What is that Herb?

A Review of the Challenges of Global Adulteration of Herbal Raw Materials & Extracts and the ABC-AHP-NCNPR Botanical Adulterants Program

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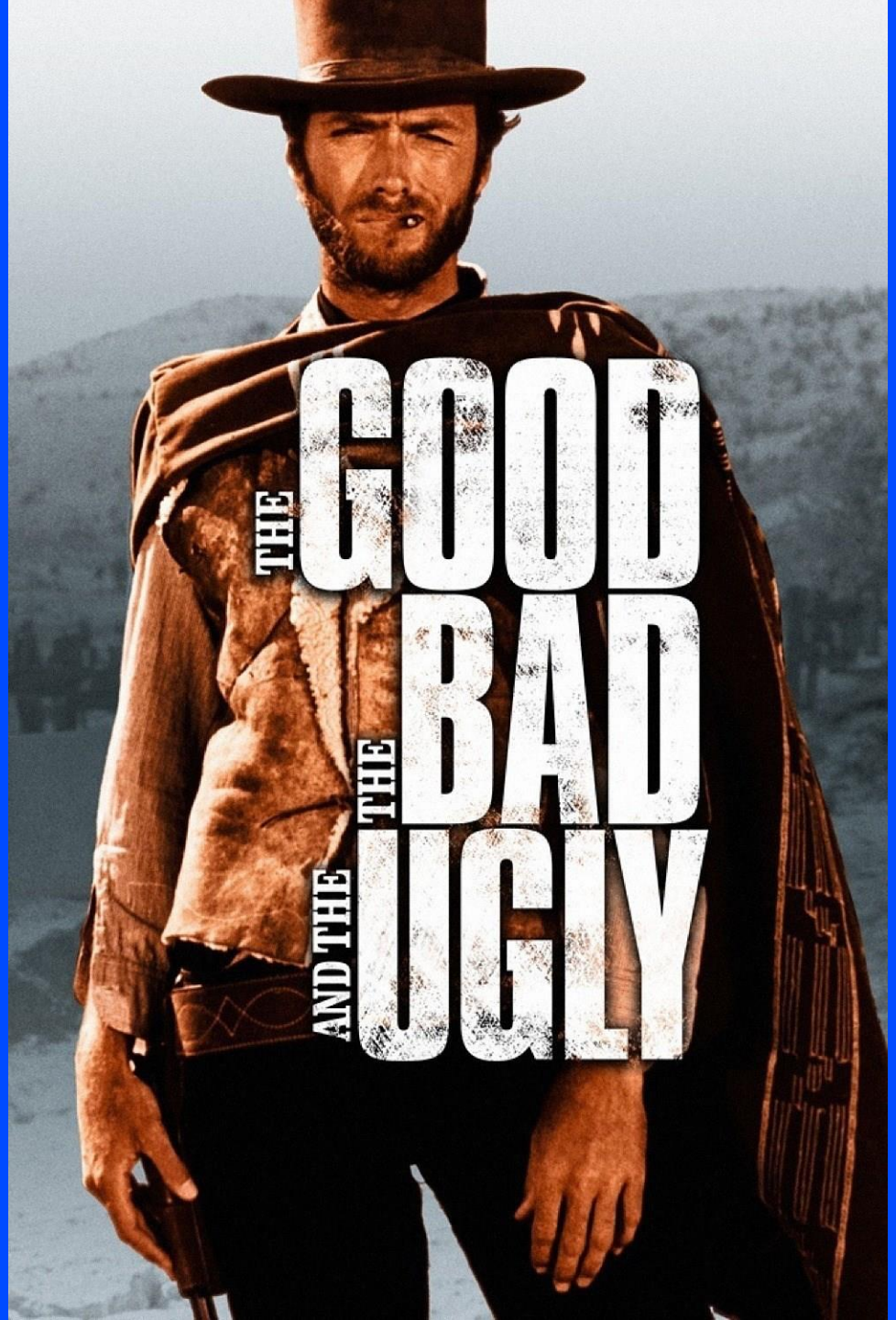
Bara Herbs Conference, Israel
November, 2016


THE GOOD
THE BAD
AND THE UGLY

"The Good"

- Increased consumer use of herbs
- Increased professional use of herbs
- Increased amount of systematic reviews & meta-analyses showing positive results/trends in controlled clinical trials

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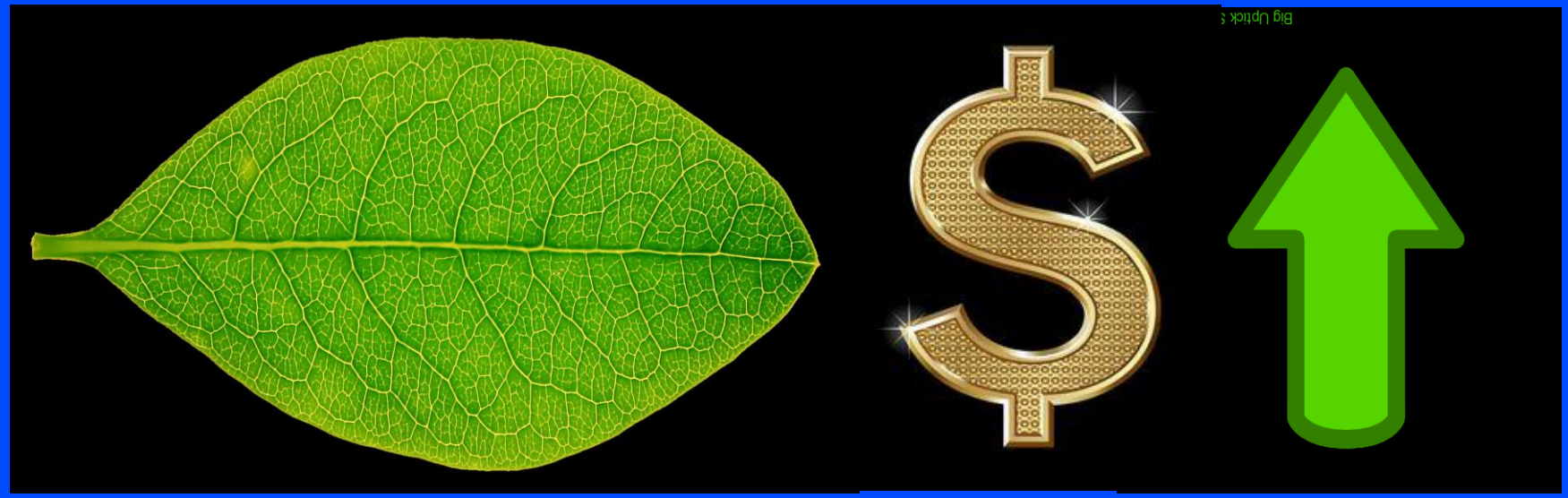
www.phytochemist.blogspot.com



Total Herbal Dietary Supplement Sales Up 7.5% in 2015 In All Channels of Trade in the U.S.

Total Est. = $6.92 Bn

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Sales of Herbal Dietary Supplements in US Increased 7.5% in 2015

Consumers spent $6.92 billion on herbal supplements in 2015, marking the 12th consecutive year of growth

By Tyler Smith[a], Kimberly Kawa[b], Veronica Eckl[b], and James Johnson[c]

[a] *HerbalGram, American Botanical Council; Austin, Texas*
[b] *SPINS; Chicago, Illinois*
[c] *Nutrition Business Journal, New Hope Natural Media; Boulder, Colorado*

Introduction

Consumer spending on herbal dietary supplements in the United States reached an all-time high in 2015. Retail sales of herbal supplements totaled an estimated $6.92 billion in 2015 (Table 1), a 7.5% increase in sales from the previous year. Consumers spent approximately $480 million more on herbal products in 2015 than in the previous year — an increase that marks the 12th consecutive year of growth for these products.

These figures, and the rest of the data* presented in *HerbalGram*'s 2015 Herb Market Report, were generously provided by the following organizations: SPINS LLC, a market research firm based in Chicago, which collaborated with IRI (Information Resources Inc.), also a Chicago-based market research company, to determine mainstream multi-outlet retail sales of herbal dietary supplements, and the *Nutrition Business Journal* (NBJ), a publication of New Hope Natural Media, a specialty media company with headquarters in Colorado.

Table 1. Total Estimated Retail Sales of Herbal Supplements*	
2000	$4.225 billion
2001	$4.361 billion
2002	$4.275 billion
2003	$4.146 billion
2004	$4.288 billion

Horehound, for the third year in a row, was the top-selling herbal supplement in the US mainstream multi-outlet channel. Sales of horehound supplements in 2015 reached almost $115 million (see Table 4), an 8.5% increase from the previous year. Since 2013, horehound supplement sales, which include lozenges with horehound as the primary ingredient, have increased by a total of almost $8 million in mainstream outlets, indicating strong, continued growth for this member of the mint (Lamiaceae) family.[1]

“The Bad
& The Ugly”

New York Times,
Business Section,
Front Pg, Sunday,
Aug. 28, 2011

Here's to Your Health, So They Claim

Ingredients of Shady Origins, Posing as Supplements

By NATASHA SINGER

BOSTON

DR. PIETER COHEN is scanning the shelves inside a shop in Chinatown here when something familiar — and potentially dangerous — catches his eye.

"What's that yellow box, behind the other one?" Dr. Cohen asks the clerk.

It is Pai You Guo, a supposedly natural weight-loss supplement from China that, according to federal authorities, has tested positive in the past for containing two hazardous drugs, including a suspected carcinogen. The product was recalled in 2009. One of Dr. Cohen's patients in the Boston area ended up in the hospital last year with a range of ailments after taking Pai You Guo, a brand-name that, loosely translated from Chinese, means "the fruit that eliminates fat."

But he has seen worse: kidney failure, heart problems, depression, addiction — all, he says, caused by tainted products sold openly as dietary supplements in shops across the nation and on the Internet.

"My patients are being harmed by this," says Dr. Cohen, an internist at the nearby Cambridge Health Alliance and an assistant professor of medicine at Harvard Medical School.

Marketing drugs in the guise of supplements is illegal in the United States. Tainted Pai You Guo is just


The whole thing is going to have to come down. It's full of lead.
K2
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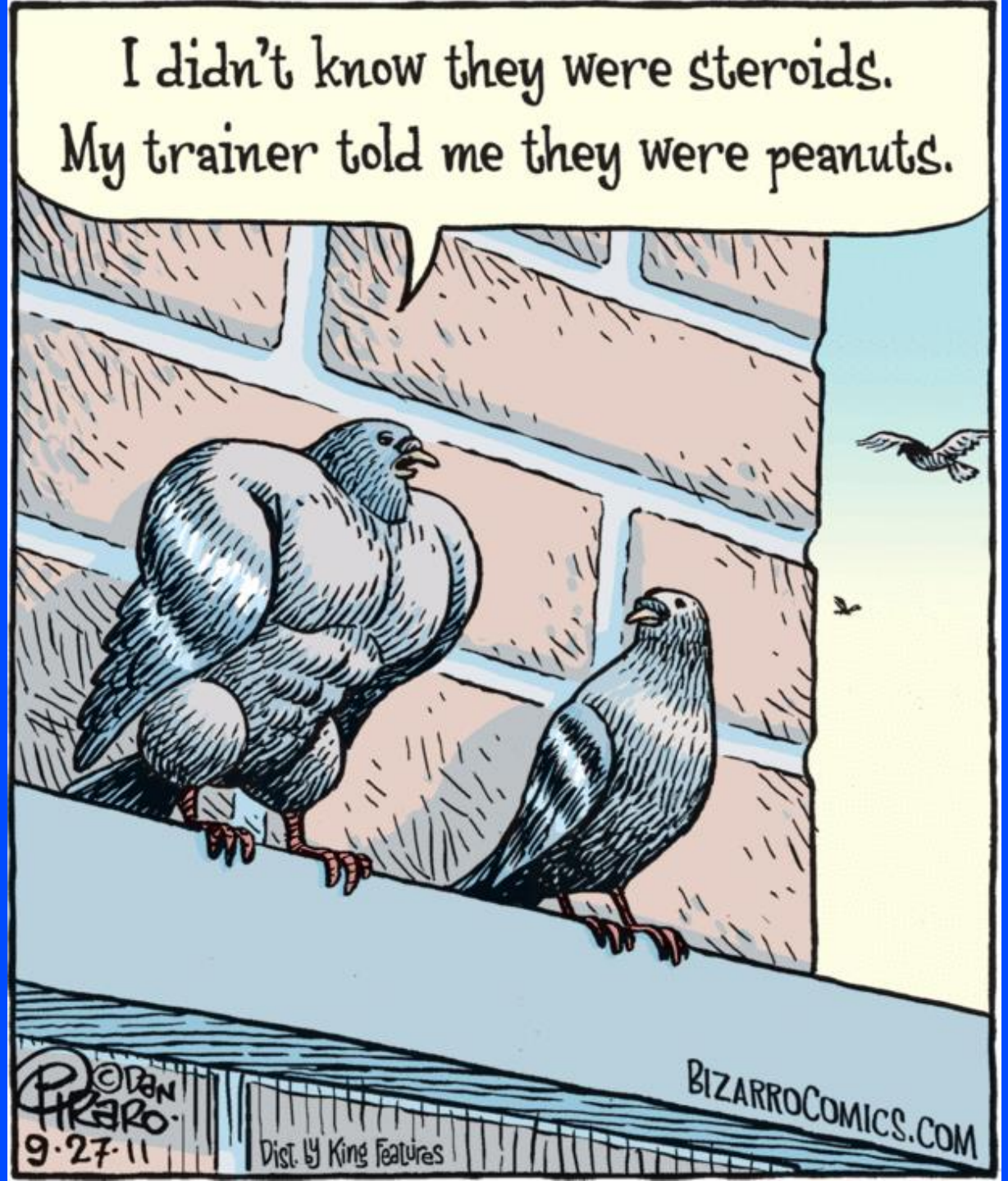
BAN
CHINESE
GOODS!
MADE IN CHINA


I didn't know they were steroids.
My trainer told me they were peanuts.
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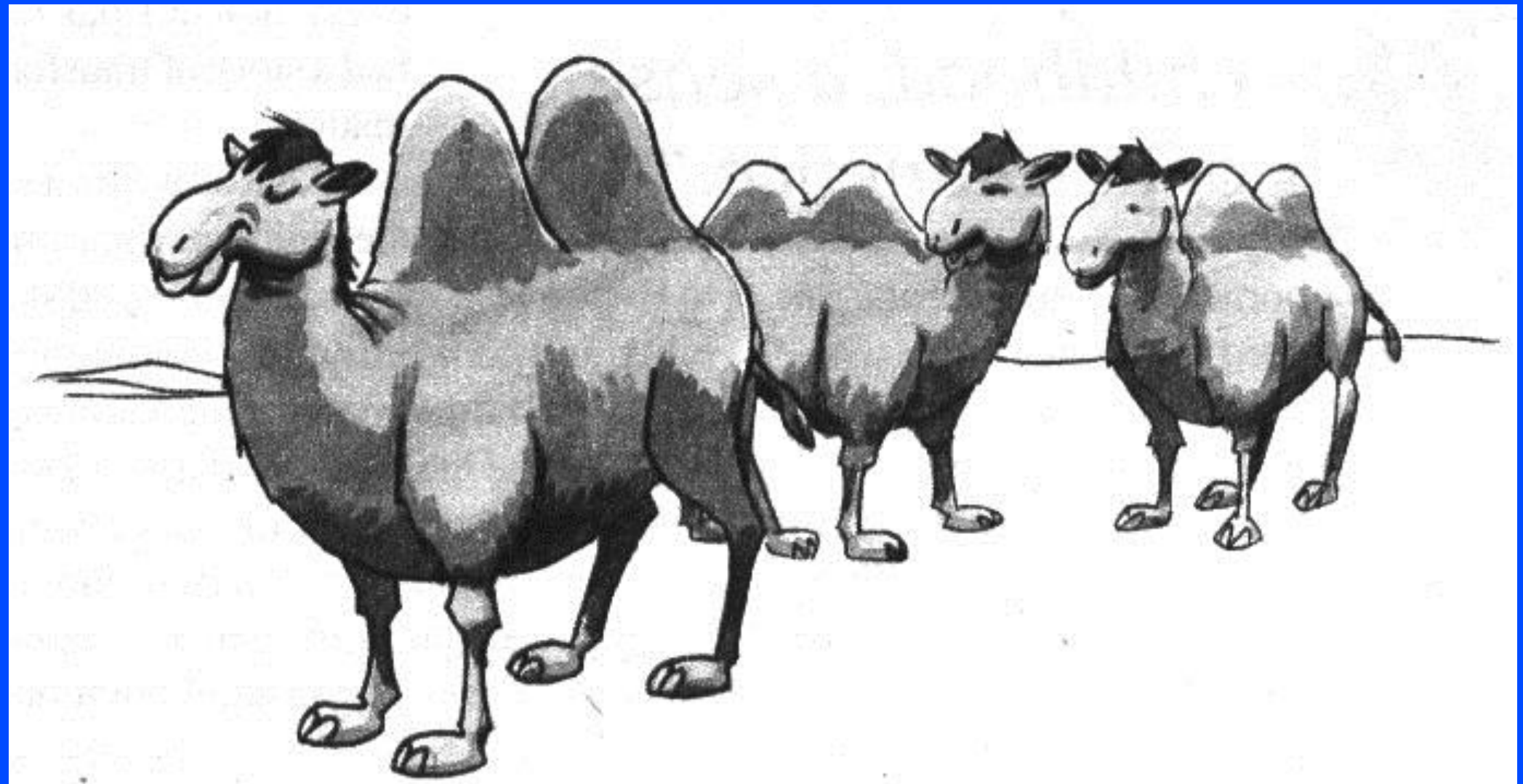

"I'll bet they're not even real."

The botanical supply chain is global; adulteration is a global challenge.

Many responsible, ethical companies in both the supply chain & in the manufacture & marketing of herbs & finished herbal products provide reliable high-quality materials & consumer goods.

Botanical Adulterants Program

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NCNPR
THE UNIVERSITY OF MISSISSIPPI

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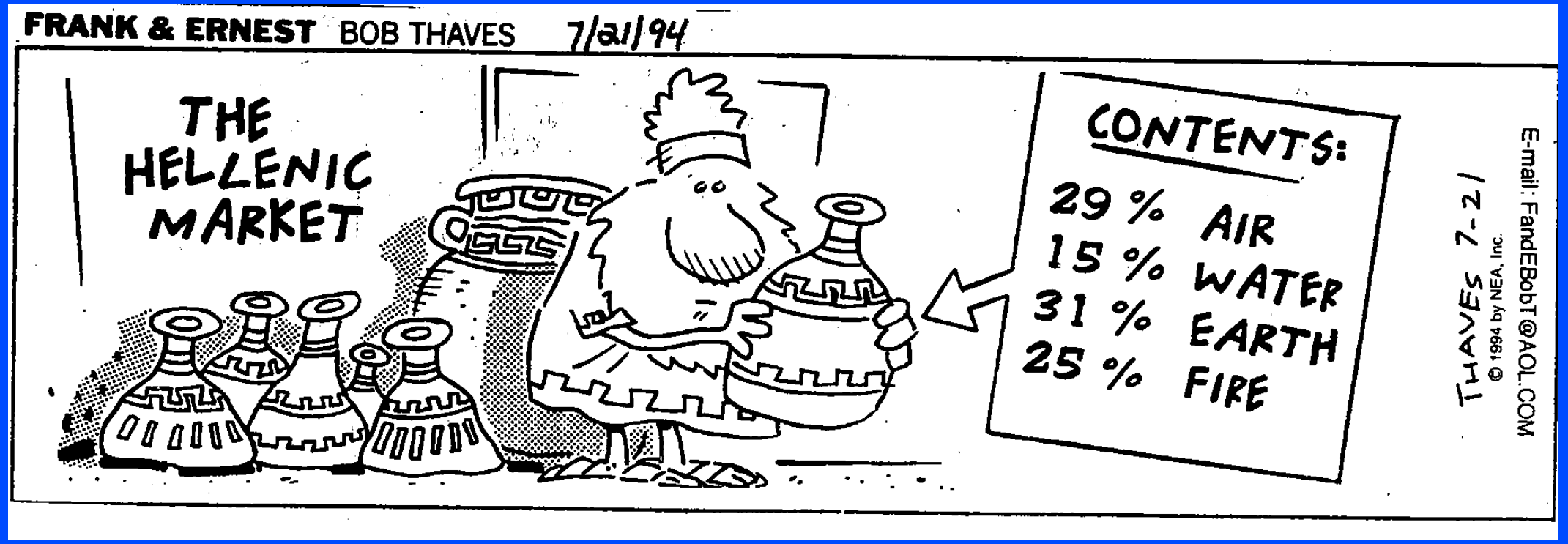
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THE HELLENIC MARKET
CONTENTS:
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15 % WATER
31 % EARTH
25 % FIRE
THAVES 7-21
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A BRIEF HISTORY OF ADULTERATION OF HERBS, SPICES, AND BOTANICAL DRUGS

BY
STEVEN FOSTER

Echinacea *Echinacea purpurea*. Photo ©2011 Steven Foster

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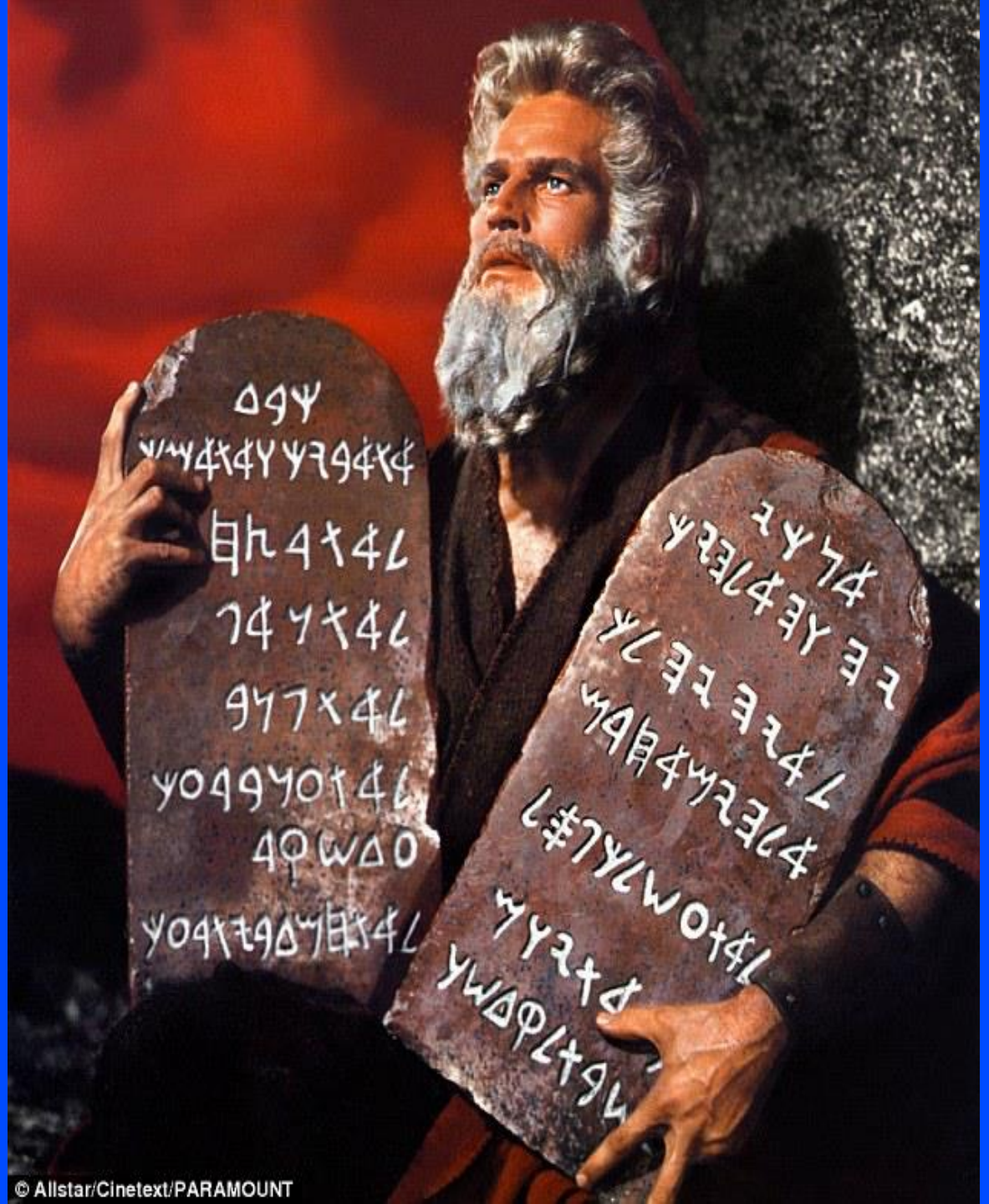
“Thou shall not commit adulteration.”

7th Commandment.
Exodus 20:14.



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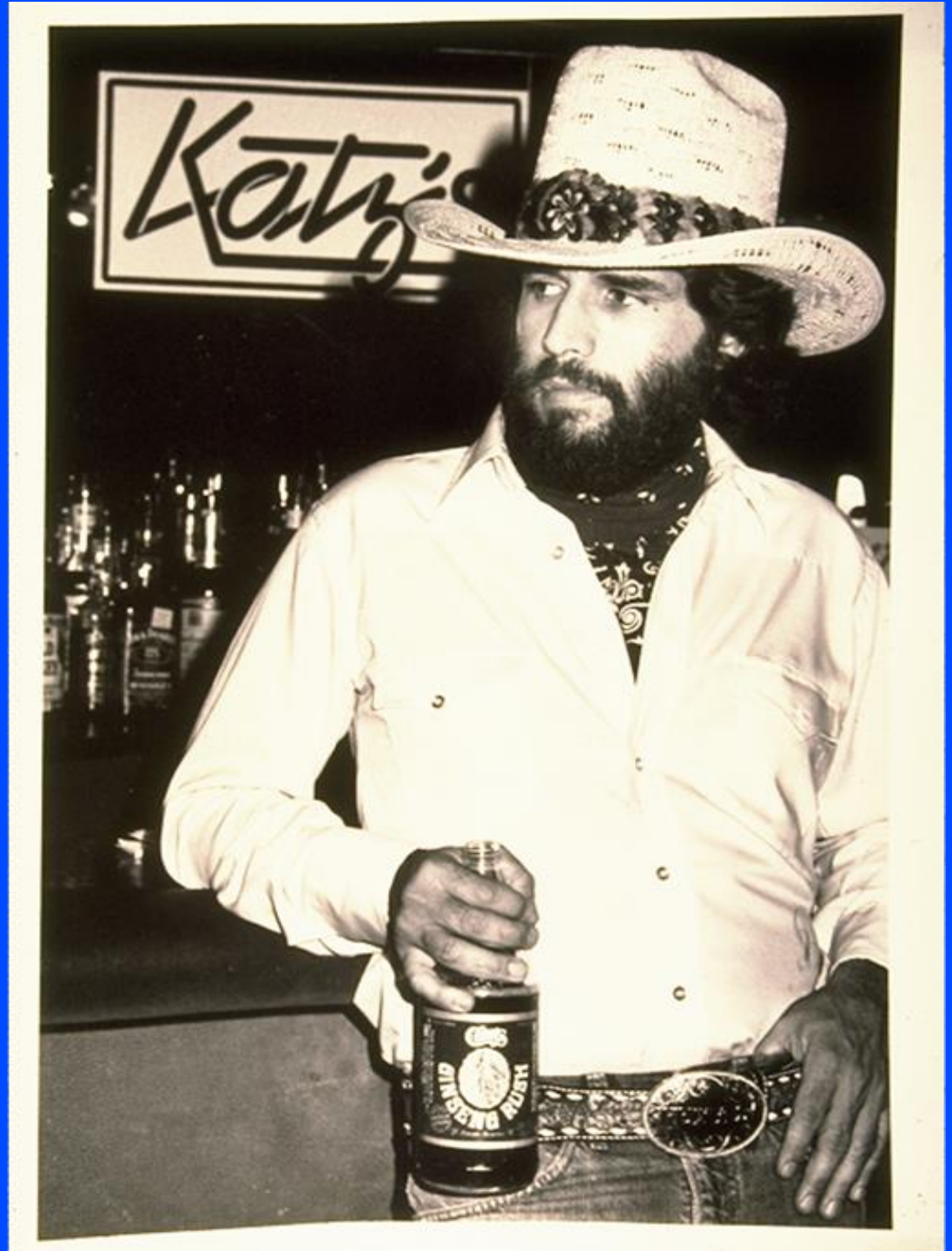

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Adulteration in the 1st Century CE – per Dioscorides

Dioscorides noted that frankincense (*Boswellia sacra*, Burseraceae) when burned was easily flammable, and the smoke was clear with a pleasant fragrance.

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Dioscorides' book "De Materia Medica" discussed adulteration

Dioscorides' *Materia Medica* provides **40 adulteration examples**, 30 including **methods of detection**:

- Organoleptic & other physical or qualitative distinctions, and/or
- geographic origin
- or an often-ambiguous botanical description.

- Physical determination included:
  - flame test (flammability or lack thereof),
  - displacement,
  - weight,
  - organoleptic tests & solubility
  - etc.

Recent Historical Examples of Accidental & Intentional Adulteration of Botanical Raw Materials & Extracts

“The Bad”

Accidental Adulteration

- Lack of full compliance with appropriate GACPs, GMPs, etc.
- Lack of adequate training of harvesters, collectors, workers in processing, and/or manufacturing plants in supply chain

הבעלות והאחריות על המידע והתכנים המופיעים במצגת שייכים לכותב בלבד ואין חברת ברא צמחים אחראית למהימנותם או לדיוקם של תכנים אילו, והם אינם מהווים ייעוץ מקצועי או התוויה רפואית.

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"The Hairy Baby Case"

JAMA The Journal of the American Medical Association

December 12, 1990, Vol 264, No. 22 >

< Previous Article

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ARTICLE | December 12, 1990

Maternal Ginseng Use Associated With Neonatal Androgenization

Gideon Koren, MD, ABMT, FRCPC; Samuel Randor, MD, ND; Sheelagh Martin, RN; Denis Danneman, MB, BCh, FRCPC

Abstract

CMAJ. 1996 Aug 1;155(3):293-5.

Elevated serum digoxin levels in a patient taking digoxin and Siberian ginseng.

McRae S[1].

Author information

Abstract

A 74-year-old man taking a constant dose of digoxin for many years was found to have an elevated serum digoxin level with no signs
effects. Common causes of elevated serum digoxin were ruled out, and the patient's digoxin level remained high after digoxin therapy
The patient then revealed that he was taking Siberian ginseng, a popular herbal remedy. The patient stopped taking ginseng, and the s
level soon returned to an acceptable level. The digoxin therapy was resumed. The patient resumed taking ginseng several months late
serum digoxin level again rose. Digoxin therapy was maintained at a constant daily dose, the ginseng was stopped once more, and th
digoxin levels again returned to within the therapeutic range. It is unclear whether some component of the ginseng was converted to di
interfered with digoxin elimination or caused a false serum assay result. The author cautions physicians to be alert to the potential for

"Siberian Ginseng" Adulteration

Periploca as culprit in digoxin assay confusion.

[Awang DVC. CMAJ. 1996 Nov 1;155(9):1237]

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Siberian ginseng toxicity may be case of mistaken identity

The article "Elevated serum digoxin levels in a patient taking digoxin and Siberian ginseng" (*Can Med Assoc J* 1996;155:293-5), by Dr. Shelagh McRae, contains serious chemical inaccuracies and probably represents yet another case of botanical misidentification by clinical investigators.

First, the statement that "eleuth-

seng for digoxin and digitoxin content, no tests for eleutherosides were conducted, which would have determined the validity of the claim that the plant ingested was *Eleutherococcus senticosus*. I suspect that the apparent rise in the patient's serum digoxin levels was due to a contribution from cardiac glycosides in *P. sepium*, a common substitute for *E. senticosus*.

This case further emphasizes the need for serious regulatory attention to assure the identity, purity and quality of marketed botanicals.

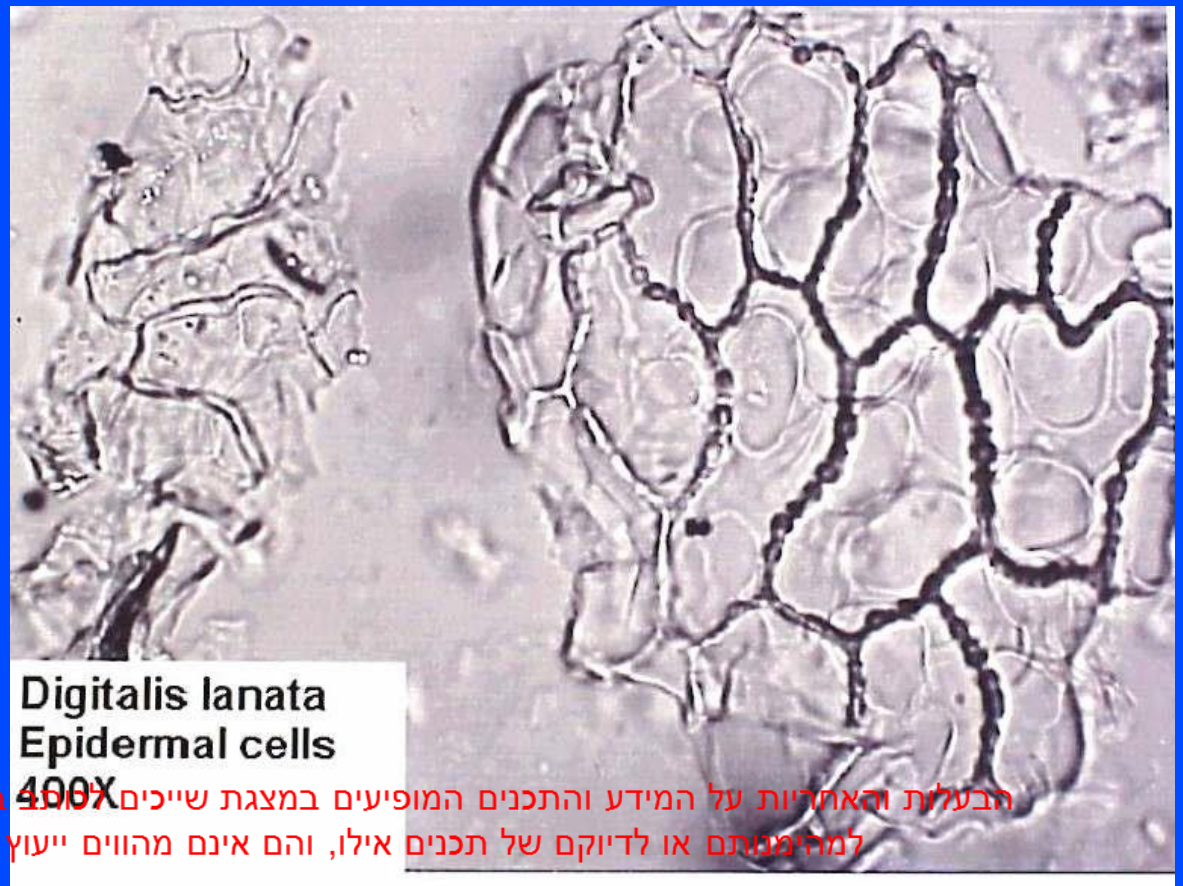
Eleutherococcus senticosus & Periploca sepium

http://www.google.com/imgres?q=Eleutherococcus+senticosus&hl=en&biw=1215&bih=633&gbv=2&tbm=isch&tbnid=QttNnY9CDteP0M:&imgrefurl=http://herbalnation.blogspot.com/2008/11/siberian-ginseng-eleuthero.html&docid=SOAhXCEma8AiWM&w=191&h=277&ei=DX9jTpuYJOHl4QTa7u2QCg&zoom=1&iact=rc&dur=289&page=1&tbnh=151&tbnw=104&start=0&ndsp=19&ved=1t:429,r:7,s:0&tx=27&ty=52

Plantain Leaf & Foxglove

Plantago lanceolata & Digitalis lanata

- “Chompers” herbal product in US accidentally adulterated w/ digitalis leaf by European supplier in 1990s.
- Major safety concern!



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Botanical Adulterants Program
BOTANICAL ADULTERANTS BULLETIN

on Adulteration of *Arnica montana*

By Stefan Gafner, PhD[a]* and Wendy Applequist, PhD[b]

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[b]*Missouri Botanical Garden, PO Box 299, St. Louis, MO 63166*
*Corresponding author: email

Keywords: *Arnica montana*, arnica flower, adulterant, adulteration, *Heterotheca inuloides*

Goal: The goal of this bulletin is to provide timely information and/or updates on issues of adulteration of *Arnica montana* flower to the international herbal products industry and extended natural products community in general. It is intended to present the available data on the occurrence of adulteration, the market situation, and consequences for the consumer and the industry.

1 General Information

1.1 Common name: Arnica[1]

1.2 Other common names:

English: Leopard's bane, European arnica, mountain tobacco, wolfs-bane[2†]

Chinese: S han jin hua (山金花)[3]

French: Arnica, arnique, bétoine des montagnes, herbe aux chutes, souci des alpes, tabac des Vosges[2]

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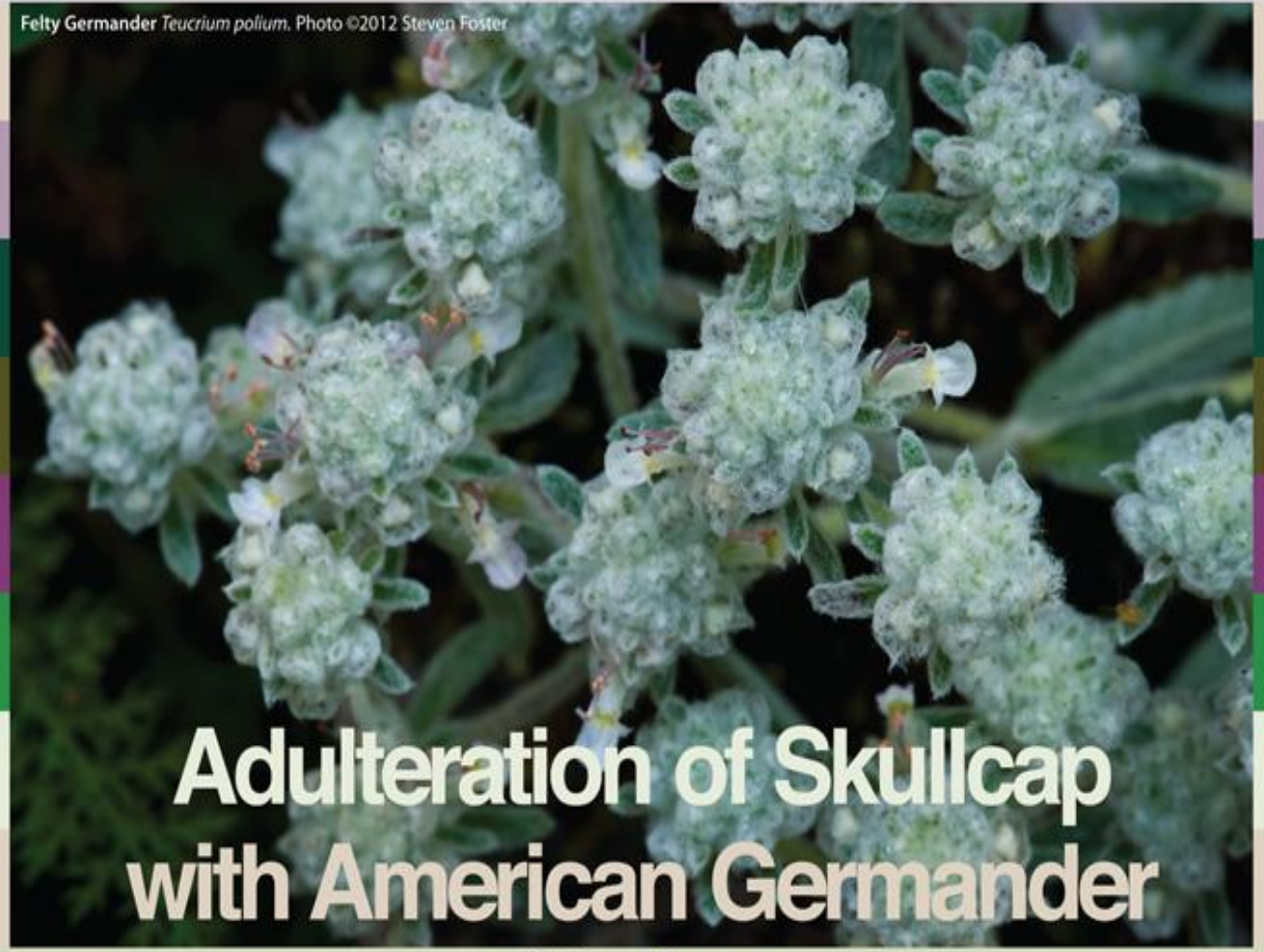
Felty Germander *Teucrium polium*. Photo ©2012 Steven Foster

Adulteration of Skullcap with American Germander

By Steven Foster

Summary

Skullcap (*Scutellaria lateriflora*, Lamiaceae), a native American plant, has been used by herbalists and medical practitioners—primarily as a mild nerve sedative—throughout the history of American herbalism. In the early 1980s, it was erroneously implicated as being a possible source of liver toxicity, mostly in combination herbal products. By the early 1990s, it became clear that suspected adulteration or substitution of members of the genus *Teucrium* were the source of the alleged toxicity that falsely implicated skullcap. Various herbal research groups have published methods for the authentication of skullcap. A paper published in 2011 suggests problem still exists. Various papers relative to the toxicity of *Teucrium* species and authentication of skullcap are

ing skullcap in the journal *Annals of Bioanalytical Chemistry*.[2] The

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BOTANICAL ADULTERANTS BULLETIN

on Adulteration of Skullcap

By Stefan Gafner, PhD*and Mark Blumenthal
*Corresponding author: email


Skullcap *Scutellaria lateriflora*
Photo ©2016 Steven Foster

Keywords: *Scutellaria lateriflora*, skullcap herb, adulterant, adulteration

Goal: The goal of this bulletin is to provide timely information and/or updates on issues of adulteration of *Scutellaria lateriflora* to the international herbal products industry and extended natural products community in general. It is intended to complement the previously published works regarding skullcap adulteration, e.g., the *American Herbal Pharmacopoeia* Skullcap Monograph published by Upton et al.[1] and the article by Foster in *HerbalGram*,[2] by presenting new data on the occurrence of adulteration, the market situation, and consequences for the consumer and the industry.

1 General Information

1.1 Common name: Skullcap[3]

1.2 Other common names:

Skullcap-Germander Confusion

- Safety of Scullcap (*Scutellaria lateriflora*) well established.
- Scullcap has been and still may be adulterated with Germander (*Teucrium chamaedrys*) in US market.
- Germander contains known hepatotoxic compounds.
- Plus, also adulterated with alternate species of *Scutellaria* (*S. incana, S. canadense*) because seed companies are selling mislabeled seeds.
- Media reports – e.g., *Consumer Reports* (2004) -- about scullcap toxicity are erroneous.

Anal Bioanal Chem
DOI 10.1007/s00216-011-5246-2

PAPER IN FOREFRONT

A flow-injection mass spectrometry fingerprinting method for authentication and quality assessment of *Scutellaria lateriflora*-based dietary supplements

Jianghao Sun · Pei Chen

Received: 20 May 2011 / Revised: 5 July 2011 / Accepted: 6 July 2011

Abstract *Scutellaria lateriflora*, commonly known as skullcap, is used as an ingredient in numerous herbal products. However, it has been occasionally adulterated/contaminated with *Teucrium canadense* and/or *Teucrium chamaedrys*, commonly known as germander, due to the morphological similarities between the two genera. The latter contains hepatotoxic diterpenes. Despite the potential

blind, placebo-controlled, cross-over study of healthy adults (n=19) revealed that SL provided dose-dependent reduction of symptoms of anxiety and tension after acute administration of SL compared with the control [6]. Previous studies have suggested that its modulation of γ-aminobutyric acid (GABA) and serotonin receptors may be partially responsible for SL's putative effects [6–8].

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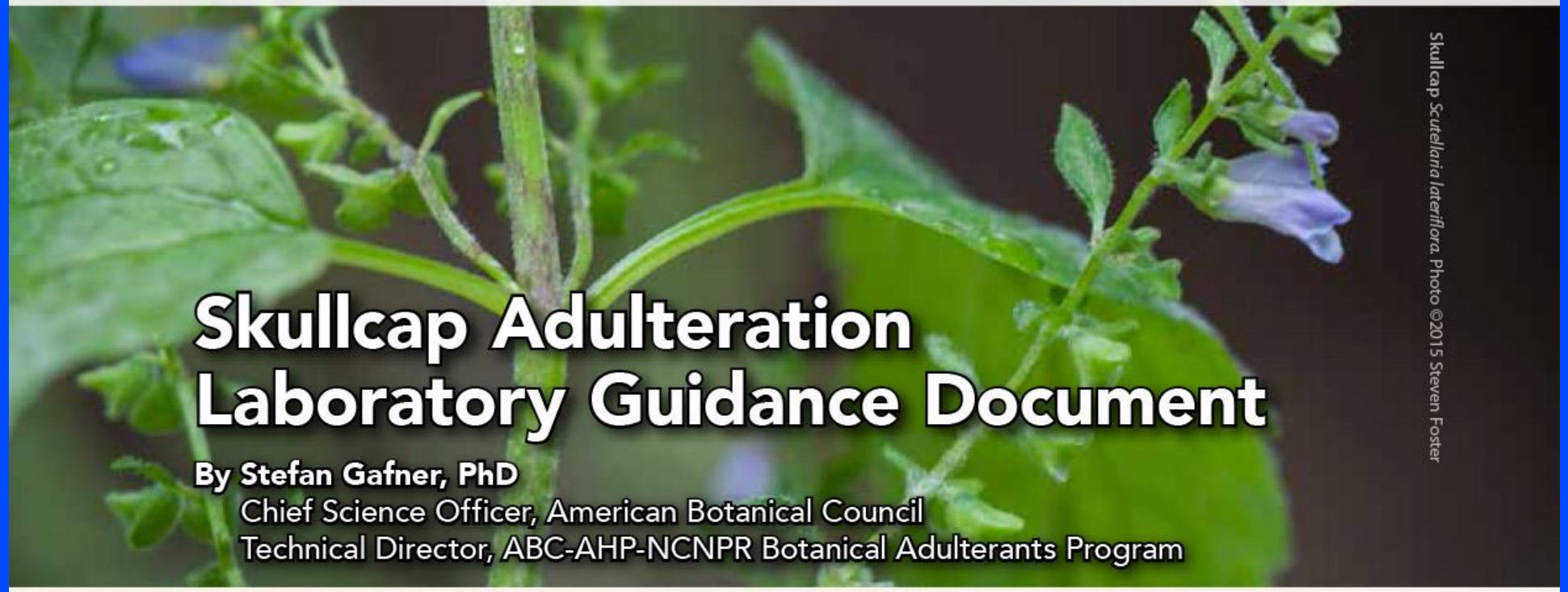


Skullcap Adulteration Laboratory Guidance Document

By Stefan Gafner, PhD
Chief Science Officer, American Botanical Council
Technical Director, ABC-AHP-NCNPR Botanical Adulterants Program

1. Purpose

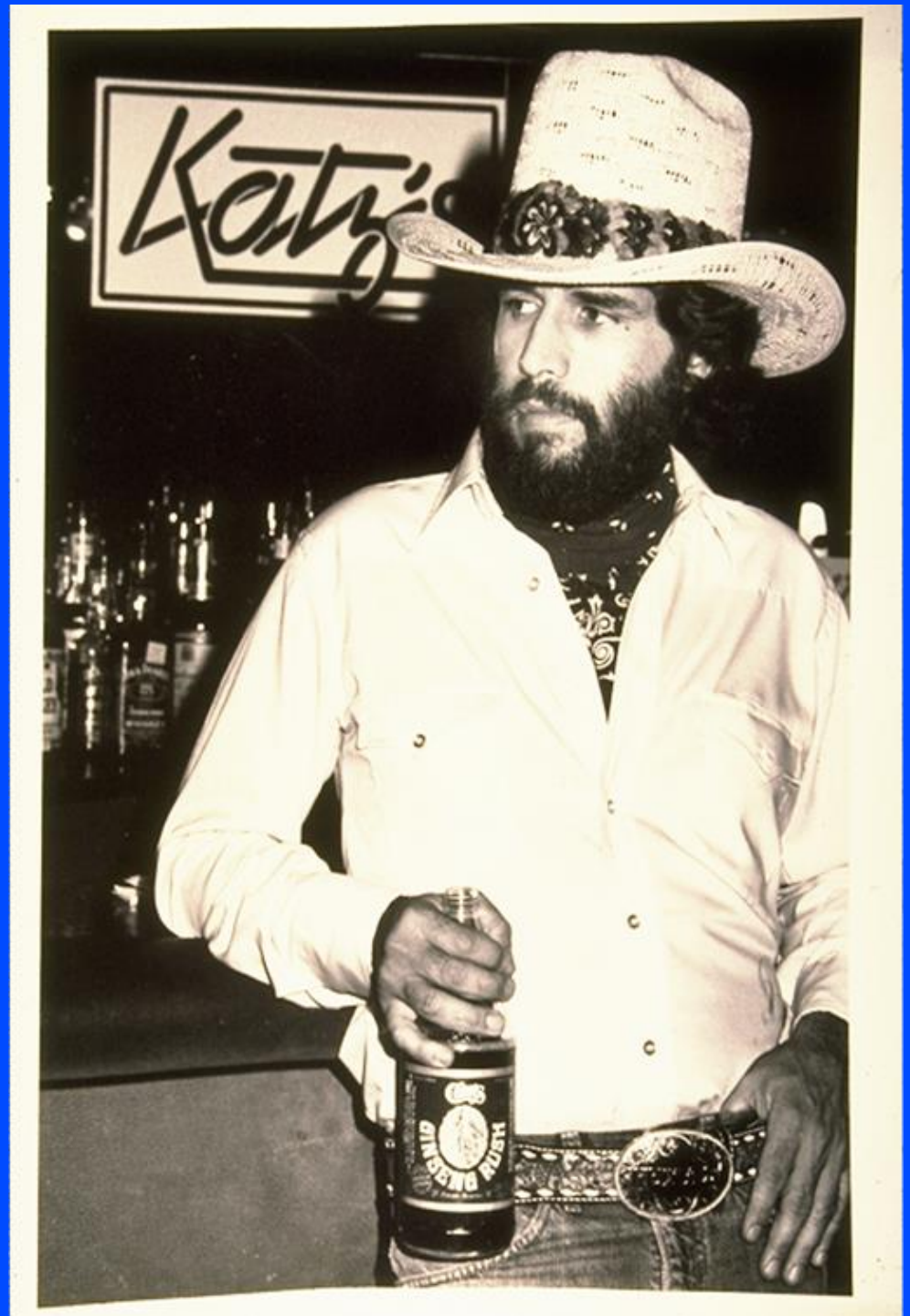
Skullcap (*Scutellaria lateriflora*, family Lamiaceae) herb has a long history of adulteration, evidenced in comments from over 100 years ago by Felter and Lloyd that "*Scutellaria versicolor* Nuttall and *Scutellaria canescens* Nuttall are the species generally collected by herbalists and substituted for *Scutellaria lateriflora*."[1] Besides the substitutions with other species from the genus *Scutellaria*, adulteration with germander (*Teucrium*) species containing hepatotoxic furano neo-clerodane diterpenes has been reported in the early 1990s and seems to persist in the herb trade in North America and possibly elsewhere.[2] This Laboratory Guidance Document presents a review of the various publicly-available analytical technologies and methods used to differentiate between authentic *S. lateriflora* and its potentially adulterating species, listed in Table 1.

2. Scope

“The Ugly”

Intentional Adulteration

= Fraud


Katy's
GOLD RUSH

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BOTANICAL ADULTERANTS BULLETIN

on Bilberry (*Vaccinium myrtillus*) Extracts

By Stefan Gafner, PhD*
*Corresponding author: email

Keywords: *Vaccinium myrtillus*, bilberry extract, adulterant, adulteration

Goal: The goal of this bulletin is to provide information and/or updates on issues of adulteration of bilberry extract to the international herbal industry and extended natural products community in general. It is intended to complement the previously published works with information on bilberry extract adulteration, e.g., the *American Herbal Pharmacopeia* monograph published by Upton et al,[1] and the article by Foster and Blumenthal in *HerbalGram*[2] by presenting new data on the occurrence of adulteration, the market situation, and consequences for the consumer and the industry.

1 General Information

#14 top-ranked herbal DS in US in mainstream market in 2012

The Adulteration of Commercial Bilberry Extracts

By Steven Foster and Mark Blumenthal

Editor's note: *This paper is part of the series being published under the aegis of the ABC-AHP-NCNPR Botanical Adulterants Program, an educational program led by the American Botanical Council, the American Herbal Pharmacopoeia, and the National Center for Natural Products Research at the University of Mississippi. The Program is financially supported and/or endorsed by a coalition of herb and dietary supplement industry members,*

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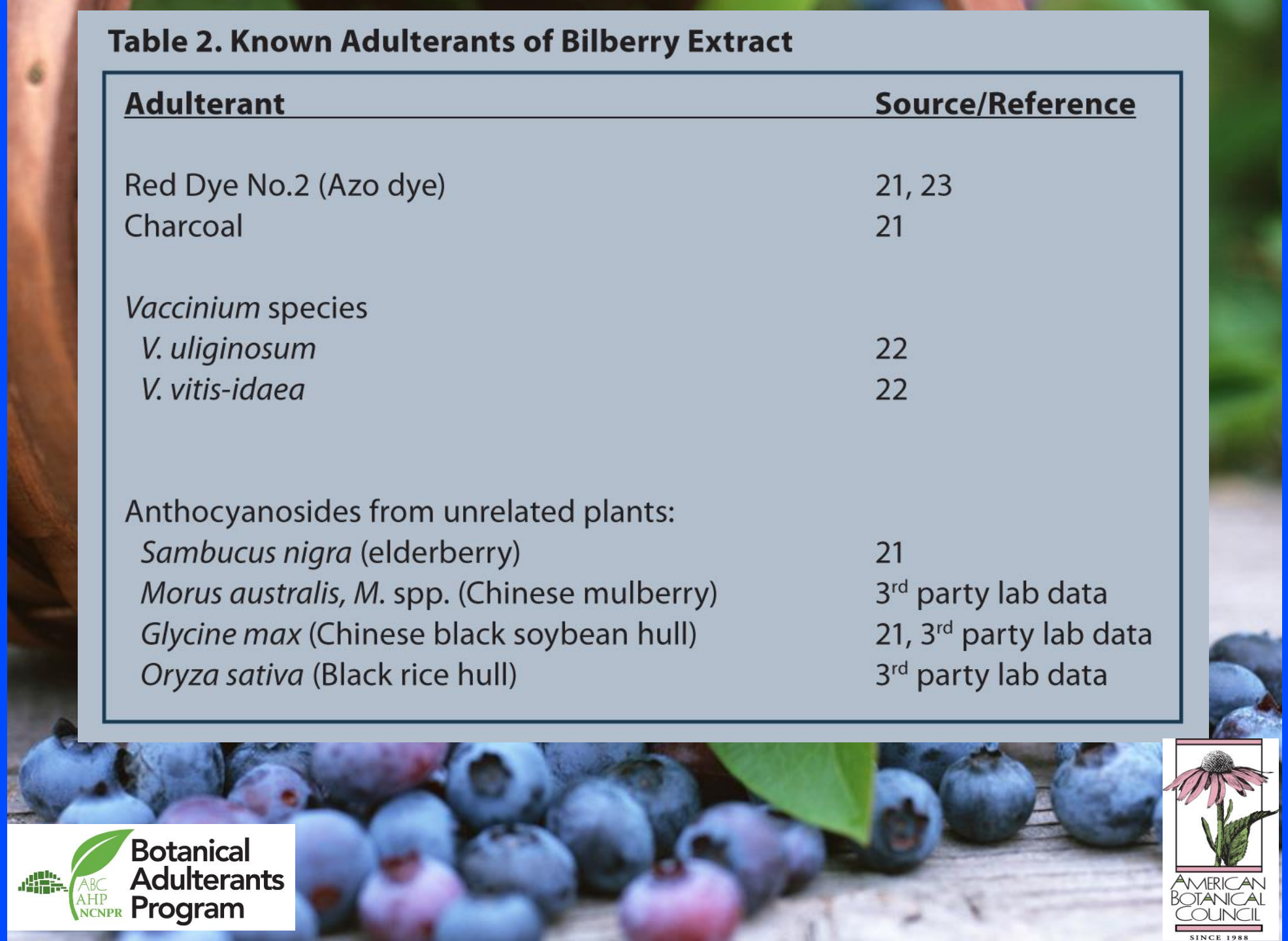
Table 2. Known Adulterants of Bilberry Extract

Adulterant	Source/Reference
Red Dye No.2 (Azo dye)	21, 23
Charcoal	21
Vaccinium species	
V. uliginosum	22
V. vitis-idaea	22
Anthocyanosides from unrelated plants:	
Sambucus nigra (elderberry)	21
Morus australis, M. spp. (Chinese mulberry)	3rd party lab data
Glycine max (Chinese black soybean hull)	21, 3rd party lab data
Oryza sativa (Black rice hull)	3rd party lab data



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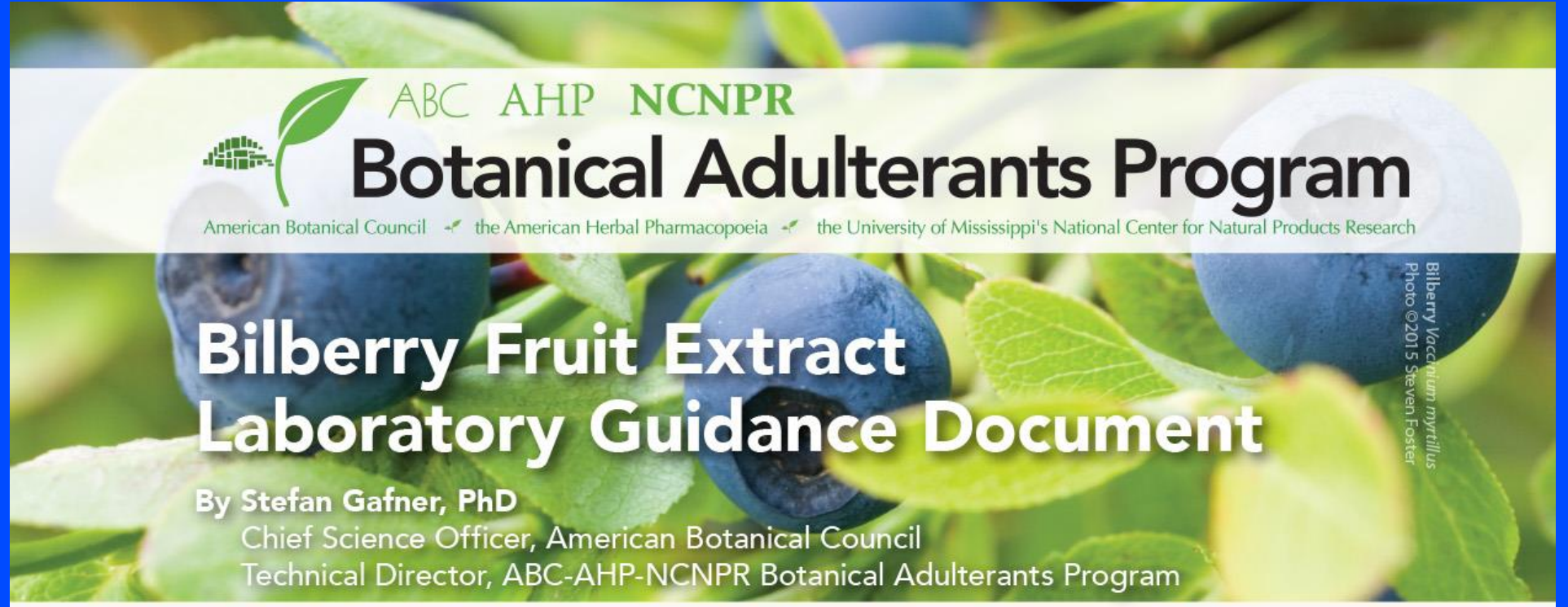

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Bilberry *Vaccinium myrtillus*
Photo ©2015 Steven Foster

Bilberry Fruit Extract Laboratory Guidance Document

By Stefan Gafner, PhD
Chief Science Officer, American Botanical Council
Technical Director, ABC-AHP-NCNPR Botanical Adulterants Program

1. Purpose

Market demand for bilberry (*Vaccinium myrtillus*, Ericaceae) fruit extracts, combined with high prices and falling profit margins have resulted in unscrupulous manufacturers selling various ingredients labeled "bilberry extract." Adulteration predominantly occurs with anthocyanin-rich extracts from other species, e.g., bog bilberry (*V. uliginosum*), lingonberry (*V. vitis-idaea*), European elder (*Sambucus nigra*, Adoxaceae), and Chinese mulberry (*Morus australis*, Moraceae). Additional adulterants reportedly include black soybean (*Glycine max*, Fabaceae) hull or black rice (*Oryza sativa*, Poaceae) extracts, and synthetic colorants like amaranth dye, an azo dye prohibited for use by the United States Food and Drug Administration (FDA) as a suspected carcinogen, and/or charcoal.[1] This Laboratory Guidance Document presents a review of the various analytical technologies and methods used to differentiate between authentic bilberry extracts and potential adulterants.

2. Scope

Previous pharmacopeial test methods for bilberry fruit extract based on UV/Vis absorption of the extract (spectrophotometric methods) are acceptable for quantification of total anthocyanidins, but have proven insufficient to detect adulteration with anthocyanin-rich extracts from other species or synthetic dyes; therefore, other analytical techniques must be used to comply with the legal requirement (for example, according to the Good Manufacturing Practice rule in the United States, and in other countries) to confirm the identity of bilberry fruit extracts. This review is a compilation of published analytical methods for bilberry fruit extracts, and an evaluation of the utility of each method to authenticate bilberry extracts or to detect potential adulterants. This Laboratory Guidance Document *does not cover the analysis of bilberry leaves or bilberry leaf extracts* but may have applications for other anthocyanin-rich berry ingredients, some of which

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on Adulteration of *Actaea racemosa*

By Stefan Gafner, PhD*
American Botanical Council, PO Box 144345, Austin, TX 78723
*Corresponding author: email

Keywords: Adulterant, adulteration, black cohosh, *Actaea cimicifuga*, *Actaea dahurica*, *Actaea heracleifolia*, *Actaea racemosa*, Chinese cimicifuga, *Cimicifuga racemosa*

Goal: The goal of this bulletin is to provide timely information and/or updates on issues of adulteration of black cohosh (*Actaea racemosa*, Ranunculaceae) to the international herbal industry and extended natural products community in general. It is intended to complement the previously published works with information on black cohosh adulteration, e.g., the American Herbal Pharmacopeia monograph published by Upton et al.,[1] and the review paper by Foster,[2] by presenting new data on the occurrence of adulteration, the market situation, and consequences for the consumer and the industry.

1 General Information

1.1 Common name: black cohosh[3]

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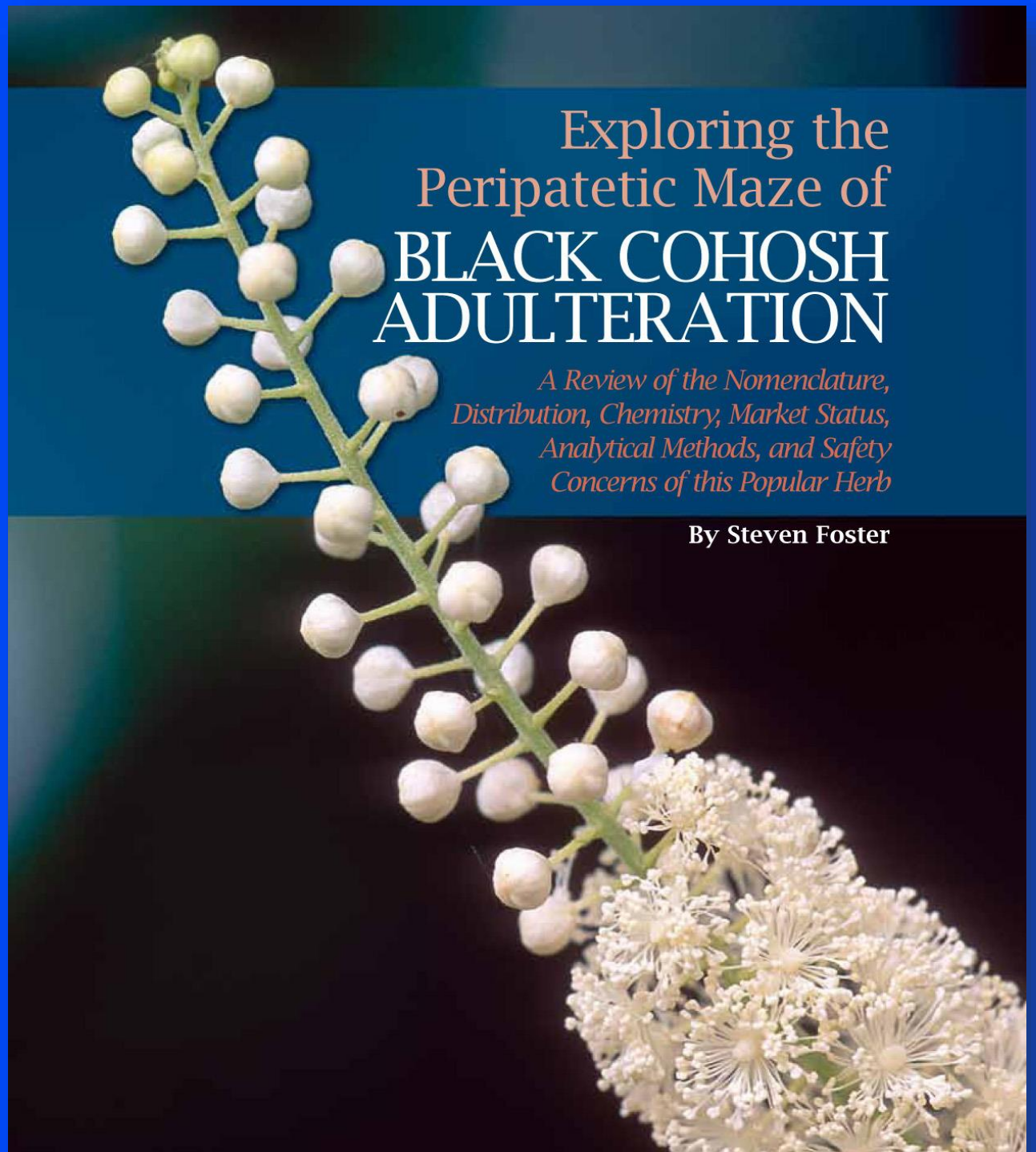
Black Cohosh: #6 selling herbal DS in US in 2015 in mainstream retail stores.



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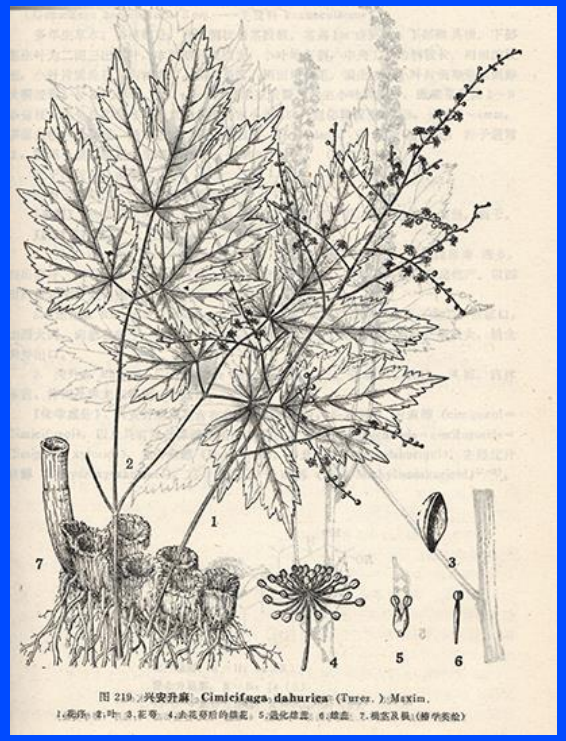
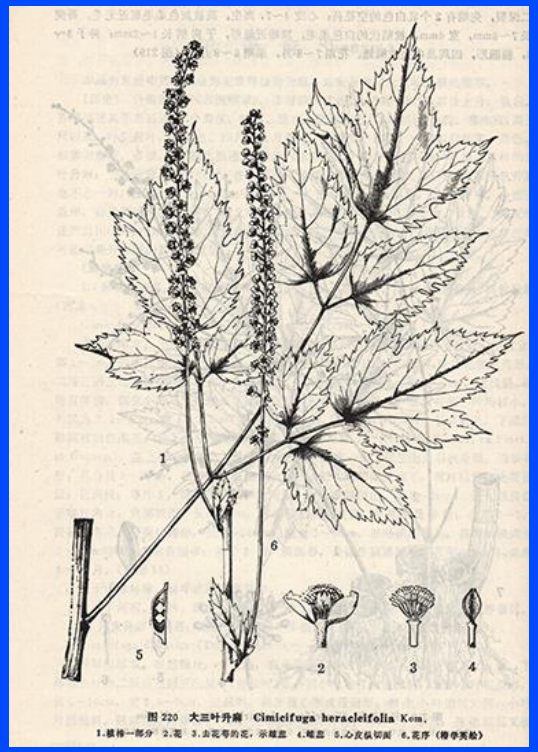
Black Cohosh Adulterants
Chinese cimicifuga • Sheng ma



Actaea dahurica
Xing an sheng ma

Actaea cimicifuga
Sheng ma



Actaea heracleifolia
Da san ye sheng ma

Botanical Adulterants Program

American Botanical Council

"Certificate of Ambiguity"

Actual "Certificate of Analysis" from US ingredient supplier selling Chinese Actae root/rhizome as "Black Cohosh"

CERTIFICATE OF ANALYSIS

Lot #: 1009547 **Black Cohosh Root** **Powder**

Product Characteristic	Specification
Botanical Name	*Cimicifuga racemosa* L.
Plant Part	Roots and rhizomes
Description	Powder: Dark brown
Preservative	None
Country of Origin	China
Treatment	Steam
Manufacturing Date	September, 2010
Expiration Date	September, 2013

JOURNAL OF AGRICULTURAL AND FOOD CHEMISTRY

Evaluation of the Botanical Authenticity and Phytochemical Profile of Black Cohosh Products by High-Performance Liquid Chromatography with Selected Ion Monitoring Liquid Chromatography–Mass Spectrometry

BEI JIANG,[†] FREDI KRONENBERG,[†] PAIBOON NUNTANAKORN,[‡] MIN-HUA QIU,[§] AND EDWARD J. KENNELLY*,[‡]

The Richard and Hinda Rosenthal Center for Complementary & Alternative Medicine, Department of Rehabilitation Medicine, College of Physicians & Surgeons, Columbia University, New York, New York 10032, Department of Biological Science, Lehman College and The Graduate Center, City University of New York, Bronx, New York 10468, and State Key Laboratory of Phytochemistry and Plant Resource in West China, Kunming Institute of Botany, The Chinese Academy of Sciences, Kunming 650204, Yunnan, People's Republic of China

Black cohosh (*Actaea racemosa* L., syn. *Cimicifuga racemosa* L.) has become increasingly popular as a dietary supplement in the United States for the treatment of symptoms related to menopause,

Profile of Black Cohosh Products by High-Performance Liquid Chromatography with Selected Ion Monitoring Liquid Chromatography–Mass Spectrometry

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Black cohosh (*Actaea racemosa* L., syn. *Cimicifuga racemosa* L.) has become increasingly popular as a dietary supplement in the United States for the treatment of symptoms related to menopause, but the botanical authenticity of most products containing black cohosh has not been evaluated, nor is manufacturing highly regulated in the United States. In this study, 11 black cohosh products were analyzed for triterpene glycosides, phenolic constituents, and formononetin by high-performance liquid chromatography–photodiode array detection and a new selected ion monitoring liquid chromatography–mass spectrometry method. Three of the 11 products were found to contain the marker compound cimifugin and not cimiracemoside C, thereby indicating that these plants contain Asian *Actaea* instead of black cohosh. One product contained both black cohosh and an Asian *Actaea* species. For the products containing only black cohosh, there was significant product-to-product variability in the amounts of the selected triterpene glycosides and phenolic constituents, and as expected, no formononetin was detected.

KEYWORDS: Black cohosh; dietary supplements; quality control; triterpene glycosides; phenolic constituents; formononetin; *Actaea racemosa*; *Cimicifuga racemosa*; Asian *Actaea* species

Species Misidentification in Black Cohosh Products in Canada

Robin J. Marles[1], Semir Omar[1], Scott Jordan[2], Mano Murty[2], Shahid Perwaiz[2], Richard Bertrand[3], Pauline Lacroix[4]
[1]Natural Health Products Directorate, [2]Marketed Health Products Directorate, [3]Inspectorate Laboratory Quebec Region, [4]Health Products and Food Branch Inspectorate
Health Products and Food Branch, Health Canada, Ottawa, ON, CANADA K1A 0K9

Introduction

Black cohosh, *Actaea racemosa* L. (synonym: *Cimicifuga racemosa* (L.) Nutt.), Ranunculaceae, is an indigenous North American herb whose root has a long history of traditional medicinal use by native peoples for a variety of purposes including for rheumatism, [illegible], childbirth and for relieving pain during menstruation. Black cohosh extracts have been used in herbal clinical practice for symptoms of menopause safely and effectively.[1,2] In Canada, each natural health product (NHP) / dietary supplement must undergo mandatory pre-market assessment of the evidence for its safety, efficacy and quality before a licence is issued authorizing it to be sold legally. Each manufacturer, importer, packager and labeller must obtain a site licence issued on the basis of evidence of compliance with the Good Manufacturing Practices requirements set out in the Natural Health Products Regulations.[4] To date, Health Canada has licensed at least 78 NHPs containing black cohosh[5] and there are additional unauthorized products on the market yet to be brought into compliance with the NHP Regulations. Of concern is the growing number of serious adverse reaction reports associated with products labelled as containing black cohosh, of which there are at least 83 cases of hepatotoxicity worldwide, although causality is controversial.[6-8] Health Canada has obtained samples of 3 products labelled to contain black cohosh that were associated with domestic serious hepatotoxicity adverse reaction reports with suspected and in one case probable causality. We report here results of laboratory analyses and subsequent steps to mitigate the risks to consumers.

Methods and Materials

Chemicals and Reagents:

HPLC grade acetonitrile (J. T. Baker), methanol (J. T. Baker), trifluoroacetic acid (Aldrich), ethanol (Commercial Alcohol Inc.) and water (Nanopure) were used for sample preparation, LC-MS analysis.

Black Cohosh Products:

The same lots of the black cohosh products as those associated with the probable adverse reactions[4] were obtained both from retail outlets and from the manufacturer (numbers correspond to products in Table 2):

1. Swiss Herbal Black Cohosh 100 mg: Black cohosh (*Actaea racemosa*) 15:1 root extract 2.5% triterpenoids 20 mg, Black cohosh (*Actaea racemosa* L.) root powder 80 mg.

2. Swiss Herbal Menopause Natural HRT Regular: Black cohosh (*Actaea racemosa*) 15:1 root extract 2.5% triterpenoids 30 mg, Novasoy® Soy (*Glycine max*) bean extract 40% isoflavones 50 mg, Dong quai (*Angelica sinensis*) 12:1 root extract 1% ligustilide 100 mg, Chaste tree (*Vitex agnus-castus*) 10:1 berry extract 100 mg, Wild yam (*Dioscorea villosa*) 2:1 root extract 6% diosgenin 50 mg, Burdock (*Arctium lappa*) 4:1 root extract 0.3% chlorogenic acid 50 mg.

3. Swiss Herbal Menopause Natural HRT Nighttime: Black cohosh (*Actaea racemosa*) 15:1 root extract 2.5% triterpenoids 100 mg, Passionflower (*Passiflora incarnata*) 6:1 flower extract 3.5% isovitexin 150 mg, Lemon Balm (*Melissa officinalis*) 8:1 leaf extract 5% rosmarinic acid 300 mg.

4. Swiss Herbal Menopause Natural HRT Extra Strength: Black cohosh (*Actaea racemosa*) 15:1 root extract 2.5% triterpenoids 100 mg, Novasoy® Soy (*Glycine max*) bean extract 40% isoflavones 100 mg, Chaste tree (*Vitex agnus-castus*) 10:1 berry extract 200 mg, Wild yam (*Dioscorea villosa*) 2:1 root extract 6% diosgenin 100 mg, Burdock (*Arctium lappa*) 4:1 root extract 0.3% chlorogenic acid 100 mg.

Standards and Controls:

Actein (99.30 % purity) [1], 23-epi-26-deoxyactein (97.60 % purity) [2], and black cohosh powder (100 % purity) reference standards were obtained from the U.S. Pharmacopeia, Maryland, USA; cimiracemoside C (96.70 % purity) [3] and cimifugin (96.10 % purity) [4] were purchased from ChromaDex (Santa Ana, CA).

Sample Preparation for the Analysis of Phytochemicals:

USP Powdered Black Cohosh 39.354 mg was dissolved in 1 mL of methanol, vortexed for 5 min., sonicated for 10 min., again vortexed for 5 min., then filtered using 0.45 µm PP Dynagard prior to injection into the LC-MS.

Black cohosh marketed products: 10 capsules were dissolved in 20 mL of methanol with mechanical agitation for 20 min., sonicated for 30 min., again mechanically agitated for 20 min, then filtered using filter paper number 40. The filtered solution was evaporated and concentrated to 1 mL under reduced pressure of nitrogen gas at 35°C. The concentrated solution was filtered using 0.45 µm PP Dynagard and concentrated to 0.25 ml under reduced pressure of nitrogen gas at 35°C. The filtered concentrated sample was then analyzed for phytochemical markers by LC-MS.

Instrumentation:

LC-MS with a Waters 2690 separation module equipped with a 996-photodiode array detector (PDA). Column was a 250 mm × 4.6 mm i.d., 5 µm, Waters YMC ODS-AQ at 30°C, flow rate 1.4 mL/min., with flow splitter 0.4 mL/min on PDA and MS; 100 min. run time. Sample volume injected was 20 µL, and data were analyzed at 205 nm. Mobile phase consisted of water (A), trifluoroacetic acid (0.05%) (B) and acetonitrile (C); gradient profile for mobile phase was: 0-8 min, 0 %(A), 80% (B) and 20 % (C); 8-8.1 min, 0-68 % (A), 80-0% (B) and 20-32 % (C); 8.1-15 min, 68 % (A), 0% (B) and 32 % (C); 15-55 min, 68-36 % (A), 0% (B) and 32-64 %(C); 55-65 min, 36-5 % (A), 0% (B) and 64-95 % (C);65-70 min, 5 % (A), [illegible] % (B) and 20 % (C). [illegible] monograph for Black [illegible]

[illegible] Electro[illegible] 275.0°C, nebulizer [illegible] Signal gain was set [illegible] LC-MS in both full [illegible] -26-deoxyactein and [illegible]

Results

[1]

Actein

[2]

23-epi-26-Deoxyactein

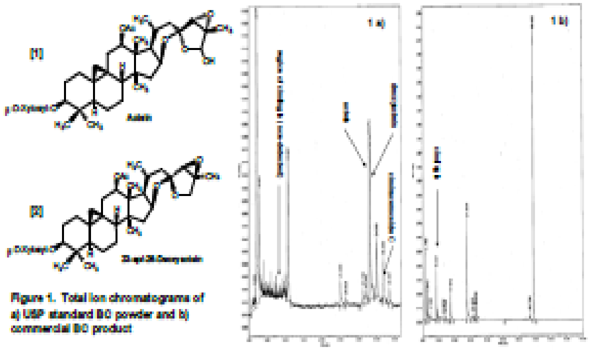

Figure 1. Total ion chromatograms of a) USP standard BC powder and b) commercial BC product

[3]

Cimiracemoside C

[4]

Cimifugin

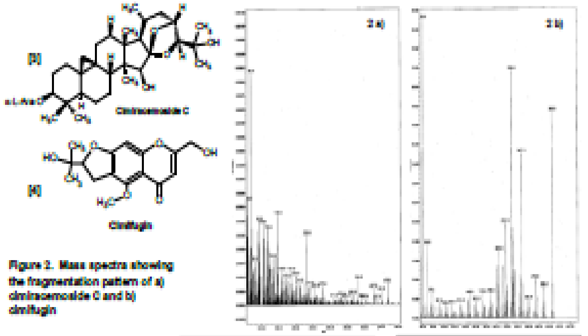

Figure 2. Mass spectra showing the fragmentation pattern of a) cimiracemoside C and b) cimifugin

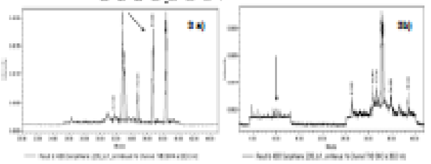

Figure 3. Representative single ion chromatograms of USP BC reference powder (SIM mode) showing a) presence of cimiracemoside C (383 m/z, 56.7 min.) and b) absence of cimifugin (306 m/z, 8.73 min.)

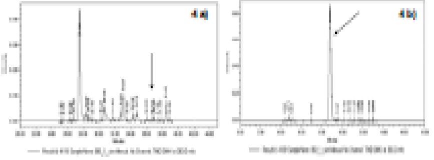

Figure 4. Representative single ion chromatograms of commercial BC product showing a) absence of cimiracemoside C (383 m/z, 56.7 min.) and b) presence of cimicifugin (306 m/z, 8.73 min.)

Table 2. Results of the LC-MS phytochemical analyses

Sample	Presence of Actein	Presence of 23-epi-26-Deoxyactein	Presence of Cimiracemoside C	Presence of Cimicifugin	Identification by Markers[34,35]

Discussion

Phytochemical Markers for the Identification of Black Cohosh in Marketed Products:

While several *Actaea* species contain both actein and 23-epi-26-deoxyactein, authentic *A. racemosa* can be distinguished by its content of cimiracemoside C and not cimifugin. [illegible]

Health Canada followed up with all other black cohosh product licence holders and found that 52 licensees were deemed to have used an appropriate identification method, 7 licensees requested cancellation of their licence, 5 licensees did not provide sufficient data to render a decision and are subject to further compliance actions, 2 licensees did not respond to the request for identity data and are subject to further compliance actions, and 11 licensees used the same third party laboratory which was using an unvalidated method giving false positive results. Those lots found to be adulterated were recalled.[illegible] Corrective steps have been validated by the Inspectorate. The implicated Swiss Herbal and other manufacturers' products tested since these corrective steps were taken have been confirmed to contain authentic black cohosh.

Alternative Methods for Unambiguous Identification of Authentic Black Cohosh:

[illegible]

Photo: Missouri Botanic Garden

Actaea racemosa Linnaeus, Sp. Pl. 1: 504. 1753

[illegible]

Photo: Montreal Botanic Garden

Relationship Between Black Cohosh and Hepatotoxicity:

[illegible]

Conclusions

[illegible]

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Botanical Adulterants Program
American Botanical Council · the American Herbal Pharmacopoeia · the University of Mississippi's National Center for Natural Products Research

Black Cohosh Laboratory Guidance Document

By Stefan Gafner, PhD
Chief Science Officer, American Botanical Council
Technical Director, ABC-AHP-NCNPR Botanical Adulterants Program
Contact: stefan@herbalgram.org

Keywords: Adulterant, adulteration, black cohosh, *Actaea cimicifuga, Actaea dahurica, Actaea heracleifolia, Actaea racemosa,* Chinese cimicifuga, *Cimicifuga racemosa*

1. Purpose

In recent years, adulteration of black cohosh (*Actaea racemosa*, Ranunculaceae) roots and rhizomes has become more apparent. Adulteration predominantly occurs with Chinese species of *Actaea* such as *A. heracleifolia*, *A. dahurica*, and *A. cimicifuga* (all known by the common name Chinese cimicifuga and by the Chinese name of *sheng ma*). Additionally, the Chinese cimicifuga (*sheng ma*) market is commonly adulterated with *Serratula chinensis* (*guang dong sheng ma* [Asteraceae]). Adulteration has also been reported with North American *Actaea* species growing in the same area as black cohosh, such as *A. pachypoda*, *A. rubra*, and *A. podocarpa*. This Laboratory Guidance Document presents a review of the various analytical technologies used to differentiate between authentic *A. racemosa* and its potentially adulterating species.

2. Scope

The various analytical methods were reviewed with the specific purpose of identifying strengths and limitations of the existing methods for differentiating *A. racemosa* from its potentially adulterating species. Analysts can use this review to help guide the appropriate choice of techniques for their specific black cohosh products for qualitative purposes. The recommendation of a specific method for testing *A. racemosa* materials in their particular matrix in this Laboratory Guidance Document does not

Black Cohosh LGD Outline - 1

1. Purpose
2. Scope
3. Common & scientific names
    - 3.1 Common Name
    - 3.2 Other Common Names
    - 3.3 Latin Binomial
    - 3.4 Synonyms
    - 3.5 Botanical Family
4. Botanical Description
5. Identification & Distinction using Macroanatomical Characteristics
6. Identification & Distinction using Microanatomical Characteristics
7. Genetic Identification & Distinction
8. Chemical Identification & Distinction
    - 8.1 Chemistry of *Actaea racemosa* & the Potential Adulterants
    - 8.2 Laboratory Methods
        - *8.2.1 HPTLC*
        - *8.2.2 HPLC and UHPLC*
        - 8.2.3 MS-Fingerprinting
        - 8.2.4 NMR
9. Conclusion

Botanical Adulterants Program

Black Cohosh LGD Outline -2

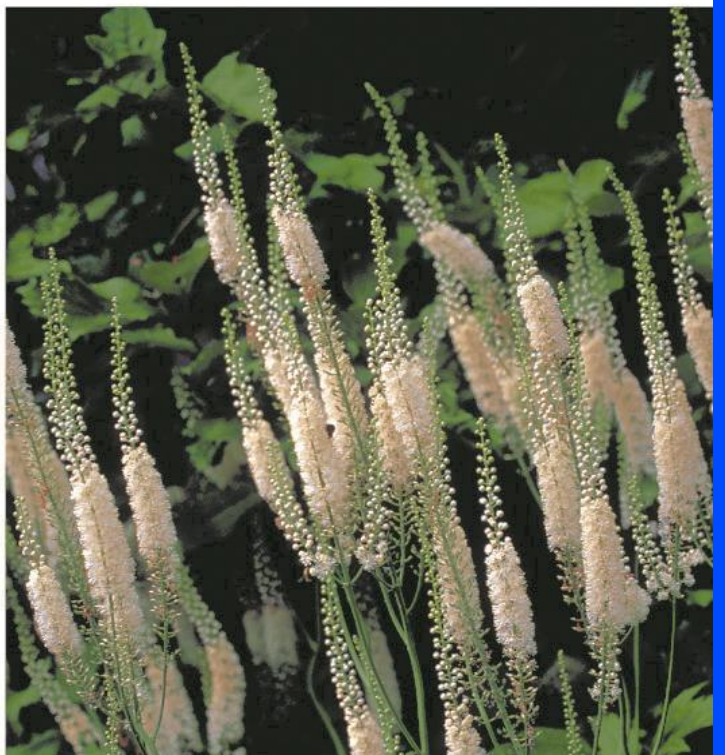
- Table 1. Scientific names, family, and common names of known black cohosh adulterants
- Table 2. Nomenclature of major triterpene glycosides from *A. racemosa* according to Qiu et al.
- Table 3. Comparison among the different approaches to authenticate *A. racemosa*
- Table 4. Comments on the published HPLC methods for *A. racemosa*

American Herbal Pharmacopoeia™
and Therapeutic Compendium

Black Cohosh Rhizome

Actaea racemosa L.
syn. *Cimicifuga racemosa* (L.) Nutt.

Standards of Analysis, Quality Control, and Therapeutics



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Determining Appropriate, Fit-for-Purpose Testing Methods: *Laboratory Guidance Documents*

Type of test	*Scutellaria lateriflora*	*Actaea racemosa*	*Vaccinium myrtillus*
Macroscopic evaluation	1	1	1
Microscopy	1	1	1
Genetic	2	2	0
TLC/HPTLC	3	8	7
HPLC/UHPLC	13	21	26
Direct MS	1	2	0
NMR	1	1	0
UV/Vis	0	0	4
Total	22	36	39
Number of reviewers	21	20	16

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BOTANICAL ADULTERANTS BULLETIN

on Adulteration of *Hydrastis canadensis* root and rhizome

By Michael Tims, PhD
Maryland University of Integrative Health, 7750 Montpelier Road, Laurel, MD 20723

Correspondence: e-mail

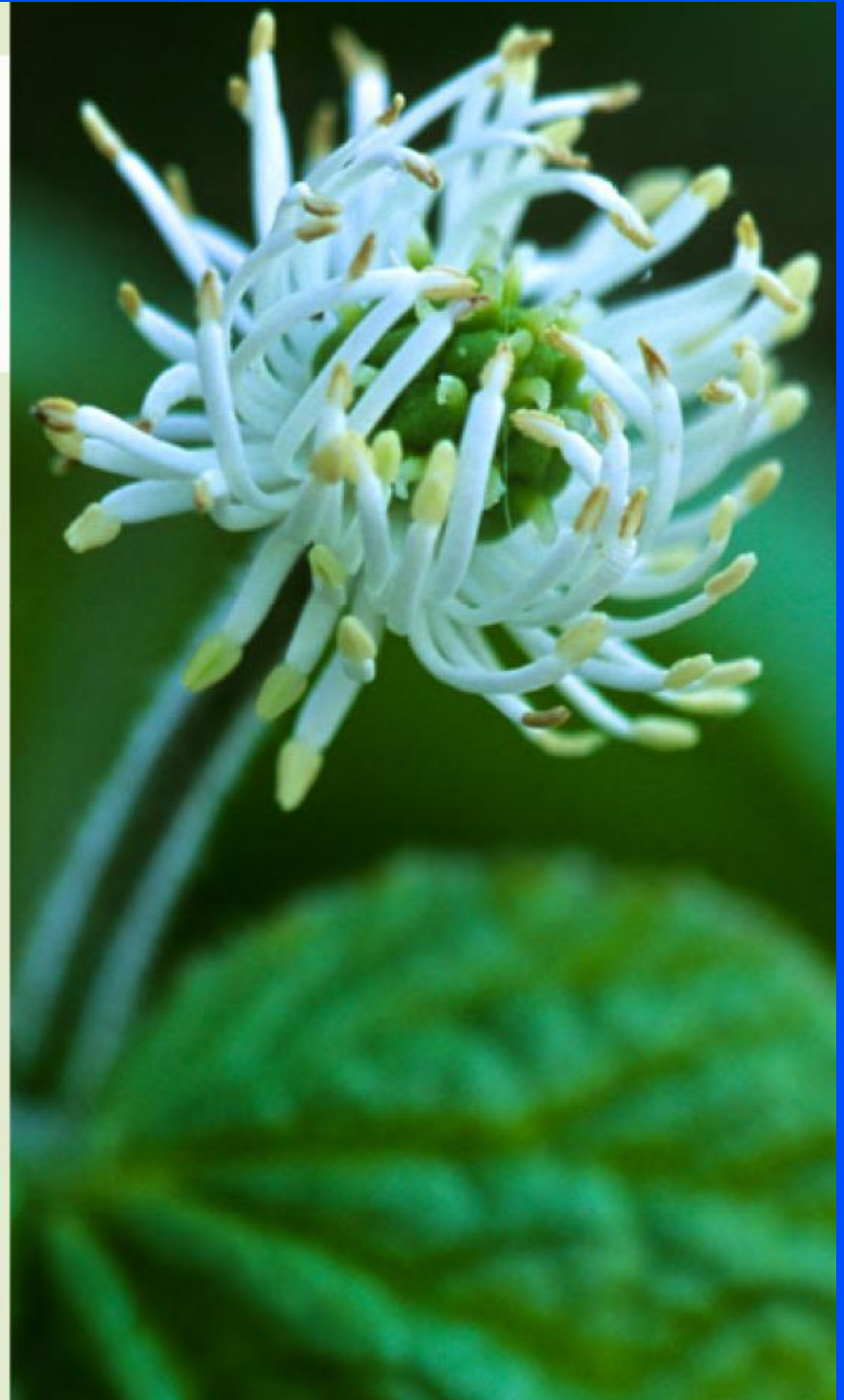
Keywords: *Hydrastis canadensis*, goldenseal root, adulterant, adulteration

Goal: The goal of this bulletin is to provide information and/or updates on issues regarding adulteration of goldenseal *(Hydrastis canadensis)* root to the international herbal industry and extended natural products community in general. It is intended to present the available data on occurrence of adulteration, the market situation, and consequences for the consumer and the industry.

1 General Information

1.1 Common name: Goldenseal[1,2]

1.2 Other common names:



Goldenseal Root

Hydrastis canadensis

http://b-and-t-world-seeds.com/images/63866.jpg

http://www.hardingsginsengfarm.com/images/hydrastis_canadensis-centre-aug2003c.jpg

Chinese Goldthread

Coptis chinensis

http://www.stchn.com/uploadfile/2007/1130174356346 74.jpg

http://www.itmonline.org/image/impet2.jpg

http://image.made-in china.com/2f0j00gBCEvMkcADqb/Coptis-Rhizoma-Coptis-Root-Berberine.jpg

Goldenseal Root Adulteration

Hydrastis canadensis

Historical adulterants	Recent adulterants
Blue cohosh (*Caulophyllum thalictroides*) **Celandine poppy** (*Stylophorum diphyllum*) **Coptis/Gold Thread** (*Coptis* spp.) **European Peony** (*Paeonia officinalis*) **Lady Fern** (*Athyrium filix-femina*) **Small Yellow Lady's Slipper** (*Cypripedium calceolus*) **Stoneroot** (*Collinsonia canadensis*) **Trillium/Birth Root** (*Trillium* spp.) **Twin Leaf** (*Jeffersonia diphylla*) **Seneca Snakeroot** (*Polygala senega*) **Virginia Snakeroot** (*Aristolochia serpentaria*) **Yellow Root** (*Xanthorrhiza simplicissima*)	**Barberry** (*Berberis* spp.) **Celandine** (*Chelidonium majus*) **Japanese Goldthread** (*Coptis japonica*) **Oregon Grape** (*Mahonia aquifolium*) **Yellow Root** (*Xanthorrhiza simplicissima*) **Yellow Dock** (*Rumex* spp.)

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BOTANICAL ADULTERANTS BULLETIN

on Adulteration of Grape Seed Extract

By Steve Kupina[a] and Stefan Gafner, PhD[b*]
[a]Polyphenolics, Madera, CA 93637
[b]American Botanical Council
Technical Director, ABC-AHP-NCNPR Botanical Adulterants Program
*Corresponding author: email

Keywords: *Vitis vinifera*, grape seed extract, adulterant, adulteration

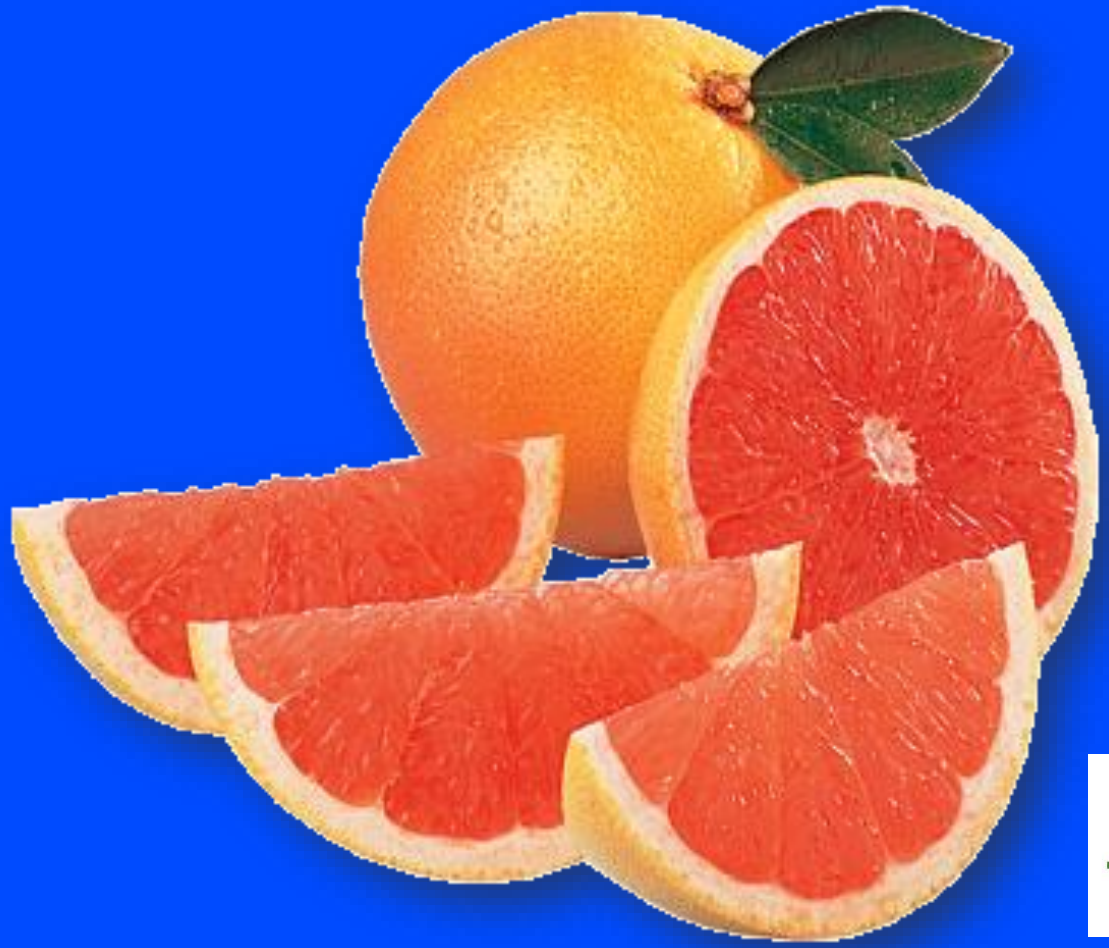
Goal: The goal of this bulletin is to provide timely information and/or updates on issues of adulteration of grape seed extract (GSE†) to the international herbal products industry and extended natural products community in general. It is intended to present the available data on the occurrence of adulteration, the market situation, and consequences for the consumer and the industry.

1 General Information

1.1 Common name: Grape[2]

1.2 Other common names:

Benzethonium chloride and/or Benzalkonium chloride for "Grapefruit Seed Extract"



Botanical Adulterants Program

Identification of Benzethonium Chloride in Commercial Grapefruit Seed Extracts

Gary Takeoka,* Lan Dao, Rosalind Y. Wong, Robert Lundin, and Noreen Mahoney

Western Regional Research Center, Agricultural Research Service, U.S. Department of Agriculture, 800 Buchanan Street, Albany, California 94710

Commercial grapefruit seed extracts (GSE) were extracted with chloroform. The solvent was evaporated, and the resulting solid was subsequently analyzed by high-performance liquid chromatography, electrospray ionization mass spectrometry, nuclear magnetic resonance (NMR) spectroscopy, and elemental analysis (by proton-induced X-ray emission [PIXE] analysis). The main constituent was identified as benzethonium chloride, a synthetic antimicrobial agent commonly used in cosmetics and other topical applications. This compound comprised 8.03% ($n = 2$) of the liquid GSE sample. Higher amounts of benzethonium chloride were found in powder GSE samples.

Keywords: *Benzethonium chloride; grapefruit seed extract; electrospray ionization mass spectrometry; PIXE analysis; antimicrobial activity*

JOURNAL OF AGRICULTURAL AND FOOD CHEMISTRY

Identification of Benzalkonium Chloride in Commercial Grapefruit Seed Extracts

GARY R. TAKEOKA,* LAN T. DAO, ROSALIND Y. WONG, AND LESLIE A. HARDEN

Western Regional Research Center, Agricultural Research Service, U.S. Department of Agriculture, 800 Buchanan Street, Albany, California 94710

Commercial grapefruit seed extracts (GSE) were extracted with chloroform. The solvent was evaporated, and the resulting solid was subsequently analyzed by high-performance liquid chromatography (HPLC), electrospray ionization mass spectrometry (ESI/MS), tandem mass spectrometry (ESI/MS/MS), and elemental analysis (by proton-induced X-ray emission analysis). Three major constituents were observed by HPLC and were identified as benzyldimethyldodecylammonium chloride, benzyldimethyltetradecylammonium chloride, and benzyldimethylhexadecylammonium chloride. This mixture of homologues is commonly known as benzalkonium chloride, a widely used

The Adulteration of Commercial "Grapefruit Seed Extract" with Synthetic Antimicrobial and Disinfectant Compounds

By John H. Cardellina II, PhD

Material called "grapefruit seed extract" (GFSE[1]) has been sold in the natural products market for 3 decades or more as an ingredient in or preservative for cosmetic and dermatological preparations and also in dietary supplements. GFSE, supposedly an extract of the seeds of the common grapefruit (*Citrus* x *paradisi,* Rutaceae), has been touted in popular literature as a natural antimicrobial agent for both topical and internal use, including, but not limited to, eczema, acne, cold sores, athlete's foot, sore throats, thrush, vaginal infections, colds, various gastrointestinal disorders and infections, allergies, and gingivitis.[2,3] Much of the commercially available GFSE is produced via proprietary methods that purportedly involve the use of catalytic processes and the addition of solvents and/or other chemicals. For example, in the case of one of the leading branded consumer products labeled as containing "grapefruit seed extract," this process has not been fully disclosed or explained in any publicly available literature, but is claimed to involve a multistep process that includes boiling ground, dried seeds and pulp in water, then "… distillation, catalytic conversion and ammoniation…"[4] to yield GFSE, the active ingredient of which "…is a quaternary ammonium chloride (a diphenol hydroxybenzene reacted with ammonium chloride) similar to benzethonium chloride…".[4]

In 1991, a collaboration led by Nishina (Food Research Laboratory, Nippon Oil and Fats Co.; Tokyo, Japan) published the first analysis of commercial GFSE and reported that preparative high-performance liquid chromatography (HPLC) led to identification of methyl *p*-hydroxybenzoate, a preservative, and triclosan, a microbicide and disinfectant.[5] Five years later, Sakamoto *et al.*, at the Japanese National Institute of Health Sciences in Tokyo, repeated the analysis of GFSE using HPLC-

ionization mass spectrometry),

GFSE with ethanolic extracts of

d themselves.[6] Like the Nishina

nethyl *p*-hydroxybenzoate and

he GFSE, respectively; perhaps

spectrometry (MS), and nuclear magnetic resonance spectroscopy (NMR). Rather than methyl *p*-hydroxybenzoate and triclosan, they found benzethonium chloride as 8% of the mass of the liquid GFSE sample. Benzethonium chloride was also found in the concentrated powder, but was not quantified. Later, Takeoka *et al.*[9] examined the contents of the same

product analyzed by Nishina *et al.*[5] by HPLC co

ESIMS and ESIMS/MS, but they found no triclo

p-hydroxybenzoate, or benzethonium chloride. I

found a mixture of benzalkonium chlorides as an

22% of the extract weight. These studies prompted

surveys of GFSE preparations and products contain

Avula *et al.* developed an HPLC-UV-MS method for the

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Table 1: Results of Analysis of GFSE Liquid Products by Ganzera *et al.*[11]

Contaminant/Adulterant	No. of products	Range of concentration
methyl *p*-hydroxybenzoate	2 products	9.88-17.89 mg/mL
propyl *p*-hydroxybenzoate	2 products	4.97-9.13 mg/mL
benzethonium chloride	4 products	2.48-176.90 mg/mL
C_{12} benzalkonium chloride	2 products	99.38-167.15 mg/mL
C_{14} benzalkonium chloride	2 products	33.86-69.07 mg/mL
C_{16} benzalkonium chloride	1 product	4.96 mg/mL

Botanical Adulterants Program

Ganzera M, Aberham A, Stuppner H. Development and validation of an HPLC/UV/MS method for simultaneous determination of 18 preservatives in grapefruit seed extract. *J Agric Food Chem*. 2006;54:3768-3772.

Cited in: Cardellina J. The adulteration of commercial "Grapefruit Seed Extract" with synthetic antimicrobial and disinfectant compounds. *HerbalGram* 2012;94:62-66.

American Botanical Council

ts, but 6 of the
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es (Table 1). The
contained methyl
%), benzoic acid
e (0.05%), propyl
%), C_{12} benzalko-
$_{14}$ benzalkonium
$_{16}$ benzalkonium

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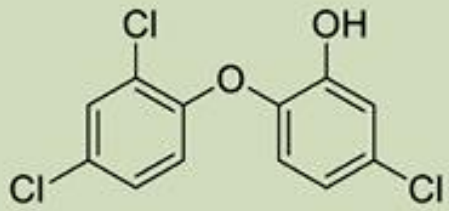
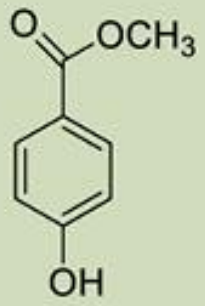
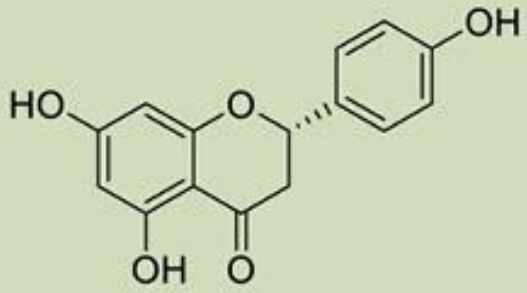
Figure 1. Structures of the Principal Disinfectants/Microbicides Found in Products Labeled "Grapefruit Seed Extract," and the Structure of Naringenin, the Most Abundant Flavonoid in Grapefruit.



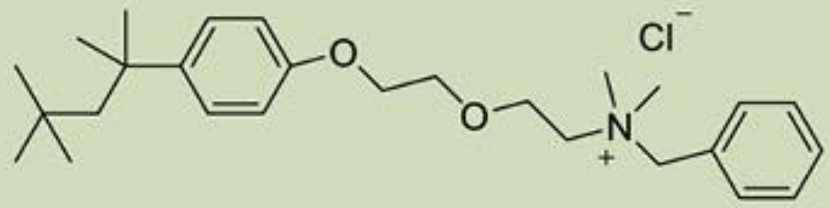
triclosan



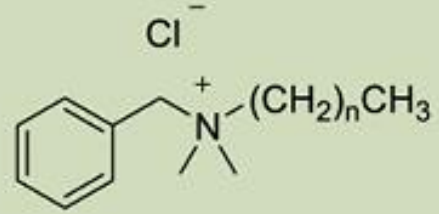
methyl *p*-hydroxybenzoate
(methyl paraben)



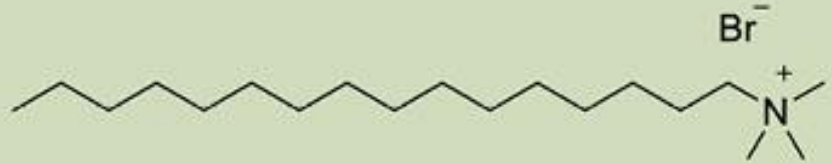
naringenin

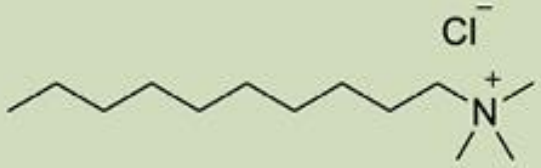


benzethonium chloride



benzalkonium chloride
n = 9, 11, 13 or 15





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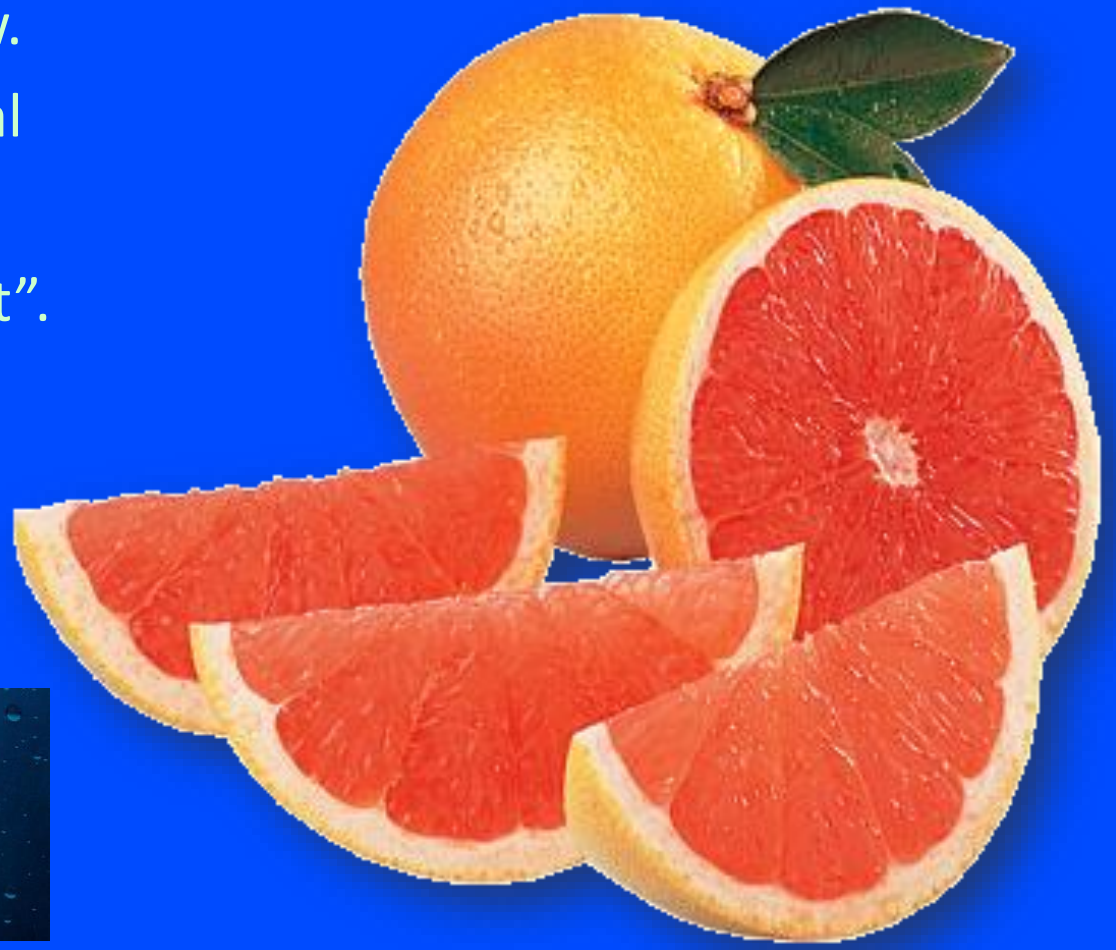
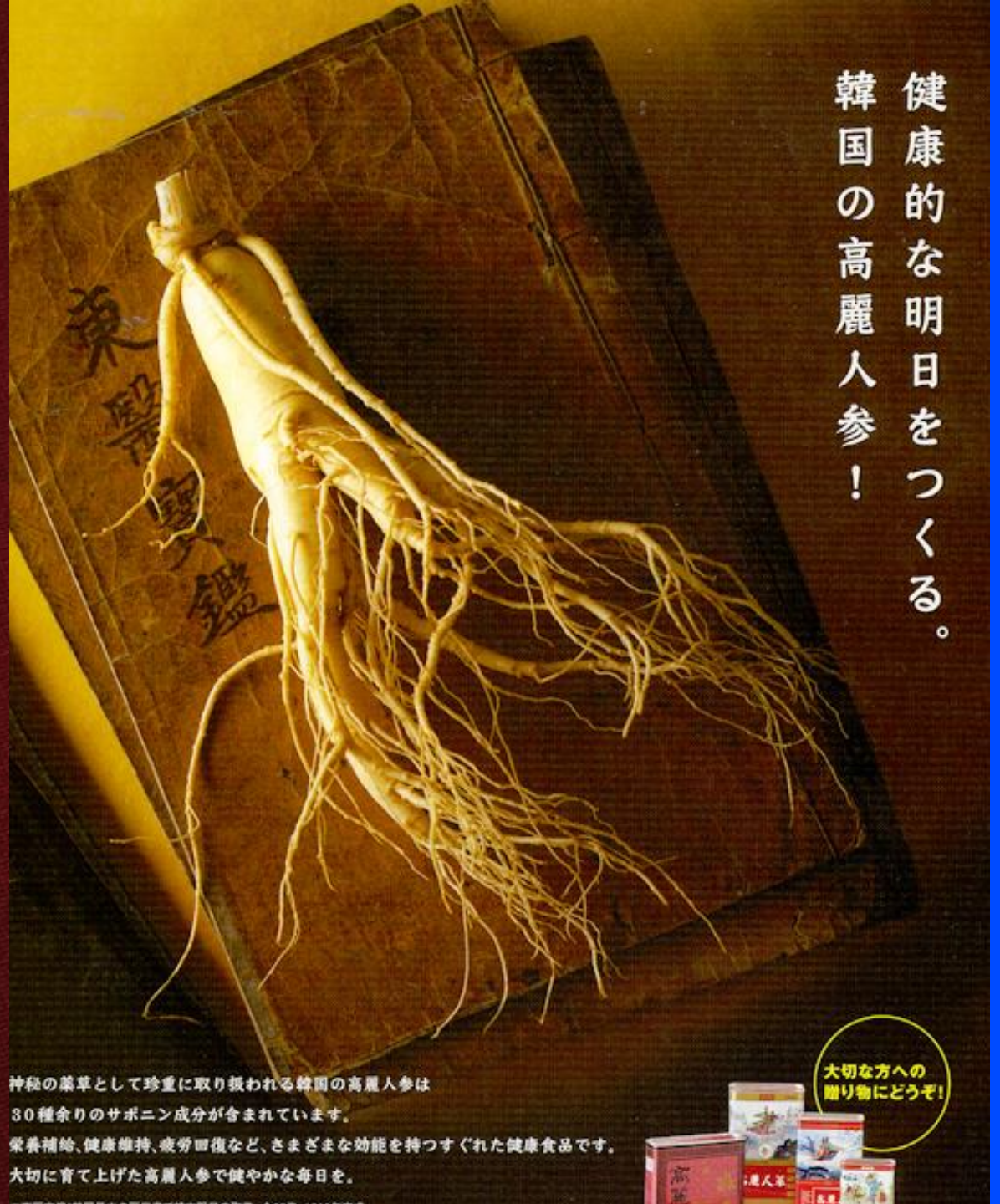
"Grapefruit Seed Extract" *Laboratory Guidance Document*

- Currently in Peer Review.
- There are no compendial methods for so-called "grapefruit seed extract".





神秘の薬草として珍重に取り扱われる韓国の高麗人参は
30種余りのサポニン成分が含まれています。
栄養補給、健康維持、疲労回復など、さまざまな効能を持つすぐれた健康食品です。
大切に育て上げた高麗人参で健やかな毎日を。

大切な方への
贈り物にどうぞ！

Ginseng:
#31 & #33 in sales
in 2015 in US
mainstream &
natural channel
markets,
respectively.

Botanical Adulterants Program

American ginseng plate from Jacob Bigelow's *American Medical Botany*, Vol. 2, published in 1818.

TOWARD AN UNDERSTANDING OF GINSENG ADULTERATION: THE TANGLED WEB OF NAMES, HISTORY, TRADE, AND PERCEPTION

By Steven Foster

Editor's note: *This article is produced under the aegis of the AB fifth from Steven Foster in his series on herb adulteration. His* racemosa, *Ranunculaceae) was the cover story of issue 98, pu two-part series on the vast subject of adulteration of Asian and ods employed to adulterate ginseng, it is constructive to unders economically important medicinal plant.*

INTRODUCTION

If there is a single word that exemplifies globa The commercial, scientific, and historical imp includes at least 2,200 years of written histo and, coupled with the European discovery of A has created an iconic bridge between East and modern human experience with medicinal plan

To simplify the discussion, *P. quinquefolius* will be referred to throughout this article as "American ginseng," the Standardized Common Name established by the second edition of the American Herbal Products Association's (AHPA's) *Herbs of Commerce*,[1] a reference text that includes common names and Latin binomials for herbs sold in the United States. (Some Canadian colleagues might scold this writer for not using the more diplomatically correct "North American ginseng.") To remain consistent with *Herbs of Commerce*, *P. ginseng* will be referred to as "Asian ginseng," in a general sense, although some prefer to use English common names that reflect the nation of origin (e.g., "Chinese ginseng" or "Korean ginseng").

The literature on ginseng is voluminous.[2,3] A PubMed search for the word "ginseng" yields more than 7,200 references to scientific papers, and a Google Scholar search for "Panax" results in 91,000 references (as of July 11, 2016). Almost any general work on medicinal plants, pharmacognosy, or herbal medicine includes ginseng, and hundreds of technical treatises, popular books, and monographs on ginseng have been published in dozens of languages.

Since the 1970s, numerous symposia on all aspects of ginseng — its botany, chemistry, clinical use, conservation, commerce, cultivation, pharmacology, and safety — have been held around the world. (Unfortunately, many important papers presented in symposia proceedings are not cataloged by indexing services, thus making that information more challenging to access.) Various organizations, such as the Korean Ginseng Research Institute, Wisconsin Ginseng Grower's Association, Ontario Ginseng Grower's Association, and others, also are dedicated to better understanding the chemistry, pharmacology, production, toxicology, and clinical applications of ginseng root and its extracts.

Intermixed source plants, rampant taxonomic confusion, and unrelated plants mislabeled as "ginseng" have created ever-evolving challenges in authentication. These

* This paper will not discuss potential contamination with agric cides; soil microbes; heavy metals; or other natural and artificia

Asian Ginseng Root Extract Adulterated w/ Leaf Extract (Panax ginseng)

- Companies are marketing Asian ginseng root extract standardized to relatively high levels of ginsenosides at what appear to be relatively low prices:
  - 10-24%

- Analysis reveals:
  - presence of chlorophyll in some samples
  - uncharacteristic profiles of ginsenosides,

    Indicating presence of extr. of ginseng leaf.

Botanical Adulterants Bulletins

1. Published	2. Completed (pending final edits)	3. In Peer-Review
1. Arnica flower 2. Bilberry fruit extract 3. Black cohosh root & rhizome 4. Goldenseal root & rhizome 5. Grape seed extract 6. Skullcap herb	1. Ginkgo leaf extract 2. Saw palmetto fruit 3. St. John's wort 	1. Synthetic antimicrobials sold as "Grapefruit Seed Extract" 2. *Rhodiola rosea* & extr.
4. Being Written	**5. Planned**	**6. Proposed**
1. Ashwagandha root 2. Cranberry fruit extract 3. Ginseng (Asian & American) root 4. Maca root	1. Boswellia tree resin 2. Eleuthero root 3. Pomegranate fruit extract 4. Tea tree leaf oil	1. Cordyceps 2. Curcumin 3. *Tribulus terristris* aerial parts/fruit

Ashwagandha

Withania somnifera

St. John’s wort

Hypericum perforatum

St. John’s Wort: #38 in sales in US in 2015 in mainstream channel.

Botanical Adulterants Program

Ginkgo Extract Adulteration in the Global Market: A Brief Review

Ginkgo biloba **(Ginkgoaceae) leaf extract is one of the most popular and well-researched herbal preparations. Worldwide, ginkgo is accepted as a formal medicine for enhancing mental acuity, a use supported by dozens of clinical trials based on a few proprietary extracts manufactured in Europe. It is also sold as a food supplement in Europe, a dietary supplement in the United States and elsewhere, and as a natural health product in Canada. Unfortunately, in the past decade, growing evidence has emerged of the production and sale of sub-standard and adulterated ginkgo extracts in the international supply chain, much of it reportedly coming from China.**

In 2003, an investigation into the quality of 10 commercial ginkgo extracts from suppliers in Europe, Asia, and North America found one sample with an unusually high content of rutin, a flavonol glycoside that occurs in many plant species (including ginkgo), and one sample with almost no ginkgo terpene lactones (e.g., the ginkgolides A and B, and bilobalide, which are exclusively found in ginkgo) or ginkgo flavonols. The authors suggested that pure rutin was added to one sample to increase the content in total flavonol glycosides.[1] Similarly, a separate study found that four out of 14 commercial ginkgo products sourced in the Edmonton (Alberta, Canada) area were likely adulterated with pure flavonols (rutin and the non-glycosylated [aglycones] quercetin, kaempferol, and isorhamnetin).[2]

A comparison of HPLC (high-performance liquid chromatography) fingerprints of ginkgo extracts from 19 different sources published in 2006 suggested that three products were adulterated with added rutin.[3] In 2008, the adulteration issue was raised again by Hermann Kurth of the German extract manufacturing company Finzelberg in a conference

describes an HPLC-UV method using genistein as a marker compound to detect adulteration of ginkgo extracts with extracts from the fruit of Japanese sophora.[8]

Adulteration with rutin of commercial ginkgo products purchased in the Turkish market was reported by Demirezer et al. in 2014.[9] Also in 2014, Australian researchers led by Hans Wohlmuth of Integria Healthcare in Australia published a relatively simple method to detect adulteration of ginkgo extract in commercial dietary supplement products.[10] By using the HPLC conditions of the United States Pharmacopeia before and after hydrolysis (the breaking of a molecule by adding water), the authors discovered admixtures of the flavonols quercetin and kaempferol in three of the eight commercial samples that were analyzed. The three adulterated samples also contained genistein, an isoflavone that has not been found in ginkgo leaves, but is characteristic of some plants in the pea family (Fabaceae), including in the genus *Sophora*. The authors noted that current pharmacopeial methods are not sufficient to detect ginkgo adulteration and proposed to analyze the samples

Gafner S. *HerbalGram*. 2016;109:58-59.

Adulteration of Ginkgo Extracts

Known adulterants

- Rutin
- Quercetin
- Kaempferol
- Flavonol-rich plant extracts (e.g., Japanese pagoda [*Styphnolobium japonicum;* syn. *Sophora japonica*])

Genistein or No Genistein?

Styphnolobium japonicum

Sophora japonica

Fabaceae

Rhodiola rosea

Wikipedia.com
By Opioła Jerzy - Own work, CC BY 2.5,
https://commons.wikimedia.org/w/index.php?curid=899285

Cranberry

Vaccinium macrocarpon, Ericaceae

Cranberry:

#2 & #14 in sales in US in 2015 in mainstream

& natural channels, respectively.

Botanical Adulterants Program

Cranberry Extract

Vaccinium macrocarpon

PACs

OPCs from Grapes (*Vitis vinifera*)

http://www.healthyfoodhouse.com/grapes-the-curative-properties/

Pomegranate

Punica granatum, Punicaceae

http://blogs.knoxnews.com/knx/constantine/pomegranate.jpg

AMERICAN BOTANICAL COUNCIL
SINCE 1988

Adulteration of Pomegranate Products — A Review of the Evidence

By John H. Cardellina II, PhD, and Mark Blumenthal

***Editor's note**: This article was produced as part of the ABC-AHP-NCNPR Botanical Adulterants Program's continuing coverage of adulteration-related issues.*

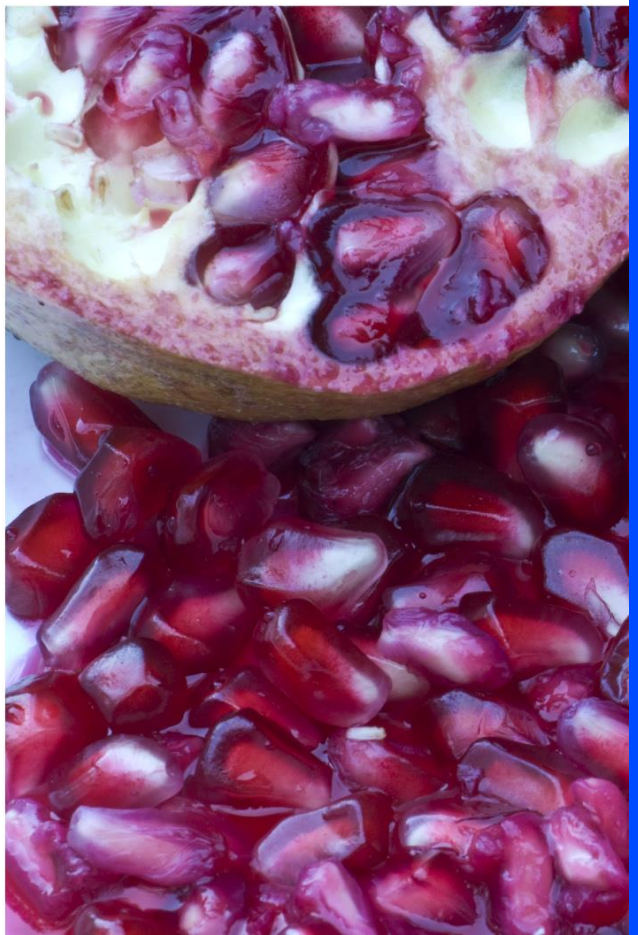
Introduction

Pomegranate (*Punica granatum*, Lythraceae) fruit juice has enjoyed considerable market growth and commercial success as a popular beverage in the United States and internationally for more than a decade. The consumption of pomegranate juice in the United States went from roughly 75 million eight-ounce servings in 2004 to about 450 million servings in 2008 — a 500% increase.[1] One review indicates that sales of pomegranate juice grew dramatically from $84,500 in 2001 to $66 million in 2005.[2] According to 2014 estimates, 150,000-200,000 metric tons of fresh pomegranates and 3.7 million gallons of pomegranate juice concentrate are sold annually (A.R. Rejaei, director of clinical regulatory affairs at POM Wonderful, email to M. Blumenthal, April 7, 2015).

As the popularity of pomegranate has increased, many suppliers of herbs and other plant-based materials have begun to produce a variety of dried pomegranate materials (e.g., dried juice concentrates and extracts) for use as ingredients with health-promoting properties in the burgeoning global market for natural products.* These concentrates and extracts are produced by various means from pomegranate juice, whole pomegranate fruit, or selected parts of the fruit.

Many manufacturers produce botanical extracts standardized to a chemical compound or a class of compounds (marker compounds) for quality control purposes and/or to help ensure consistent, reproducible biological activity. Following this trend, some manufacturers of pomegranate fruit extracts (PFEs) are standardizing their PFEs to ellagic acid (EA), a common phenolic compound widely distributed in nature. EA has a number of reported beneficial physiological activities, with much work focusing on the compound's antioxidant activity.[3] (EA was recently found to have pro-oxidant properties as well.) The antioxidant activities of EA metabolites formed in the intestinal tract ("colonic metabolites," such as urolithin A) are thought to be responsible for the therapeutic effects attributed to EA.[4,5]

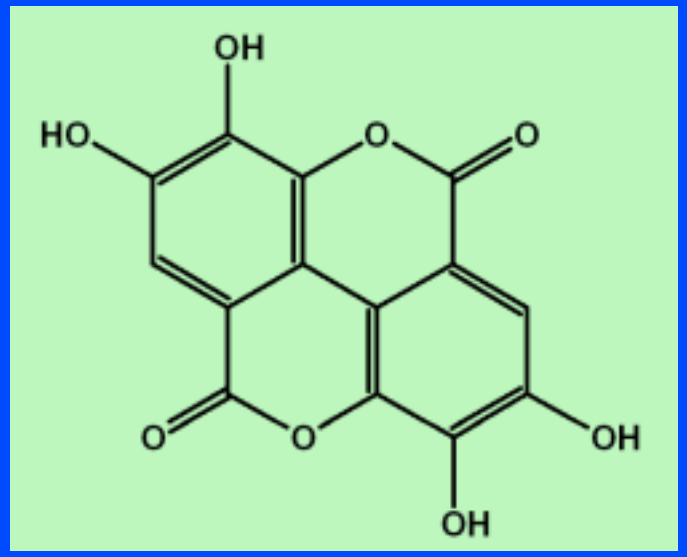
A number of PFEs are marketed with claims of high levels of EA (ca. 40-70%), but



* Natural products may be referred to as functional foods, dietary supplements (in the United States), natural health products (in Canada), therapeutic goods (in Australia), or food supplements (in Europe), depending on where they are sold.

Pomegranate Fruit Juice & Extracts

Extracts Adulterated w/ Exogenous Ellagic Acid



Pomegranate & Ellagic Acid

- EA is an antioxidant compound found in many fruits.
- Pomegranate extracts claim 40-70% EA.
- EA found in pom. @ ca. 3%
- Up to 5% EA upon hydrolysis during extraction
- EA is inexpensive; made chemically and/or via extraction from wood pulp.

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Tea Tree Oil

Melaleuca alternifolia

http://healthinfotips.blogspot.com/2010/11/tea-tree-melaleuca-alternifolia-healing.html

- Reportedly adulterated
- ATTIA developing analytical methods.
- ABC-AHP-NCNPR Botanical Adulterants Program currently seeking published & unpublished evidence of adulteration.

NBTY Signs Agreement with New York Attorney General Regarding DNA Testing of Herbs

NY AG finds no evidence for non-compliance with cGMPs

By Stefan Gafner, PhD

On September 20, 2016, NBTY, Inc., the largest dietary supplement manufacturer in the United States, signed an agreement with the Office of the New York Attorney General (NY AG) to develop and incorporate enhanced herbal authentication methods, including DNA barcoding, into its quality control procedures.[1,2]

The agreement comes more than 18 months after an investigation initiated by the NY AG in February 2015 alleged that four out of five herbal dietary supplement products sold at retailers GNC, Walgreens, Walmart, and Target did not contain ingredients listed on the label. The allegations were based on the results of a controversial DNA barcoding approach, which suggested that only five of the 24 commercial products analyzed contained DNA of the labeled species. These results led the NY AG to demand that the four retailers remove the products from their shelves in the state of New York.[3]

The accuracy of the results, however, was immediately questioned by experts in the field of botanical ingredient authentication.[4,5] Although details of the method used were not released, these experts indicated that because the majority of the products were made from herbal extracts, which contain plant DNA that is frequently fragmented or degraded, DNA barcoding was unlikely to provide useful or definitive results upon which to base regulatory action. The investigation reported finding DNA from species in the following genera: *Oryza* (found in 19 samples), which includes rice (*O. sativa*, Poaceae); *Allium* (in nine samples), which includes garlic (*A. sativum*, Amaryllidaceae) and onion (*A. cepa*);

uted Associated Press article published shortly after the NY AG's initial announcement did attempt to cover the growing controversy surrounding the NY AG's reliance on only the DNA barcoding analytical method.[10] A detailed review on the investigation by the NY AG was published in *HerbalGram* issue 106.[11]

NBTY, which had contract-manufactured herbal supplements sold at Walgreens and Walmart under the retailers' respective brands, responded to and fully cooperated with the NY AG's investigation, providing documentation confirming that the supplements in question were produced and labeled in accordance with current good manufacturing practices (cGMPs), as required by federal law (i.e., none of the supplements were found to be deficient, adulterated, mislabeled, or a potential hazard to public health, as initially alleged by the NY AG).[3,7,8]

On March 27, 2015, in a highly publicized development, supplement retailer GNC signed an agreement with the NY AG to implement DNA-barcoding testing methods on all botanical ingredients in its dietary supplements before such ingredients were processed into extracts.[12]

While NBTY maintains that

'Strengths and Limitations of DNA Barcoding' Article Published in *Planta Medica*

ABC Chief Science Officer Co-authors Review of DNA Barcoding Analysis

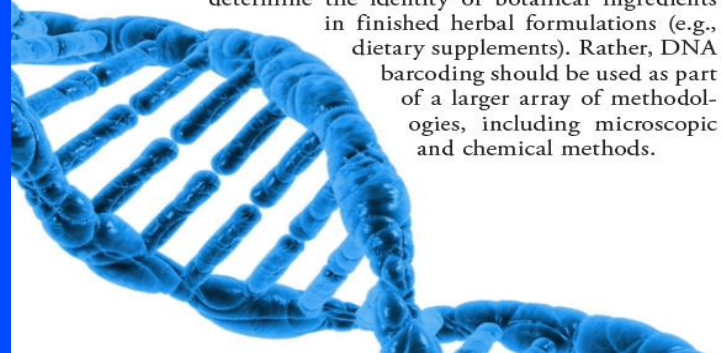
Editor's note: *American Botanical Council (ABC) Chief Science Officer Stefan Gafner, PhD, co-authored the* Planta Medica *article with Iffat Parveen, PhD, Natascha Techen, PhD, and Ikhlas Khan, PhD, all researchers at the internationally respected National Center for Natural Products Research (NCNPR) at the University of Mississippi (a US Food and Drug Administration [FDA]-funded Center of Excellence in the area of medicinal plant analysis), and Susan Murch, PhD, an expert in the analysis of botanical ingredients at the University of British Columbia in Canada. Interested parties are encouraged to obtain the original article from the journal.*

Background

In July 2016, the respected, peer-reviewed medicinal plant journal *Planta Medica* published an online paper[1] written by various experts in medicinal plant analysis. The paper reviews the strengths and limitations of DNA barcoding analytical methods — a subject that has received significant global attention since the New York attorney general's (NY AG's) now-infamous and highly flawed DNA analysis of various herbal dietary supplements, which was covered by *The New York Times* and other major news outlets in 2015.

Based on the DNA analysis, the NY AG took regulatory action against four major retailers for allegedly selling mislabeled herbal supplements. (The products produced and sold by retailer GNC were later deemed by the NY AG to be compliant with state and federal regulations and allowed back onto retail shelves in New York; actions against Target, Walgreens, and Walmart are still pending.) The NY AG has been criticized for relying solely on DNA barcoding analysis as the basis for his regulatory actions. These criticisms have come from a variety of sources: from plant analytical experts in academia, government, and industry, to industry sources and ABC publications.

As noted in the paper, DNA barcoding methods should not be used as the sole analytical method to determine the identity of botanical ingredients in finished herbal formulations (e.g., dietary supplements). Rather, DNA barcoding should be used as part of a larger array of methodologies, including microscopic and chemical methods.



Article Summary

The authors of the *Planta Medica* article begin with an overview of DNA barcoding and discuss the steps (extraction, amplification, and sequencing) involved in the technology, as well as its strengths and limitations for plant identification.

DNA barcoding, which involves the use of short genomic regions to distinguish species of animals, plants, fungi, bacteria, and other organisms, has become an increasingly popular technology to determine the authenticity of botanical ingredients in herbal medicines and dietary supplements. Plant DNA barcoding, initially used predominantly in academia to determine the relationship among species (phylogeny), is now used by many groups, including dietary supplement manufacturers, contract analytical laboratories, government agencies (e.g., the FDA), and, as noted previously, the office of the NY AG. The outcome of DNA barcoding varies depending on the method of DNA extraction, primer choice, amplification, and sequencing. In addition, the success of the technology depends on the presence of high-quality DNA and the absence of interfering compounds in the material analyzed.

A number of extraction methods are used in practice. The choice of the method depends on the material to be analyzed. Different plant parts (DNA is more difficult to obtain from bark or root compared to leaves or flowers) and metabolite compositions (e.g., presence of polysaccharides or polyphenols) will affect the extraction efficiency. The choice of the genomic region is crucial for the success-

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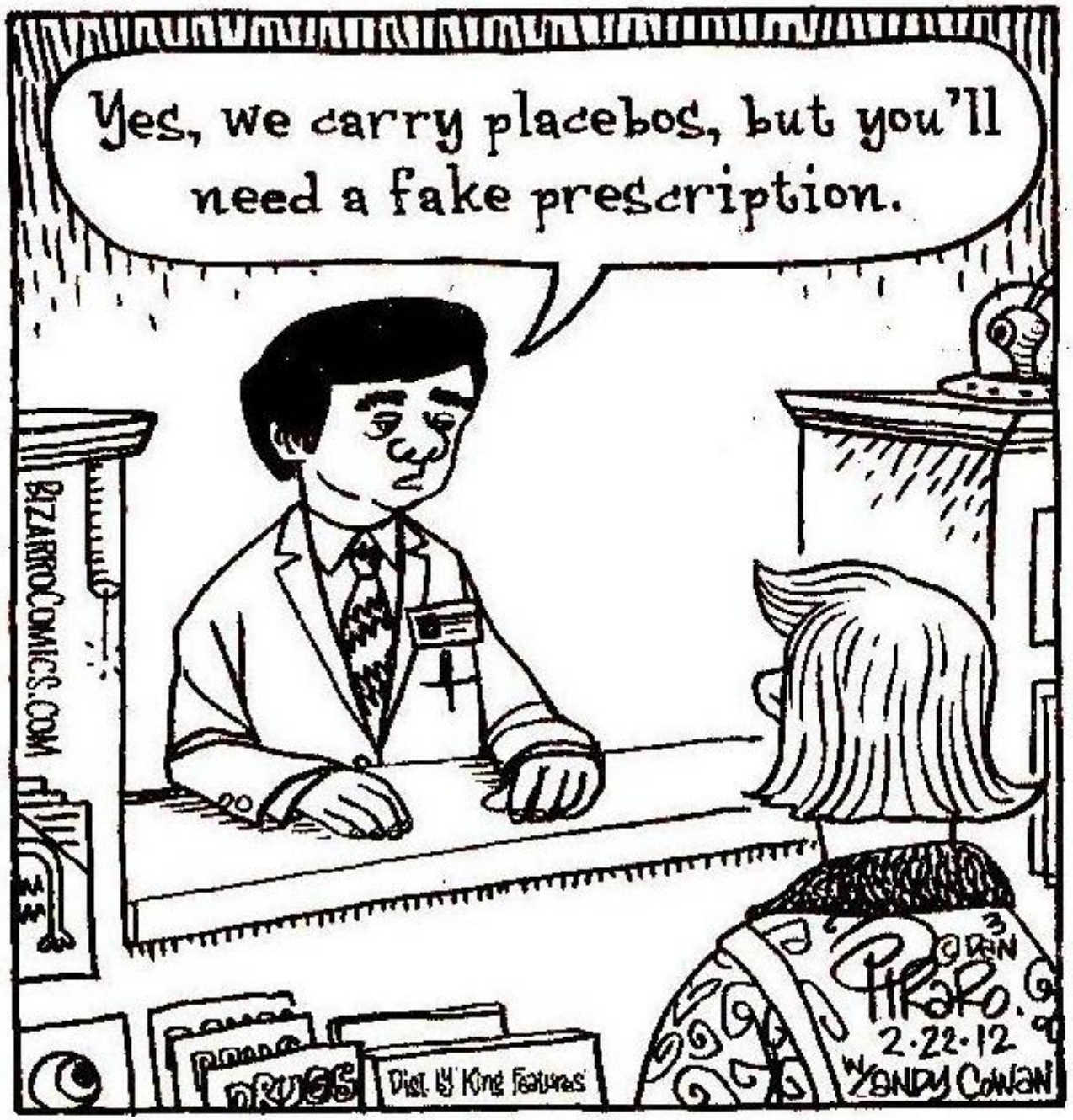
Yes, we carry placebos, but you'll need a fake prescription.
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“Dry Labbing”

How to Qualify an Analytical Laboratory for Analysis of Herbal Dietary Ingredients and Avoid Using a “Dry Lab”

- A review of issues related to using a contract analytical laboratory by industry, academia, and regulatory agencies
  - By Paula M. Brown, PhD, Joseph M. Betz, PhD, and Frank L. Jaksch, Jr.
  - *HerbalGram* 99 (2013)

How to Qualify an Analytical Laboratory for Analysis of Herbal Dietary Ingredients and Avoid Using a "Dry Lab"

A review of issues related to using a contract analytical laboratory by industry, academia, and regulatory agencies

By Paula M. Brown, PhD, Joseph M. Betz, PhD, and Frank L. Jaksch, Jr.

Romeo. "Your Plantain leaf is excellent for that."
Benvolio. "For what, I pray thee?"
Romeo. "For your broken shin."
— *Romeo and Juliet*, act I, scene II

Thus the lowly plantain (*Plantago* spp., Plantaginaceae) became a featured player in one of the most famous and beloved pieces of English literature. Being a man of his times (late 16th-early 17th century), William Shakespeare made numerous references to herbs in his work. In addition to the mention of plantain in *Loves Labors Lost* (act III, scene I), *Troilus and Cressida* (act III, scene XX), and *The Two Noble Kinsmen* (act I, scene II), there are references to roses (*Rosa* spp., Rosaceae) in *Romeo and Juliet*. And, in *Hamlet*, Ophelia presents to various characters rosemary (*Rosmarinus officinalis*, Lamiaceae), pansies (*Viola tricolor*, Violaceae), fennel (*Foeniculum vulgare,* Apiaceae), columbines (*Aquilegia vulgaris*, Ranunculaceae), rue (*Ruta graveolens*, Rutaceae), daisies (*Bellis perennis*, Asteraceae), and violets

and the attendant explosion of knowledge about the world. Author and photographer Steven Foster discussed the second trend in his *HerbalGram* article about historical adulteration.[4] Meanwhile, as commerce grew and new processing methods for materials (medicines, as well as everything else) became available, incentives and opportunities to cheat also increased. Advances in science and technology provided the twin benefit of being able to better identify and test superior material *and* to detect cheats. The 1918 *United States Dispensatory* (USD, 20th edition)[5] entry for plantain provided descriptive information on the herb as well as a few newly identified organic chemicals. The Plantain Leaf monograph had been eliminated from the USD by the time the 25th edition was published in 1955.[6] but Bisset

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Calendar
Press Kit

Three leading nonprofit organizations have initiated this large-scale program to educate members of the herbal and dietary supplement industry about ingredient and product adulteration. Partners include the American Botanical Council (ABC), the American Herbal Pharmacopoeia (AHP), and the University of Mississippi's National Center for Natural Products Research (NCNPR).

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Botanical Adulterants MONITOR

ISSUE #1 — 2014

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Botanical A
Program

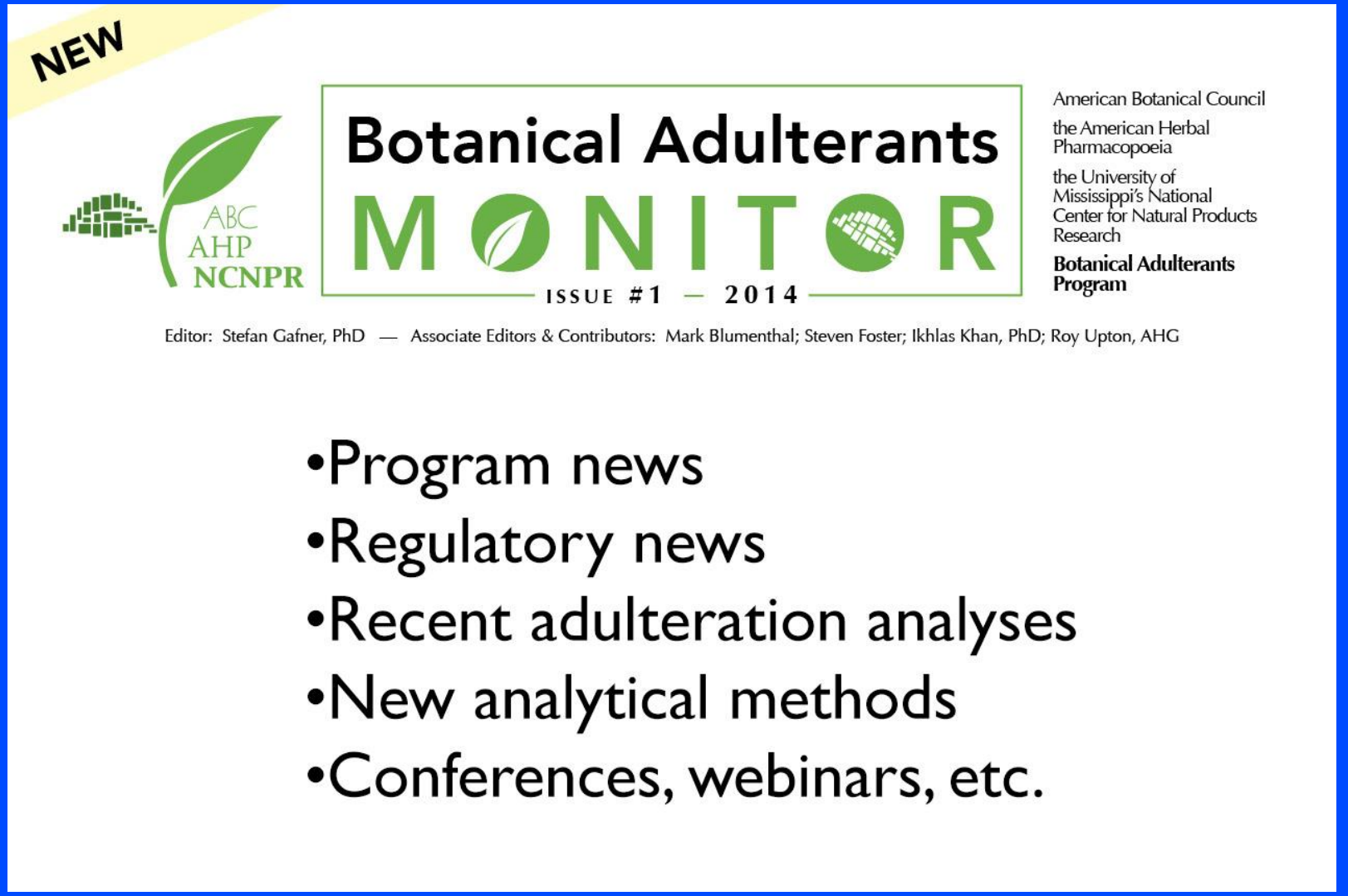
Editor: Stefan Gafner, PhD — Associate Editors & Contributors: Mark Blumenthal; Steven Foster; Ikhlas Khan, PhD; Roy Upton, A

Dear Reader

It is my pleasure to introduce to you the first edition of the "Botanical Adulterants Monitor." Adulterati materials has been a topic of continued media attention and sensational press coverage of research pu example, there is the highly flawed DNA barcoding study by Newmaster et al. published in *BMC Medic* October. The authors of the paper curiously concluded that close to 60% of the 44 tested North Ameri products contained materials from undeclared botanical sources. This study led to increased confusion and producers of herbal products, and to attacks in the mainstream media on the dietary supplement calls for more stringent regulations. (See the ABC critique, here.)

Our goal for this newsletter is to provide newly available information on issues surrounding accidental adulteration — and, to a lesser extent, the equally important problems of contamination — as reporte agencies or in published studies. In general, the content of the "Botanical Adulterants Monitor" will foc solutions to current problems related to adulteration and botanical ingredient authenticity ... MORE

Stefan Gafner, PhD
Chief Science Officer, ABC
Technical Director, ABC-AHP-NCNPR Botanical Adulterants Progra



"Monitor" is available *free-access* every 2-3 months via Botanical Adulterants Program homepage or by registering on ABC website: www.herbalgram.org.

Botanical Adulterants Program

ABC AHP NCNPR

Total Publications, Sept 15, 2016

- *HerbalGram* articles 9
- Botanical Adulterant Bulletins 6
- Laboratory Guidance Documents 3
- "Botanical Monitor" Newsletter 8

Total ***26***

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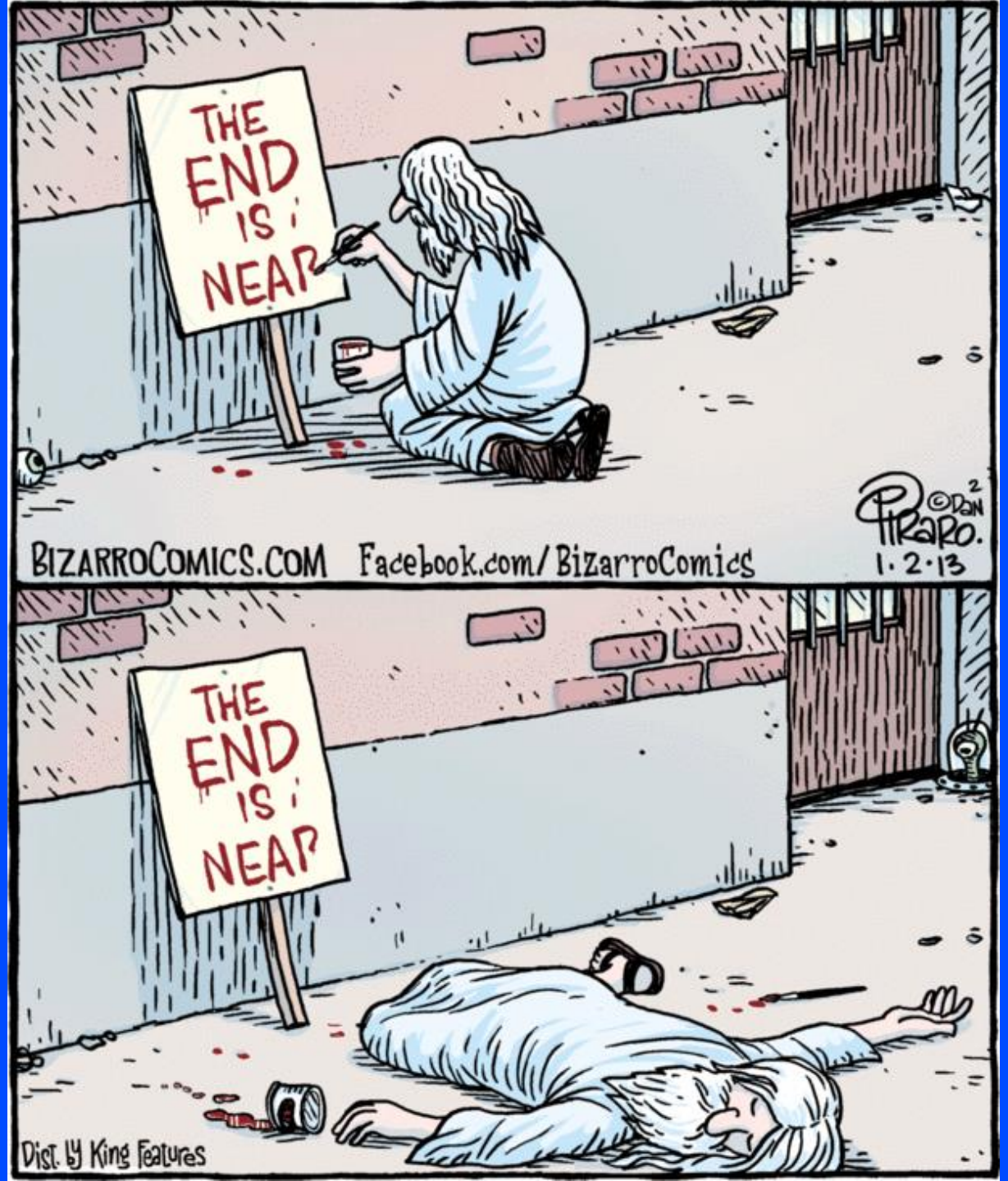
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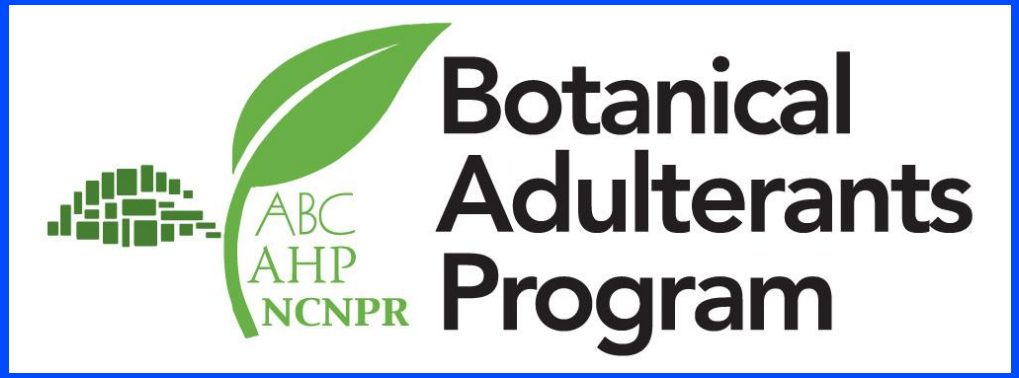

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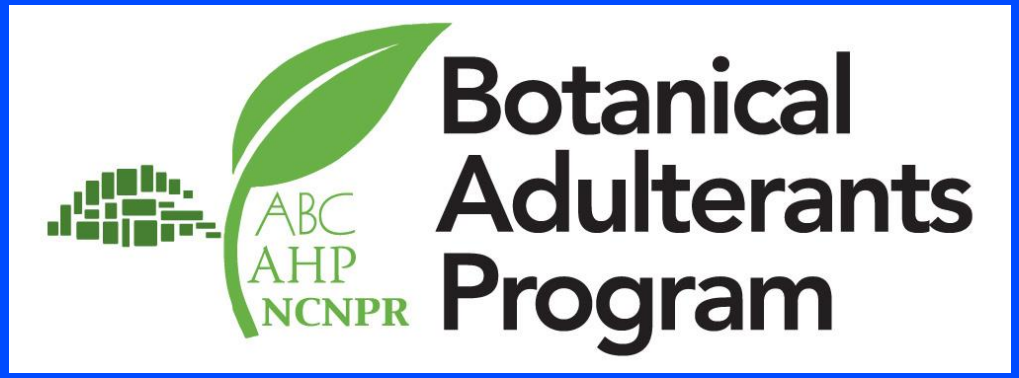

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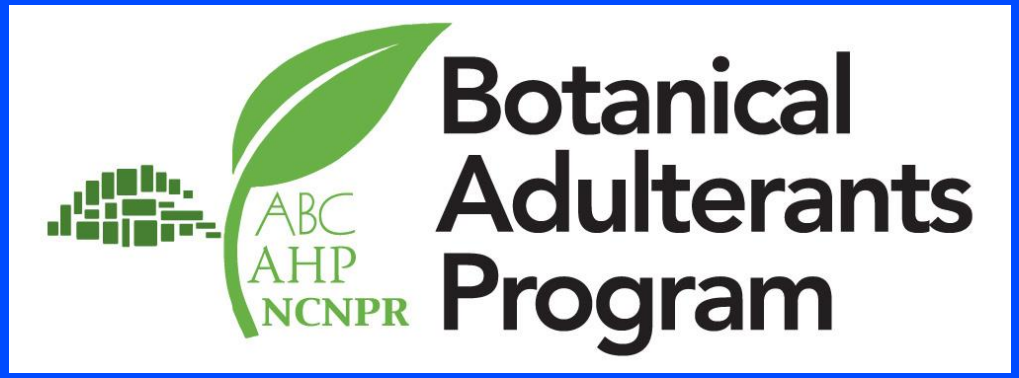

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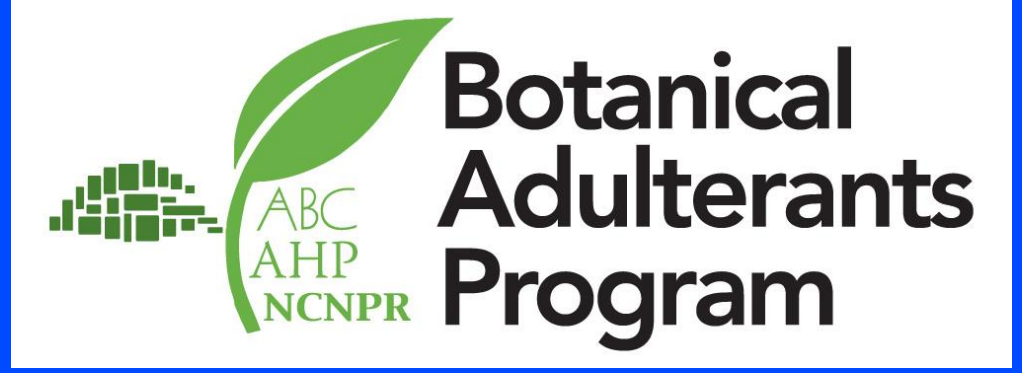

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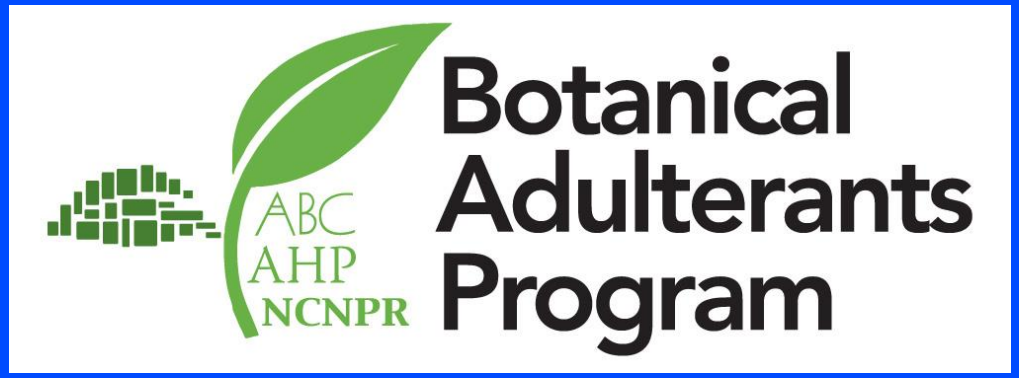

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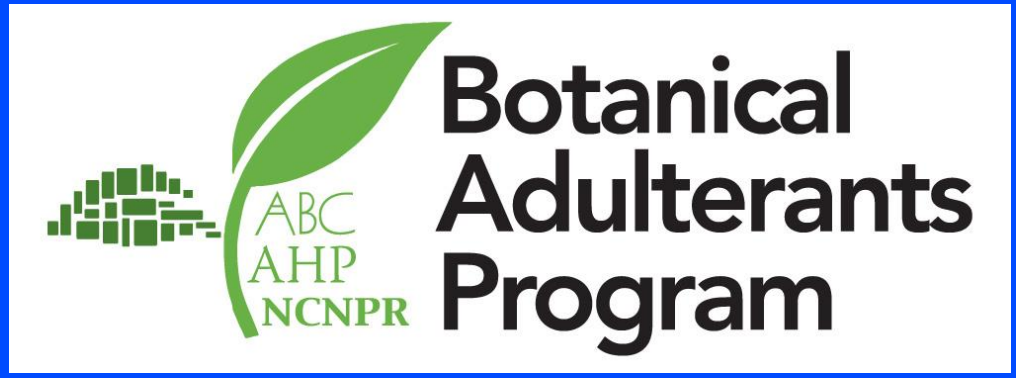

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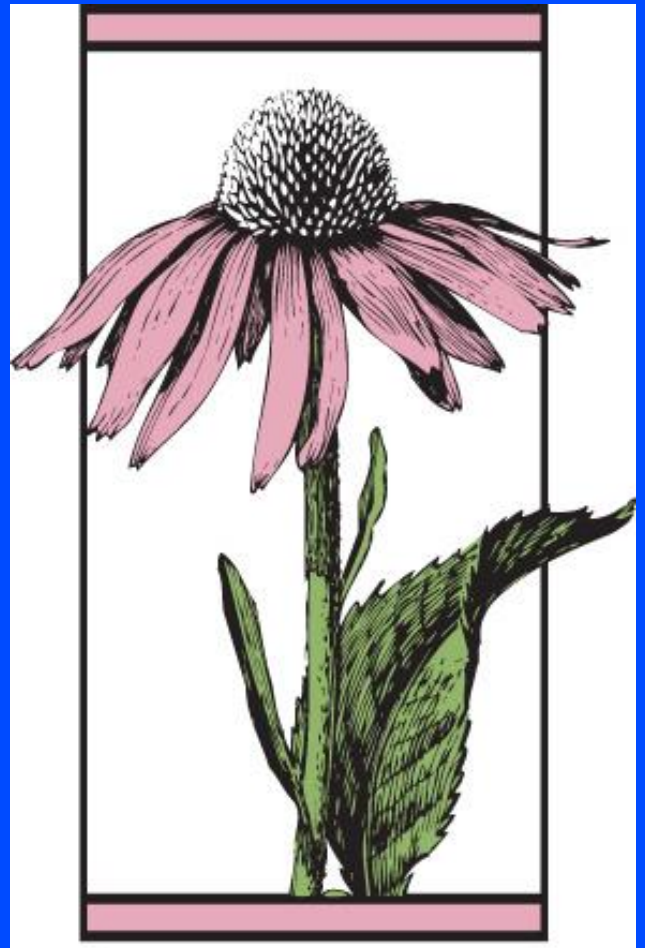

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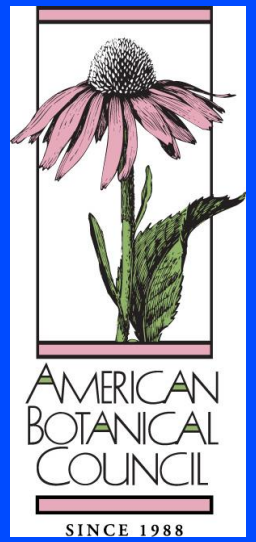

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