing methods on the constituent profiles of botanical ingredients. The last chapter details some of the particularities of botanical ingredients used in cosmetic formulations.

There are a few chapters in this book that I consider particularly helpful for people involved in quality control of



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botanical ingredients. The introduction to genetic methods by Danica Harbaugh Reynaud, PhD, provides a good overview of the strengths and limitations of DNA-based authentication of botanical ingredients. Tables 5.2 and 5.3 summarize plant species that the author found adulterated by closely related or very distant species. Examples of unexpected adulteration include the substitution of picrorhiza (*Picrorhiza kurrooa*, Plantaginaceae) root with banana (*Musa acuminata*, Musaceae) root, or the substitution of cramp bark (*Viburnum opulus*, Adoxaceae) with the bark of Tatar maple (*Acer tataricum*, Sapindaceae). The differences among the various DNA techniques described in this chapter may be rather difficult to understand for readers without any experience in the topic, but overall, this chapter is a helpful introduction to DNA methods, the limitations of which (e.g., the author states that DNA methods are inappropriate

to authenticate dried herbal extracts) are of particular relevance in light of the recent actions by the New York Attorney General in testing herbal dietary supplements, many of which were dried herbal extracts.

In Chapter 7, James Harnly, PhD, Joe Jablonski, PhD, and Jeff Moore, PhD, review statistical tools for the identification of botanical ingredients. The chapter is accessible to those who may not have much experience with statistics, and it explains the most commonly used chemometric methods. The difference between supervised models (where samples are identified prior to classification, and the statistical model determines if the unknown sample falls within the acceptable range established using authenticated materials) and unsupervised models (where samples are compared without any knowledge of the identity) is presented, and the most commonly used methods to build a statistical model are explained. The fact that the authors used dairy (milk) rather than a botanical dietary ingredient to illustrate the various statistical approaches does not detract from the usefulness of the chapter. Because the use of statistical models for the identification of botanicals increasingly is regarded as the standard in the industry, this chapter is a great read for anyone interested in becoming more familiar with advanced statistical tools.

A rather unusual analytical approach for botanicals is described in Chapters 9 and 10, where the authors discuss the usefulness of radioactive or stable isotope analysis for dietary supplements. One example is the use of radioactive ¹⁴C in assessing if an ingredient is of natural origin.



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Since equilibrium exists between the ^{14}C production in the atmosphere and its decay, any living plant will incorporate a very small amount of $^{14}\text{CO}_2$ through photosynthesis. This is in contrast with fossil fuel-derived products that are lacking any ^{14}C activity. The difference in ^{14}C activity can be used to determine if a component (e.g., vanillin) originated from a plant source, or if it was manufactured starting with petroleum-based material. The ratio of the stable hydrogen ($^2\text{H}/^1\text{H}$) and oxygen ($^{18}\text{O}/^{16}\text{O}$) isotopes can be used to determine the geographical origin of plant material based on the fact that these isotope ratios are affected by the climate and therefore their abundance varies across the globe.

Of the three chapters on NMR for botanical ingredient analysis, the chapter by Kimberly Colson, PhD, Jimmy Yuk, PhD, and Christian Fischer, PhD, is the most effective in providing an overview of the technique's potential. NMR is shown to be a very powerful method for ingredient identification, but the authors also note the other possibilities that quantitative NMR has to offer. The example given in the book is the quantification of organic acids and saccharides in *Aloe vera* (Xanthorrhoeaceae). For qualitative analysis, the development of a spectral database is crucial. And while a routine quality control sample may be run by a technician, the database establishment can be performed only by an experienced NMR analyst, since the experiments and the experimental parameters must be carefully selected. The authors have devoted a subchapter to the key points for the development of a spectral database, but a company interested in the technology will most likely depend on the instrument vendor to set this up.

Of much interest to quality control personnel in the dietary supplement industry is Chapter 14, which concerns the practical use of FT-NIR for identification of botanicals. Written by Cynthia Kradjel, the chapter starts with an overview of FT-NIR, emphasizing the importance of the development of a database using authenticated botanical material

and the need for adequate statistics. It is one of the few chapters that contains information on the regulatory requirements and specifics on method validation.

Some chapters may have more limited appeal. The application of the complete reduction to amplitude frequency table (CRAFT) for data mining of NMR spectra may be helpful for very specific experiments, but I wonder how much interest readers will have in this particular method. The last chapter on aspects of quality issues with botanicals used in the cosmetics industry is focused heavily on agricultural aspects of botanicals, while some of the important challenges unique to cosmetic ingredients (e.g., the demand for colorless or odorless botanical ingredients, or the solubility and stability issues that result from the large amounts of water in the matrices of cosmetic products) are not discussed.

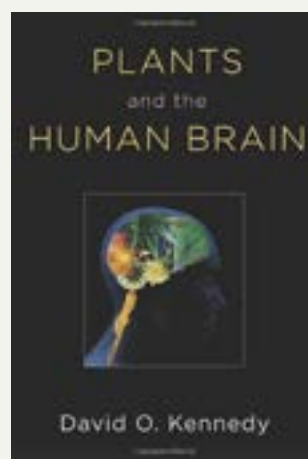
Overall, the book covers a mixture of methods that are in use and those that show promise to become more widely used for the analysis of botanical ingredients. It is not only an interesting read for analytical geeks like me, or for those who want to learn more about quality control of botanicals, but also a helpful resource for those thinking about expanding their analytical capabilities for botanical ingredient analysis in a contract analytical laboratory or the dietary supplement industry. As the authors state in the preface, "gaps remain, which future editions may rectify." In this regard, the editors may consider including an overview of HPLC and gas chromatography (GC), two of the most widely used techniques in botanical analysis, in the next edition. HG

—Stefan Gafner, PhD

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Plants and the Human Brain by David O. Kennedy. Oxford, UK: Oxford University Press; 2014. Hardcover; 400 pages. ISBN: 978-0199914012. \$59.95.

David O. Kennedy, PhD, professor of biological psychology at Northumbria University and director of the Brain, Performance and Nutrition Research Centre has produced a landmark contribution to psychopharmacology and human health. In this sophisticated text, he presents an impressive multi-disciplinary treatise in which he systematically and convincingly expounds on the premise that the co-evolutionary battle between plants and their insect predators, and human neurophysiological similarity to the latter, are the underlying reasons that phytochemicals have provided the prepon-



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derance of our psychotropic drugs throughout the ages.

Dispensing with foreword and introduction, the book begins Part I — "Why Do Plant Secondary Metabolites Affect Human Brain Function?" — with a chapter titled "From Shamans to Starbucks," which provides a whirlwind history of psychopharmacology and the role of plant drugs in religion, divination, recreation, and medicine. The remainder of this part systematically explains the role of plant secondary metabolites as attractants to pollinators, or defense compounds against grazing bugs and animals, and the evolutionary biochemical similarity of insect and human brains. In each instance, the text is accompanied by relevant biochemical structures and diagrams as well as extensive, up-to-date references, totaling 1,434 in all.

The presentation is scholarly, and the author examines each concept from molecular to molar levels to support each concept.

As an author who has trod similar phytopharmacological territory in the past¹, I expected the book to examine the usual alkaloidal and herbal suspects such as morphine, cocaine, the entheogens (dimethyltryptamine, mescaline, psilocybin), and St. John's wort (*Hypericum perforatum*, Hypericaceae), ginkgo (*Ginkgo biloba*, Ginkgoaceae), kava (*Piper methysticum*, Piperaceae), valerian (*Valeriana officinalis*, Caprifoliaceae), ginseng (*Panax* spp., Araliaceae), et al., which it does quite admirably. However, I was delighted to note that Kennedy has chosen to go far beyond the usual constricted pale in incorporating book sections on phenolics and terpenes. These ubiquitous plant chemicals have heretofore received short shrift in scientific investigation, and certainly in the dietary advice we receive, but are deserving of much greater emphasis. Thus, the reader learns that these agents that provide much of the color, odor, and taste of our plant foods also yield essential antioxidants that may protect us from development of cancer, slow aging, and allay dementia. These agents also subtly or otherwise alter our brain chemistry, providing possible solutions to issues of anxiety, depression, and other prickly problems of modern life.

Evolutionarily, this makes perfect sense, as our hunter-gatherer forebears were habitual opportunists who availed themselves of whatever fruit, berry, or nut was available on the trail. Such dietary diversity may be lacking contemporaneously. Our current preoccupation with exotic cuisines may also betray evolutionary longing, not simply for tastes to cover spoiled food, but for rather trace dietary elements that tweak our neurochemistry and correct nutritional imbalances. After learning the underlying reasons to diversify our intake of plant-based nutrients, the reader may well be motivated to seek out outstanding chemovars in the store or grow them personally. Jo Robinson's recent book would be a worthy companion in this regard.²

In the course of the narrative, Kennedy expounds on some fascinating concepts. While readers may be familiar with the theory of hormesis — that exposure to a low-level stressor may steel an organism against a more serious future threat — perhaps fewer will be aware that ingesting products of stressed plants may be beneficial to humans because of *xenohormesis*, the theory that, for example, the antioxidant protection that flavonoids offer plants may extend to the humans that ingest them. A salient example would be the ability of polyphenols to interact with mammalian sirtuin genes that regulate cellular aging processes. This is an active area of research that offers promise that we may not only live longer, but lead more healthy lives along the way.

Other fun facts include that the jasmonates in plants, which modulate production of secondary metabolites, are analogous to prostaglandins in animals, that morphine and dimethyltryptamine are trace endogenous compounds in mammals; that ginseng's allelopathy to prevent germination

of neighboring plants derives from the same compounds that serve as human adaptogens; and the observation that a fortuitous evolutionary mutation (SNP, single nucleotide polymorphism) in GABA receptor pore structures distinguishes humans from insects such that the ginkgolides and bilobalides that are overtly toxic to them have a 10,000-fold safety margin for us, allowing free use for their benefits of cognitive enhancement and as bulwarks against dementia.

Finding deficiencies in this book is a fool's errand. I noted a dearth of typos, only an incomplete reference and a couple of factual quibbles. It is extensively and rationally referenced, well-indexed, and impeccably presented. More than an impressive collection of facts, the author has succeeded brilliantly in integrating the evidence on the foundation of a clear premise and building each successive layer of evidence to support it with compelling facts and reasoned synergistic examples. Much of science today is effective in dissecting mechanisms and explaining how things work, but it is rarely so brilliant in its exposition or demonstrating why things are as they are. Students, teachers, and researchers of herbal medicine, biochemistry and phytochemistry, nutrition, psychopharmacology, ecology, and entomology should all avail themselves of the opportunity and pleasure to read this beautifully written book. HG

—Ethan Russo, MD

Medical Director, PHYTECS
Vashon, Washington

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Natural Products Chemistry: Sources, Separations, and Structures by Raymond Cooper and George Nicola. Boca Raton, Florida: CRC Press; 2014. Softcover; 206 pages. ISBN: 978-1-4665-6761-0. \$99.95.

The discipline of pharmacognosy — “the study of the physical, chemical, biochemical, and biological properties of drugs, drug substances, or potential drugs or drug substances of natural origin, as well as the search for new drugs from natural sources,” as defined in the introduction of *Natural Products Chemistry* — encompasses a multitude of approaches, specialties, skills and techniques, and even the knowledge of various organisms including plants, bacteria, and marine life. To capture the broad view of this scientific field is challenging, but authors Raymond Cooper, PhD, and George Nicola, PhD, have succeeded in this endeavor with their introductory text.

Starting out with a foreword by distinguished pharmacognosist Koji Nakanishi, PhD, this book is organized into sections, beginning with a chapter on the variety of natural products sources, followed by chapters covering extraction and separation techniques, compound structure elucidation, biosynthesis pathways, and main compound classes. Subsequent sections discuss natural products in health, and Section IV, “Nature’s Pleasures and Dangers,” examines sweeteners and toxins, among other interesting natural products. The scope of this book is quite broad, and individual subjects and examples are discussed briefly with the aim of introducing the reader to as many aspects of pharmacognosy as possible.

Offset text boxes titled “Historical Note” include anecdotes and maintain the reader’s interest with fascinating accounts. For example, Chapter 10 mentions that sweet wormwood (*Artemisia annua*, Asteraceae) has been used in traditional Chinese medicine for the treatment of malaria; however, it was not until a mid-century screening program by the Chinese army that the antimalarial compound artemisinin was discovered. Chapter 9 discusses how the antibiotic penicillin, isolated from the fungi *Penicillium notatum* (Trichocomaceae) and *P. chrysogenum*, was used to save soldiers’ lives from infection during World War II. The authors state that the usage of penicillin at that time, prior to the full characterization of its “structure” and “purity,” would not have been approved by the modern-day United States Food and Drug Administration. Detailing real-world applications and historical accounts of diverse natural products is a great strategy for illustrating pharmacognosy’s importance to human health and history.

Color photos from photographer Steven Foster provide bright visual accompaniments to the corresponding botanical chemistry descriptions, and the text contains myriad structure



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illustrations of the compounds discussed. Questions at the end of each chapter provide useful summaries and are written to prompt the reader to think beyond the written contents. This approach offers great discussion points for use in classroom instruction.

Overall organization of the material is logical, but some chapters might have been better placed. For example, Chapter 11 (“Carotenoids”) and Chapter 12 (“Vitamins”) may have been more appropriate in Section II (“Selected Classes of Natural Products”) than in Section III (“Natural Product Contributions to Human Health”). Notably absent from Section II is a chapter on terpenes. Although there is a dedicated chapter on these compounds in Section III, their broad bioactivity and presence across plant families warrants more attention in an introductory text.

The book suffers from a few other minor limitations. Oddly, Latin binomials and standard common names are used inconsistently, and some appear without the other. Also, content concerning biochemical pathways of mammalian mechanisms of action would have been useful or easily made more detailed, especially in Section III. For example, in Chapter 5 (“Sugar and Fat and All of That”), “NO,” an abbreviation for nitric oxide, should have been spelled out prior to the abbreviation, and the contribution of certain fatty acids to its synthesis is unclear as written. An additional sentence here would have been welcome. Expanding further on mammalian bioactivity would have increased this text’s applicability and interest to medical students and health professionals. Additionally, some of the compound structures did not reproduce well and seem out of proportion or of insufficient resolution.

Despite these small shortcomings, *Natural Products Chemistry* is a great basic overview of pharmacognosy that will be useful for undergraduate classes or introductory graduate work in this field. The text is written in a straightforward and accessible manner, aptly lending itself to use both in classes and in labs. In this regard, the book accomplishes its goals of introducing the varied field of pharmacognosy and establishing the discipline as vibrant, diverse, and constantly applicable and necessary to human society. I certainly would recommend its use in universities, medical schools, and pharmacy programs. HG

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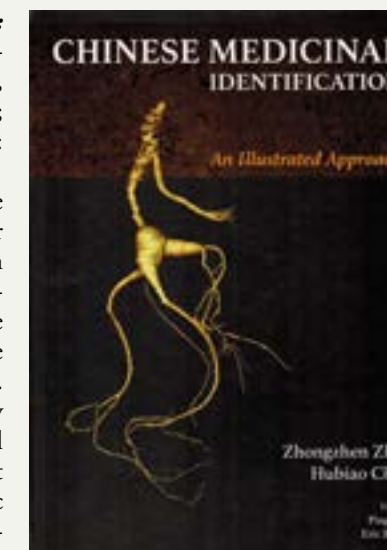
Chinese Medicinal Identification: An Illustrated Approach by Zhongzhen Zhao and Hubiao Chen. Taos, New Mexico: Paradigm Publications; 2014. Hardcover; 560 pages. ISBN: 978-0912111995. \$129.00.

Chinese Medicinal Identification is the latest of several texts by the lead author Zhongzhen Zhao, PhD, associate dean of Chinese medicine at Baptist University in Hong Kong. Professor Zhao is one of the world’s leading authorities on the authentication of Chinese herbal drugs. His co-authors and editors are equally renowned authorities on traditional Chinese medicine. The focus of this text is on the macroscopic and morphologic characteristics of crude Chinese medicinal plants. Texts such as these are extremely valuable for establishing the basis for identifying crude botanical ingredients in a scientifically valid manner, an important aspect of dietary supplement good manufacturing practices (GMPs).

The text begins with a colorful history of the application of macroscopic examination in Chinese literature starting with the concept of *Bian Zhuang Lun Zi*, defined as “differentiating appearance to determine quality.” *Bian Zhuang Lun Zi* is described as “an essential foundation for practitioners dedicated to authentication and herbal pharmacy.” While primarily applied by traditional Chinese herbalists with dispensing pharmacies in much the same manner as today’s herbalists, Chinese medical practitioners, and naturopathic physicians, macroscopic evaluation remains a critical evaluation tool for dietary supplement and botanical medicine manufacturers that is far underutilized and overshadowed by chemical (e.g., high-performance liquid chromatography [HPLC]) or molecular techniques (DNA).

The introductory historical chapter is followed by a review of the basic principles of macroscopic evaluation, which includes the evaluation of physical and organoleptic characteristics (appearance, color, taste, smell) as well as novel testing techniques such as evaluating botanical ingredients using water (e.g., floating cloves [*Syzygium aromaticum*, Myrtaceae] in water as a test of quality) and fire, techniques not readily found in early Western pharmacognosy texts. A key benefit of macroscopic examination underscored by the authors is its simplicity and the rapidity by which both identity and quality can be assessed inexpensively and in an environmentally sound manner that does not require the chemical solvents typical of chemical analytical methods.

The next 10 chapters provide detailed and clearly articulated, albeit brief, macroscopic descriptions of more than 400 medicinal ingredients used in traditional Chinese medicine, including roots and rhizomes, stems and woods, tree and root barks, leaves, flowers, fruits and seeds, whole herbs, seaweed, fungi and resins, zoological substances,



and minerals. Consistent with early works of pharmacognosy, each entry provides the origin of the drug plant, where it is produced, how it is cleaned and processed, its primary properties and functions, and specifics regarding quality assessment. The text is accompanied by more than 1,000 high-quality color photographs of materials — which include approximately 350 botanical ingredients — showing the intact whole botanical as well as the typical forms (i.e., slices) used for decocting. Each photograph is annotated with some of the key identifying features of the plant material, which can be used either as a model or a reference standard for manufacturers to develop their own identification standards. Of particular importance are the

differentiating characteristics of closely related or adulterating species.

It is difficult to find fault with a work of this depth and quality. If there were any, it would be two-fold. First, the text and interested readers may have benefited from a more detailed discussion regarding macroscopic and organoleptic evaluation. The subject is very broad and rich, and it is worthy of further development. Secondly, the photographs reflect a relatively small sampling of the most common forms of the ingredients available on the Asian market; however, many other forms that do not conform to the authors’ descriptions exist in the broad international market and differ from Chinese herb materials cultivated in North America.

The authors and editors are among the most-noted authorities on the authentication of Chinese medicinal plants, and this work reflects a tremendous amount of historical and modern classical botanical pharmacognosy knowledge in this particular aspect of medicinal plant evaluation. *Chinese Medicinal Identification* is an incredibly valuable contribution to the herbal literature and is specifically useful for those involved in the use of Chinese medicinal plants in botanical dietary supplements and Chinese medicine. It is also of value to small manufacturers and traditional practitioners with dispensaries that, due to GMP requirements, need authoritative references that provide ways for identifying medicinal plant materials in a scientifically valid manner, and without the need for the often-toxic chemical solvents required in the performance of other forms of analysis. Works such as this text help us preserve the traditional aspect of the larger world of traditional herbal medicine. HG

—Roy Upton, RH, DAc
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Daniel Frank Austin 1943-2015

Economic botanist and taxonomist Dan Austin, PhD, died January 20, 2015, the day after suffering a major stroke.

Dr. Austin, long-serving book review editor for *Economic Botany*, is a name well known to many botanists and to most members of the Society for Economic Botany (SEB), where he served on its council from 1993 to 1996.

Dan hosted SEB's 44th Annual Meeting at the Arizona-Sonora Desert Museum in Tucson, where he had relocated after "retiring" in 2001. He remained active after leaving academia, publishing 11 papers in *Economic Botany* in addition to his book review duties. Dan also published in the



Journal of Ethnopharmacology; *Ethnobotany Research and Applications*; and, frequently, "The People and Plant Interactions Series" of *The Palmetto*, the journal of the Florida Native Plant Society.

As an undergraduate at Murray State College (now Murray State University) he earned a bachelor's degree in biology in 1966. His interests shifted from wildlife biology to botany after attending a seminar by Walter Lewis, PhD, a biology professor at Washington University and an esteemed botanist and ethnobotanist (as well as 1990

SEB president and 2006 SEB Distinguished Economic Botanist). Dan, who had developed an interest in the Lamiaceae family, spoke with Professor Lewis. An invitation to pursue his doctoral studies with Prof. Lewis ensued, and Dan joined his labs at Washington University and the Missouri Botanical Garden in St. Louis. At Prof. Lewis' suggestion, Dan switched his focus to Convolvulaceae, and it remained his primary research interest throughout his career.

After completing his doctoral work in 1970, Dr. Austin and his wife Sandra moved to Boca Raton, Florida, to accept an assistant professor position at the newly formed Florida Atlantic University (FAU). FAU's being on the edge of the tropics was ideal for Dan, with tropical plants growing in his backyard. He revitalized FAU's incipient herbarium, which eventually grew to 30,000 specimens, before its demise after he retired (the Florida Tropical Garden subsequently acquired the specimens with the exception of plants from Convolvulaceae, which went to Arizona).

In addition to building the plant collection, Dan also built a graduate program and developed popular undergraduate courses, including Ecology of Southern Florida and Plant Taxonomy. He directed 22 master's thesis projects on a variety of topics. Eight of his students earned doctoral degrees at other institutions.

Dan retired in 2001 and moved to Tucson to begin a new phase of his career. His Arizona productivity was not

a post-retirement surge but a reflection of his consistent and prolific scholarship.

Dan has left a remarkable 308 publications, in addition to book reviews (126) and technical reports. The publications include 158 journal articles in 58 journals. More than one-third of his articles appeared in three journals: *Economic Botany* (22), *Florida Scientist* (18), and *Taxon* (16). That distribution reflects his three primary research foci: Convolvulaceae (especially *Ipomoea*) systematics, the vegetation and flora of southern Florida, and economic botany. His interest in morning glory taxonomy naturally led to the other two emphases. Dan once told me that Convolvulaceae was the perfect family to study; it was largely tropical, and its taxonomy had not been confounded by hobbyists and horticulturalists, as had been done in Cactaceae and Orchidaceae. Moreover, the family contained one very important economic species — *Ipomoea batatas*, the sweet potato. The latter species justified research on the family from the perspective of funding agencies. Twenty-six of his more than 150 publications on Convolvulaceae dealt with *I. batatas* or related species, as did four of his six papers, which have been cited more than 25 times. His taxonomic work established the foundation for understanding the domestication of sweet potato.

Dan's second academic interest was the vegetation and flora of southern Florida. He wrote 114 journal articles, popular articles, and other contributions on this topic. Thirty-seven of these concerned exotic and invasive species, a major threat to the state's natural ecosystems. He was among the first to publicize the impact of alien flora, and this area of research produced his second most-cited paper. Most of Dan's Florida publications (87) focused on native plants, including rare and endangered species. He wrote 27 articles for *The Palmetto*, the primary publication of the Florida Native Plant Society, with more than half regarding species with human uses.

His magnum opus was *Florida Ethnobotany* (CRC Press, 2004) — a 900-plus page book that detailed 500 Florida plant species and their uses from published data that he had compiled. The tome includes more than the typical descriptions of plant use; it is as much a linguistic treatment as an ethnobotanical resource. Not surprisingly, Dan paid special attention to taxonomy and describes the derivation of generic names and specific epithets, as well as relevant taxonomic history, for each species. He also included an extensive list of common names and their meanings from throughout each plant's range. *Florida Ethnobotany* won the 2005 Mary W. Klinger Book Award from the SEB.

Another Austin contribution was the underused neologism "ethnoflora." More inclusive than the botanical pharmacopeia, the ethnoflora represents the subset of a flora that is used by humans. Unlike its definition in the online Merriam-Webster Dictionary, Dan would not have limited the scope of the flora to "aboriginal" use.

Like his 22 *Economic Botany* publications, Dan's interest in plant-people interactions spanned his entire career and resulted in journal articles, encyclopedia summaries, popular articles, and books — 95 in total. His 2010 *Baboquivari Mountain Plants: Identification, Ecology, and Ethnobotany* (University of Arizona Press) earned a second Klinger Award in 2011, making him the only author to be twice honored.

Many laud Dr. Austin's efforts as book review editor for *Economic Botany* beginning in 1993. The book review editor's

work can be onerous. He edited well over 1,300 reviews and wrote 126, impishly reserving the books close to his interests for his own appraisal. Twenty-one years of access to the most important texts on the subject granted him a grasp of the ethnobotanical literature that few others have had. Most would agree that he set the standard for the quality and expediency of book reviews.

The final phase of the Austin career could be called the desert years. A sabbatical in Arizona initiated a deep fascination in desert plants. His relocation to Arizona in 2001 inspired him to launch new studies and begin publishing on Arizona flora, a new area of research that culminated a decade later with a floristic treatment of Convolvulaceae for a region of southwestern Arizona.

Dr. Daniel F. Austin made significant contributions to botanical science in several fields. Besides his floristic, Florida, and econobotany papers, he established 28 infrageneric names and 48 new species or new species combinations in Convolvulaceae. He was honored several times by the Florida Native Plant Society and was elected a Fellow of the Linnean Society of London. Two Convolvulaceae species were named for him, *Merremia austinii* and *Hildebrandtia austinii*, as well as a new genus of Convolvulaceae — *Daustinia*.

Academic achievements and awards alone do not adequately convey Austin's impact on botany. Dan introduced hundreds of undergraduates to the marvels of Florida plants, collaborated with botanical colleagues around the world, and served as the major advisor for more than 20 students.

I met Dan in 1978, at the suggestion of Iain Prance (1996 SEB president and 2002 Distinguished Economic Botanist), and a year later began graduate studies with him at FAU. I learned too late that the easiest way to pass an Austin taxonomy exam was not through study. One merely drove by the Austins' home to learn what was flowering. The landscaping eventually assumed the form of a tropical jungle, through little effort or intent by Dan. He simply let nature take its course. Whatever seed landed in his yard was allowed the chance to germinate and establish.

During my tenure at FAU, Dan and I and other graduate students spent many delightful days slogging through the swamps of the Fakahatchee, trying to avoid the ubiquitous alligators and water moccasins and the much more dangerous human poachers. Those days were the most enjoyable part of my career. HG

—Bradley C. Bennett, PhD
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Acknowledgments

The author thanks Sandy Austin, Jim Burch, Julie Jones, Dan Moerman, John Rashford, Jim Snyder, George Staples, Bryan Steinberg, Bruce Tatje, and Bob Voeks for their contributions or for sharing their memories of Dr. Austin, especially George Staples for his discussion and careful review of a draft of the manuscript. This HerbalGram tribute is edited and condensed from a lengthier article by Dr. Bennett for *Economic Botany* (Volume 69, Issue 1).

Walter Lewis Remembers Dan Austin: A Professor's Tribute to His Student

The loss of such a fine person and esteemed plant systematist and ethnobotanist on January 20, 2015, was a great shock for all those who knew Daniel F. Austin. Thanks to Ken Robertson in nearby Illinois, who sent the news to the Missouri Botanical Garden (MoBot) where I happened to be; I received it while working on *Rosa* in the Lehman Herbarium. I was completely stunned. I remained seated for some time looking outside, just some yards away from the building where Dan conducted much of his thesis research on Convolvulaceae for his PhD program. Both he and Ken were among my first doctoral students, and those pleasant times very many years ago vibrated throughout my body.

I mention this because both Dan and Ken were exceptional students at Washington University in St. Louis, and Dan in particular wanted to study and collect morning glories (*Ipomoea* spp., Convolvulaceae) in Brazil and other areas of South America. The University provided the funds for their botanical field research, and although Ken's thesis would be in the Rosaceae, I had hoped that they both would leave St. Louis and so learn and experience new floras together. I understood that their collecting of Convolvulaceae specimens in Brazil was successfully accomplished by traveling by motorcycle, and they brought back fine material for Dan's thesis and the MoBot herbarium. (To note, both Dan and Ken received their PhDs in botany with high honors.) All those grand old memories were too much for me, and I dropped everything and went home before noon to quietly contemplate his unexpected passing.

After completing his degree, Dan left St. Louis for a faculty position at Florida Atlantic University and to work as a research associate with the Fairland Tropical Garden in Coral

Gables. There he continued his research in the Convolvulaceae, reinforced by collections made in Africa and Asia, and discovered a new interest in American *Ipomoea* and the uses of morning glories for health. The latter triggered his joining the Society of Economic Botany where many of his numerous and valuable research papers would be published in the journal *Economic Botany*. Dan was a prolific and careful writer and investigator, and, eventually, he took over my time-consuming responsibilities as book review editor for the journal. Sometime after this, as an emeritus professor, Dan left Florida for the West where he, his wife Sandra, and her mother settled near Tucson. He then assumed affiliations in Tucson with the Arizona-Sonora Desert Museum, the University of Arizona's Department of Plant Sciences, and the Drylands Institute.

During his time in Arizona he hosted an annual meeting of the Society of Economic Botany at the Desert Museum; many of us from the East found new beauty in the uniqueness of the desert vegetation while having a good time and reflecting with Dan. He was a grand and gracious host, and he taught us well about the desert in just a short time. The Arizona meeting was the last time I would be with Dan, although monthly I would read his reviews regarding new publications in *Economic Botany* with interest and pleasure. My sincere and deeply felt sympathy goes out to Sandra for her loss of a great man and botanist.

—Walter H. Lewis, PhD
Professor Emeritus
Washington University in St. Louis
Senior Botanist, Missouri Botanical Garden

Photo ©2015 Tiffany Talbott/Smithtea.com



Steven Dean Smith 1949-2015

There are people who can see possibilities and potential in the places many of us miss. Their vision opens our eyes and, in this case, awakens our palates to something that we now can't imagine doing without. Steven Smith, a tea (*Camellia sinensis*, Theaceae) entrepreneur and visionary who was once described as "Merlin meets Marco Polo" by Tazo® brand strategist Steve Sandstrom, was one of these people.

On March 23, Smith died at age 65 at his home in Lake Oswego, Oregon, due to complications from liver cancer.

"Steve Smith was some kind of genius when it came to tea and also to business," said tea educator and writer James Norwood Pratt, who knew Smith since 1980. "He was one of the most gifted creators of tea blends and tea businesses in our or any other time. He is among those principally responsible for our present tea renaissance. His wry smile and sense of humor never left him and never failed to lift up his friends' hearts. We felt honored by his friendship and his presence will continue to be a blessing to us."

Steven Dean Smith was born on May 29, 1949. He attended Portland State University before dropping out and joining the Navy during the Vietnam War. He spent his years of service on the aircraft carrier USS Hancock, which was patrolling waters and engaged in operations in Southeast Asia.

After Smith was discharged from the Navy, he saw potential in the early organic food movement and took a job as a manager of a natural foods store. When the store was closing, a regular customer named Stephen Lee purchased a large amount of the store's remaining inventory of herbs and spices and launched the Stash Tea Company. While Lee had

the idea, he needed help selling the product. Smith abandoned his business concept of producing ginger beer and found instant success with Stash, selling \$15,000 of products in just three weeks. He joined Stash as a co-founder, and the pair was on their way to creating one of the best-known American tea companies in history.

"I felt that by increasing the quality of the product inside, we could fundamentally change the way people felt about tea," Smith said, according to a 2012 interview on the Portland Food and Drink website.

Smith and Lee hit upon the idea of sourcing and distributing Oregon-grown peppermint (*Mentha x piperita*, Lamiaceae) through Stash. They redeveloped a wheat threshing machine, were trained to drive tractor-trailers, and eventually sold hundreds of tons of mint to Lipton® and Celestial Seasonings®. This endeavor brought in the funds needed to help Stash grow on a massive scale, eventually reaching annual revenues of \$10 million. In 1994, Japanese tea vendor Yamamotoyama® purchased the company.

This was just the first stage of the Smith-Lee partnership in tea. The two joined forces to launch Tazo Tea, a tea juggernaut that sold to Starbucks® in 1999 for \$9 million. After the sale, Smith joined the Starbucks team, continuing to offer vision and guidance around the potential of tea, according to the *Los Angeles Times*. (Lee went on to found Kombucha Wonder Drink®.)

In 2006, Smith retired to the south of France before returning to Oregon with his wife Kim DeMent to open Steven Smith Teamaker three years later. This beloved business, sited in an old blacksmith shop in Portland, sells small-batch artisanal tea. At first Smith resisted the use of his name, but his marketing team convinced him. They proposed Steven Smith Teamaster, but he preferred the more humble "teamaker" moniker.

Smith was well-respected in the tea community for his contributions to advance the role of tea in America, as well as for his kindness and generosity. For many years he worked with Mercy Corps to help in India's tea growing areas, improving the conditions for tea workers. Earlier this year he was inducted to the Specialty Food Association's Hall of Fame.

"I met Steve Smith in the 90s," recalled Pearl Dexter, *Tea Magazine* founding editor. "While on a visit to the Northwest he invited me ... to tour Tazo headquarters. The place was impeccable and everyone's manners the same. ... Steve had an amazing smile and his popularity never interfered with recognizing the hard work of those in the tea industry less popular than he." Many other tea enthusiasts tell stories of small moments with Smith when he took the time to welcome them and to share his excitement and tea knowledge.

Rajah Banerjee, owner of India's Makaibari Tea Estate, worked closely with Smith on the Mercy Corps Community Health and Advancement Initiative (CHAI). "Steven was the most caring and sensitive entity that the tea world has been privileged to have in her fold. I have known him for three decades and what was most remarkable was his

intensity to initiate projects for the upliftment of the marginalised in the tea growing regions he was associated with. It was an exciting time to conceptualise, organise, and execute the very successful CHAI initiative at Darjeeling, which has benefited so many families in the region."

Smith leaves his wife, DeMent; a son, Jack; a daughter, Carrie Smith-Prei; three sisters; and two grandchildren. He was previously married to Teri Schwarz. The family has asked that donations in his memory be made to Mercy Corps' School Education Retention Program, which aims to help children in Assam finish high school and go to college.

Steven Smith Teamaker will continue under the leadership of DeMent, along with Tony Tellin who has been Smith's "right hand man" for 17 years. Tellin is currently the company's master tea blender. The company has 30 employees and will soon open a 25,000 square foot warehouse, blending lab, café, and tasting room.

There is no doubt that tea enthusiasts for years to come will remember this generous and visionary man each time they lift their cups. HG

—Katrina Ávila Munichello

Editor's Note: This tribute originally appeared in *World Tea News*. Credit: *World Tea News*. Reprinted with permission.

Friends Remember Steven Smith:

From the moment Steve began harvesting peppermint in the fields of Oregon in the early '70s, he displayed the brilliance, ingenuity, and entrepreneurial spirit that marked his entire career. I was honored to have known him in those early days when he was my vendor at Celestial Seasonings, and I am privileged to have had him as a friend and colleague throughout the many phases of his ventures. He had an incredible design eye, great taste buds, and amazing creativity that produced products that have enriched the lives of millions of people. Everything he did was marked with a personal graciousness that made you realize you were in the presence of a very special person. May Steve journey on to ever greater fields of creativity.

—Caroline MacDougall
Founder and CEO, Teccino Caffé

Steven has been a friend and mentor for many years. His knowledge, humor, and open humanity have been an inspiration to me and all who have had the honor of knowing him. We will miss his guidance and most of all his presence.

—Ray Wolfson
Co-Owner, Matrix Marketing

Steve was a valued friend for over 35 years, and he was a supporter of the educational mission of ABC. He was highly creative and generous, and he played a prominent role in introducing high-quality teas to the American market. His legacy of uncompromising excellence and his dedication to the communities that grew his teas touched lives around the world and forever altered the tea market in the United States and beyond.

—Mark Blumenthal
Founder and Executive Director
American Botanical Council

James Lauritz Reveal 1937-2015

Jim Reveal, PhD, author of the Reveal system of botanical classification and leading authority on American plant taxonomy, passed away on January 9, 2015, at the age of 73. The majority of his research and writing in the field of botany involved the identification and study of plants in the Polygonaceae subfamily Eriogonoideae, commonly known as the wild buckwheats. Dr. Reveal discovered or identified more than 50 plant varieties; most of his discoveries were plants native to the American Southwest. He also devoted much of his time and energy to protecting and conserving endangered plant species, and he had a long-standing research interest in the botanical history of the American West.

Born in Reno, Nevada, Dr. Reveal earned his bachelor's and master's degrees from Utah State University. After earning his master's in 1966, he served as a pre-doctoral fellow for the Smithsonian Institute in Washington, DC. He earned his doctorate in 1969 from Brigham Young University in Provo, Utah. While still a doctoral student in 1968, he documented five new species of plants at a nuclear testing site in Nevada. After earning his degree, he was hired as an assistant professor of botany at the University of Maryland; he became a full professor in 1981 and continued to teach at the university until his retirement in 1999, whereupon he was awarded the title of professor emeritus.

Dr. Reveal began his crusade for plant conservation and endangerment when he became a member of the Smithsonian's Endangered Species Committee. Serving on the committee from 1974 to 1982, he successfully lobbied for the sweeping 1973 Endangered Species Act (ESA) to include endangered plant life. In 1975, upon direction from the government to identify plant species most in need of protection, Dr. Reveal and the Committee produced a report recommending that more than 3,000 species receive "threatened" or "endangered" status. The first plants to be listed as endangered appeared in 1977. Since its implementation, the ESA has become one of the most effective tools in the continuing effort to protect species — both plant and animal — and their habitats in the United States.

In 1978, Dr. Reveal married C. Rose Broome, PhD, and they became close collaborators on many projects through Dr. Broome's work at the US Department of Agriculture (USDA) and Dr. Reveal's position as the director of the Norton-Brown Herbarium at the University of Maryland, which he held from 1979 to 1999. Pursuing his deep and abiding interest in history and nomenclature, Dr. Reveal became known as an authority on the history of American botany, with a particular focus on the Lewis and Clark expedition. He wrote several articles and books about the plant life the expedition encountered on its trek, and he curated a collection called the Lewis and Clark Herbarium in conjunction with the University of Maryland and Cornell University.

Dr. Reveal's interests were not limited strictly to American taxonomy, however. "Thank goodness Jim accepted my invi-



tations to accompany me on trips to China (circa 1980 or 1981) and to Panama, collecting and vouchering plants for the NCI [National Cancer Institute] cancer screening program," wrote preeminent American economic botanist James A. Duke, PhD (email, March 27, 2015). "I think we brought back 800 total pounds of some 200-400 plant species for the program from China alone — of course with the permission of the Chinese. Tough trip, but Jim was tough too. We made it and enjoyed those hard-working trips." Upon his retirement from the Norton-Brown Herbarium, Dr. Reveal had collected over 9,000 plant specimens from North

America, Central America, and China.

He developed the Reveal system of botanical classification in 1999, a taxonomic system applied to a large group of angiosperm taxa with ten parts, beginning with Magnoliidae and ending with Asteridae. "Pure taxonomists, unlike us economic taxonomists," wrote Dr. Duke, "do their taxonomic things, often making unwelcome but overdue changes in the scientific names of organisms — in our case, plants. That was Jim's forte. Though a great field botanist, Jim was also always a great correspondent. Any time I had a pure taxonomic question, I'd call on Jim, and have a solid, credible answer often almost immediately."

Dr. Reveal joined the Angiosperm Phylogeny Group (APG) shortly thereafter to co-author the APG II and III classification systems. He remained active and working up until his passing; he was serving as an honorary curator of the New York Botanical Garden and as an adjunct professor at Cornell at the time of his death. He also served as a mentor to the Eriogonum Society, a nonprofit organization dedicated to promoting and protecting the species that Dr. Reveal knew so well.

The diligence and service that Dr. Reveal brought to the botanical community did not go unrecognized, and he earned a number of honors and awards throughout his career. In 1994, the University of Maryland awarded him the Faculty Award for Excellence in Service; he was also a fellow of the Washington Academy of Sciences and the Linnean Society of London. Of his more than 500 publications, many received awards or nominations from organizations such as the Association of College and Research Libraries, the Council of Botanical and Horticultural Libraries, and the National Garden Club. He also received the Edger T. Wherry Award from the North American Rock Garden Society in 2009 and the Merritt Lynn Fernald Award from the New England Botanical Club in 2010.

Cornell University paid tribute to Dr. Reveal's memory with a botanical photo exhibit featuring his photography at the Albert R. Mann Library on campus. "Wildflowers for a Winter Season" was originally planned as a collaboration between the library and Dr. Reveal before his sudden passing. In his lifetime, Dr. Reveal was recognized for his contributions to botany with four species and one genus named in his honor: *Castilleja revealii*, Orobanchaceae; *Eriogonum revealianum* (syn. *E. corymbosum* var. *revealianum*), Polygonaceae; *Montanoa revealii*, Asteraceae; *Rumfordia reveallii*, Asteraceae; and *Revealia* (Asteraceae). HG

—Hannah Bauman



Jerome Arthur "Jerry" Halperin 1937-2015

Jerry Halperin, who served as the CEO and executive vice president of the United States Pharmacopeia (USP) from 1990 to 2000, passed away after a long illness on February 10, 2015, at the age of 77. His belief in a globalized medical community drove his career, and he worked tirelessly to create a constantly evolving landscape for improved drug quality, quality standards, and the (re)inclusion of herbs and dietary supplements into the scope of USP.

Born on February 21, 1937, in Paterson, New Jersey, Halperin earned his bachelor's degree in pharmacy from Rutgers University in 1958. After graduation, he began what would be a 25-year career in public service in Albuquerque, New Mexico, for the US Public Health Service (PHS). He decided to continue his education and earned a master's degree in public health from Johns Hopkins School of Hygiene and Public Health in 1961. While at Johns Hopkins he met his wife, Barbara Hott; they married in 1963.

While working for PHS, Halperin was transferred around the country. In Boston, Massachusetts, he attended the Massachusetts Institute of Technology as a Sloan Fellow and earned his second master's degree, in the science in management. In 1974, his family made one last move to Maryland, where he worked for the US Food and Drug Administration (FDA). When he retired from the FDA in 1983, he was acting director of the FDA Office of Drugs in the combined National Center of Drugs and Biologics with the rank of Rear Admiral; at the time, he was the fourth PHS officer in pharmacy to achieve that distinction.

Halperin's retirement from public service did not indicate a retirement from his career. In 1983, after leaving the FDA, he entered the private sector and served as vice president of technology for product development, clinical, regulatory affairs, and quality assurance at CIBA Consumer Pharmaceuticals, a division of CIBA-Geigy, Inc. (now Novartis). He worked at CIBA until 1990, when he assumed the mantle of leadership at USP. While CEO of USP, he advanced the global reach and impact of the organization through many programs including expanded compendial standards (e.g.,

for multi-vitamins and botanicals), agreements with other pharmacopeias and regulatory authorities, exchanges of scientific experts, and improved stakeholder relationships. He also served as a member of the World Health Organization's Expert Advisory Panel on the International Pharmacopoeia and Pharmaceutical Preparations and was an expert member of the board of pharmaceutical sciences of the International Federation of Pharmacy.

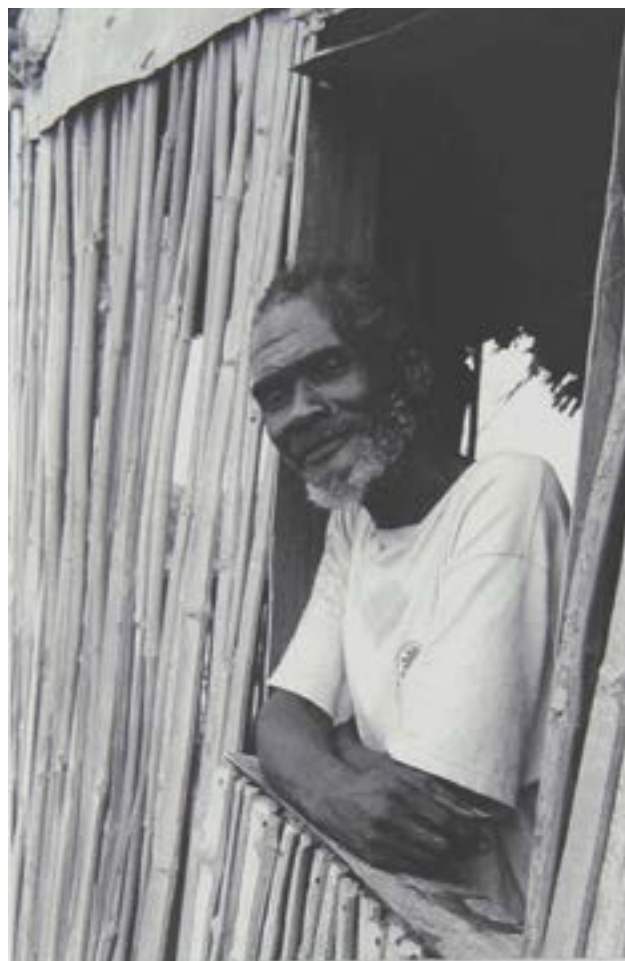
"Jerry Halperin's leadership at USP can be characterized as the beginning of the globalization of USP," said USP Executive Vice President and Chief Science Officer V. Srini Srinivasan, PhD. "Recognizing the growth of the pharmaceutical industry in the BRIC countries (Brazil, Russia, India, and China), he reached out to key stakeholders to participate in the compendial revision process. The seeds of globalization sown by Jerry Halperin were nourished by his successor Roger Williams, MD (2000-2014), who continued the globalization by establishing USP sites in Brazil, China, and India, which fulfilled the dream of Jerry Halperin to be in close alignment with those countries."

Upon resigning from USP in 2000, Halperin once again found that full retirement did not suit him, and he became the CEO of the Food and Drug Law Institute (FDLI). When he left FDLI in 2006, he finally assumed full retirement in Silver Spring, Maryland. He received numerous honors throughout his long career, including the Rutgers Alumnus of the Year Award in 1981; four honorary doctoral degrees; induction into the Italian Pharmacopoeia in 1992; the Remington Honor Medal from the American Pharmacists Association in 2001; and the Distinguished Service Award from the Drug Information Association in 2001.

"Jerry was a great visionary and leader for USP," said American Botanical Council Founder and Executive Director Mark Blumenthal. "He saw the potential for the growth of herbal dietary supplements after the passage of the Dietary Supplement Health and Education Act of 1994 (DSHEA) and moved quickly to invite many of us in the herbal community to participate in USP's new-found mission to include the development of standards and test methods for herbal dietary supplements into USP's mission and authoritative publications. Jerry was well-aware that the very earliest editions of the USP from the 1820s and on included mainly botanical medicines. He saw the pendulum swinging back in the herb direction, and he positioned USP to re-assert its previous role in the herbal area."

Jerry Halperin is survived by Barbara, his wife of over 50 years; two daughters, Alicia Halperin Odom and Rachel Halperin Montgomery; four grandchildren; his sister, Linda Halperin Nissenbaum; and a niece and nephew. HG

—Hannah Bauman



**Lloyd "Jamba" Scott
1937-2014**

Lloyd "Jamba" Scott, a Jamaican herbalist of the Maroon tradition and educator of scores of naturopathic physicians and herbalists, died in Jamaica in November 2014 of natural causes. He was 77.

Lloyd Scott was born in Penn Hill, in the Jamaican parish of St. Mary. As a young man, he was a gifted athlete and excelled in boxing and cycling, winning many championship cycling events in Jamaica. He was a talented farmer on land inherited by his family in Islington, Jamaica, where he grew commercial smilax (*Smilax* spp., Smilacaceae), ginger (*Zingiber officinale*, Zingiberaceae), and turmeric (*Curcuma longa*, Zingiberaceae), as well as many other herbs, for the market in the United States.

He was also a master sculptor and carver, taking the name Chamba (later, Jamba), which means "chopping up of wood" in Patois, a creole language of Jamaica. A champion fisherman, his student Mike Daum documented on film Jamba's catching barracuda with only a hand line and his machete.

He studied herbal medicine by spending time with elder family members and friends and apprenticing in the Jamaican Cockpit country on the parish of Trelawny, learning the many

closely held herbal medicines used by the Maroons. Later, he served as the village bush doctor and elder in Islington, where he treated the villagers for many decades.

Jamaican Maroons are the descendants of indentured servants and slaves brought from Ghana, Ivory Coast, and Sierra Leone to Jamaica by the Spanish in the 1500s. (Maroon comes from the Spanish word *cimarrón* meaning "wild" or "untamed.") The Maroons kept alive their Ashanti and Coromantee languages and medicine customs from Africa, combining them with native Jamaican Arawak traditions. The Maroons were continuously joined by many other fugitive slaves, and the word Maroon became synonymous with the "untamed, fugitive slave people of the hills."

Following a 14-year struggle called the First Maroon War against British colonizers, the Maroons signed a peace treaty granting them total freedom. The Maroons of Jamaica still maintain their independence and identity as The Maroon Federation, and Maroon territory is considered a sovereign nation within the tiny island of Jamaica. One of their strongest tenets is the healing power of nature and their deep knowledge of the myriad Jamaican herbs and their uses.

As a young biology student, I (EZ) traveled with my high school classmates to the remote regions of Jamaica. There, I met and befriended Jamba Scott. While in Jamaica pursuing a graduate level course over winter recess, I fell ill with intestinal dysentery. I tried conventional medicine, which caused significant adverse effects and did not seem to be helping. Feeling weak and depleted, I approached Jamba and one of Jamba's herbal teachers, an elder bush doctor known as Pop-A-Top, for help and advice. They suggested that "Maroon science" and herbology would bring rapid, welcomed relief where "Babylon medicine" (Western medicine) would not.

For three days I received a steady diet of a strong decoction made from ferns, Jamaica allspice (*Pimenta dioica*, Myrtaceae), cloves (*Syzygium aromaticum*, Myrtaceae), guava (*Psidium guajava*, Myrtaceae), sea grape (*Coccoloba wifera*, Polygonaceae), and many other Maroon herbs. The remedies were prepared by Jamba and Pop using their traditional "Maroon science."

The herbal treatment quickly produced positive results that the conventional medicines did not. This experience prompted a personal conversion in me, and I began researching ethnobotany — the cultural, medical, and spiritual aspects of plant healing. I asked Jamba if I could become his apprentice, even though I was a non-Maroon. Jamba agreed; he was advised by his grandmother's *duppy* (spirit) in a dream that he could trust me with this sacred knowledge and that I would be the right person to help pass his secrets on to the world as an "ethical ethnobotanist," giving back to the community and the local people.

Jamba continued to mentor me and my students, teaching them self-sufficiency and the benefits of living as he did, a Jamaican countryman close to the earth. Many people would accompany me to Jamaica, and Jamba's teachings radically changed the lives of many of these visitors. In addition, Jamba worked with the Jamaica Wholistic

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**Carl Djerassi
1923-2015**

Known as the "Father of the Pill," chemist and researcher Carl Djerassi, PhD, died on January 30, 2015, at the age of 91 from complications due to bone and liver cancer. Though he is credited with first synthesizing the key component of oral contraceptives, it is an accomplishment that he shared with other scientists, and a title that he never felt comfortable embracing. His legacy, both personal and professional, encompasses much more.

"Carl abhorred this ['Father of the Pill'] term and had always steered away from this designation," wrote Joseph Chang, PhD, chief scientific officer and executive vice president of product development at Nu Skin (email to M. Blumenthal, March 6, 2015). Formerly, Dr. Chang worked at Pharmanex, now a division of Nu Skin, with Dr. Djerassi. "It's true he was the third member of a team responsible for the economical synthesis of norethindrone, but Carl was more than a chemist. His talents ranged far and wide and in later years, Carl transitioned seamlessly from a professor of chemistry [and] an art collector to a novelist and playwright. He singlehandedly created a new genre called science-fiction."

Born in Vienna, Austria, Dr. Djerassi and his mother fled to Bulgaria to escape the increasing persecution of the Jews; later, in 1939, he moved to New York City. Showing the initiative and brashness that would come to define his adult life, Dr. Djerassi wrote directly to the first lady, Eleanor Roosevelt, to ask for assistance in funding his education. She responded, and her charity to a struggling refugee helped him earn a degree in chemistry, summa cum laude, from Kenyon College at the age of 18. He earned his PhD from the University of Wisconsin in 1945, the same year he became a naturalized citizen of the United States. After earning his degree, he began working as a research chemist at CIBA Pharmaceutical Co. in New Jersey, where he developed and patented tripele-namine (now sold by Novartis as Pyribenzamine®), the first commercial antihistamine. Four years later, at the age of 26, Dr. Djerassi became the associate director of research at Syntex in Mexico City. It was there that he would take the first steps toward the development of oral contraceptives.

Dr. Djerassi's work at Syntex first was directed at synthesizing cortisone from diosgenin, a molecule derived from an inedible species of wild Mexican yam (*Dioscorea mexicana*, Dioscoreaceae). At the time, cortisone was derived mainly from animals, which caused the supply to be expensive and difficult to obtain. While Djerassi was successful in his partial synthesis of cortisone using diosgenin, he made a life-changing discovery: diosgenin could also be synthesized into progesterone, the synthetic version of the female sex hormone. Initially, the discovery was intended to treat infertility, as progesterone injections were already available for that purpose. While scientists were aware that estrogen and progesterone could halt ovulation, using it for contraceptive purposes was impractical and would have involved daily injections for the patient. Again starting with diosgenin, Dr. Djerassi and his team were the first to synthesize norethindrone, a form of progesterone that remained bioavailable during oral delivery. This would become the key ingredient in oral contraceptives, developed and tested by Gregory Pincus, PhD, and Harvard gynecologist John Rock, MD, between 1954 and 1956.

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Following the discovery of norethindrone, Dr. Djerassi entered the world of academia, teaching chemistry at Wayne State University in Michigan before moving to Stanford University in California, where he would retire as professor emeritus in 2002. At Stanford, he became notable for his progressive hiring practices and dedication to increasing the diversity of the chemistry field, in particular his willingness to promote and empower women. During his tenure, he continued to hold a variety of positions at Syntex, including serving as president of the company from 1968 to 1972.

In 1968, Dr. Djerassi helped found the Zoecon Corporation and under its auspices continued to pursue his research, this time creating new, environmentally responsible methods of insect control. He maintained an interest in natural products and their chemistry, synthesizing marine natural products and pioneering new methods in organic chemistry.

“He had a long interest in nature as a source or template for drugs,” wrote Janice Thompson, PhD, who worked in Dr. Djerassi’s lab as a research associate (email to M. Blumenthal, February 2, 2015). “Indeed, he and Alex [Alejandro] Zaffaroni, PhD, (early CEO of Syntex) shared this interest and they founded Affymax (1988) to go back to nature looking for drugs with modern methods. Because of my similar interests, I was an early employee of the company, and I managed the natural product chemical collections (among other things),” continued Dr. Thompson. “Our initial focus was on plant extract collections from China, with an emphasis on traditional Chinese medicines [TCMs]. Some years later, he provided the initial funding for what became Pharmanex, and this company was focused on bringing TCMs to market in the United States right after DSHEA [Dietary Supplement Health and Education Act of 1994].”

The multiple commercially successful products Dr. Djerassi produced allowed him to indulge in his favorite hobbies, includ-

ing art, and he became an avid collector of the Swiss-German painter Paul Klee. After the death of his daughter Pamela, who was a poet and a painter, in 1978, Dr. Djerassi became a patron of many aspiring artists; he sold some of his collection to open the Djerassi Resident Artists Program, an artist colony near Woodside, California, in her memory. Since its inception, more than 2,000 artists have participated in the program.

Following his own artistic desires, Dr. Djerassi began publishing his own short stories and fiction in 1986. His novels created a genre he termed “science-in-fiction.” Combining his scientific background and literary flair, he sought to integrate two fields of study that were perceived by some to be incompatible — art and science — and examine the human side of scientists and their work. In 1997, he continued in this vein as a playwright. His seven plays have been performed around the world, and all of his works have been translated into several different languages. He also published his memoir, *This Man’s Pill* (Oxford University Press, 2001), to commemorate the 50th anniversary of his discovery in Mexico.

Dr. Djerassi’s work gained him international acclaim and a staggering number of awards. For his work on the synthesis of a steroid contraceptive, he received the National Medal of Science in 1973, the first Wolf Prize in Chemistry in 1978, and was inducted into the National Inventors Hall of Fame in the same year. He received 32 honorary doctorates from institutions around the world, and his native Austria honored his work by issuing a stamp with his likeness in 2005.

Carl Djerassi — a self-described “intellectual bigamist” and “intellectual smuggler” — died at his home in San Francisco, California. He is survived by his son, Dale; stepdaughter, Leah Middlebrook; and a grandson. HG

—Hannah Bauman

JAMBA continued from page 76

Herbal Association, leading workshops with herbalists throughout Jamaica, and was one of the first farmers in St. Mary to introduce neem (*Azadirachta indica*, Meliaceae) as a natural insecticide.

Jamba worked with my business partner Ellen Kamhi, PhD, RN, photographer Tom “Asher” Hammang, and me to document the Jamaican bush. Ellen and I co-authored *The Natural Medicine Chest* (M. Evans & Company, 1999), which includes a section, “Herbs from The Shaman’s Garden,” that chronicles Jamba’s herbal knowledge. His contributions included sections on the Maroon ethnobotany and medical uses of 20 herbs. Jamba, Ellen, and I also collaborated on several other projects, including EcoTours for Cures, an adventure travel company focusing on ethnobotanical and cultural journeys so that interested travelers could observe, work with, respect, and preserve indigenous cultures and their knowledge, chronicling it for future generations. Jamba has been featured in many international magazines, articles, and radio programs discussing the medicinal herbs of the West Indies.

Since 1990, Jamba instructed scores of naturopathic students and herbalists eager to meet and work with him and immerse themselves in field research about Jamaican botanical medi-

cines, including noted herbal leaders such as Ric Scalzo, founder and CEO of Gaia Herbs; Geo Espinosa, ND, director of the Integrated Urology Center at New York University; and Jamaica’s most esteemed herbalist, Diane Robertson.

As Mark Plotkin, PhD, a world-renowned ethnobotanist and expert on the Maroons, has stated on Ellen’s and my syndicated radio program *Natural Alternatives*: “Every time a shaman dies, it is like a whole library of information being burnt to the ground, lost forever.”

Lindsay Chimileski, ND, who wrote her naturopathic thesis on Jamaican herbs, said of Jamba, “I am honored to have learned from and connect[ed] with Jamba. I know that his strong spirit lives on through [Dr. Zampieron] and all his students, friends, and family ... but I feel a weight on my heart thinking about Jamaica without Jamba’s physical presence, knowing eyes, loving smile, and one-of-a-kind dancing.”

A tribute and memorial ceremony was held for Jamba in March 2015 in Jamaica. HG

—Eugene Zampieron, ND, RH(AHG)
—Ellen Kamhi, PhD, RN, AHG, AHN-BC

Publications

American Herb Association Quarterly Newsletter: \$20/yr. AHA, P.O. Box 1673, Nevada City, CA 96969.

Australian Journal of Herbal Medicine: Quarterly publication of the National Herbalists Association of Australia (founded in 1920). Deals with all aspects of Medical Herbalism, including latest medicinal plant research findings. Regular features include Australian medicinal plants, conferences, conference reports, book reviews, rare books, case studies, and medicinal plant reviews. AUD/\$96 plus AUD/\$15 if required by airmail. National Herbalists Association of Australia, 33 Reserve Street, Annandale, NSW 2038, Australia.

Medical Herbalism: Subtitled “A Clinical Newsletter for the Herbal Practitioner.” Edited by Paul Bergner. \$36/yr, \$60/2 yrs. Canada \$39/yr. Overseas \$45/yr. Sample/\$6. Medical Herbalism, P.O. Box 20512, Boulder, CO 81308.

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Caesalpinia gilliesii, Fabaceae

Photo by Matthew Magruder
Hasselblad 500CM camera
Sonnar C 150mm lens 1/125 sec @ F/4
+ Extension Tube 56E
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Commonly called the bird of paradise (though unrelated to the similarly common-named plants of the South American genus *Strelitzia*), *Caesalpinia gilliesii* is an ornamental plant native to South America and naturalized in the southwestern United States.¹ The genus *Caesalpinia* consists of more than 100 species found in tropical and temperate areas around the world.² The species is named for Scottish physician and botanist John Gillies, and the genus is named for 16th century Italian botanist Andrea Cesalpino. The drought- and deer-resistant plant flourishes in arid climates, and the flowers attract bees, butterflies, and hummingbirds. Many plants in the genus *Caesalpinia* are toxic to humans, and *C. gilliesii* is no exception.³ Due to their high tannin content, the seeds and pods can cause severe gastrointestinal upset if ingested, though the presence of these same tannins led to their use in tanning and dyeing processes. *Caesalpinia gilliesii* contains cesalin, an anticarcinogenic compound found to be “highly active” against certain types of tumorous growths in animal studies.¹ Other *Caesalpinia* species have traditional medicinal uses — *C. mexicana* root powder has been used to treat wounds, sores, and ulcers, while its cooked pods have been eaten in small amounts for stomach infections; a decoction of *C. jamesii* stems and leaves has been used as a foot wash and deodorant. HG

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