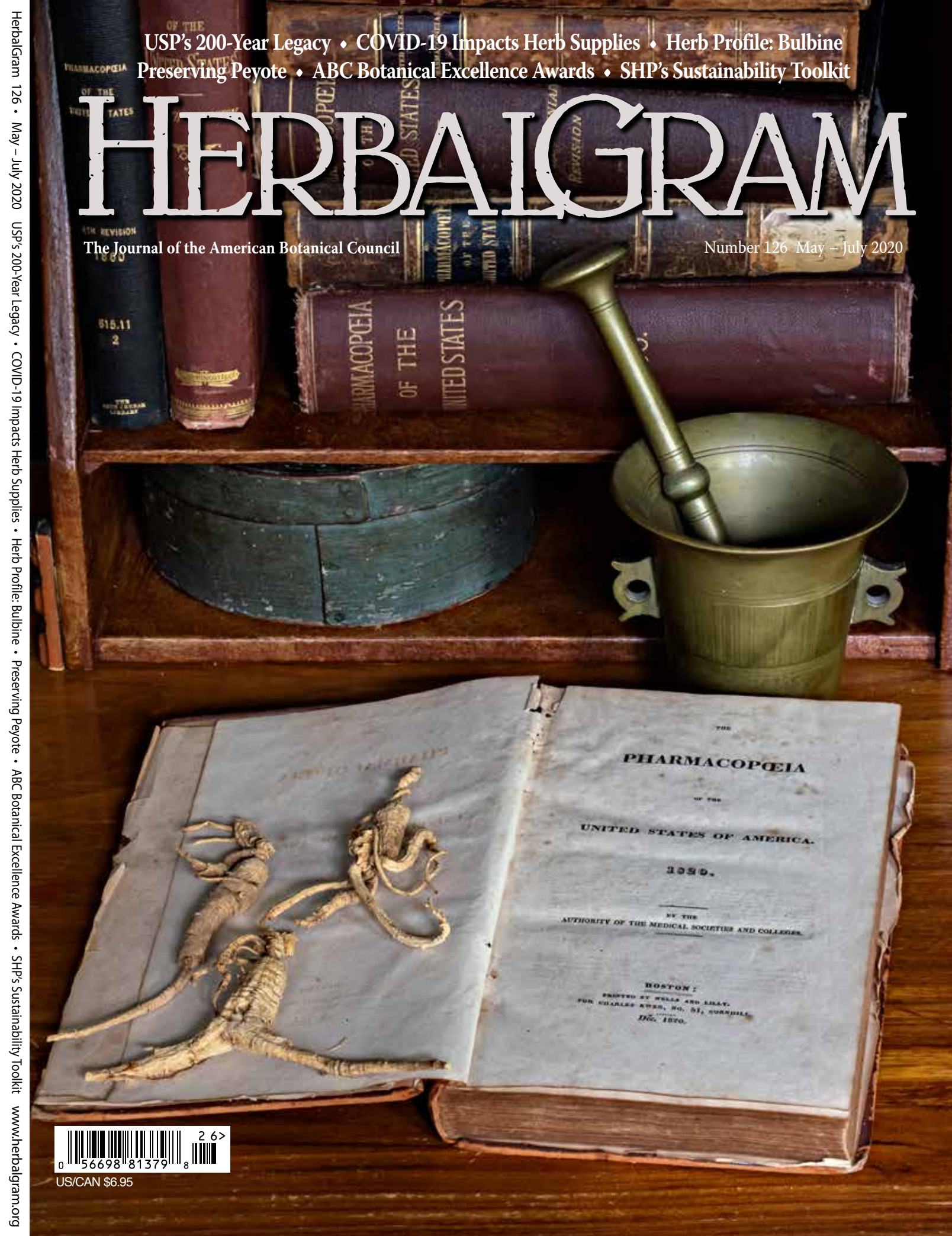
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# HERBALGRAM

The Journal of the American Botanical Council

Number 126 May – July 2020




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# dear *reader*

We are writing this at the end of April 2020, after many of us around the world have been under some form of stay-at-home order for at least the past five to seven weeks due to COVID-19, the disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Since the virus has started to impact the lives of billions of people during the past few months, we have received inquiries about what herbs we would recommend for prevention and/or treatment of this novel coronavirus. As a science-based organization, we cannot and will not make such recommendations: There simply is no scientific or clinical trial-based evidence to do so. Results from research on botanical or conventional pharmaceutical medicines are preliminary; making any suggestions for prevention or treatment based on such data can be misleading.

Nevertheless, consumers in what appear to be record numbers in the United States (and possibly elsewhere) are purchasing a wide range of dietary supplements, both nutritional (e.g., vitamin C) and botanical (e.g., echinacea and elderberry), to enhance their immune systems in the hope of preventing or lessening the severity and duration of COVID-19. Of course, we believe that maintaining optimal wellness, including a properly functioning immune system, as part of normal dietary and health practices, is desirable. However, the mere mention of traditional use of or modern research on herbs to modulate immunity, whether directly tied to COVID-19 or not, may be inferred as making a COVID-19-related claim, something we do not wish to do.

The increased consumer demand for herbal dietary supplements and recent supply chain disruptions have led to shortages of some botanicals. In response, we present Karen Raterman's article in which she delves into some of these supply chain impacts. Her article was completed in April, and, although the situation is evolving rapidly, experts predict supply disruptions for the foreseeable future. Along these lines, ABC issued a Member Advisory in early April noting that supply shortages can cause some sellers to offer lower-cost, adulterated, or fraudulent ingredients. The ABC-AHP-NCNPR Botanical Adulterants Prevention Program urges responsible herb industry members to continue, even enhance, their diligence in their quality control testing for identity and authenticity of botanical raw materials, extracts, and essential oils. We include the advisory in this issue.

Also of interest is the brief article on the Sustainable Herbs Program's (SHP's) new 14-section, 52-page "SHP Sustainable & Regenerative Practices Toolkit." Released on the eve of Earth Day's 50th anniversary, the toolkit is available for free on SHP and ABC's websites. The toolkit provides extensive resources for small and large companies, and even private households, that wish to become more committed to sustainable social and environmental best practices. The coronavirus outbreak reminds us that, as denizens of planet Earth, we are all connected.

This issue also includes an extensive cover article about the United States Pharmacopeial Convention (USP), which publishes the *United States Pharmacopeia* and is observing its 200th anniversary this year. In 1820, 11 physicians founded USP and, later that year, published the first edition of the pharmacopeia, which was intended to bring nationwide uniformity to the quality of drugs, many of which, at that time, were botanical. Two hundred years later, USP is still compiling and publishing methods for determining the quality of medicines, as well as many popular botanical dietary ingredients. A tip of the hat to our good friend Josef Brinckmann and his colleagues at USP for their article.




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HERBALGRAM
The Journal of the American Botanical Council



**Valerian** *Valeriana officinalis*
Photo ©2020 Steven Foster

**50** **Quality Standards for Botanicals: The Legacy of USP's 200 Years of Contributions**
*By Josef Brinckmann, Robin Marles, PhD, Paul Schiff, PhD, Hellen Oketch-Rabah, PhD, Geeta Tirumalai, Gabriel Giancaspro, PhD, and Nandakumara Sarma, PhD*

Two centuries ago, a small group of physicians banded together to found the United States Pharmacopeial Convention (USP) in an effort to help protect consumers from poor-quality medicines. Later that year, the organization published the first edition of *The Pharmacopoeia of the United States of America* (*USP*), which set specifications for first-choice drugs, most of which at that time were based on plants. Over the past 200 years, *USP*'s quality standards have expanded and evolved to reflect new knowledge and technologies, and USP remains committed to its mission to "help ensure the quality, safety, and benefit of medicines and foods."

**66** **Herbal Companies Brace for Supply Chain Impacts of COVID-19**
*By Karen Raterman*

The herbal industry has experienced economic impacts and disruptions due to the coronavirus disease-2019 (COVID-19). These disruptions, combined with a surge of consumers seeking products for immune-health benefits, have caused concerns as companies seek to maintain the integrity and quantity of their botanical materials. Many companies in the herb and dietary supplement industries are responding to these challenges by using new suppliers and alternative formulations, and some who are dealing with supply shortages for key ingredients are limiting their sales to existing customers.

# departments


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Common Barberry

(*Berberis vulgaris*, Berberidaceae)




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*Pharmacopoeia of the United States of America* (1820) with American ginseng (*Panax quinquefolius*) roots
Photo ©2020 Steven Foster


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# Bulbine

*Bulbine frutescens, B. latifolia* (syn. *B. natalensis*), and *B. narcissifolia*
Family: Xanthorrhoeaceae (syn. Asphodelaceae)

**By Josef Brinckmann and Thomas Brendler**

## INTRODUCTION

*Bulbine* species are geophytic (plants that have a subterranean storage organ known as a corm), aloe-like succulent perennials with rosettes of fleshy leaves. The amount of water stored above ground (succulence) in *Bulbine* species, however, may be more important for survival than the amount stored in the corm (geophytism).[1] The *Bulbine* genus includes approximately 78 species[2] with a highly disjunct distribution,[1] occurring almost entirely in southern Africa,[1,2] but with six species in Australia.[3] This article concerns the most widely used African species: *B. latifolia* (syn. *B. natalensis*), known as broad-leaved bulbine,[4] and as *rooiwortel* ("red root") in Afrikaans due to its red-orange corm[5]; *B. frutescens*, known as stalk-bulbine,[6] burn jelly plant, cat's tail, and snake flower[7]; and *B. narcissifolia*, known as strap-leafed bulbine and snake flower.[3] While much of the literature and trade refers to *B. latifolia* and *B. natalensis* as separate species, version 1.1. of The Plant List (2013) and the updated World Flora Online treat them as synonyms.[8] In this article, we use the Latin name referred to in the cited references.

*Bulbine frutescens*, which occurs in South Africa (in the provinces of Free State,[9] Northern Cape, Eastern Cape, Western Cape, and KwaZulu-Natal), Swaziland,[6] and Lesotho,[7] has yellow, sometimes orange, star-shaped flowers.[10] *Bulbine latifolia* (*B. natalensis*) is distributed in the fynbos/dry scrub-forest ecotone (transition area between two biomes) region of South Africa[5] (in Free State,[9] Mpumalanga, KwaZulu-Natal, and Eastern Cape), as well as in Malawi, Mozambique, and Zimbabwe.[4] It has yellowish fleshy roots, small yellow flowers with spreading petals, and small blackish, flattened, wind-dispersed seeds.[10] *Bulbine narcissifolia*, which is gray-green and stemless with yellowish exudate, small bright yellow flowers, and bluish-green, flat twisted leaves,[10] is widely distributed in South Africa (in Western Cape, Eastern Cape, Free State, KwaZulu-Natal, North West, Gauteng, and Limpopo), as well as in Lesotho, Botswana, and Ethiopia.[3]



**Bulbine** *Bulbine frutescens*
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Most of the material of commerce is sourced from wild collection and subject to licensing and access and benefit-sharing (ABS) requirements as per the Nagoya Protocol of the Convention on Biological Diversity (CBD).[11] Various suppliers of wild-collected *B. natalensis* plant parts hold the requisite bioprospecting and export permits for legal trade to companies domestically and for the export market.[12] In recent years, a few enterprises began to pioneer commercial cultivation, including the 10-hectare Canterbury Farm of Botanica Natural Products growing *B. frutescens* in Alldays, Limpopo, South Africa, with US Department of Agriculture (USDA) National Organic Program (NOP) certification,[13,14] and the Edakeni Muthi Futhi Trust growing *B. natalensis* on a 17-hectare farm in Dakeni, a village in Zululand, KwaZulu-Natal.[15] Cultivated *B. natalensis* is also subject to South Africa's Bioprospecting, Access and Benefit-Sharing Regulations. Under this framework, a benefit-sharing agreement was made in 2011 between the Edakeni Muthi Futhi Trust and the Edakeni community in uMlalazi Municipality, KwaZulu-Natal.[16]

## HISTORY AND CULTURAL SIGNIFICANCE

Preparations of *Bulbine* plant parts are traditional medicines of the Xhosa and Zulu peoples of southern Africa.[17,18] The genus name *Bulbine* stems from the Greek *bolbine* or *bolbos*, meaning "bulb" or "onion." In Latin, *Bulbine* means "little onion" or "bulb."[10]

The genus *Bulbine* was named by German botanist Nathanael Matthäus von Wolf (1724-1784) in his 1776 publication *Genera plantarum vocabulis characteristicis definita*, referring to *Anthericum* as a synonym.[19] In 1781, *Anthericum latifolium* was described by Swedish naturalist Carl Linnaeus the Younger (1741-1783), stating its habitat as "Caput Bonae Spei" (Cape of Good Hope).[20] It was renamed *Bulbine latifolia* in 1825 by German botanist Kurt Polycarp Joachim Sprengel (1766-1833). The species name *latifolia* refers to its broad leaves.[21] In 1809, German botanist and plant taxonomist Karl Ludwig von Willdenow (1765-1812) named the species *Bulbine frutescens*, listing *Anthericum frutescens* as a synonym and also naming its habitat as the Cape of Good Hope.[22] In 1834, German botanist Joseph zu Salm-Reifferscheidt-Dyck (1773-1861) named the species *Bulbine narcissifolia*, but added "*patria ignota*," meaning native origin unknown.[23] The Latin species name *narcissifolia*, means "with leaves like a Narcissus" (daffodil).[24]



**Bulbine** *Bulbine frutescens*
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Zulu men and adolescents ingest an aqueous decoction of unspecified parts of *B. latifolia* (known as *ibhucu*) as an emetic in purification rites for the purpose of preventing antisocial behavior. The Xhosa people prepare a decoction of the subterranean parts to treat convulsions in children.[17,25] Older literature reported that Zulu healers administered an infusion of *B. frutescens* root and leaf as an emetic "to patients thought to be going mad as a result of being bewitched."[17] South African Rastafarian bush doctors distinguish two types of *B. latifolia* roots for different uses: thin red roots are used to treat blood circulation and erectile dysfunction associated with diabetes, and thick yellow roots are used as a blood purifier and to treat kidney and bladder problems.[26] The fresh leaf gel of both *B. frutescens* and *B. asphodeloides* is applied topically to treat wounds, cuts, grazes, burns, sores, rashes, itches, cracked lips, mosquito bites, ringworm, and herpes.[7]

A survey of local indigenous people, herbalists, and traditional healers in Eastern Cape province found that an aqueous decoction of dried whole plant (including roots, rhizomes, and leaves) of *B. latifolia* is used to treat stomach ailments and rheumatism.[27] A decoction of the ground leaves of *B. latifolia* also is used in traditional veterinary medicine in Eastern Cape province to control parasites, including ticks and helminths, in goats.[28] The leaf sap of *B. narcissifolia* is used traditionally for burns, wounds, and rashes, and the leaf sap of *B. natalensis* is used for diarrhea, burns, rashes, sunburn, corns, and warts. Decoctions of both dried whole plant and leaf of *B. frutescens* are used for treating diarrhea and topically for burns, rashes, blisters, insect bites, cracked lips, and mouth ulcers.[27] In western Free State, *B. narcissifolia* tea is taken orally to treat kidney problems.[9]

In 2004, a monograph for *B. frutescens* was prepared through the Pharmacopoeia Monograph Project of the South African Traditional

Medicines Research Group at the University of the Western Cape's School of Pharmacy with support from the South African Medical Research Council.[29] In 2010, a monograph for this species appeared in the first edition of the *African Herbal Pharmacopoeia*.[7]

## CURRENT AUTHORIZED USES IN COSMETICS, FOODS, AND MEDICINES

In the South African market, dry extract of *B. natalensis* tuber is used as a natural ingredient in non-medicinal food supplement products labeled with the claim "testosterone booster."[30] The leaf juice of *B. frutescens* is also produced in South Africa for soap and veterinary applications (i.e., to help increase skin hydration and elasticity).[13]

In the European Union (EU), *B. frutescens* leaf juice is authorized for use as a skin-conditioning component of cosmetic products.[31] However, for use in oral ingestion products, *B. natalensis* is presently classified as a Novel Food. A request has been submitted to the European Commission for a determination on whether it will require authorization under the Novel Food Regulation. According to the information available to Member States, *B. natalensis* was not used as a food or food ingredient before May 15, 1997. Therefore, before it may be placed on the market in the EU as a food or food ingredient, a safety assessment under the Novel Food Regulation is required.[32]

In Canada, *B. natalensis* is regulated as an active ingredient of licensed natural health products (NHPs), which require pre-marketing authorization from the Natural and Non-prescription Health Products Directorate (NNHPD).[33] At the time of this writing (February 2020), there were three licensed multi-herb NHPs containing an extract of *B. natalensis* as one of the active ingredients.[34]

In the United States, several products labeled as containing an extract of *B. natalensis* are listed in the National Institutes of Health's (NIH's) Dietary Supplement Label Database, mostly with male sexual enhancement-oriented names like "Fornatab," "Insane Testosterone Booster," and "Ultra Male RX."[35] No *Bulbine* species, however, are listed in the American Herbal Products Association's *Herbs of Commerce* first edition (1992)[36] or second edition (2000).[37] Bulbine is also not found in the US Food and Drug Administration's (FDA's) inventory of Generally Recognized as Safe (GRAS) notices.[38] No public information was found on the status of bulbine extracts either as an old dietary ingredient (ODI) or new dietary ingredient (NDI). It is possible that an independent GRAS conclusion (formerly called GRAS Self-Determination or Self-Affirmed GRAS) has been made or an NDI Notification has been submitted, of which the authors of this article are not aware.

## MODERN RESEARCH

Despite *Bulbine* species' being well-documented for their traditional uses, modern-day research is still scant. No clinical trials with efficacy endpoints could be found in the literature for preparations of *Bulbine* species.

Investigation of the composition of *Bulbine* species started in the 1990s, when van Staden and Drewes (1994) isolated the anthraquinone knipholone from *B. latifolia* and *B. frutescens*.[39] It took almost 10 years until these findings were affirmed and other phenylanthraquinones (4′-*O*-demethylknipholone-4′-*O*-β-D-glucopyranoside and gaboroquinones A and B) were isolated from *B. frutescens*.[40] Mutanyatta et al. (2005) elucidated four novel *O*-sulfated phenylanthraquinones, along with their non-sulfated parent compounds from the root of *B. frutescens*.[41] The first chemical investigation of *B. natalensis* was reported by Bae et al. (2016),[42] who isolated chrysophanol, 10,7′-bichrysophanol, knipholone, and isoknipholone. An additional six anthraquinones, one naphthalene derivative, bulbnatalonosides A-E, bulbnatalone, and bulbnatalol were isolated from the stem of *B. natalensis* by the same group.[43,44] These authors subsequently published their development and validation of a method for identification and quantification of anthraquinone-type compounds in *B. natalensis* samples and dietary supplements.[45]

A number of experimental studies have attempted to substantiate traditional uses of *Bulbine* species. Widgerow et al. (2000) predicted hydration and antibacterial properties for an extract of *B. frutescens* in scar management.[46] Mocktar (2000) confirmed antimicrobial activities of methanolic extracts of *B. frutescens*, *B. narcissifolia*, and *B. abyssinica* in a battery of tests against *Klebsiella pneumoniae*, *Staphylococcus aureus*, *Salmonella typhi,* and *Shigella flexneri* and demonstrated that a *B. frutescens* root extract inhibited *Candida albicans*.[47] Brine shrimp assay was used to assess toxicity. Most extracts proved toxic at high concentrations, with the exception of root extracts of *B. frutescens*, *B. narcissifolia*, and *B. abyssinica*.

Antimicrobial, anti-inflammatory, antioxidant, wound-healing, and other activities affecting skin parameters received renewed attention in the 2010s and have since remained the focus of investigations.[27,43,44,48-58] Coopoosamy (2011) showed moderate activity against gram-positive bacteria with acetone and ethyl acetate extracts of *Bulbine* species but low to no activity with water extracts,[27] implying polarity of the active compounds, which was confirmed in experiments conducted by Mzindle (2017).[53] *Bulbine* anthraquinones were tested for antimicrobial activity, and bulbnatalonoside A showed a moderate inhibitory effect against methicillin-resistant *Staphylococcus aureus* (MRSA).[43,44] In an experimental setting, Pather et al. (2011 and 2012) demonstrated a wound-healing effect of *B. natalensis* and *B. frutescens* leaf gels (specifically, an increase in tensile strength by increasing fibroplasia, collagen deposition, and maturation).[48,49]

Other effects investigated include antidiabetic,[59-63] androgenic,[64,65] antiproliferative,[66,67] and anti-HIV.[68] An aqueous extract of *B. frutescens* whole plant was shown to increase glucose utilization significantly more than insulin in C2C12 cells, and to promote glucose uptake in

Chang liver cells (HeLa).[60] Kibiti (2016) demonstrated antidiabetic effects — presumably through affecting carbohydrate metabolism, oxidative stress, and opportunistic infections — with aqueous and acetone extracts of *Bulbine* species and the essential oil of *B. abyssinica*.[61] Odeyemi and Afolayan (2018) investigated polyphenolic fractions of a methanolic extract of *B. abyssinica* leaves and found them to be amylase and glucosidase inhibitors, active against free radicals, as well as showing ferric ion-reducing capacity.[62] Yakubu and Afolayan (2009 and 2010) showed a prosexual stimulatory potential, as well as anabolic and androgenic activities with an aqueous extract of *B. natalensis* stem in male rats.[65,69]

Crude aqueous and ethanolic extracts of *B. natalensis* and *B. frutescens* leaf, bulb, and root were investigated for cytotoxicity in a human laryngeal carcinoma cell line (HEp-2).[66] While all *Bulbine* species fractions showed the ability to induce HEp-2 cell death, likely through apoptosis (caspase-3 induction), no clear link could be established between apoptosis and cytotoxicity. Isofuranonaphthoquinone isolated from *B. frutescens* showed significant antiproliferative effects on Jurkat T-cells by producing reactive oxygen species resulting in apoptosis and inhibiting glutathione transferase and drug efflux pumping activities.[67] Shikalepo et al. (2018) demonstrated moderate inhibitory activity with an extract of *B. frutescens* aerial parts on HIV-1 protease, reverse transcriptase, and integrase enzymes in vitro.[68]

Yakubu and Afolayan (2009) demonstrated localized systemic toxicity with a *B. natalensis* stem extract in male Wistar rats; specifically, an increase in platelets and monocytes and a decrease in neutrophils, eosinophils, basophils, and lymphocytes. They also reported an increase in atherogenic index and of serum concentrations of cholesterol and triacylglycerols, and a decrease in high-density lipoprotein, pointing toward an increased risk of atherosclerosis with long-term consumption.[64]

On the other hand, Hofheins et al. (2012) performed a placebo-controlled, double-blind clinical trial to assess the short-term safety of supplementation with an undefined extract of *B. natalensis* (ProLensis™; Sports Nutrition Research, Ltd.; Franklin Square, New York) in 32 healthy male adults by assessing changes in heart rate, blood pressure, and renal, hepatic, and hematological biomarkers.[70] Supplementation was found to be safe at 650 mg/day (28 days) of *B. natalensis* as no significant differences occurred between groups in 27 of the 29 markers. The only changes were a marginal increase in alkaline phosphatase compared to a parallel decrease in the placebo group and a decrease in creatinine compared to no change in the placebo group; however, these changes were within normative clinical limits.

**Bulbine** *Bulbine frutescens*
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## ADULTERATION

Because of the wide use of *Bulbine* genus plant parts within South Africa, it is possible that materials of different related species of the same genus could be substituted.[3] According to the *African Herbal Pharmacopoeia*, *Bulbine frutescens* gel can be intentionally adulterated or confused with the gel of the leaves of various *Aloe* species, and gel powder can be adulterated with various undeclared substances such as malic acid or lactic acid.[7] A recent study quantifying levels of heavy metals in frequently used South African medicinal plants found very high levels, especially of aluminum and iron, in samples of *B. natalensis* obtained from open street markets.[71]

## SUSTAINABILITY AND FUTURE OUTLOOK

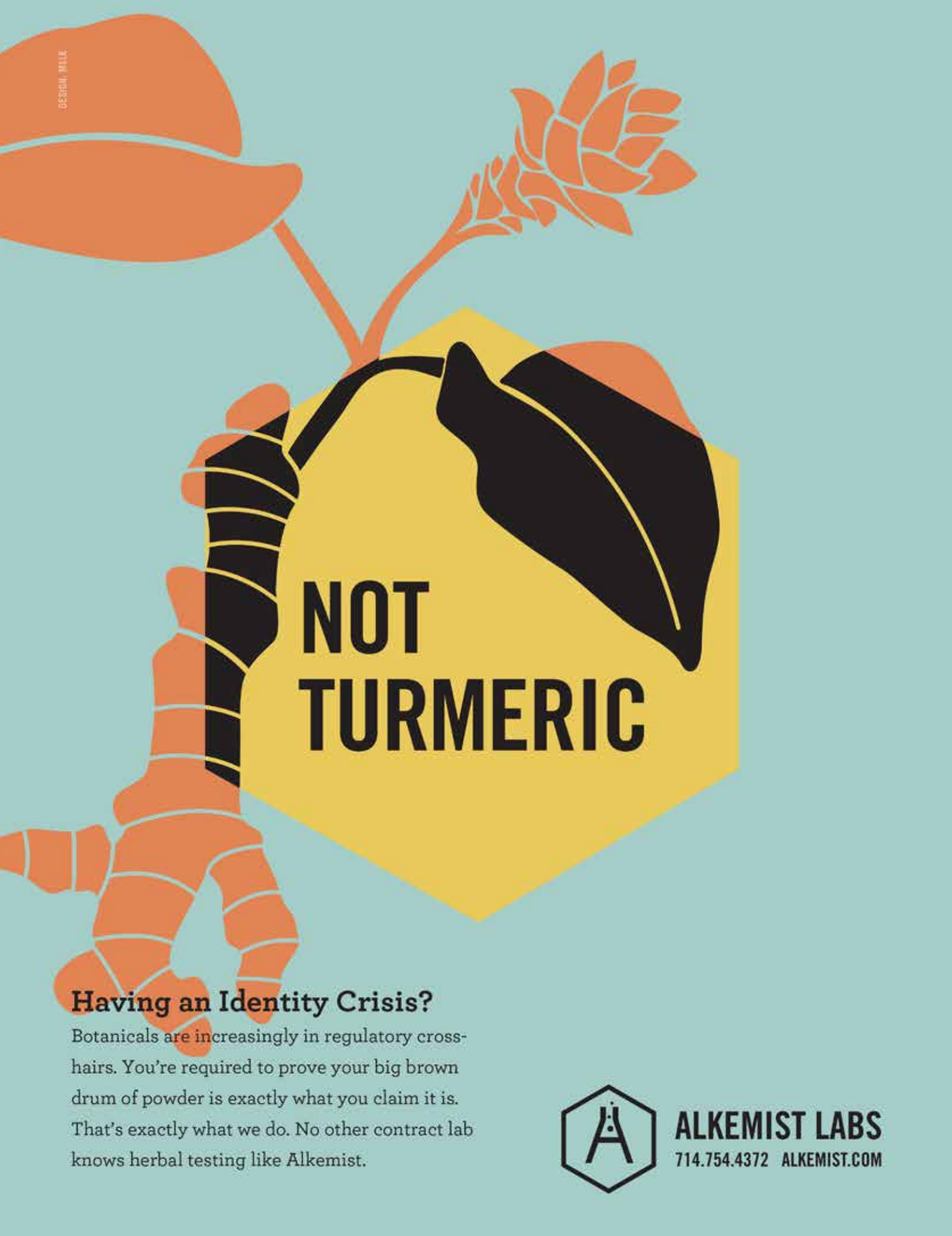
The conservation status of the *Bulbine* species discussed in this article has not yet been assessed using the International Union for Conservation of Nature's (IUCN's) Red List Categories and Criteria. An early 1970s vegetation and botanical exploration of the Addo Elephant National Park (AENP) in Eastern Cape, South Africa, ranked *B. frutescens* as very common, *B. natalensis* as rare, and *B. narcissifolia* as present (but without an occurrence ranking).[72] The current manual used by nature and field guides operating in AENP lists only *B. abyssinica* and *B. frutescens*, noting that roots of the latter are eaten by porcupines.[73] A survey conducted in 1999-2000 in the communities of Tsehlanyane and Bokong, Lesotho, found that wild populations of some commercialized plant species, including *B. narcissifolia*, were decreasing in the area due to overharvesting.[74]

Already in the 1980s, *B. latifolia* was reported among plant species most frequently demanded by consumers in KwaZulu-Natal and with large quantities in regional trade.[75] In the early 2000s, it was reported that increased demand for *B. latifolia* corm in the Rastafarian community led to cases of illegal and destructive wild-harvesting practices.[5] One study reported that *B. latifolia* was among the 10 most frequently sold plant species in Eastern Cape and observed to be unsustainably harvested at the study sites.[76] A 2009 dissertation on the use and conservation status of medicinal plants in Western Cape found *B. frutescens* to be the fifth most frequently used medicinal plant out of 112 plants in the survey.[18] Although *B. latifolia* ranked 55th in that survey, a 2010 dissertation listed it among the most culturally important medicinal plants used by Rastafarian bush doctors of Western Cape. Wild harvesting of this species in the area of Knysna, Western Cape, and Eastern Cape was described in the 2010 dissertation as destructive, unsustainable,[26] and of conservation concern. A more recent study ranked *B. latifolia* among three medicinal substances that are important to trade in both Eastern Cape and Western Cape.[77]

The market for ingredients and products made from South African species of *Bulbine* is growing beyond the region and entering Europe and the Americas in the form of cosmetics, personal care products, dietary supplements, natural health products, novel foods, and veterinary products. A recent use is topical application of *B. frutescens* leaf gel to soothe new tattoos, applying the anti-inflammatory and wound-healing properties of the gel. New global demand may not be satisfied by sustainably sourcing solely from wild populations. *Bulbine* species are relatively easy to cultivate, and innovative companies in South Africa are actively developing raw material production bases where voluntary standards for sustainable agriculture (e.g., organic) are being implemented. Furthermore, some sustainable wild-collection operations have entered into ABS agreements with indigenous communities. If the global market for southern African *Bulbine* species products continues to grow, it should be possible to scale up production through both sustainable agriculture and sustainable wild collection, in both cases within a context of ABS. HG

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# Fig and Saffron Adoptions Support ABC's Adopt-an-Herb Program

**By Connor Yearsley and Hannah Bauman**

**The American Botanical Council (ABC) welcomes the adoptions of fig (*Ficus carica*, Moraceae) by Euromed, a Mollet del Vallès, Spain-based phytomedicine company, and saffron (*Crocus sativus*, Iridaceae) by Pharmactive Biotech Products, a Madrid, Spain-based manufacturer of standardized natural ingredients, through ABC's Adopt-an-Herb botanical research and education program.**

These adoptions support ABC's extensive HerbMedPro database, ensuring that this unique research and educational resource remains up to date for researchers, health professionals, industry members, students, consumers, and other members of the herbal and dietary supplement and natural medicine communities.

HerbMedPro is a comprehensive, interactive online database that provides access to important scientific and clinical research data on the uses and health effects of more than 265 herbs, spices, medicinal plants, and fungi.

## Euromed Adopts Fig

"Euromed is a longtime supporter of ABC initiatives," said Andrea Zangara, Euromed's head of scientific communication and marketing. "Fig is our second adoption through the Adopt-an-Herb program, with milk thistle [*Silybum marianum*, Asteraceae] being the first. Euromed recognizes the essential role ABC plays in educating health professionals, natural product industry stakeholders, and consumers about the health benefits of herbal supplements.

"Euromed is committed to expanding the body of safety and efficacy studies on botanical products and relies on organizations like ABC to disseminate this information," Zangara added. "The fig adoption fits perfectly with our mission to develop, innovate, and supply high-quality, traceable, sustainable, and evidence-based botanical ingredients for a healthier world."

Mark Blumenthal, ABC's founder and executive director, said: "ABC truly appreciates Euromed's adoption of fig on ABC's highly useful HerbMedPro database. Not only is fig a widely popular food in many parts of the world (it's one of my favorites!), it also has health benefits. Euromed's fig adoption will allow ABC to stay current on the scientific and medical research on fig, confirming the proposition that food is medicine."



**Fig** *Ficus carica*
Photo ©2020 Steven Foster

### *About Fig*

The *Ficus* genus belongs to the mulberry family (Moraceae) and includes about 800 species or more, making it one of the largest genera of flowering plants. Of these species, *F. carica* is the most important as a human food source. The fruit is botanically classified as a syconium, a fleshy receptacle with many tiny flowers. Native to western Asia and the Mediterranean, *F. carica* is a fast-growing temperate deciduous shrub or small tree that can grow to 30 feet tall. It is noted for its spreading habit and attractive foliage.

*Ficus carica* may have been the first domesticated fruit crop. Fig remains from about 11,400 years ago were found at Gilgal I, a village near Jericho in Israel. About 5,000 years ago, the Sumerian King Urukagina reportedly wrote about fig. Excavations of the Uluburun shipwreck, a Late Bronze Age shipwreck discovered in 1982 off the Mediterranean coast of Turkey, yielded fig remains among the cargo. The ancient Greeks reportedly received figs from Caria in Anatolia, hence the species name *carica*. In the Bible, in Song of Songs, King Solomon praised figs. And, according to some historical accounts, King Nebuchadnezzar II planted figs in the hanging gardens of Babylon about 2,500 years ago.

Each *Ficus* species depends on its own fig wasp species for pollination. These tiny wasps can lay eggs only in the

flowers of their partner figs, and the figs can be pollinated only by their wasps. Any wasps that do not exit the figs are broken down by enzymes as the figs ripen. Some species of *Ficus* produce fruits year-round, which sustains their wasp pollinators. This also benefits animals that may otherwise struggle to find food for much of the year. *Ficus* fruits are eaten by more than 1,200 animal species, which disperse the seeds and the seeds of other plants. Ecologists have thus called figs "keystone resources."

Figs are dense in nutrients and a good source of vitamins, minerals, carbohydrates, other sugars, organic acids, fiber, polyphenols, and the phytochemical abscisic acid (ABA). Yet, in the American diet, figs reportedly account for less than 1% of total fruit consumed annually. One promising health application of ABA is its apparent ability to stimulate cellular uptake of blood sugar, Zangara said. This may be why a sweet fruit like fig seems to have better glycemic responses than refined sugars. In vivo and in vitro studies suggest that fig fruits, stems, leaves, and latex have anti-inflammatory, antimicrobial, antioxidant, and antitumor effects. In human clinical trials, figs have shown efficacy for treating atopic dermatitis, constipation, and warts.

### *About Euromed*

Euromed was founded in 1971 by the German pharmaceutical group Madaus to ensure vertical integration and superior quality for its leading phytomedicine, a standardized milk thistle extract, and other phytomedicines. Recently, Euromed launched a new product line of fruit and vegetable extracts, including fig, inspired by the documented health benefits of the Mediterranean diet.

According to Zangara, *F. carica* grows naturally throughout Spain, and its dry fruits have one of the highest concentrations of ABA found in nature. The Spanish figs in Euromed's supply chain are farmed sustainably and sourced locally, which reduces transportation and the company's carbon footprint. Euromed has developed an osmotized water-only extraction technology (Pure-Hydro Process™), which preserves naturally occurring compounds, including ABA, while avoiding residues of organic solvents and minimizing environmental impact.

Many Americans do not consume adequate fruits and vegetables and may therefore have deficient ABA levels, Zangara noted. Euromed claims that its fig extract ABAlife® delivers the scientifically documented health benefits of ABA while avoiding additional calories associated with eating figs. In one published clinical trial with Euromed's proprietary Spanish fig fruit extract, healthy participants experienced beneficial modulation of postprandial glycemic responses.

### Pharmactive Adopts Saffron

"Pharmactive is more than pleased to adopt one of the most fascinating and valued plants in the world," said Pharmactive Founder and CEO Jean-Marie Raymond. "Saffron is helping millions of people around the world maintain a positive mood, manage anxiety, and get restorative sleep every day. The excellent safety profile of saffron makes it perfect for different stages of life, including the elderly and adolescents."

Blumenthal said: "ABC is deeply grateful to our friends at Pharmactive for adopting saffron on ABC's powerful HerbMedPro database. Saffron is a traditional spice, often considered the most expensive in the world. The past decade has witnessed a virtual explosion of scientific and clinical research on the effects of saffron extracts on the human central nervous system, including its positive effects for people with mild-to-moderate depression. In fact, the emerging saffron research is so impressive that ABC published a review of the clinical literature in *HerbalGram* issue 110."

### *About Saffron*

Saffron is an autumn-flowering perennial. The main part of the plant used medicinally is the dried stigma. With only three stigmas per plant, saffron is among the most expensive spices in the world, which makes economically motivated adulteration common. It is used as a food additive due to its aroma, color, and bitter taste, as well as in various systems of traditional medicine. It has not been

PHARMACTIVE BIOTECH PRODUCTS

**Saffron**
*Crocus sativus*



**Saffron** *Crocus sativus*
Photo ©2020 Steven Foster

reported in the wild and probably descends from wild saffron (*C. cartwrightianus*). The *Crocus* genus includes 85 known species, but *C. sativus* is favored for its medicinal properties.

Saffron's stigmas contain volatile and non-volatile compounds, including terpenes and their esters and carotenoids, all of which are responsible for saffron's color and taste. The petals, which are used less often in medicinal preparations, contain glycosides of the flavonoids quercetin and kaempferol. Saffron has been used in the traditional medical practices of Egypt, Greece, India, and Persia, where it was used for respiratory disorders, menstrual disorders, painful urination, and mood disorders.

Modern applications of saffron focus largely on cognitive function and mood support, and some human clinical trials have compared the effects of saffron preparations to leading conventional pharmaceutical drugs used for Alzheimer's disease and mild-to-moderate depression. Other promising areas of research for saffron extracts focus on its anti-inflammatory actions for reproductive health, glaucoma and macular degeneration, and weight loss and exercise.

### *About Pharmactive*

Pharmactive Biotech Products, SL, is a privately owned company that develops and manufactures standardized natural ingredients that are supported by scientific evidence. The company prides itself on having high standards and dedicated research and development investment. Pharmactive states that it is the first company to introduce a standardized saffron extract for mood management. Pharmactive partners internationally with universities and research organizations to boost its research and development capabilities and generate new opportunities for its customers.

Because of saffron's demand and limited supply, Pharmactive takes active steps to ensure its customers receive an unadulterated product. Raymond noted: "The quality of the raw material and the extraction process are the keys to preserving the beneficial properties, and full control is the key to avoiding adulteration." Pharmactive traces its extracts from field crops to in-house production.

### About Adopt-an-Herb and HerbMedPro

Euromed and Pharmactive are among the 65 US and international companies and organizations that have supported ABC's educational efforts to collect, organize, and disseminate reliable traditional and science-based information, including clinical studies, on herbs, medicinal plants, and other botanical- and fungal-based ingredients through the Adopt-an-Herb program. This program encourages companies, organizations, and individuals to "adopt" one or more specific herbs for inclusion and ongoing maintenance in the HerbMedPro database. To date, 73 herbs have been adopted.

Each adopted herb is researched continuously for new scientific articles and botanical, chemical, pharmacological, toxicological, and clinical studies, ensuring that its HerbMedPro record stays current and robust. Access to the studies is organized conveniently by publication type, with each study condensed to a one-sentence summary with a link to the study's official abstract on PubMed (the US National Library of Medicine's free-access database) or other publicly accessible databases.

HerbMedPro is available to ABC members at the Academic level and higher. Its "sister" site, HerbMed, is available to the general public at no cost, with access to 25-30 herb records from the larger HerbMedPro database. In keeping with ABC's position as an independent research and education organization, herb adopters do not influence the scientific information that is compiled for their respective adopted herbs. HG

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# ABC Board of Trustees Members Recognized with Prestigious Horticultural Awards

**By Hannah Bauman**

**In March 2020, two members of the American Botanical Council (ABC) Board of Trustees were honored for their achievements in the fields of horticultural science and gardening. Holly Shimizu, former executive director of the United States Botanic Garden in Washington, DC, received the Scott Medal and Award from the Scott Arboretum of Swarthmore College and Michael J. Balick, PhD, director and senior philecology curator of the New York Botanical Garden's Institute of Economic Botany, received the American Horticultural Society's (AHS's) H. Marc Cathey Award.**

## Holly Shimizu Receives Scott Medal and Award


Holly Shimizu

The Scott Medal and Award are given annually to an individual, organization, or corporate body who "has made an outstanding national contribution to the science and the art of gardening." The purpose of the award is "to promote a greater love of nature, make the nation more conscious of the beauty of the outdoors, [and] develop a greater knowledge and love of plants and flowers."[1]

Shimizu, a nationally recognized horticulturist, consultant, and educator with a commitment to plant conservation and sustainability, was nominated for the award by Ari Novy, PhD, president and CEO of the San Diego Botanic Garden, and Paul W. Meyer, former director of the Morris Arboretum of the University of Pennsylvania. Shimizu would have received the award and presented the keynote speech at the Scott Arboretum's Spring Celebration on March 15, 2020, but the event has been rescheduled to October 18. For her speech, Shimizu plans to focus on stewardship, sustainability, and a healthier planet through habitat and soil preservation, highlighting the efforts of organizations and initiatives, including ABC and its Sustainable Herbs Program, the Ecological Landscape Alliance, United Plant Savers, and the Sustainable SITES Initiative. Shimizu joined the ABC Board of Trustees in 2017.[2]

"It is an incredible honor to receive this prestigious award, which has been given to people I have admired throughout my life," wrote Shimizu (email, March 18, 2020). "Sharing my own love for and excitement about plants, herbs, gardens, and the environment with people over the years has been extremely rewarding, filled with rich experiences and continued learning, and it has brought me together with amazing people."

## Michael Balick Receives H. Marc Cathey Award


Michael Balick, PhD

The award, named in honor of horticultural scientist and former AHS President H. Marc Cathey, PhD, is given every other year as a part of AHS's Great American Gardeners Awards to an individual for "outstanding scientific research that has enriched horticulture and plant science."[3] Formerly known as the Scientific Award until its name change in 2000, the award has been given since 1953. It is scheduled to be presented to Balick at the 2020 Great American Gardeners and Book Awards Ceremony and Banquet on June 18, 2020, at AHS's River Farm headquarters in Alexandria, Virginia.

Balick works with indigenous peoples in tropical, subtropical, and desert environments to document and preserve traditional medicinal plant knowledge while evaluating these plants for potential pharmaceutical applications. His most recent project focuses on documenting the diversity, local use, and management of plant resources in Micronesia and Melanesia to implement a conservation plan to help these communities sustainably manage these resources. Balick has served on the ABC board since 1999, and was profiled in *HerbalGram* issue 82.[4]

"Marc Cathey was one of the most significant figures of his day in the field of horticulture, outreach, and research, and it is wonderful to see his legacy continued by the American Horticultural Society," Balick wrote (email, March 18, 2020). "It is said that researchers stand on the shoulders of the giants who preceded them, and Dr. Cathey was certainly one of those giants, his influence reaching millions of people through his work in public horticulture, plant introductions, lectures, and radio shows. Many of us, therefore, have been privileged to stand on his shoulders. I always enjoyed listening to him talk about plants. I am grateful to the AHS for recognizing our work at The New York Botanical Garden, particularly the efforts to preserve plant biodiversity and cultural knowledge of plants, which are all essential to maintaining environmental resilience in the face of global change." HG

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# ADOPT-AN-HERB

HerbMedPro™ PROGRAM

The American Botanical Council's Adopt-an-Herb Program provides a mutually beneficial opportunity to support ABC's nonprofit educational efforts and promote a company's most important herbs.

One of the benefits of supporting the Adopt-an-Herb Program is that it ensures that the most current information on the adopted herb is available through ABC's powerful HerbMedPro™ database.

HerbMedPro provides online access to abstracts of scientific and clinical publications on more than 250 commonly used medicinal herbs. A free version, HerbMed®, is available to the general public and includes access to adopted herbs. HerbMedPro is available as a member benefit to all ABC members at the Academic Membership level and up.

In addition to ensuring that recently published information on an adopted herb is up to date on HerbMedPro, another benefit adopters enjoy is being included among their peers in each issue of ABC's acclaimed quarterly, peer-reviewed scientific journal, *HerbalGram*, on the ABC website, and at scientific, medical, and other educational conferences. Press releases also are issued on new adoptions, bringing attention to the program, the adopted herb, and the adopting company. Each adopted herb is featured on its own page on the ABC website.

Parties interested in taking part in the Adopt-an-Herb Program are invited to contact ABC Development Director Denise Meikel at 512-926-4900, extension 120, or by email at denise@herbalgram.org.

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# American Botanical Council Announces Annual Botanical Excellence Awards

**By ABC Staff**

**In March 2020, the American Botanical Council (ABC) announced the recipients of its six 2019 Botanical Excellence Awards. Typically, the ABC Botanical Excellence Awards are presented at the annual American Botanical Celebration and Awards Ceremony during the Natural Products Expo West trade show in Anaheim, California, in early March. However, because Expo West was canceled, the 15th annual ceremony did not occur.**

The 2019 ABC James A. Duke Excellence in Botanical Literature Award was given to *Flora of the Voynich Codex: An Exploration of Aztec Plants* (Springer, 2019) by Arthur O. Tucker, PhD, and Jules Janick, PhD.

San Francisco, California-based Napo Pharmaceuticals, a subsidiary of Jaguar Health, received the 2019 ABC Varro E. Tyler Commercial Investment in Phytomedicinal Research Award. Napo specializes in the research, development, and production of novel plant-derived therapeutic agents and has successfully developed and commercialized an extract from the sap of the Amazonian tree dragon's blood, or *sangre de drago* (*Croton lechleri*, Euphorbiaceae).

The 2019 ABC Norman R. Farnsworth Excellence in Botanical Research Award was given to Rachel Mata, PhD, a pharmacist, pharmacognosist, and natural products researcher who has spent most of the past five decades investigating the quality, composition, and benefits of Mexican medicinal plants and fungi.

Mary L. Hardy, MD, received the 2019 ABC Fredi Kronenberg Excellence in Research and Education in Botanicals for Women's Health Award. Hardy is board certified in internal medicine, specializes in botanical and integrative medicine, and is a leader in integrative oncology. For more than 25 years, in both her practice and research, she has combined complementary and alternative medicine (CAM) with Western medicine.

Thomas Brendler received the 2019 ABC Champion Award. Brendler, the founder of the consulting firm PlantaPhile, has dedicated countless hours to ABC and its publications since joining the ABC Advisory Board nearly a decade ago.

Mary Blue, Katheryn Langelier, and Nicole Telkes received the 2019 ABC Mark Blumenthal Herbal Community Builder Award. These three herbalists became the face of the "Tradition Not Trademark" movement when they were sued for trademark infringement and battled in court to keep the herbal legacy product "fire cider" a generic term.

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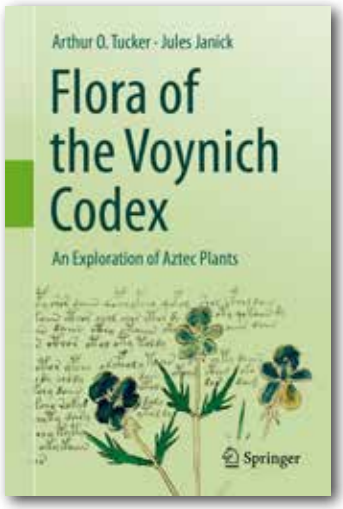
BOTANICAL EXCELLENCE AWARDS

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## *Flora of the Voynich Codex* Receives ABC Duke Award

The Voynich Codex, an illustrated manuscript written in a fanciful, mysterious language, has confounded historians and botanists and inspired a dedicated community of amateur sleuths. This latest work by Tucker and Janick follows their previous book on the subject, *Unraveling the Voynich Codex* (Springer, 2018). The 2019 Duke Award was given posthumously to Tucker, who died in August 2019, when the book was in press.

ABC gives the Duke Award annually to books that contribute significantly to the medicinal plant-related literature and the fields of botany, taxonomy, ethnobotany, pharmacognosy, phytomedicine, and other related disciplines.




The Duke Award was created in 2006 to honor economic botanist and author James A. Duke, PhD, who died in December 2017. Duke's prestigious career achievements in economic botany and ethnobotany included decades of work as the lead medicinal plant expert at the United States Department of Agriculture and the authorship of more than 30 reference and consumer books. Among his many other activities and positions, he was also a co-founding member of ABC's Board of Trustees.

The Voynich Codex was named for Polish book dealer Wilfrid Voynich (1865-1930), who purchased the manuscript in

Italy in 1912. However, the provenance of the codex is as mysterious as the figures on its pages. Voynich estimated it was from the 13th century, and carbon dating performed by the University of Arizona in 2011 dated the samples from 1404 to 1438. However, Tucker and Janick maintain that the plants and animals illustrated in the codex were native to North America and point to a 16th-century origin, a hypothesis that the authors expanded on in *Unraveling the Voynich Codex* and further explore in *Flora of the Voynich Codex*, in which they identify the plants, many of which were used as traditional herbal medicines by the Aztec people of southern Mexico.

Internationally noted medicinal plant photographer, botanical author, and ABC Board of Trustees member Steven Foster, who served on the Duke Award selection committee, commented: "Since its discovery in the early 20th century, the Voynich Codex has been analyzed by religious historians, Roger Bacon specialists, early European history experts, conspiracy theorists, and space alien pundits, among others. This year's recipient of the Duke Award has taken a morphological botanical approach to deciphering the iconic plant figures in the Voynich Codex and provides a clear linkage to the flora of Mexico. Clarity of time, place, and subject matter provide foundational scholarship for further research."

Tucker, a professor emeritus of botany at Delaware State University, published his first article on the codex in *HerbalGram* issue 100 in 2013 and began his collaboration with Janick, the James Troop Distinguished Professor of Horticulture at Purdue University, in 2015. In 2016, after they organized a symposium on the subject, it caught the attention of Kenneth Teng, an editor for Springer.

"Springer is proud to be the publishing partner of Prof. Janick and the late Prof. Tucker in their journey to uncover the secrets of what many [consider to be] the world's most mysterious book," wrote Teng, who facilitated the publication of both books. "This is the first and only publication that completely identifies all the plant species from the original Voynich manuscript. *Flora of the Voynich Codex*, which was meticulously researched, sheds light on the possible Mesoamerican origin of this fascinating manuscript."

Janick said: "Arthur would have been elated by this award, since his efforts to unravel the Voynich Codex, the world's most mysterious manuscript, consumed him for the last seven years of his life. In *Flora of the Voynich Codex*, identification [of the plants] was extended to 166 phytomorphs, all but one [of which is] indigenous to the New World. It reinforced our mantra that there was no way that a manuscript with a sunflower [*Helianthus* sp., Asteraceae] and an armadillo could be a 15th-century European work [as both species are native to the Western Hemisphere]…. The award is a final tribute to my dear friend and an indefatigable botanist."

**ABC James A. Duke Award Recipients***

2019: *Flora of the Voynich Codex: An Exploration of Aztec Plants*
2018: *Ethnopharmacologic Search for Psychoactive Drugs*, Volumes I and II
2017: Reference/technical: *Chinese Medicinal Plants, Herbal Drugs and Substitutes*
2017: Consumer/popular: *Joseph Banks' Florilegium*
2016: *Handbook of Essential Oils*, 2nd edition
2015: *Clinical Aromatherapy*, 3rd edition
2014: *Ancient Pathways, Ancestral Knowledge*
2013: *Principles and Practice of Phytotherapy*, 2nd edition
2012: Reference/technical: *Medicinal Plants and the Legacy of Richard E. Schultes*
2012: Consumer/popular: *Smoke Signals*
2011: Reference/technical: *American Herbal Pharmacopoeia: Botanical Pharmacognosy*
2011: Consumer/popular: *Healing Spices*
2010: *Botanical Medicine for Women's Health*
2009: *An Oak Spring Herbaria*
2008: *Mabberley's Plant Book*, 3rd edition
2007: Google Book Search
2006: *Medicinal Spices*
2005: *The Essential Guide to Herbal Safety*

*In some years, ABC presents the Duke award to two books — one in the reference/technical category and the other in the consumer/popular category.

## Napo Pharmaceuticals Receives ABC Tyler Award

Dragon's blood grows in the Amazon basin in Peru and neighboring countries. The red latex has been used as a traditional medicine by indigenous peoples for centuries, possibly millennia. Napo Pharmaceuticals isolated and developed a botanical drug called crofelemer from this latex. Crofelemer, a naturally derived proanthocyanidin oligomer, is effective for treating several types of diarrhea. In 2012, the US Food and Drug Administration (FDA) approved crofelemer for symptomatic relief of non-infectious diarrhea in patients with HIV/AIDS on antiretroviral therapy. To date, crofelemer is one of only two drugs approved by the FDA under its special guidance for chemically complex botanical drugs.

The ABC Tyler Award was created to honor one of the most respected US scientists in late-20th century herbal medicine and pharmacognosy (the science of drugs of natural origin, usually from plants). Varro E. Tyler, PhD, who died in 2001, was an early trustee of ABC and vice

Jaguar Health

president of academic affairs and dean of the College of Pharmacy and Pharmaceutical Sciences at Purdue University. He was the senior author of six editions of a leading pharmacognosy textbook that was used widely in colleges of pharmacy in the United States, and numerous other professional and popular books and academic articles. Tyler encouraged scientific and product integrity and envisioned a rational phytomedicinal health care sector that valued the proper evaluation of a phytomedicinal products' quality, safety, and efficacy.

"We are very grateful to the American Botanical Council for this recognition," said Steven King, PhD, Jaguar Health's executive vice president of sustainable supply, ethnobotanical research, and intellectual property. "We in turn would like to specifically acknowledge the intellectual contribution of local and indigenous peoples of the northwest Amazon basin for identifying the healing properties of traditional plant medicines. We would like to be sure that the international medical and patient communities know that indigenous science and ethnomedical expertise continue to provide solutions to medical challenges for humans and animals."

Lisa Conte, Jaguar Health's president and CEO, said: "We are delighted to receive this award that recognizes our focus on developing and commercializing novel, sustainably derived therapeutics to enhance gastrointestinal health around the globe. We are also pleased to be among the distinguished group of past recipients that includes our esteemed partner Indena," in reference to Indena SpA, one of the world's largest producers of clinically tested botanical extracts for the food, dietary supplement, cosmetic, and pharmaceutical industries. Indena received the ABC Tyler Award for 2008.

Research on crofelemer began in 1994, when it was investigated by the now-defunct Shaman Pharmaceuticals. The first report of crofelemer's potential to treat diarrhea was in 1995 when it improved symptoms of cholera-induced diarrhea in mice. The FDA approached Shaman to investigate crofelemer for the treatment of diarrhea, one of the most common adverse side effects in people living with HIV/AIDS (PLWHA) who use antiretroviral therapy, which was becoming more common at the time. In addition, a significant portion of the HIV patient population, particularly the growing segment of PLWHA who have lived with the virus for 10 years or more, suffers from HIV enteropathy, which is chronic diarrhea due to the direct or indirect effects of HIV on the gastrointestinal tract.

**ABC Varro E. Tyler Award Recipients**

2019: Jaguar Health/Napo Pharmaceuticals
2018: GW Pharmaceuticals
2017: Pharmatoka
2016: Brassica Protection Products
2015: MediHerb/Integria Healthcare
2014: SFI (Soho Flordis International)
2013: Wakunaga Pharmaceutical Company
2012: Horphag Research
2011: Bioforce AG
2010: New Chapter
2009: Bionorica AG
2008: Indena SpA
2007: Dr. Willmar Schwabe Pharmaceuticals

Crofelemer's first-in-class antisecretory mechanism of action and local activity in the gut provide a therapeutic benefit that is independent of the cause of the diarrhea. After proof-of-concept human studies in PLWHA, crofelemer was fast-tracked by the FDA, which approved it on December 31, 2012. Crofelemer was launched under the brand name Fulyzaq® and was renamed Mytesi® in 2016. Each Mytesi tablet contains 125 mg of the new molecular entity crofelemer in a delayed-release formulation.

In addition to HIV-associated diarrhea, crofelemer has been studied in human clinical trials for the treatment of traveler's diarrhea, diarrhea related to irritable bowel syndrome (IBS), and in acute infectious diarrhea. To date, 34 human clinical trials have been conducted on crofelemer. In addition, there have been three clinical trials with crofelemer in dogs for chemotherapy-induced diarrhea, two in dairy calves (for scours, a form of diarrhea that usually occurs in young calves), two in horses (for ulcers), and one specifically in foals for diarrhea.

Gafner commented: "Napo Pharmaceuticals not only has compelling science, but also an exceptional track record with its sustainability practices (its harvesting process, initiatives to conserve the habitats in which *Croton lechleri* trees grow, and benefit-sharing strategies with the countries and cultural groups with which it collaborates). This company is a role model for the entire botanical drug and dietary supplement industries."

ABC Founder and Executive Director Mark Blumenthal commented: "Professor Varro Tyler strongly believed that companies dealing with botanicals should invest in research on their phytomedicinal ingredients and products. In the 1990s, I had the good fortune to accompany him on two trips to the Peruvian Amazon, where we witnessed the traditional use of the red sap of sangre de drago. With Napo Pharmaceuticals' sustainable management of the trees for harvesting the sap and their development of an FDA-approved drug, I firmly believe that Tyler would fully support our choice of Napo Pharmaceuticals for this award in his name."

## Rachel Mata Receives ABC Farnsworth Award

ABC presents this annual award, named in honor of the celebrated professor Norman R. Farnsworth, PhD, to an individual who has made significant research contributions in the fields of pharmacognosy, ethnobotany, ethnopharmacology, or other scientific disciplines related to medicinal plants. Farnsworth, who died in 2011, was a highly published and internationally renowned research professor of pharmacognosy, a senior university scholar in the College of

Pharmacy at the University of Illinois at Chicago, and one of the founding members of ABC's Board of Trustees.

Mata, professor emerita in the Department of Pharmacy, School of Chemistry, National Autonomous University of Mexico (Universidad Nacional Autónoma de México), is best known for her work on the chemistry of Mexican medicinal plants, fungi, and lichens. Additionally, she has also made important contributions to the development of analytical methods for botanical ingredient quality control, some of which have been used for the preparation of monographs of herbal remedies included in the second edition of the *Mexican Herbal Pharmacopoeia*.


Rachel Mata, PhD

For almost 50 years, Mata has been at the forefront of research in the fields of ethnobotany and ethnopharmacology, natural products drug discovery, and analytical chemistry. Besides the discovery of many new compounds from traditional medicinal plants published in, among other publications, a series of papers under the title "Chemical studies on Mexican plants used in traditional medicine," she also contributed to the discovery of numerous natural compounds of agrochemical interest, such as limonoids with herbicidal and insecticidal properties.

The impact of Mata's many scientific contributions extends beyond her more than 180 scientific papers, book chapters, and books. She has taught and mentored more than 100 graduate, master's, and bachelor's students, including prominent Mexican natural products researchers. She also served as president of the Phytochemical Society of North America in 1997.

Throughout her career, Mata has received numerous awards and recognitions, most notably the Norman R. Farnsworth Research Achievement Award granted by the American Society of Pharmacognosy in 2014. At the national level, Mata has been distinguished with the National University Award (Teaching in Natural Sciences) in 2000, the Martín de la Cruz Prize awarded by the Mexican Ministry of Health in 2002, and the Andrés Manuel del Río National Chemistry Award in 2013, granted by the Mexican Chemical Society. In 2019, the *Journal of Natural Products*, the official journal of the American Chemical Society and the American Society of Pharmacognosy, published a special edition in her honor.

Gafner said: "I have become familiar with Prof. Mata's work through her many presentations at the annual meeting of the American Society of Pharmacognosy. In my opinion, through the quality of her impressive body of work and her collaborative spirit, she has become the face of pharmacognosy research on Mexican medicinal plants. I consider her one of the giants in the field of botanical natural products research and believe that she is most deserving of this award."

Mata wrote: "I am very pleased and grateful to receive the 2019 ABC Norman R. Farnsworth Excellence in Botanical Research Award. I would like to thank ABC for honoring me with this award. I accept this award in honor of my mentors, colleagues, and students, who over the years have shared their scientific work with me in the area of pharmacognosy. To be recognized by ABC is a true honor, because this organization really endorses the rational use of medicinal plants, which, for many years, has been one of the main goals of my research at the National Autonomous University of Mexico in Mexico City. The fact that this year the award turns to Mexico reflects the worldwide inclusion of ABC.

"To receive an award named after the late Professor Norman R. Farnsworth is overwhelming," Mata added. "Professor Farnsworth's legacy to the world of modern pharmacognosy is invaluable. He was an inspiration for many generations of pharmacognosists, including me. I feel even more honored to be placed in such distinguished ranks as those of the past honorees, most of whom have been colleagues at one time or another and who have made important contributions to the world of medicinal plants."

**ABC Norman R. Farnsworth Award Recipients**

2019: Rachel Mata, PhD
2018: Otto Sticher, PhD
2017: Raphael Mechoulam, PhD
2016: Ameenah Gurib-Fakim, PhD
2015: John T. Arnason, PhD
2014: Harry Fong, PhD
2013: Gordon Cragg, PhD
2012: De-An Guo, PhD
2011: Djaja Soejarto, PhD
2010: A. Douglas Kinghorn, PhD
2009: Rudolf Bauer, PhD
2008: Ikhlas Khan, PhD
2007: Hildebert Wagner, PhD
2006: Edzard Ernst, MD, PhD
2005: Joseph Betz, PhD

## Mary L. Hardy Receives ABC Kronenberg Award

The ABC Fredi Kronenberg Award was created in 2018 and named in honor of distinguished researcher, educator, and longtime ABC Board of Trustees member Fredi


Mary Hardy, MD

Kronenberg, PhD, who died in April 2017. Kronenberg dedicated her professional life to the study of medicinal plants and phytomedicines for women's health conditions. She was particularly interested in phytoestrogen-containing botanicals, such as black cohosh (*Actaea racemosa*, Ranunculaceae), for the treatment of menopause symptoms.

Kronenberg was a champion of integrative medicine and co-founded the Richard and Hinda Rosenthal Center for Complementary and Alternative Medicine at Columbia University, the first CAM program at an Ivy League school and the first government-funded CAM research and educational center. For 10 years, she also co-directed an on-site five-day continuing education course for physicians and other health care providers interested in botanical medicine.

**ABC Fredi Kronenberg Award Recipients**

2019: Mary Hardy, MD
2018: Aviva Romm, MD
2017: Tieraona Low Dog, MD

"I am very touched and honored to be given this award and doubly honored for the sisterhood I find myself in," Hardy said. "This is a lovely way to remember my dear friend Fredi, and it is a great privilege to be included in the company of two of the leaders in women's health: Aviva Romm and Tieraona Low Dog, the prior recipients of this award."

Hardy earned an MD at Louisiana State University in her hometown of New Orleans. In 1998, she co-founded the Cedars-Sinai Integrative Medicine Medical Group (one of the first integrative medicine clinics in the United States) at the Cedars-Sinai Medical Center in Los Angeles. From 2000 to 2004, Hardy was a research associate at RAND Corporation in Santa Monica, California, which develops solutions to make people safer and healthier. There, Hardy evaluated the safety and efficacy of CAM therapies and received sponsorship to evaluate alternative cancer practices and concerns about the safety of the traditional Chinese herb ephedra (*Ephedra sinica*, Ephedraceae).

From 2002 to 2005, she was the associate director of the Center for Dietary Supplement Research in Botanicals at the University of California, Los Angeles (UCLA), where she led the scientific management of the center and research design process, established seminar programs for fellows, and qualified botanical materials for research. From 2005 to 2009, Hardy was the co-director of the Health and Wellness Program of the Venice Family Clinic, the largest free clinic in the United States.

She has served on expert committees of the United States Pharmacopeial Convention, including a panel to develop methods to assess risk for multi-component dietary supplements, including botanical products. She also has served as a botanical medicine and clinical trials expert on committees of the Natural Health Products Directorate of the Canadian government. Hardy has been considered an integrative medicine expert by the US National Institutes of Health's Office of Dietary Supplements, the Medical Board of California, the American Medical Association, the American Pharmacists Association, *National Geographic*, CBS, NBC, Discovery Channel, and *The Los Angeles Times*.

She co-authored a book, *Reader's Digest Best Remedies: Breakthrough Prescriptions That Blend Conventional and Natural Medicine* (The Reader's Digest Association, 2006), and has been on several editorial and advisory boards. She has received grants to study the effects of manuka honey (produced from the nectar of *Leptospermum scoparium* [Myrtaceae]) during radiation for breast cancer and the effects of black cohosh on normal mammary gland and mammary tumor development. Currently, she is the director of Wellness Works, a consulting and educational company in Los Angeles that she founded in 2012.

For the last 20 years, Hardy has taught in medical schools at the University of Southern California and UCLA and been on faculty for integrative medicine fellowships at Georgetown University in Washington, DC, and the Academy of Integrative Health and Medicine (AIHM) in San Diego. Her areas of expertise include the safety of botanical and dietary supplements, botanical medicine, and patient-provider communication.

Romm, who received the ABC Fredi Kronenberg Award for 2018, endorsed Hardy for the award. In her endorsement, Romm praised Hardy for working "tirelessly and selflessly behind the scenes with no thought of fame or glory, only the advancement of the work," adding that Hardy has pushed successfully "for the integration of evidence-based botanical medicine into medical and scientific settings.

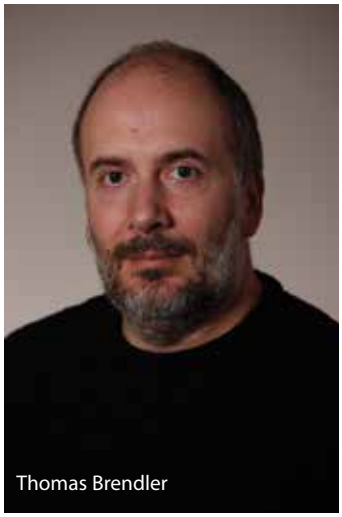
"Mary is an inspiration to work alongside," Romm added. "She often asks the most incisive questions … and has a command of the literature…. Yet she shares with the most admirable qualities of confidence, humility, collegiality, and generosity. I cannot think of anyone more deserving, or fitting, to receive this award. I am quite confident that Fredi would agree."

## Thomas Brendler Receives ABC Champion Award

The ABC Champion Award was created to recognize individuals who have been outstanding supporters of ABC and have helped the organization promote and achieve its nonprofit research and educational mission, whether through monetary support or contributions of

time. The generosity of ABC's friends and members is vital to the nonprofit's continued success and growth.

"I feel very honored to receive this award, as much as I feel honored to join the ranks of previous recipients," said Brendler. "As my friend and colleague Josef Brinckmann once pointed out, we don't do what we do with awards in mind. We find satisfaction and gratification in the opportunity to contribute to the shaping of the herb, botanical, and phytomedicinal industry. Nonetheless, as this award acknowledges my personal and professional dedication to improving the world of herbs and natural products, I am deeply grateful for the recognition."


Thomas Brendler

For 10 years, Brendler has contributed to ABC publications by serving as an expert reviewer, editor, and author. Since 2010, Brendler has worked as an HerbClip consulting editor, helping ensure the accuracy of ABC's biweekly research summaries. In 2011, Brendler joined the ABC Advisory Board, and he frequently has volunteered his time as a peer reviewer of articles related to his numerous areas of expertise, which includes African medicinal plants, commercialization and regulation of medicinal plant ingredients, phytochemical analysis, and traditional and historic plant use, among others. In 2017, Brendler co-authored the Botanical Adulterants Prevention Bulletin on cranberry (*Vaccinium macrocarpon*, Ericaceae) for the ABC-AHP-NCNPR Botanical Adulterants Prevention Program.

**ABC Champion Award Recipients**

2019: Thomas Brendler
2018: Jim Emme
2017: Dick Griffin
2016: Josef Brinckmann
2015: Ed Smith
2014: Terry Lemerond

Most recently, in late 2018, Brendler became a regular contributor to ABC's quarterly, peer-reviewed journal *HerbalGram* as co-author of its in-depth Herb Profiles. Joining forces with Traditional Medicinals' Josef Brinckmann, who received ABC's Champion Award for 2016, Brendler is primarily responsible for the "Modern Research" and "Current Authorized Uses" sections of the profiles. His first Herb Profile, on black cohosh, appeared in *HerbalGram* issue 121, a special women's health-themed issue published in early 2019. Since then, Brendler has co-authored profiles on tongkat ali (*Eurycoma longifolia*, Simaroubaceae), copalchi (*Hintonia latiflora*, Rubiaceae), guayusa (*Ilex guayusa*, Aquifoliaceae), birch (*Betula* spp., Betulaceae), and bulbine (*Bulbine* spp., Xanthorrhoeaceae syn. Asphodelaceae).

*HerbalGram* Managing Editor Tyler Smith acknowledged Brendler's ongoing contributions to the publication. "For years, Thomas has been one of our most reliable peer reviewers and contributors, and he took this commitment to another level when he signed on as co-author of *HerbalGram*'s Herb Profiles. Each profile takes dozens of hours to produce, and he and Josef regularly submit drafts before assigned deadlines. Thomas not only has expertise in a wide range of medicinal plant-related fields, but he also is a skilled writer and editor, and genuinely a pleasure to work with."

Brendler added: "For my entire professional career of soon-to-be 30 years, the trinity of quality, efficacy, and safety has been my guiding principle when assisting clients with product or supply-chain development. A significant part of this effort consists of researching, assembling, and disseminating reliable information on herbs and their functions, not only to my industry and academic clients, but also to the general public and consumers. Inasmuch as this very much aligns with ABC's nonprofit mission, it has always been both an honor and a pleasure to contribute to ABC's endeavors as an advisor, editor, and author."

In addition to his consulting work with PlantaPhile, Brendler is the principal scientist in the research and development department at Traditional Medicinals. He is also a co-founder of the Association for African Medicinal Plants Standards (AAMPS) and has served as its director since 2005. He is affiliated with the Department of Botany and Plant Biotechnology at the University of Johannesburg, South Africa. Brendler has co-authored numerous books, book chapters, and scientific articles, and is on the editorial boards of *Phytotherapy Research* and the *Journal of Ethnopharmacology*. In addition to being part of the ABC Advisory Board, he is a member of multiple organizations and committees, including the US Pharmacopeial Convention's Botanical Dietary Supplements and Herbal Medicines Expert Committee, the Society for Medicinal Plant and Natural Product Research (GA), the European Scientific Cooperative on Phytotherapy (ESCOP), the International Society for Ethnopharmacology, and the American Herbal Pharmacopoeia.

## 'Fire Cider Three' Receive ABC Herbal Community Builder Award

This annual award is given to individuals who have played a significant role in creating a sense of community among herbalists, botanical researchers, members of the herb and natural products communities and industries, and others who work in the area of medicinal and aromatic plants.

Herbalist and author Rosemary Gladstar originated the modern iteration of fire cider, an apple (*Malus* spp.,



Nicole Telkes, Katheryn Langelier, Mary Blue, and Rosemary Gladstar. Photo ©2020 Nicole Telkes

Rosaceae) cider vinegar-based tonic that contains various fiery herbs, including cayenne pepper (*Capsicum annuum*, Solanaceae), garlic (*Allium sativum*, Amaryllidaceae), and horseradish (*Armoracia rusticana*, Brassicaceae), as a part of her herbal education course in the winter of 1979-1980. Gladstar also received the first ABC Mark Blumenthal Herbal Community Builder Award for her many efforts and activities in the North American herbal community. She praised the efforts of Blue, Langelier, and Telkes to keep the name "fire cider" generic.

"We realized early on that we were committed and willing to fight for this," Gladstar wrote. "We felt it was important to take a stand for these traditional herbal products that are part of a shared legacy.… [Blue, Langelier, and Telkes] were fully committed to what they believed in, and so fully committed to the herbal community that they would risk everything to stand up for their herbal traditions."

In 2012, the Pittsfield, Massachusetts-based company Shire City Herbals filed for a trademark for the name "Fire Cider" for its own version of the blend. The three herbalists started an online campaign to bring the trademark to the attention of herbalists and consumers and exhorted them to make their own "fire cider" on the basis that the term was generic and thus not eligible for trademark.

In 2015, Shire City Herbals sued Blue, Langelier, and Telkes for trademark infringement and trade disparagement following their efforts to cancel the "Fire Cider" trademark and boycott the company. The company initially sued them for $100,000; however, these charges were dismissed before the trial began. At that point, the defendants had to decide whether to pursue their attempt to cancel the trademark.

"There was this moment when we all paused to wonder what we should do next," wrote Gladstar. "It made perfect sense for them to quit while they could. They had a lot at stake to lose and nothing to win except a name they wanted to give back to the herbal community. I can't recall who spoke first, but one of them said, 'Heck no, I'm not going to quit now. I'm in this to the end.' And then the other two chimed in, and just like that, they were ready to press forward."

During the nine trial days in 2019, many members of the herbal community lent their support to the Fire Cider Three at the US District Courthouse in Springfield, Massachusetts. Supporters attended the trial and provided food for the defendants, families held picnics on the courthouse lawn, and many herbalists brought samples of their own fire cider to share. Blue, Langelier, and Telkes risked their livelihoods on the outcome of the lawsuit, and the community rallied around them in response. In September 2019, United States District Judge Mark G. Mastroianni ruled in favor of the defendants and canceled the trademark.

Blumenthal was an expert witness for the defense, providing extensive market data on herbal dietary supplement sales that were used to invalidate the testimony of Shire City's expert witness, who claimed that the name "Fire Cider" was not generic.

"The Fire Cider Three took an important stand for traditional herbalism and its nomenclature and pushed back against expropriation by a commercial entity," said Blumenthal. "I believe that it was in the best interest of the herbal and medicinal plant community for ABC to use its resources to support the defendants and their laudable position, and now, to honor them publicly with this award."

Telkes thanked ABC for the recognition after a tough five years, saying: "I am extremely grateful and honored to have been chosen as a recipient of the Community Builder Award from the American Botanical Council."

Blue commented: "The American Botanical Council was an integral force in our victory and continues to honor and support our work to defend herbal traditions with this award. We are deeply humbled and honored to be recognized by ABC this way. Thank you for this continued support and acknowledgment."

Langelier added: "It's a great honor to receive this award and recognition from ABC. I have so much gratitude for the overwhelming support we received from the herbal community, Rosemary Gladstar, and our lawyers. Nikki, Mary, and I were a force that stood up for what we believed in: Protecting other herbalists from being sued and for fire cider to be recognized as a generic term.

An article on the Fire Cider lawsuit is available in *HerbalGram* issue 125. HG

**ABC Mark Blumenthal Herbal Community Builder Award Recipients**

2019: Mary Blue, Katheryn Langelier, and Nicole Telkes
2018: Linnea and Larry Wardwell
2017: Jon Benninger
2016: Ikhlas Khan, PhD
2015: Michael Tierra
2014: Loren Israelsen
2013: Sara Katz
2012: Rosemary Gladstar

# ABC Launches Expansion Plan with Purchase of Neighboring Property

**By Hannah Bauman**

**On February 24, 2020, the American Botanical Council (ABC) closed on the purchase of a residential property adjacent to the historic 2.5-acre Case Mill Homestead that has served as the nonprofit's headquarters since 1998. This investment marks the beginning of an expansion period for ABC as it looks to the future.**

The existing homestead was once part of a 450-acre series of land grants in the 1840s. It includes the original three-story building and carriage house from 1853, an annex, and grounds that have provided a home for ABC's herbal library, an open-air classroom for visitors, public meeting spaces, office space for employees, herbal themed gardens, and much more. Since purchasing the property in 1997, ABC has renovated and restored the buildings, created more than 20 herb demonstration garden beds, and added a greenhouse and annex building. ABC also installed a rainwater capture system and adheres to organic land management principles, along with other sustainable practices.

Now, with the purchase of the property on Walnut Hills Drive on its northwest property line, ABC has the opportunity to re-knit a small piece of the original land grant back together to make ABC's vision and mission for the future a reality.

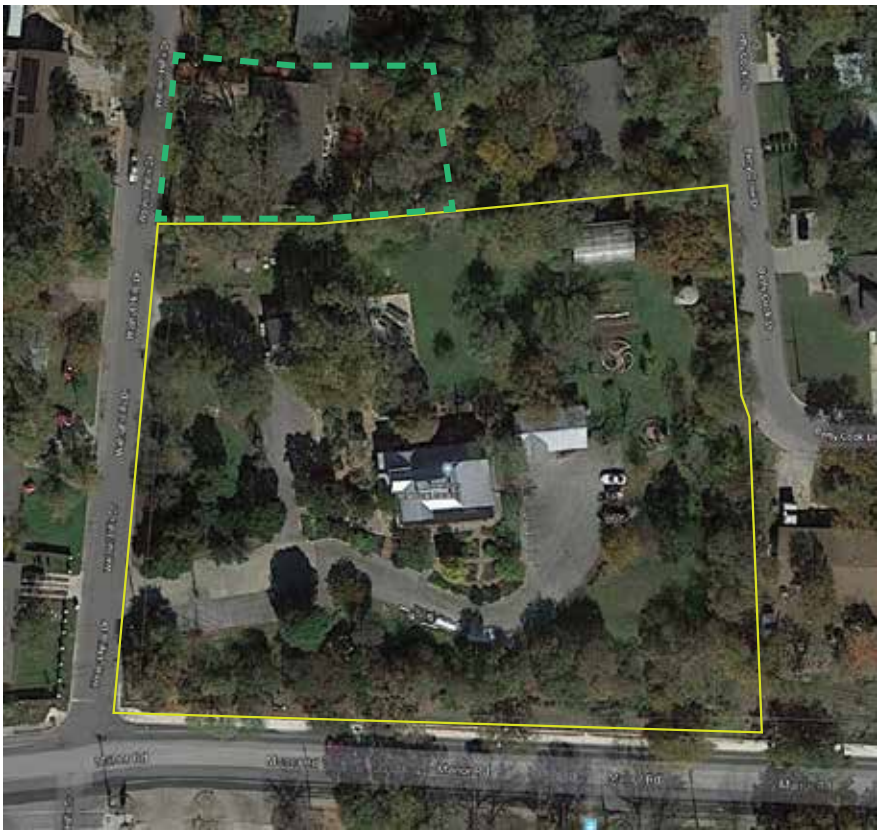
The Walnut Hills property, which consists of a third-acre site with a three-bedroom, two-bathroom, 1,700-square-foot house, went on the market on January 3, 2020. In this northeast Austin neighborhood about five miles from downtown, many homeowners are long-time residents, and homes generally do not go on the market often. Additionally, the competitive Austin real estate market means that when an opportunity arises, it does not stay for long.

ABC Founder and Executive Director Mark Blumenthal recognized the opportunity for ABC to expand its footprint and make a solid real estate investment, and the need to move quickly, but he needed permission from ABC's Board of Trustees. In 2016, a property adjacent to ABC's northeastern property line went on the market, but at that time, the board declined to make the purchase. This time, though, the board agreed to the investment, with a few conditions: primarily that the property must be able to produce a modest positive cash flow for ABC until the loan is paid off. Because the property is zoned for residential use only, it will serve as a short-to-medium-term rental until ABC can petition the city for a change to commercial zoning.

Rick Kingston, PharmD, CSPI, chairman of the ABC Board of Trustees, endorsed the move. "The acquisition of the Walnut Hills property provides ABC with a tangible asset that will help us expand the ABC campus to meet the growing needs of our community and organization," he wrote (email, March 9, 2020).

Holly Shimizu, former executive director of the United States Botanic Garden and member of the ABC Board of Trustees, was also enthusiastic. "The purchase of the Walnut Hills property is an important step for ABC," she wrote (email, March 9, 2020). "It is a strong financial investment that also provides potential opportunities as ABC strategically plans its path forward."

With the board's endorsement, Blumenthal approached several close friends of the organization for donations. The first one arrived on January 10, 2020. Inspired by the positive feedback he received, he and Denise Meikel, ABC's development director, devised a fundraising effort that would invite all ABC members and registered users of ABC's website to support the effort. The initial donations,



Aerial view of ABC's Case Mill Homestead. Current property shown in yellow outline and Walnut Hills expansion shown in green dashed outline.


Walnut Hills Drive property.

along with ABC's existing legacy fund, helped provide a significant down payment that allowed ABC to meet the seller's deadline and purchase the property while leaving the organization with a manageable loan note.

Though he moved quickly, Blumenthal gave the matter serious thought, not only about what could happen for ABC with the property, but what might happen without it. "When I first learned that our long-time neighbor JJ Jenkins was placing his house on the market, I believed it was essential that ABC do whatever possible to ensure that we would be the new owners," he said (oral communication, March 5, 2020). "First, I saw the house as an excellent way to expand ABC physically, as well as our nonprofit mission and activities. Second, I felt compelled to protect the boundaries of our historic and much-beloved Case Mill Homestead. We did not want an owner or tenant who might spray pesticides that could 'drift' into our organic gardens. And third, with the Austin real estate market booming like it has been for the past few decades, I realized that it is also a good short- and long-term investment for ABC."

ABC staff envisions uses that will further the herbal outreach, education, and research that form the core of ABC's nonprofit mission.

The previous opportunity to purchase the property on ABC's northeastern perimeter on Betty Cook Drive, which is directly behind the Walnut Hills property, was not approved by the board due to an unclear plan for its use, which also would be dependent on zoning changes.

However, Blumenthal privately arranged for his stepson to purchase the property, with an agreement that ABC might purchase it in the future. Combined, the Betty Cook and Walnut Hills properties would add another two-thirds of an acre and two buildings to the existing homestead (see aerial photo).

ABC is still seeking funds to completely pay off the Walnut Hills property note. By paying off the loan on the property, proceeds from renting the property in the short-term could be directed to ABC operations to further enhance the organization's research and educational mission and projects.

As for the future of the Walnut Hills property and perhaps the Betty Cook property, the ABC board and staff members have many ideas. Once paid off, the Walnut Hills property might provide housing for visiting interns, guests, ABC staff, or invited lecturers. After a zoning change, it could serve as an expansion of ABC's library or extra classrooms for staff and local educators. Regardless, ABC staff envisions uses that will further the herbal outreach, education, and research that form the core of ABC's nonprofit mission.

To donate and help ABC achieve its vision of having the resources to completely pay off the Walnut Hills Drive property, please visit https://rb.gy/ip0qq9. All contributions will be gratefully received. HG

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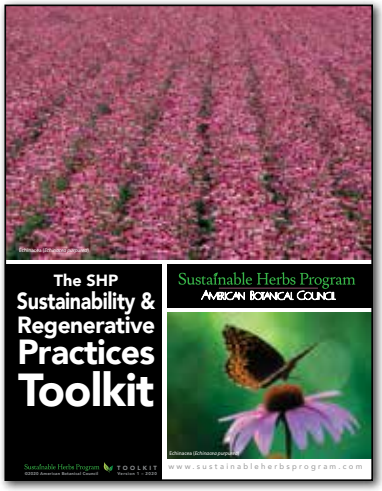
# Sustainable Herbs Program Releases Free Sustainability Toolkit on Earth Day's 50th Anniversary

## *Extensive 'how-to' resource for herb and medicinal plant industry includes special video and webinar series*

**By ABC Staff**

**On the eve of Earth Day's 50th anniversary, the nonprofit Sustainable Herbs Program (SHP) published The SHP Sustainability & Regenerative Practices Toolkit.[1] The SHP Toolkit is an online collection of practical resources and best practices for the botanical industry that businesses of any size can use to become more socially and environmentally responsible. SHP also created a video that explains the purpose and content of the new toolkit.**

Available for free on SHP's website, the 14-section, 52-page toolkit is part of an extensive set of educational videos, articles, newsletters, and blog posts offered by SHP to educate and inspire members of the global medicinal plant industry and community. This valuable collection of resources provides information about how to operate according to values and guidelines that enhance sustainability and regeneration for supply chains and value networks of botanical raw materials, extracts, and essential oils.




The toolkit supports SHP's goals to improve the quality of botanical ingredients, their sustainable and ethical sourcing, and to enhance the quality of life of people working in botanical ingredient value networks. The SHP Toolkit also serves as a roadmap for companies to create greater overall transparency about how herbal teas, dietary supplements, cosmetics, and other botanical products reach consumers.

The SHP Toolkit was created by SHP Director Ann Armbrecht, PhD, with input and assistance from the 17-member SHP Advisory Group and the American Botanical Council (ABC).

"Our own health and wellness are inextricably connected with the health and wellness of the human and ecological systems in which we live and on which we depend," said Armbrecht. "Many of us as individuals and as companies are asking how we want to emerge from the current pandemic crisis. How can we put in place systems that recognize and build on our interdependence and practices that support biodiversity, social equity, and healthy soils? This toolkit provides resources to begin or continue this journey."

The SHP Toolkit includes:

- Videos that highlight stories from the field and case studies about various topics that educate through meaningful examples of best practices.
- Discussion questions that reflect on those examples and how they can apply to the unique circumstances of individual companies.
- Action items in each section to deepen the learning experience.

SHP also has organized periodic webinars on botanical sustainability topics, including "The Business Case for Sustainability," "Creating a Culture of Sustainability and Regeneration," and "Relationships through the Supply Network," among others. These webinars will feature conversations with medicinal plant sustainability experts from various areas of the medicinal plant industry and nonprofit environmental, conservation, and research organizations.

"The SHP Toolkit is a significant contribution to the movement toward sustainable and regenerative practices in the global herb and medicinal plant industry," said Mark Blumenthal, ABC founder and executive director. "While many people in herb companies, and elsewhere, are interested in becoming more sustainable, they are often unsure where and how to begin. This toolkit provides them with many resources to do so."

The SHP Toolkit and all other SHP educational resources, including more than 35 videos, are available for free on the SHP website. SHP is supported by content contributions from medicinal plant experts and generous financial donations from the public and leading members of the international botanical industry, including raw material and extract suppliers, and manufacturers of herbal products.

Inaugural Underwriters for SHP include: Applied Food Sciences, Inc.; dōTERRA; Euromed; EuroPharma; Gaia Herbs; HumanN; Indena; MediHerb; MegaFood; Nature's Way; New Chapter; Now Health Group, Inc.; Pharmatoka SAS; RFI Ingredients, LLC; Standard Process; Thorne Research, Inc.; the United Natural Products Alliance; Valensa International; and Verdure Sciences. Additional Underwriters and Supporters include: Banyan Botanicals; Biotropics Malaysia Berhad; Herb Pharm; Ixoreal Biomed Pvt. Ltd.; PLT Health Solutions, Inc.; Pukka Herbs; and VDF FutureCeuticals. HG

### Reference

1. The SHP Sustainability & Regenerative Practices Toolkit. Sustainable Herbs Program website. Available at: http://sustainableherbsproject.com/healthy-worlds/companies/. Accessed May 5, 2020.

# Botanical Adulterants Prevention Program Publishes Turmeric Laboratory Guidance Document

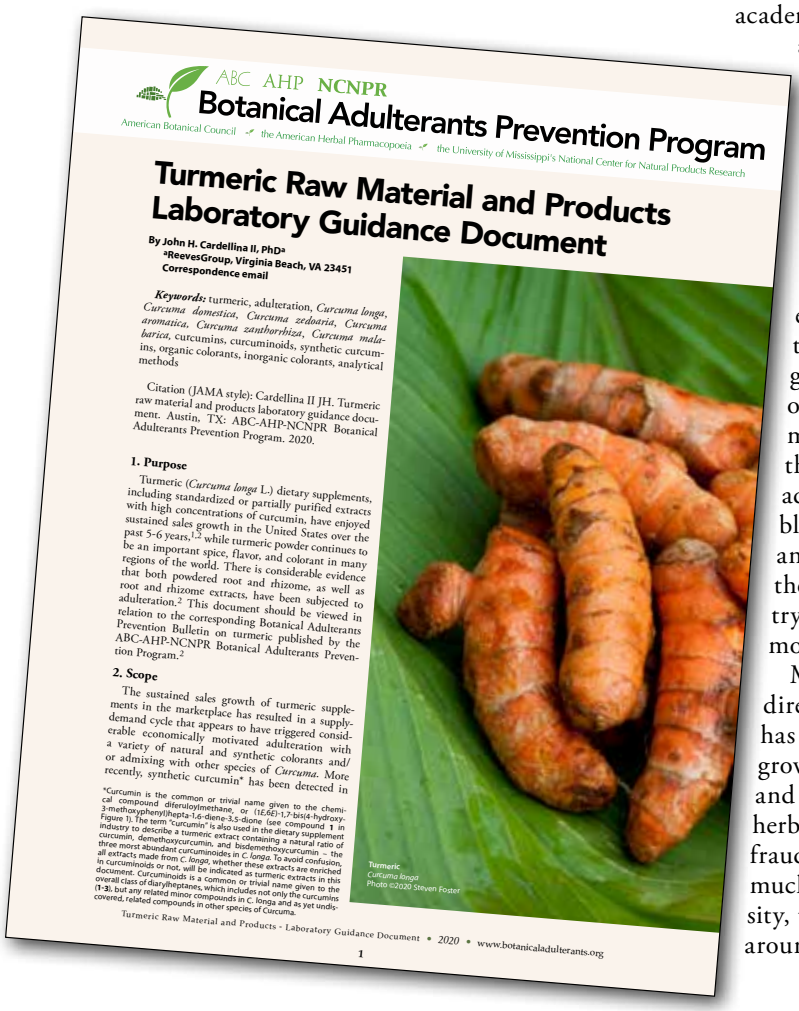
## *New publication evaluates authentication methods and describes adulteration with confounding species, undeclared pigments, and synthetic curcuminoids*

**By ABC Staff**

**The ABC-AHP-NCNPR Botanical Adulterants Prevention Program (BAPP) recently published a Laboratory Guidance Document (LGD) on turmeric (*Curcuma longa*, Zingiberaceae) raw material and products.**

Turmeric has a long history of use as a spice and medicinal plant, but its popularity in countries outside Asia has recently started to surge because of its medicinal properties. In 2018, turmeric dietary supplements ranked second in sales in the US natural channel and third in the US mainstream channel, according to *HerbalGram*'s 2018 Herb Market Report.[1]

Reports of turmeric adulteration often describe substitution with other *Curcuma* species or the undeclared admixture of starches or dyes. More recently, the addition of undeclared synthetic curcumin, one of the naturally occurring substances in turmeric, and mixtures of synthetic curcuminoids to turmeric extracts have been reported. Synthetic curcuminoids can be made for about one-third of the cost of natural curcuminoids, giving some suppliers a financial incentive to dilute or replace turmeric extracts with synthetic materials.


ABC AHP NCNPR
Botanical Adulterants Prevention Program
American Botanical Council • the American Herbal Pharmacopoeia • the University of Mississippi's National Center for Natural Products Research

Turmeric Raw Material and Products Laboratory Guidance Document

By John H. Cardellina II, PhD[a]
[a]ReevesGroup, Virginia Beach, VA 23451
Correspondence email

*Keywords:* turmeric, adulteration, *Curcuma longa*, *Curcuma domestica*, *Curcuma zedoaria*, *Curcuma aromatica*, *Curcuma xanthorrhiza*, *Curcuma malabarica*, curcumins, curcuminoids, synthetic curcumins, organic colorants, inorganic colorants, analytical methods

Citation (JAMA style): Cardellina II JH. Turmeric raw material and products laboratory guidance document. Austin, TX: ABC-AHP-NCNPR Botanical Adulterants Prevention Program. 2020.

1. Purpose

Turmeric (*Curcuma longa* L.) dietary supplements, including standardized or partially purified extracts with high concentrations of curcumin, have enjoyed sustained sales growth in the United States over the past 5-6 years,[1,2] while turmeric powder continues to be an important spice, flavor, and colorant in many regions of the world. There is considerable evidence that both powdered root and rhizome, as well as root and rhizome extracts, have been subjected to adulteration.[2] This document should be viewed in relation to the corresponding Botanical Adulterants Prevention Bulletin on turmeric published by the ABC-AHP-NCNPR Botanical Adulterants Prevention Program.[2]

2. Scope

The sustained sales growth of turmeric supplements in the marketplace has resulted in a supply-demand cycle that appears to have triggered considerable economically motivated adulteration with a variety of natural and synthetic colorants and/or admixing with other species of *Curcuma*. More recently, synthetic curcumin* has been detected in

*Curcumin is the common or trivial name given to the chemical compound diferuloylmethane, or (1*E*,6*E*)-1,7-bis(4-hydroxy-3-methoxyphenyl)hepta-1,6-diene-3,5-dione (see compound **1** in Figure 1). The term "curcumin" is also used in the dietary supplement industry to describe a turmeric extract containing a natural ratio of curcumin, demethoxycurcumin, and bisdemethoxycurcumin – the three morst abundant curcuminoides in *C. longa*. To avoid confusion, all extracts made from *C. longa*, whether these extracts are enriched in curcuminoids or not, will be indicated as turmeric extracts in this document. Curcuminoids is a common or trivial name given to the overall class of diarylheptanes, which includes not only the curcumins (**1-3**), but any related minor compounds in *C. longa* and as yet undiscovered, related compounds in other species of Curcuma.

Turmeric
*Curcuma longa*
Photo ©2020 Steven Foster

Turmeric Raw Material and Products - Laboratory Guidance Document • 2020 • www.botanicaladulterants.org
1

The new LGD was written by John H. Cardellina II, PhD, a noted expert in natural products chemistry and analysis. The LGD evaluates published analytical methods to detect the adulteration of turmeric root/rhizome raw material and extracts and finished turmeric products and summarizes the main advantages and disadvantages of each method regarding its suitability for use in a quality control laboratory. In addition, the document details the chemical composition of turmeric root and rhizome, potential confounding species, and known adulterants. The LGD was reviewed by 29 international experts from academia, third-party contract analytical laboratories, and the herbal dietary supplement and herb and spice industries. BAPP published a Botanical Adulterants Prevention Bulletin on turmeric in May 2018.

Stefan Gafner, PhD, chief science officer of ABC and technical director of BAPP, explained: "Because adulteration of turmeric comes in various forms, a number of orthogonal methods (i.e., multiple methods that can measure different analytes in a sample) are needed to ensure that the turmeric ingredient is authentic. Chromatographic methods may be useful for the detection of other *Curcuma* species or certain pigments, but they may miss the undeclared admixture of starches or the presence of lead chromate, which is sometimes added to impart a stronger yellow color. The possible addition of synthetic curcuminoids presents yet another analytical challenge. As such, we hope that the turmeric LGD will be a useful guide for industry quality control analysts tasked with selecting the most appropriate assays for turmeric authentication."

Mark Blumenthal, ABC founder and executive director and BAPP founder and director, said: "BAPP has identified turmeric as a common spice with a growing public demand for its medicinal properties, and which unscrupulous sellers in the international herb market have adulterated with lower-cost and fraudulent materials. BAPP's LGD on turmeric will be a much-needed resource for hundreds of industry, university, third-party, and government analytical laboratories around the world."

Cardellina said: "The adulteration of turmeric is one of the more complex cases that BAPP has tackled. Synthetic organic and inorganic colorants used to improve the color of poor grade or fraudulent raw material present serious health and safety concerns, while substituting or admixing with other species of *Curcuma* deprives consumers of the beneficial compounds provided by turmeric. The addition of synthetic curcuminoids can create safety issues due to the possible presence of reagents and side products from the synthetic methods used. Fortunately, this LGD reviews a substantial number of analytical methods to address these many forms of adulteration."

The turmeric LGD is the 10th publication in the series of LGDs published by BAPP. As with all publications in the program, the LGDs are freely available on ABC's website.

## About the ABC-AHP-NCNPR Botanical Adulterants Prevention Program

The ABC-American Herbal Pharmacopoeia (AHP)-National Center for Natural Products Research at the University of Mississippi (NCNPR) Botanical Adulterants Prevention Program is an international consortium of nonprofit professional organizations, analytical laboratories, research centers, industry trade associations, industry members, and other parties with interest in herbs and medicinal plants. The program advises industry, researchers, health professionals, government agencies, the media, and the public about various challenges related to adulterated botanical ingredients sold in commerce. To date, more than 200 US and international parties have financially supported or otherwise endorsed the program.

The program has produced 57 extensively peer-reviewed publications, including *HerbalGram* articles, Botanical Adulterants Prevention Bulletins, LGDs, and Botanical Adulterants Monitor e-newsletters. HG

## Reference

1. Smith T, Gillespie M, Eckl V, Knepper J, and Morton Reynolds C. Herbal Supplement Sales in US Increased by 9.4% in 2018. *HerbalGram*. 2019;123:62-73.



**Turmeric** *Curcuma longa*
Photo ©2020 Steven Foster

# The Importance of BAPP during the COVID-19 Pandemic

*Member Advisory: April 8, 2020*

Dear Friends and Colleagues:

As we work through this unfortunate and disruptive COVID-19 pandemic, we hope that everyone remains safe and healthy.

During this crisis, the American Botanical Council (ABC) and the ABC-AHP-NCNPR Botanical Adulterants Prevention Program (BAPP) are concerned about the integrity of botanical supply chains and value networks that provide botanical ingredients for products intended to enhance consumer health, and remain committed to providing essential resources for the herb industry and medicinal plant community. Near-term supply chain strategies should include heightened quality control vigilance and diligence, particularly related to confirming the identities of botanical raw materials, extracts, and essential oils.

Since 2011, BAPP has produced many consumer protection tools that can help. We are all in this challenging situation together, and BAPP wants to work more closely with our friends and colleagues in any way that can help enhance supply chain integrity and prevent adulterated materials from entering the dietary supplement, conventional food, cosmetic, and natural products markets.

Herbal supply chain disruptions — whether due to crop failures, weather issues, political developments in countries where herbs are sourced, or any unplanned changes in the supply and demand of botanical materials — can lead to adulteration. When numerous ingredients are disrupted because of a global pandemic, it is predictable that some suppliers and sellers of botanical (and other) ingredients may attempt to take even greater advantage of short- or long-term supply dislocations and shortages. Based on many years of experience in the botanical industry, we think it reasonable to expect an increase in ingredient adulteration. And, new forms of adulteration may emerge.

The US Food and Drug Administration recently announced reduced inspections amid the pandemic, which means less government oversight of storage and production facilities in the botanical supply chain in the United States and elsewhere. This may entice some companies to loosen their testing requirements, thus possibly enabling the sale of adulterated material. Accordingly, buyers should be vigilant to assure ingredient quality, particularly the determination of proper identity. Responsible buyers, even those with robust quality control (QC) programs, may need to double- or even triple-down on QC measures that deal with ingredient identity and authenticity.

Analytical laboratories are busy with ingredient testing, as buyers seek to source from alternative suppliers and establish supply chain redundancy to preserve and protect an uninterrupted supply of authentic botanical ingredients. Integrating the QC resource tools that are freely available from BAPP into industry quality programs — especially into ingredient specification, qualification, and testing protocols — is more important than ever before.

Buyers of botanical ingredients are encouraged to engage their quality teams to review and adopt BAPP tools and other appropriate resources (e.g., the United States Pharmacopeia, European Pharmacopoeia, American Herbal Pharmacopoeia, and others) as soon as possible. Until it is clear how the situation will evolve over the next several months, we encourage an abundance of caution and heightened testing to protect all botanical stakeholders.

As of March 2020, BAPP has published 57 peer-reviewed documents on its website. These include 20 Botanical Adulterants Prevention Bulletins, which describe herbs that are subject to adulteration and how this adulteration is done, and 10 Laboratory

We are all in this challenging situation together, and BAPP wants to work more closely with our friends and colleagues in any way that can help enhance supply chain integrity and prevent adulterated materials from entering the dietary supplement, conventional food, cosmetic, and natural products markets.

Guidance Documents (LGDs), which thoroughly review published laboratory analytical methods and evaluate their fitness-for-purpose to deal with the types of adulteration that have been confirmed for particular botanical ingredients. The importance of BAPP's LGDs cannot be overstated. Some analytical methods can be "fooled" by some of the more sophisticated types of adulteration.

In response to the recent publication of BAPP's turmeric (*Curcuma longa*, Zingiberaceae) LGD, Steve Mister, president and CEO of the Council for Responsible Nutrition (CRN), wrote:

> The supply chain disruptions brought about by COVID-19 will likely bring supply shortages of turmeric that will heighten the temptation to substitute other substances … that may be adulterated and even dyed to look like turmeric. [BAPP] offers ways to identify products, spot counterfeit or inferior materials, and protect your supply chains. Adopting appropriate methods is an excellent way to protect your consumers and avoid introducing fraudulent material into the market. That's what it means to be "responsible."

During these challenging times, we are reminded that we are all together on one planet. With your cooperation, participation, and support, we can take the current supply disruption and create transformative changes that will benefit everyone.

We thank you for your continuing support, engagement, and collaboration. We hope that you, your loved ones, and your associates will remain safe and healthy as we move through this, together. HG

Gratefully,

**Mark Blumenthal**, ABC Founder & Executive Director; BAPP Founder & Director
**Stefan Gafner, PhD**, ABC Chief Science Officer; BAPP Technical Director
**Ikhlas Khan, PhD**, Director, National Center for Natural Products Research, University of Mississippi
**Roy Upton, AHG (DAyu)**, President, American Herbal Pharmacopoeia
**Michael D. Levin**, Special Expert Consultant to BAPP; Founder, Health Business Strategies, LLC

## BAPP Survey

In early February 2020, BAPP sent a notice about a survey to help determine how many stakeholders in the botanical industry have been using BAPP publications, particularly the bulletins and laboratory guidance documents. By February 28, 105 responses had been received. Numerous respondents indicated that they not only read BAPP's extensively peer-reviewed and authoritative publications, but they also use them as the basis for setting or resetting botanical ingredient specifications for the development of herb products they manufacture and/or market. Some respondents also stated that they have changed ingredient suppliers as a result of the new specifications.

If you are in the botanical industry and have not yet reviewed and responded to this brief survey, we invite you do so now at https://tinyurl.com/tpe9x3e. Your comments and feedback are important to us.



## Join more than 200 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 Prevention Program, a multi-year, supply chain integrity program providing education about accidental and intentional adulteration of botanical materials and extracts on an international scale.

Botanical Adulterants Prevention Program

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

### Underwriters, Endorsers, and Supporters of the ABC-AHP-NCNPR Botanical Adulterants Prevention Program*

As of May 5, 2020

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**Trade Associations**

American Herbal Products Association (US)
Australian Self Medication Industry (Australia)
Australian Tea Tree Industry Association (Australia)
British Herbal Medicine Association (UK)
Canadian Health Food Association (Canada)
Complementary Medicines Australia (Australia)
Consumer Healthcare Products Association (US)
Council for Responsible Nutrition (US)
Global Curcumin Association (GCA)
International Alliance of Dietary/ Food Supplement Associations (IADSA)
National Animal Supplement Council (US)
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United Natural Products Alliance (US)

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American Association of Naturopathic Physicians
American Herbalists Guild
American Society of Pharmacognosy
AOAC International
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Integrative Healthcare Policy Consortium
Irish Register of Herbalists (IRE)
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University of Bridgeport College of Naturopathic Medicine

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# Preserving Peyote

## *Native American Church leaders ask that the sacred cactus not be decriminalized*

**By Connor Yearsley**

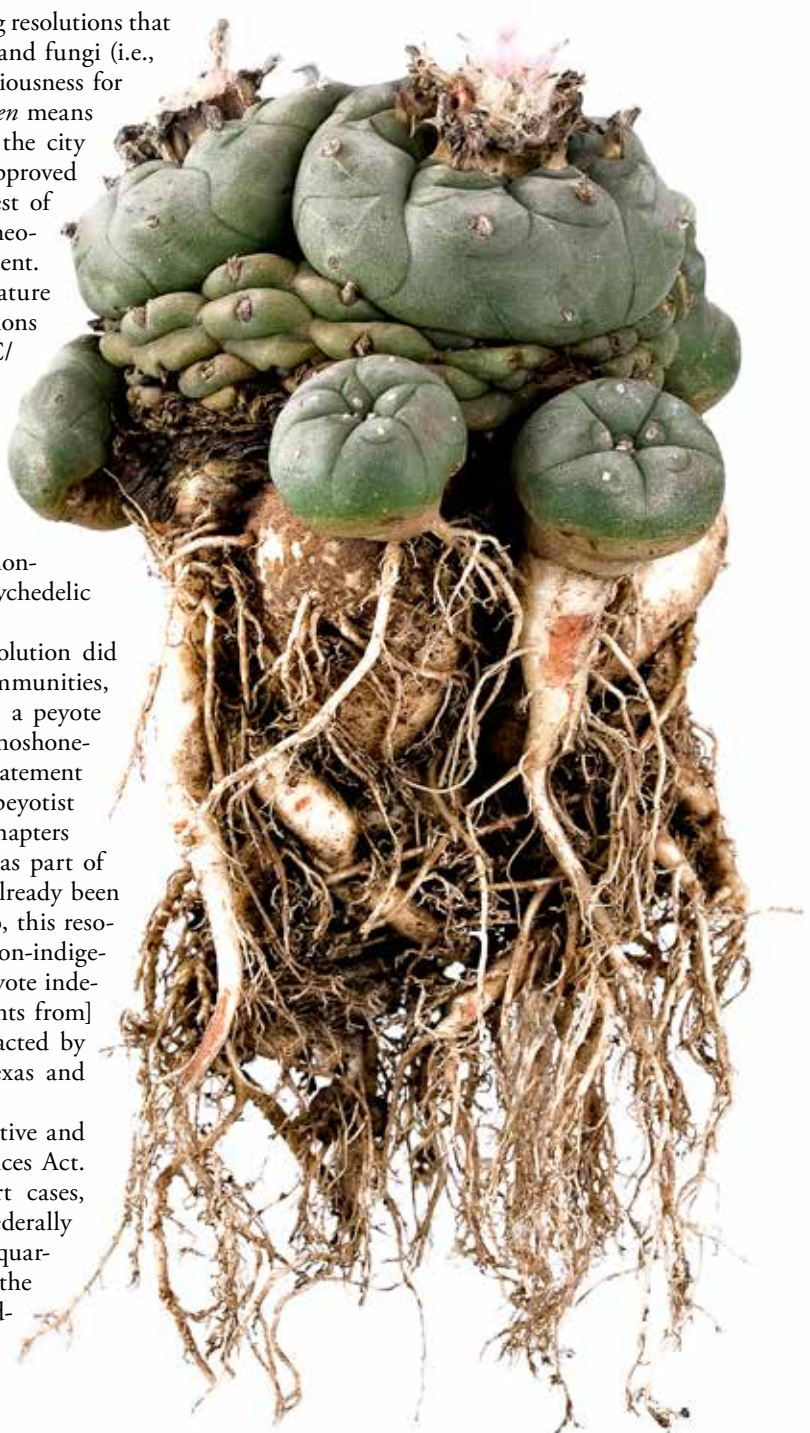
**In March 2020, the National Council of Native American Churches (NCNAC) and the Indigenous Peyote Conservation Initiative (IPCI) released a joint statement requesting that decriminalization efforts exclude peyote (*Lophophora williamsii*, Cactaceae) cactus. They believe that decriminalizing peyote would put additional environmental stress on the already severely declining wild populations of this medicinal and psychoactive cactus, which is sacred to members of the Native American Church (NAC) and other North American indigenous peoples.[1]**

In the United States, many cities are considering resolutions that would decriminalize various entheogenic plants and fungi (i.e., those that produce an unordinary state of consciousness for religious or spiritual purposes; in Greek, *entheogen* means "generating the divine within"). In June 2019, the city council of Oakland, California, for example, approved a resolution making "the investigation and arrest of individuals involved with the adult use of entheogenic plants" a low priority for law enforcement. The nonprofit organization Decriminalize Nature wrote and lobbied for the resolution, which mentions peyote. This resolution prompted the NCNAC/IPCI statement.[2,3]

"Any local governmental resolution that gives [non-indigenous] people the impression that they now have rights to acquire, possess, use, or transport … peyote in or from Texas would be misleading and may lead to their prosecution," the statement reads. It also suggests that non-indigenous people who want to experience psychedelic substances should seek alternatives.[1]

"It was obvious to me that the Oakland resolution did not involve any consultation with indigenous communities, particularly the NAC," said Dawn Davis, PhD, a peyote researcher, lifelong peyotist, member of the Shoshone-Bannock tribes of Idaho, and a signer of the statement (oral communication, March 20, 2020). "As a peyotist and member of the NAC, I believe that most chapters of the NAC would not want to include peyote as part of this resolution, because, first of all, peyote has already been decriminalized for use by indigenous peoples. So, this resolution is essentially [allowing] for use by [some] non-indigenous people. Unless these people are growing peyote independently, they would most likely seek out [plants from] wild populations, which are already being impacted by the increase in psychedelic tourism both in Texas and Mexico."

Peyote is listed in Schedule I, the most restrictive and punitive schedule of the US Controlled Substances Act. However, after decades of advocacy and court cases, peyote was legalized for use by members of federally recognized Native American tribes with one quarter Native American blood, with the passing of the American Indian Religious Freedom Act Amendments of 1994.[1]



**Peyote** *Lophophora williamsii*
Photo ©2020 Lollo J

"If you had asked me 10 years ago, I would have been supportive of removing peyote from Schedule I," Davis said. "But, after witnessing what is actually happening with peyote and realizing that its decline is steeper than it was 10 years ago, I think that having it listed as a Schedule I substance has provided a lot of protection for peyote, because that is a huge deterrent for people."

Davis was raised as part of the NAC. "I was part of the NAC before I even realized it was called the NAC," she said. "We used to call them 'peyote meetings.' It wasn't until I was in my 20s that I understood that this was the NAC…. I have had a relationship with this medicine my entire life. For me, it is sacred in a way that is hard to explain. I feel a responsibility to protect this plant for use by indigenous peoples but also to protect the plant for [the sake of] the plant."

Peyote is native to limestone soils of the Tamaulipan thornscrub ecoregion and the Chihuahuan Desert of southwestern Texas and northern Mexico.[4] Its limited range is a significant factor in its decline.[1] About 95% of Texas land is privately owned, which means that most or all peyote from the United States comes from private land, Davis noted. That means that to obtain peyote, members of the NAC either need to have relationships with landowners or go through state-sanctioned peyote distributors (*peyoteros*). Davis is concerned that decriminalizing peyote would cause more trespassing and poaching like was seen in the 1970s, and this may strain, not strengthen, relations with landowners.

"Some state-recognized tribal people are not afforded rights to peyote," Davis added. "So, that is a problem. I recognize that decriminalizing peyote may allow state-recognized tribes to use peyote. But I believe that is a battle that needs to be handled separately from the decriminalize movements that are currently happening in US cities. I believe that the right for state-recognized tribes to partake in peyote needs to happen at a higher level."



**Peyote** *Lophophora williamsii*
Photo ©2020 Dawn Davis

Dennis McKenna, PhD, a renowned expert on psychoactive plants and fungi, has a different perspective. "The notion that any organism should be 'criminalized' is abhorrent," he wrote (email, April 23, 2020). "This is reflective of the attitude that humans own nature. I do not believe that humans own nature, and I believe that these psychedelic organisms are not the property of any group, even indigenous peoples. They are a common heritage of humanity. Use of any organism, as medicine, food, or for other purposes, is an expression of symbiosis. To prohibit an organism's use by humans in symbiotic relationships is the wrong solution.

"We recognize that plants like peyote have been sustained for generations under the stewardship of indigenous peoples," McKenna added. "Their role as stewards, not owners, of these species should be recognized and protected. But to restrict access to peyote for all but indigenous peoples is not the correct solution, in my opinion. Instead, we should seek to create a consensus within the psychedelic community, which includes both indigenous and non-indigenous peoples, that overharvesting and environmental degradation of peyote habitats is wrong and should be prohibited by law."

## Peyote: The Divine Messenger

Peyote is a small, bulbous, spineless, soft cactus that is usually blue-green to gray-green with pink to white flowers. This slow-growing species may take 10-30 years to mature before flowering, which causes

conservation concerns. Most of the plant grows underground. Only its top, or "button," which can be three inches in diameter when mature, is visible.[5,6] Peyote often can be found growing underneath the creosote bush (*Larrea tridentata*, Zygophyllaceae), also known locally as *chaparral* or *gobernadora*.[7]

The buttons are cut off but can regrow, according to Davis. They contain the psychedelic alkaloid mescaline, which is also present in the San Pedro cactus (*Echinopsis pachanoi*, Cactaceae). Mescaline reportedly is one of the most selective serotonergic psychedelics.[8] The buttons are bitter and may be eaten fresh or dried, brewed into a liquid, or ground into powder.[6,9] The mescaline content percentage is higher when the buttons are dried instead of fresh.[8]

Peyote and mescaline's effects resemble those of lysergic acid diethylamide (LSD) and psilocybin mushrooms (primarily from the fungal genus *Psilocybe* [Hymenogastraceae]).[8] Ingestion of the cactus can cause mystical feelings, visual and auditory hallucinations, distorted perceptions of time and space, nausea and vomiting, increased heart rate and body temperature, impaired coordination, euphoria, and anxiety.[6,8,9] These effects typically peak within two hours but can last eight hours or longer.[8] Despite its Schedule I status, peyote (or mescaline) may be able to treat mental health conditions like depression, anxiety, post-traumatic stress disorder (PTSD), and addictions, and may reduce criminal behavior.[2,10]

"Peyote" is thought to derive from a Nahuatl word, which may mean "silk cocoon or caterpillar's cocoon," perhaps because of the tufts that grow from the plant, but sources vary on the translation. The cactus has been used for millennia. Archaeological remains of peyote buttons from caves along the Rio Grande in Texas suggest that indigenous peoples knew about the plant's psychoactive effects about 5,700 years ago or more.[11] The earliest known European record of peyote is from the Spanish Franciscan friar Bernardino de Sahagún (1499-1590), who wrote: "There is another herb like tunas [*Opuntia* spp., Cactaceae] of the earth. It is called Peiotl…. Those who eat or drink it see visions either frightful or laughable."[12]

In the late 1800s, peyote was adopted more widely, as northern and eastern Native American tribes were forced to relocate to reservations in the West and were introduced to the cactus through contact with southwestern tribes like the Lipan Apache, Carrizo/Comecrudo, and Huichol (Wixáritari).[7] The Huichol people of northern Mexico make peyote pilgrimages through the desert and stop to use more peyote along the way. According to their legend, a Huichol hunter stalked a blue deer, which escaped across the desert and left peyote cacti in its tracks. The Huichol believe peyote connects them to the spirit world.[6,13]

Peyote reportedly was incorporated into NAC rituals in the late 1800s. Today, the NAC, which combines elements of Christianity and Native American ritual, has more than 200,000 members from many tribes and is the largest indigenous religion in the United States. Peyote has been called the *sine qua non* (an absolutely essential part) of the NAC and is consumed as a sacrament during all-night services. But now, due to supply shortages, it is not uncommon for the buttons used during these



**Peyote** *Lophophora williamsii*
Photo ©2020 Loren Magruder

services to be the size of a US penny.[7] The buttons typically sell for about 35 cents each.[2] Preserving peyote is vital to preserving the identity of the NAC.[7]

Davis thinks peyote was a "savior" for indigenous peoples and provided a sense of comfort during a time of removal, displacement, genocide, and warfare. Now, the cactus is threatened by human-related factors including development, mining and oil drilling, cattle ranching, plowing, poaching, and more. "The plants are being harvested before they have matured and before they have flowered [i.e., before they have produced offspring]," Davis added. "I don't want to say that the NAC is growing to a point where the supply can't meet the demand, but I believe that it is getting there."

Previously, up to two million peyote buttons were harvested from the wild in Texas per year.[4] Peyote is listed in Appendix II of the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES).[14] Appendix II includes species that are not necessarily threatened with extinction but for which trade must be controlled to avoid overexploitation. For these species, including peyote, "an export permit or re-export certificate issued by the Management Authority of the State of export or re-export is required."[15]

According to Davis, peyote cannot be cultivated legally, but people are still doing it. "For me, cultivation is plan B, because I think that the focus should be to protect peyote as a plant," she said. "When a plant grows in its native habitat, it feeds off of that habitat. So, when you pull the plant out of its habitat and try to grow it outside of its natural range, it may not be successful…. There's a lot to say about the sacredness of peyote in its natural habitat. It is nurtured by other plants…. Peyote contains more than 50 alkaloids. Who is to say that the alkaloidal contents would be the same if peyote is pulled out of its habitat?"

Recently, the IPCI, the Native American Rights Fund, the NCNAC, and the Riverstyx Foundation purchased a 605-acre ranch in Jim Hogg County, Texas, within the "peyote gardens." The land, which the IPCI helps manage, is a place where indigenous peoples from around the country can pilgrimage and connect in prayer with peyote in its natural habitat, but harvesting is currently not allowed. It will also be used as a demonstration and research site to explore the *in situ* sustainability of peyote populations and propagation of peyote seedlings.[2,16] HG

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# *Fantastic Fungi* Film Explores the Magic and Mystery Underneath Your Feet

**By Connor Yearsley**

**Fungi frequently are forgotten and taken for granted. In fact, without knowing it, people trod over about 300 miles of sprawling fungi with each step. That is according to *Fantastic Fungi: The Magic Beneath Us*, a documentary film that was released in the United States in October 2019. At the end of April 2020, the film had a 100% rating on both Rotten Tomatoes and Flixster.**

Directed by Louie Schwartzberg, written by Mark Monroe, and narrated by Brie Larson, the film features interviews with a host of notable naturalists and scientists, including Andrew Weil, MD, and Dennis McKenna, PhD. Renowned mycologist (fungi expert) Paul Stamets, however, is definitely the star. Throughout, his enthusiasm and passion for fungi are contagious, and the insights he shares reflect a lifetime of research and knowledge.



Movie poster courtesy of Moving Art

The film is replete with stunning visuals and cinematography that may be worth the watch alone. This includes fascinating time lapses of fungi growing and breaking down everything from fruit to termites to a mouse. Kaleidoscopic geometric patterns occur throughout and presumably are meant to elicit the feeling of using the psychedelic compound psilocybin (derived primarily from the fungal genus *Psilocybe* [Hymenogastraceae]). In key places, the music by Adam Peters elevates and reinforces the mood.

In the film, Stamets says that fungi "can heal you. They can feed you. They can kill you." Though the focus is mostly on the positive aspects of fungi and mycophilia, or the love of fungi, it is admitted that mycophobia, or a fear of fungi, exists too, perhaps because of their association with death, decay, and disease. The film emphasizes that while fungi do represent the end of life, they also represent the beginning of life and enable restoration, rejuvenation, and resurrection. Described as nature's "digestive tract," fungi help generate life-giving soils.

A recurring theme is how fungi are omnipresent on one hand but "hidden" from view on the other. In fact, humans inhale fungal spores with each breath, from their first breath to their last. Fungi are out of sight, out of mind, and typically much less conspicuous than members of the plant and animal kingdoms. The interconnectedness of fungi, plants, and animals is also explored. For instance, nutrients can pass from tree to tree through underground fungal "passageways," and, after trees remove carbon dioxide from the atmosphere, much of that carbon travels underground, where it is stored by fungi. Without fungi, plant life would choke the Earth, the film explains.

The incredible diversity of fungi is also a central topic, from luminescent and purple fungi to the Earth's largest (by area) known living organism: a specimen of *Armillaria ostoyae* (Physalacriaceae) called the "Humongous Fungus" in Oregon. "Pando," a clonal colony of quaking aspen (*Populus tremuloides*, Salicaceae) trees in Utah, however, is considered the largest known living organism by mass.

Fungi, which produce chemical compounds that are not produced by other organisms, are proposed as sources of viable solutions to many of the world's biggest problems, from human to environmental health concerns. Stamets stresses the importance of preserving old-growth forests as repositories of fungal resources. As explained, fungi can break down oil and filter water. And lion's mane (*Hericium erinaceus*, Hericiaceae) may be able to promote the regeneration of nerve cells, which suggests possible benefits for people with Alzheimer's disease, for example. These and a wealth of other abilities led some people in the film to describe feeling empowered by fungi.

The use of fungi to reduce viruses in honeybees, which was covered extensively in *HerbalGram* issue 125,[1] is mentioned briefly, but I would have liked a longer segment on this important and timely research. This could have been an opportunity for some great videography showing the bees and fungi in action. The film also could have discussed the potential importance of a fungus' substrate (the material on or from which an organism lives, grows, and/or obtains its nourishment), and how it can impact the fungus' chemistry and value.

Much of the second half is dedicated to psilocybin. As explained, psilocybin can induce synesthesia, or a blending

of the senses (e.g., hearing colors). The film suggests that psilocybin use by ancestors of modern humans may have played a role in the development of the modern human brain. The recent history of psilocybin is covered, from its introduction into popular culture by the ethnomycologist Robert Gordon Wasson (1898-1986), to its stigmatization and, recently, the resurgence of interest in its therapeutic use.

The testimonies of two end-stage cancer patients, a man and a woman, are particularly meaningful. They participated in recent clinical trials that assessed the effects of psilocybin on depression and anxiety associated with existential distress.[2] The man said that just a single dose of psilocybin made him more comfortable with living because he was no longer afraid of dying. Despite the stigma against psilocybin, given its hallucinatory effects, after hearing these testimonies, it is difficult to deny that it can have profound, life-changing effects for some people in some circumstances, whether extenuating or not. In fact, the film explains that many study participants ranked their psilocybin session among the most meaningful experiences of their lives, and many compared it to the birth of their first-born child.

As this review may just scratch the surface of the film, the film itself may just scratch the surface of the fungi kingdom, which is described as a "frontier of knowledge." This is not a criticism, at all, but more a testament to the subject. In fact, perhaps it speaks to how much people take fungi for granted and how little is known about them that they could be summarized so well in *Fantastic Fungi*, which runs only 81 minutes. To summarize plants, for example, in one documentary of equal length would seem impossible, even though fungal species greatly outnumber plant species and have existed longer than land plants.[3] After watching *Fantastic Fungi*, maybe more people will become mycophiles; be left with a greater appreciation of the complexity, diversity, and versatility of these organisms; and be inspired to expand the knowledge-base and find the next fungal-related scientific breakthrough.

Schwartzberg said he loves taking audiences on journeys through time and scale (oral communication, March 12, 2020). "I really try to share the wonders of nature's intelligence, by making the invisible visible and using cinematic techniques like time lapse, slo-mo, micro, and macro," he said. "By showing nature's beauty, rhythm, and patterns, I want people to fall in love with nature, because if people fall in love with it, then they will protect it. We need that to create a sustainable future for our planet.

"One thing that I discovered [while] making *Fantastic Fungi* is that the underground mycelial network is a beautiful economy where nutrients are shared for ecosystems to flourish," Schwartzberg added. "I hope audiences will



*Mycena chlorophos*
Photo ©2020 Steve Axford and courtesy of Moving Art

take away [the idea] that communities survive better than individuals. Nothing in nature lives alone. This could be a model for us to replicate in our cultural and political society. Sharing is nature's way of doing things."

The film presented challenges. "Shooting time lapse is a very slow and difficult process filled with a lot of failure," Schwartzberg said. "It takes a tremendous amount of patience. I have had cameras running non-stop for decades in my studio. And all of that time is squeezed into hours of film. So, it is very challenging, but the results are breathtaking."

Stamets is "very pleased" with the film and would consider making another with Schwartzberg (email, March 5, 2020). "Louie approached me after seeing my lecture at a Bioneers conference in the mid-1990s," Stamets wrote. "He showed me some time lapses that blew my mind. After I [later] committed, it took [more than a decade]! I wanted to show how we are all interconnected via mycelia [the vegetative part of a fungus' life cycle that consists of many thread-like tubes], and that mycelia have the resources to help us and our ecosystems survive and improve. We share a great consciousness with nature, and mushrooms are a portal. We need to reconnect with each other and with nature. That most showings of the film were sold out reflects the hunger that has built up for the need to understand the meaning of our being."

The film is available on www.fantasticfungi.com for digital download ($14.99) and streaming ($4.99). HG

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**Pink oyster fungus** *Pleurotus salmoneo-stramineus*
Photo ©2020 Upthink and courtesy of Moving Art

# Implications of Climate Change for Medicinal Plant Distribution and Composition

**Reviewed**: Applequist WL, Brinckmann JA, Cunningham AB, et al. Scientists' warning on climate change and medicinal plants. *Planta Med*. January 2020;86(1):10-18. doi: 10.1055/a-1041-3406.

**By Mariann Garner-Wizard**

In 1992, the Union of Concerned Scientists published a "World Scientists' Warning to Humanity," with 1,575 signatories that alerted the public that human damage to the Earth, its resources, and its lifeforms must be curbed to avoid catastrophe. In 2017, a second notice, with 15,364 signatories from 184 nations, noted that few concerns raised in the 1992 statement had been adequately addressed, and most had worsened. They named climate change (CC) as one of the major threats. After the publication of the second notice, the Alliance of World Scientists called for additional, discipline-specific "Scientists' Warnings" that highlight effects of CC on environmental and human well-being. Early responses addressed impacts on wetlands, microbial communities, and wildfire regimes. In January 2020, the journal *Planta Medica* published a new Scientists' Warning that assessed threats to medicinal plants due to CC, habitat loss, and overharvesting.

Medicinal plants are considered a vital component of health care for an estimated 70% to 95% of people living in developing countries, and medicinal plants increasingly are sought by those in wealthier developed nations. The use of herbal remedies in veterinary medicine can affect the health of humans consuming livestock products and the economic security of animal owners. Traditional medicinal plant collection and sales offer livelihoods to millions of people, and the global trade in medicinal plants has been estimated at more than $32.6 billion annually.



**Chinese licorice** *Glycyrrhiza uralensis*
Photo ©2020 Steven Foster

CC is predicted to decrease the availability and abundance of many medicinal plants, some to the point of extinction. CC may also affect the chemical composition of plants, potentially altering their biological effects. Each of these threats is discussed.

Nearly 600 plant species have become extinct since the publication of Carl Linnaeus' *Species Plantarum* in 1753. In general, wild plants are endangered by CC, habitat loss and fragmentation, invasive species and new pathogens, and increased grazing due to low predator populations. Medicinal plants also are threatened by unsustainable harvests and harvesting methods. American ginseng (*Panax quinquefolius*, Araliaceae), for example, has declined in abundance and average size due to the high demand in China and illegal harvesting in its native ranges in North America. Other slow-growing, popular herbs show similar declines.

CC may further reduce or alter suitable ranges for the continued existence of many medicinal plants. Many are moving to higher elevations or

latitudes, increasing species competition there. For some species, relationships with commensal organisms or pollinators will be harmed by these moves. (Commensalism is a type of relationship in which one organism benefits and the other is not affected.) With an overall reduction in beneficial insects, harmful ones, like the bark beetles (*Dendroctonus* spp.) wreaking havoc on North America's coniferous forests, have proliferated and increased their range. Many fungal pathogens thrive in warmer winters and are an increasing threat to forest species, as are fires, which are occurring with greater frequency and intensity. In central Canadian black spruce (*Picea mariana*, Pinaceae) populations, these factors reportedly have changed net productivity, carbon stocks, and soil nitrogen levels. CC may not only increase the damage of plant pests and pathogens, fire, and drought, but these factors may contribute to further CC due to feedback loops that are "inadequately understood but perhaps catastrophic." Farmland expansion and development, intensive grazing, and overharvesting may interact additively and synergistically with other factors driving and resulting from CC.

Phenological changes (i.e., changes in an organism's life cycle in relation to seasonal variations in climate) due to CC have been noted, especially in nival (perpetually snow-covered regions) or subnival species in montane ecosystems. Alpine meadows are among the most threatened ecosystems, with species at the highest elevations at risk from other species seeking higher ground.

Arid zones are also likely to see rapid changes from CC. Chinese licorice (*Glycyrrhiza uralensis*, Fabaceae), which grows wild in desert steppes, has degraded substantially due to CC and human disturbance. So far, cultivated licorice plants have been shown to produce roots with "considerably lower" active constituents than wild-harvested ones. China, once a major exporter of this herb, has become a major importer, potentially threatening sustainability in other producer nations.

Secondary metabolites, many of which are bioactive compounds that provide medicinal benefits, may increase or decrease with different stressors. For some plants, temperature, elevation, and rainfall are important determinants for secondary metabolite concentrations. The interplay among these factors affects each species differently, making predictions about the effects on phytoconstituents difficult. Decreased or increased potency of plant medicines would most affect those who lack resources for complex testing and quality control. Higher atmospheric carbon dioxide, a driver of CC, may partly counter effects of drought on metabolism for some species. Effects of CC on plants used as both food and medicine are particularly important to determine.

Various methods to mitigate the harmful effects of CC on medicinal plants, such as ex situ conservation and assisted migration, have been proposed and are underway. However, they will not completely alleviate harm to indigenous peoples from decreased availability or access to economically and culturally important plants. While advocating strong efforts to slow CC, the authors of the *Planta Medica* paper suggest that local and national communities should act quickly to assure preservation of valuable medicinal plants. Examples include community gardens, preservation of traditional knowledge, conservation programs including habitat protection, training wildcrafters in sustainability, use of sustainability certification programs for commercial material, as well as regional quality monitoring programs. HG



**American ginseng** *Panax quinquefolius*
Photo ©2020 Steven Foster

# Nigella Seed Oil Improves Liver Parameters in Patients with Nonalcoholic Fatty Liver Disease

**Reviewed:** Khonche A, Huseini HF, Gholamian M, Mohtashami R, Nabati F, Kianbakht S. Standardized *Nigella sativa* seed oil ameliorates hepatic steatosis, aminotransferase and lipid levels in non-alcoholic fatty liver disease: A randomized, double-blind and placebo-controlled clinical trial. *J Ethnopharmacol*. 2019;234:106-111. doi: 10.1016/j.jep.2019.01.009.

**By Heather S. Oliff, PhD**

| Study Details: At a Glance | |
|---|---|
| **Study Design** | Randomized, double-blind, placebo-controlled trial |
| **Participants** | 120 men and women with nonalcoholic fatty liver disease |
| **Intervention** | *Nigella sativa* seed oil (Barij Essence Pharmaceutical Co.; Kashan, Iran) |
| **Control** | Mineral oil (placebo) |
| **Disclosures** | None declared |

Nonalcoholic fatty liver disease (NAFLD) begins with steatosis (accumulation of triglycerides in the liver) and can progress to steatohepatitis (NAFLD with inflammation and cell damage), fibrosis, cirrhosis, or hepatocellular carcinoma. No drug therapy has been approved to treat NAFLD, and dietary modification and exercise to reduce body weight are the only recommended treatments. Nigella (*Nigella sativa*, Ranunculaceae) seed oil (NSO) is used in Iranian traditional medicine to treat liver diseases. Experimental evidence suggests that NSO may reduce steatosis and improve lipid profiles and markers of liver function. However, clinical studies on NAFLD are lacking. Hence, the purpose of this randomized, double-blind, placebo-controlled study was to evaluate the efficacy of NSO in the treatment of NAFLD.

Patients (N = 120; mean age of 47 years) with NAFLD confirmed by ultrasonography participated in this study conducted at Baqiyatallah Hospital in Tehran, Iran. Excluded patients had a Child-Pugh score* greater than 7; hepatic disease other than NAFLD; were taking a drug that affects NAFLD; or were pregnant, planning pregnancy, or lactating.

Cold-pressed NSO was purchased from Barij Essence Pharmaceutical Company (Kashan, Iran). The thymoquinone and fatty acid content of the NSO were determined using high-performance liquid chromatography (HPLC) and gas chromatography (GC), respectively. The NSO contained 0.987 ± 0.07 mg thymoquinone per mL. The main fatty acids were linoleic acid (49.37%), palmitic acid (20.27%), oleic acid (5.76%), stearic acid (5.48%), palmitoleic acid (0.94%), arachidic acid (0.90%), and myristic acid (0.63%).

Patients were randomly assigned to receive either 2.5 mL NSO (n = 60) or 2.5 mL mineral oil (placebo; n = 60). Both NSO and placebo were mixed with 1.25 mL honey and 1.25 mL water, and both were similar in appearance and smell. All patients were instructed to take 5 mL of the syrup every 12 hours for three months. The patients were asked not to make changes to their diet or physical activity over the course of the study. At baseline and at three months, ultrasonography was performed, and blood samples were drawn for analysis. The primary outcome measures were hepatic steatosis (graded via ultrasound) and serum levels of alanine aminotransferase (ALT), aspartate aminotransferase (AST), low-density lipoprotein cholesterol (LDL-C), and triglycerides (TG). The secondary outcome measures were body mass index (BMI), complete blood cell count, and serum levels of high-density lipoprotein cholesterol (HDL-C), blood urea nitrogen, and creatinine.

There were no significant differences between groups at baseline. Compliance was good (patients took at least 80% of their assigned doses) in both groups. At baseline, no patients had fatty liver grade 0 (normal liver). However, at three months, 18 patients in the NSO group and four patients in the placebo group had fatty liver grade 0. Overall, the NSO group had a significant decrease in fatty liver grade compared with the placebo group ($P < 0.01$). ALT, AST, and TG levels significantly decreased and HDL-C levels significantly increased in the NSO group compared with the placebo group ($P = 0.001$ for all). There were no significant changes in the other measured parameters. No adverse events were reported.

In summary, three months of NSO supplementation improved liver steatosis, as well as liver aminotransferases, TG, and HDL-C levels in patients with NAFLD. The authors hypothesize that the reductions of hepatic steatosis and aminotransferases indicate that NSO may reverse hepatic injury and protect the liver in patients with NAFLD. Since there were no changes in body weight, the benefits of NSO were not due to weight loss. Acknowledged limitations of this study include the small sample size, short duration, and the lack of elastography, a type of medical imaging used to measure liver fibrosis. The authors concluded that larger, longer trials to evaluate NSO in the treatment of non-alcoholic steatohepatitis, hepatic fibrosis, and cirrhosis are warranted. HG

* The Child-Pugh score is a tool to assess the prognosis of chronic liver disease and cirrhosis.

# Effect of Grape Seed Procyanidin Extract on Diabetic Retinopathy

**Reviewed**: Moon SW, Shin YU, Cho H, Bae SH, Kim HK. Effect of grape seed proanthocyanidin extract on hard exudates in patients with non-proliferative diabetic retinopathy. *Medicine*. May 2019;98(21):e15515. doi: 10.1097/MD.0000000000015515.

**By Sandra Jean, MS**

| Study Details: At a Glance | |
|---|---|
| **Study Design** | Randomized, double-blind, placebo-controlled trial |
| **Participants** | 124 men and women with type 2 diabetes mellitus |
| **Treatment** | Grape seed procyanidin extract (Entelon®; Hanlim Pharm; Seoul, South Korea) |
| **Controls** | Calcium dobesilate (Doxium®; Ilsung Pharmaceuticals; Seoul, South Korea) or placebo (content not provided) |
| **Disclosures** | None declared |

The leading cause of visual impairment in people with diabetes is diabetic macular edema (DME). DME is characterized by swelling of the retina and hard exudates (HEs), which are lipid deposits in the retina. HEs are often treated by invasive procedures such as macular photocoagulation and intravitreal (into the back of the eye) injections of drugs. However, these treatments have a short duration of action and can cause serious complications. Non-invasive, long-lasting treatments for HEs are needed to prevent vision loss.

Grape (*Vitis vinifera*, Vitaceae) seed procyanidin extract (GSPE) has been shown to reduce capillary permeability and fragility. Procyanidins are flavonoids that possess antioxidant and anti-inflammatory activities. In in vitro studies, GSPE has been shown to inhibit the vascular endothelial growth factor signaling pathway, the main pathway responsible for diabetic retinopathy (retina damage) progression. The purpose of this randomized, double-blind, placebo-controlled trial was to assess the effectiveness and safety of GSPE in the treatment of HEs associated with non-proliferative diabetic retinopathy in patients with type 2 diabetes mellitus (T2DM). The effects of GSPE were also compared to calcium dobesilate (CD), an oral medication widely used for diabetic retinopathy.

The trial enrolled patients at 12 hospitals in South Korea from November 2012 to January 2015. Patients were included if they were 40-78 years old; had T2DM that was well-controlled with drugs for at least three months; hemo-



**Grape** *Vitis vinifera*
Photo ©2020 Steven Foster

globin A1c ≤ 9%; DME with HEs with central subfield mean thickness (CSMT) ≤ 300 µm; and best-corrected visual acuity (BCVA), a measure of vision impairment, ≥ 20/40.

Patients were excluded if they had laser therapy, intravitreal injections, or intraocular surgery within six months of enrollment or another macular disease, severe hypertension, severe renal insufficiency, or were taking sulodexide, kallidinogenase, or bilberry (*Vaccinium myrtillus*, Ericaceae) extract.

Patients (N = 124) were randomly assigned to receive 150 mg/day GSPE (Entelon®; Hanlim Pharm; Seoul, South Korea), 750 mg/day CD (Doxium®; Ilsung Pharmaceuticals; Seoul, South Korea), or placebo (content not provided) in an approximately 2:2:1 ratio. The daily dose was divided into three capsules, and the intervention lasted 12 months.

Comprehensive eye exams were conducted at baseline and during study visits at months three, six, nine, and 12. The eye exams assessed BCVA, intraocular pressure, total macular volume, and CSMT using optical coherence tomography and the Early Treatment Diabetic Retinopathy Study map. Adverse events (AEs) were recorded at each study visit. Blood was drawn at baseline and 12 months for safety monitoring.

Patients were randomly assigned to the GSPE group (n = 51), CD group (n = 47), or placebo group (n = 26). Sixteen patients did not complete the first study visit, so the intent-to-treat population included 108 patients. An additional 22 patients (nine in the GSPE group, seven in the CD group, and six in the placebo group) did not complete the trial because of poor compliance or protocol violations. There were no significant differences in baseline characteristics among the three groups.

The rate of treatment success, which was defined as a decrease in HE grade severity of more than two grades at month 12, was highest in the GSPE group (43.90%), followed by the CD group (14.29%) and the placebo group (8.00%). The success rate was significantly higher in the GSPE group compared to the CD group ($P$ = 0.0029) and the placebo group ($P$ = 0.0021).

Changes in macular thickness were not significantly different among the three groups at month 12. Total macular volume decreased in the GSPE group at months nine and 12; however, there was no statistically significant difference among the three groups overall. Furthermore, no significant changes in BCVA or progression of diabetic retinopathy were observed among the groups. Four patients in the GSPE group and two patients in the CD group had gastrointestinal AEs that may have been related to the treatments. There were no statistically or clinically relevant differences in vital signs and blood values among the groups after the intervention.

The authors concluded that GSPE therapy for one year improved HEs in patients with non-proliferative diabetic retinopathy. GSPE was more effective than CD in reducing HEs. Although GSPE did not affect visual acuity in this population, the authors suggested that GSPE can be considered as adjunct therapy in patients with a larger number of central HEs that impair their vision or in patients who do not want to have intravitreal injections.

GSPE's mechanism of action in reducing HEs is not known. In human and animal studies, procyanidins have been shown to reduce blood cholesterol and the size of cholesterol deposits in arteries. However, no significant changes in blood lipid levels occurred in the GSPE group in this study.

According to the authors, limitations of the study were that the sample size was relatively small, the study population had only mildly increased macular thickness, and blood levels of GSPE were not measured. HG


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# Systematic Review of Green Tea Consumption and Risks for Dementia, Alzheimer's Disease, and Cognitive Impairment

**Reviewed**: Kakutani S, Watanabe H, Murayama N. Green tea intake and risks for dementia, Alzheimer's disease, mild cognitive impairment, and cognitive impairment: A systematic review. *Nutrients.* May 24, 2019;11(5):1165. doi:10.3390/nu11051165.

**By Heather S. Oliff, PhD**

Green tea (*Camellia sinensis*, Theaceae) leaf contains catechin polyphenols that are reported to have neuroprotective effects in various assays, including the reduction of oxidative stress and inflammation, inhibition of beta-amyloid aggregation, and prevention of apoptosis. Epidemiological studies have reported a correlation between green tea consumption and decreased risk of neurodegenerative disease and cognitive impairment. The purpose of this systematic review was to evaluate the association between green tea beverage intake and risk of dementia, Alzheimer's disease (AD), and cognitive impairment.

PubMed was searched from inception through August 23, 2018. Included articles met these criteria: (1) English-language article published after 1966, (2) included free-living (non-institutionalized) populations, (3) reported original data on the relationship between green tea intake and risk of dementia, AD, mild cognitive impairment (MCI), or cognitive impairment, and (4) were cohort, case-cohort, nested case-control, case-control, or cross-sectional studies. Studies that evaluated green tea in combination with other factors such as metabolic enzyme activity or other dietary factors were excluded. Reference lists of included articles also were screened. The reporting quality of each included study was assessed using the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) checklist. The methodological quality was judged by various other factors.

| Study Details: At a Glance | |
|---|---|
| **Study Design** | Systematic review |
| **Included Studies** | Three cohort longitudinal studies and five cross-sectional observational studies |
| **Participants** | 37,578 total participants |
| **Disclosures** | The study was funded by Suntory Global Innovation Center Limited, a subsidiary of the Suntory Group, which includes beverage companies. The authors are employees of Suntory Global Innovation Center Limited. |

A total of 81 articles were located, and eight articles met the eligibility criteria. A meta-analysis was precluded due to the high degree of heterogeneity among studies and limited number of high-quality studies. Therefore, only a



**Green tea** *Camellia sinensis*
Photo ©2020 Steven Foster

qualitative assessment was conducted. The eight included articles reported the results of three cohort longitudinal studies conducted in Germany (n = 1) and Japan (n = 2) and five cross-sectional observational studies conducted in China (n = 2), Taiwan (n = 1), and Japan (n = 2). Together the studies included a total of 37,578 participants (723 to 13,645 participants per study). The categorization of green tea consumption varied significantly among studies and included: (1) < 1 cup/day, 1-2 cups/day, 3-4 cups/day, or ≥ 5 cups/day compared with no consumption; (2) consumption versus no consumption; (3) 1-6 days/week compared with no consumption; (4) 1-6 days/week or > 7 times/week compared with no consumption; and (5) ≤ 3 cups/week, 4-6 cups/week, 1 cup/day, or ≥ 2 cups/day.

The STROBE assessments indicated one study was high quality, two were medium quality, and five were low quality. The only high-quality study reported that high green tea intake was significantly associated with a low hazard ratio for dementia. The results of the two medium-quality studies were conflicting; one study found green tea consumption was not correlated with AD risk, while the second study found green tea intake was associated with a significantly lower risk of MCI or dementia (although the odds ratio of developing only dementia did not change with green tea consumption). The five low-quality studies reported: (1) green tea consumption decreased the odds ratio of MCI only in men aged 55 to 65 years old; (2) green tea consumption had no effect on the odds ratio for cognitive impairment; (3) green tea consumption decreased the risk of cognitive impairment (two studies); and (4) green tea consumption significantly lowered the odds ratio for all-cause dementia. Safety was not assessed.

Overall, six of the eight studies reported a preventive effect associated with green tea consumption. Based on this evidence, the authors concluded that "it is possible that green tea intake might prevent the incidence of dementia, AD, MCI, or cognitive impairment." They point out that the inconsistent study results may be due to heterogeneous classification of green tea consumption.

Limitations of this review are that only one database was searched, only articles published in English were included, few studies were eligible, and many of the included studies were poor quality. The authors noted that to draw a solid conclusion regarding the impact of green tea consumption on the risk of developing dementia, AD, MCI, or cognitive impairment, further data from "well-designed and well-conducted cohort studies are well founded and required." HG



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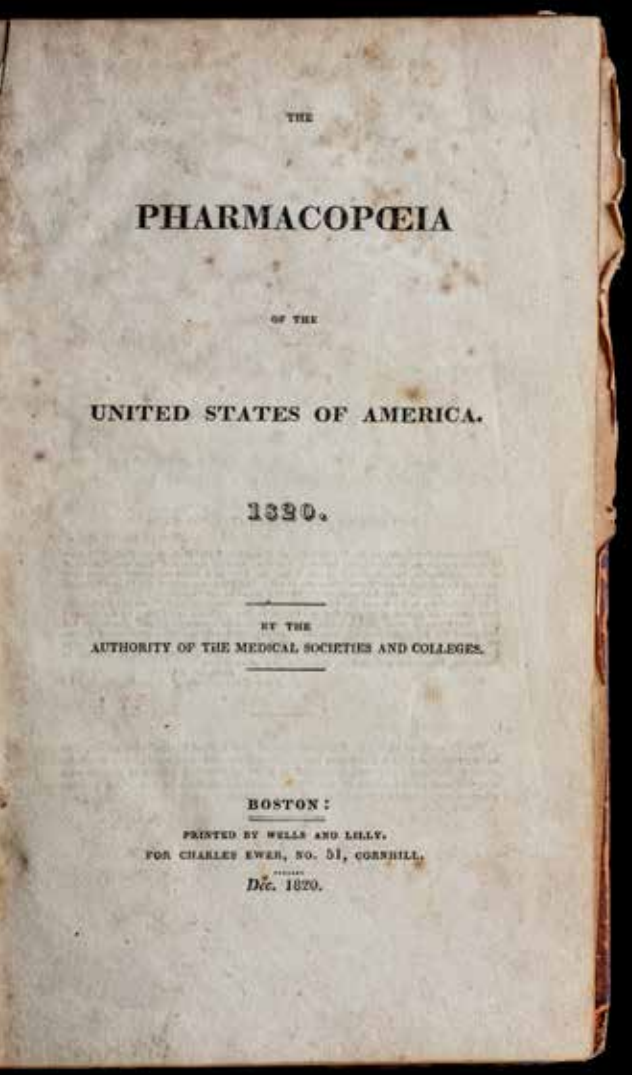
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OF THE

UNITED STATES OF AMERICA.

1820.

BY THE

AUTHORITY OF THE MEDICAL SOCIETIES AND COLLEGES.

BOSTON:

PRINTED BY WELLS AND LILLY.

FOR CHARLES EWER, NO. 51, CORNHILL.

Dec. 1820.

Above: Cover of the *Pharmacopoeia of the United States of America*, published in 1820.
Below: Current 2020 *USP–NF* website.




# QUALITY STANDARDS FOR BOTANICALS

## The Legacy of USP's 200 Years of Contributions

By Josef Brinckmann,[a] Robin Marles, PhD,[a] Paul Schiff, PhD,[a] Hellen Oketch-Rabah, PhD,[b] Geeta Tirumalai,[b] Gabriel Giancaspro, PhD,[b] and Nandakumara Sarma, PhD[b*]

[a] United States Pharmacopeia (USP) Botanical Dietary Supplements and Herbal Medicines Expert Committee
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The *Pharmacopoeia of the United States of America* (*USP*),† first published in 1820, was intended to bring nationwide uniformity to the quality of drugs, most of which at the time were based on botanical and mineral ingredients. Over the last 200 years, the United States Pharmacopeial Convention (USP) has adapted to evolving technologies and products and has continued to provide public quality standards for botanical, chemical, and biological medicines. This article examines the history of the evolution of botanical quality standards, as well as the current status of botanical monographs for drugs, herbal medicines, dietary supplements, and excipients (i.e., antioxidants, binders, bulking agents, coloring agents, flavoring agents, pharmaceutical bases, sweetening agents). It also provides an outlook for the future, in which USP anticipates adapting to rapid changes in technologies. This article is an abbreviated version of a more detailed paper by the authors and has been revised for *HerbalGram*. The full-length paper, as referenced in this article, can be accessed at: http://abc.herbalgram.org/site/DocServer/HG126-USP-Legacy-FullPaper-5-1-20.pdf/.

### HISTORICAL CONTEXT

As the settlements of European colonists expanded through the 16th to 18th centuries, native American botanical species and their uses in the indigenous systems of medicine were observed, documented, classified in a European context, and initially monographed in pharmacopeias of the colonial powers. The American War of Independence (1775-1783) created an urgent need for pharmacopeias that could serve the needs of military hospitals. William Brown (1748-1792), Physician-

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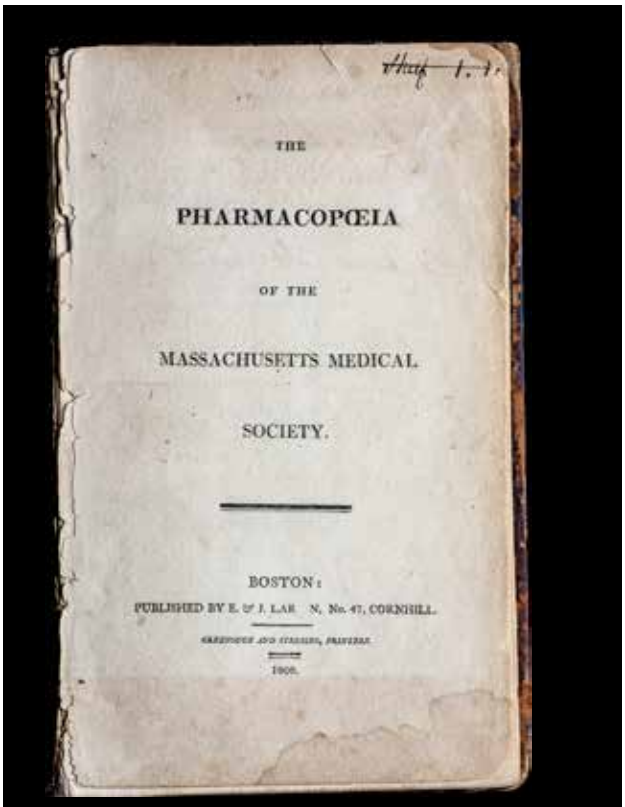
† The abbreviation USP (without italics) is used in this article to refer to the United States Pharmacopeial Convention, and the abbreviation *USP* (in italics) is used to refer to the pharmacopeial compendium.

General of the Middle Department of the Continental Army, while stationed at the army hospital in Lititz, Pennsylvania, compiled a work now known as the *Lititz Pharmacopoeia*, published in 1778. (The full title, translated from Latin, is *Pharmacopoeia of simple and efficacious remedies for use of the military hospital, belonging to the army of the Federated States of America; especially adapted to our present poverty and straitened circumstances, caused by the ferocious inhumanity of the enemy, and the cruel war unexpectedly brought upon our fatherland*.)[1] Much of the traditional knowledge of the indigenous peoples was adopted more formally into American medical practice and, by the late 18th century, codified in the first pharmacopeias and dispensatories of the new country, the United States of America.[2] Examples of plants native to North America that were of medicinal importance to indigenous peoples and were also published in Scottish physician William Cullen's (1710-1790) 1769 handbook on medicines included capsicum (*Capsicum annuum*, Solanaceae), sarsaparilla (then *Smilax sarsaparilla*, now *S. glauca*, Smilacaceae), sassafras (*Sassafras albidum*, Lauraceae), and Seneca snakeroot (*Polygala senega*, Polygalaceae).[3]

Publishing in English, another factor in the development of a truly American pharmacopeia, was championed by physicians James Jackson (1777-1867) and John Collins Warren (1778-1856), who formed the committee for the 1808 *Pharmacopoeia of the Massachusetts Medical Society*.[4] Dr. Samuel Latham Mitchill (1764-1831; misspelled "Mitchell" in the 1820 and 1831 editions of the *USP*) and Dr. Valentine Seaman (1770-1817) followed a similar approach in their *Pharmacopeia of the New York Hospital*, published in 1816.[5] They wanted their work to be written in English and mutually convenient to the physician and pharmacist. Most European pharmacopeias at that time were written in Latin.

The United States Pharmacopeial Convention was founded on January 1, 1820, by 11 forward-thinking physicians, three of whom were responsible for leading the effort. The idea to form a national pharmacopeia originated with Dr. Lyman Spalding (1775-1821), a passionate physician and masterful organizer from New York; the previously mentioned Mitchill, a charismatic statesman and former senator from New York as well as a physician who was president of the USP Convention and helped promote the creation of the first national pharmacopeia; and Dr. Jacob Bigelow (1787-1879), from Harvard University in Massachusetts, an expert in plant drugs and an experienced editor, who oversaw its publication. Physicians at the time wanted "to recognize the full range of truly American medicinal plants that patriotic medical gentlemen expected."[6]

Building on the pharmacopeias of the Massachusetts Medical Society and the New York Hospital and under the direction of Mitchill, the first national *Pharmacopoeia of the United States of America* was published in 1820.[7] It was divided into sections, beginning with the front matter, historical introduction, and preface, followed by the *materia medica* (a primary list of 217 drugs, including 145 botanicals); most of the entries were botanicals or botanically derived ingredients.[8] This section was followed by a secondary list of 71 drugs with ingredients of "doubtful efficacy" and whose use was uncertain, including 67 botanicals; a section on weights and measures; and an


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1808.

Cover of the *Pharmacopoeia of the Massachusetts Medical Society*, published in 1808.

## GLOSSARY OF IMPORTANT TERMS

| | |
|---|---|
| **Compendium** | A compendium (plural: compendia) is a compilation of knowledge about a particular subject (e.g., articles of botanical, algal, or fungal origin). |
| **Pharmacopeia** | A pharmacopeia (also spelled "pharmacopoeia") is a compendium of standards and quality specifications, providing tests to confirm the composition, identity, quality, purity, and strength of defined articles used in medicines and foods. |
| **Dispensatory** | A dispensatory is a compendium that supplements the pharmacopeia, providing commentary on the pharmacopeial articles, posology (dosing), and indications for their therapeutic, nutritional, or other uses. |
| **Formulary** | A formulary, in the strict sense, is a compendium of formulations currently in use, although the current *National Formulary* (*NF*) also includes standards for excipients of botanical origin as well as other articles and preparations that do not appear in the *USP*. The *USP* and the *NF* are official compendia of the United States of America. |
| ***Materia medica*** | *Materia medica* is the Latin term for substances used in medicine. |
| **Monograph** | A pharmacopeial monograph provides a specification with acceptance criteria and tests to verify the composition, identity, quality, purity, and strength of the defined article. |
| **Officinal** | Officinal means stocked by apothecaries and standardly used in medicine. Although the title *National Formulary of Unofficial Preparations* replaced the term "Unofficinal" in the 1896 revision, the two terms are not exactly synonymous. |

untitled section of 329 preparations and compositions.[9] In the section that included formulae for the preparation and compositions of medicines, all articles that were presented by the District Conventions (that held regional meetings prior to the National Convention) were included, except in cases where two preparations were considered similar, in which case only one formula was included. A visual representation of the botanicals in the *USP 1820* is available at www.usp.org/trustX*I*.

Some native North American plants included in *USP 1820* were substitutes for European plants of the same genus with similar qualities. The pharmacopeia reflected the therapeutics of the time, including tonics, strong laxatives, diuretics, and flavoring herbs. The preparations included cerates (waxy preparations for external use), confections, decoctions, extracts, honeys, infusions, liniments, mixtures, ointments, pills, plasters, powders, spirits, syrups, tinctures, troches (lozenges), vinegars, washes, waters, and wines. Recipes and compounding techniques were included, but no analytical methods appeared in the monographs.[9] The USP also recognized that new medical discoveries would lead to many new articles that would expand the *materia medica* to an unmanageable size. The USP therefore planned for the "retrenchment of superfluities," creating what became known as the process of "omission" of articles from the pharmacopeia in the later years.

There were two second editions of the *USP*, the New York version of 1830[10] and the Philadelphia version of 1831[11]; the latter was more accurate and actually became the first decennial revision of the *USP*, also called *USP I*. From these versions onward, the monographs included brief botanical descriptions, macroscopic, and organoleptic properties to be verified for identification of the articles. The complexity of this information increased with subsequent editions. However, to address the need for standards of identity, purity, and strength, additional detailed information on each *USP* article was included in *The Dispensatory of the United States of America*, which was published from 1833 to 1973.




**Figure 1.** A black cohosh tincture product ("Tincture Cimicifuga N. F. IV.") illustrating raw material quality in compliance with Black Cohosh *USP IX* (1910). Photo courtesy of Scott Jordan, PhD

As *Pharmacopoeia of the Massachusetts Medical Society* authors Jackson and Warren noted in 1808:

"In this, as in former ages, men are creating confusion by creating names. The object of the reforms in scientific language is to obviate this evil and to establish nomenclature upon solid grounds."

As *USP* evolved into an authoritative compendium for drugs of first choice, other efforts for "standardization of names and formulas for dosage forms of drugs not described elsewhere" were in development.[12] One such publication was the *National Formulary* (*NF*), which was intended to provide formulas that could be "compounded on a small scale that physicians and self-medicating public wanted." The first issue of the *National Formulary of Unofficinal Preparations* was published in 1888 by the American Pharmaceutical Association (APhA), now called the American Pharmacists Association.[13] The first editions of the *USP* and the *US Dispensatory* were authoritative but not official; the *USP* and the *NF* achieved legal recognition with the passage of the Food and Drug Act of 1906.

Botanicals have always been prone to intentional economically motivated adulteration or unintentional substitution with closely resembling species that may share the same common name. Collaboration between pharmacists and physicians improved the quality of standards in the early years. The role and importance of pharmacy and public trust in medicines grew with the increase in quality standards made available in the *USP*. Gregory J. Higby, PhD, pharmacy historian and former executive director of the American Institute of the History of Pharmacy, described the methods used by Dr. William Procter, Jr. (1817-1874) in examining the adulteration of aloe (*Aloe* spp., Xanthorrhoeaceae) latex.[14] Procter used an intelligent combination of organoleptic sensory tests (color, appearance, odor) coupled with comparison of observations of authentic material for solubility in different solvents and the ash values to distinguish the "original" material from the adulterated aloe.

Standardization of botanical and chemical nomenclature for pharmacopeial articles was another goal of the *USP*. As *Pharmacopoeia of the Massachusetts Medical Society* authors Jackson and Warren noted in 1808: "In this, as in former ages, men are creating confusion by creating names. The object of the reforms in scientific language is to obviate this evil and to establish nomenclature upon solid grounds."[4]

Botanicals and botanically derived medicines were considered critical for the US Army Medical Department during the Civil War.[15] These included South American cinchona (*Cinchona* spp., Rubiaceae) tree bark extract; quinine (obtained from cinchona tree bark extract); opium (*Papaver*

*somniferum*, Papaveraceae) capsule exudate; camphor (a monoterpene ketone obtained by distillation of the bark and wood of the East Asian camphor tree [*Cinnamomum camphora*, Lauraceae]); and ginger (*Zingiber officinale*, Zingiberaceae) rhizome. Issues of quality and adulteration concerned the pharmacists and physicians of the mid-19th century. In addition, the need for larger-scale manufacturers to adopt and use the pharmacopeia was highlighted during the 1870-1900 revisions. *USP* came to be valued increasingly as a source of industry-wide standards for nomenclature, strength, and purity, while the role of the compounding guide was assumed by the *US Dispensatory*.[15]

## BOTANICALS IN *USP 1820* AND THEIR CONTINUED USE IN 2020

The first issue of the *USP*, published on December 15, 1820, contained monographs for 217 drugs in its Primary List,[16] of which about 130 listed substances were herbal drugs used by Native Americans.[8] For example, pharmacist John Uri Lloyd (1849-1936) wrote that the medical uses of black cohosh (Figure 1), then called "black snake root" (then *Cimicifuga serpentaria*, now *Actaea racemosa*, Ranunculaceae), were introduced "by the Indians" to "early domestic American medicine." An aqueous decoction preparation of black cohosh was indicated for "diseases of women, for debility, to promote perspiration, as a gargle for sore throat, and especially for rheumatism."[17] While most of the botanicals in *USP 1820* were native plant species, by 1820 many European species had become naturalized in North America and adopted for use in indigenous medicine as well.

Several botanicals described in *USP 1820* have remained relevant for health care and appear in the *USP–NF* 2020 edition. These include many native American species such as black cohosh root, capsicum fruit, ipecac (then *Callicocca ipecacuanha*, now in the *USP* as *Cephaëlis acuminata* or *Cephaëlis ipecacuanha*, both of which are subsumed under the currently accepted name *Carapichea ipecacuanha*, Rubiaceae) rhizome and root, podophyllum (*Podophyllum peltatum*, Berberidaceae) rhizome and root, and slippery elm (*Ulmus rubra*, Ulmaceae) inner bark, among others.

*USP* also included imported botanicals that still appear in *USP–NF* as of 2020. Some of these are African plants such as aloe (*Aloe spicata*) latex; myrrh (*Commiphora molmol* syn. *C. myrrha*, Burseraceae) oleo-gum resin; and senna (then *Cassia senna*, now *Senna alexandrina*, Fabaceae) leaflet. Asian species include garlic (*Allium sativum*, Amaryllidaceae) bulb; ginger rhizome; opium capsule exudate; turmeric (*Curcuma longa*, Zingiberaceae) rhizome; and the European species include valerian (*Valeriana officinalis*, Caprifoliaceae syn. Valerianaceae) root. Many of the aforementioned botanicals that appeared in *USP* in both 1820 and 2020 are top-selling herbs in the US market today as dietary supplement ingredients, especially aloe, black cohosh, garlic, ginger, senna, and turmeric.[18]



**Figure 2.** Dr. Charles Rice at his desk in the Bellevue Hospital library in New York City. Source: American Institute of the History of Pharmacy

## BOTANICALS IN THE *NATIONAL FORMULARY* AND THEIR MIGRATION TO *USP*

The *National Formulary of Unofficinal Preparations* was first published by the authority of APhA in 1888. The title of this compendium changed to *National Formulary* from the fourth edition in 1916 onward. The immediate predecessor and basis for the *NF* that today accompanies the *USP* was the *New York and Brooklyn Formulary of Unofficinal Preparations*, published in 1884, edited by Dr. Charles Rice (1841-1901) (Figure 2), a pharmacist and chair of the Committee of Revision for the 1880 edition of the *USP*. The *National Formulary of Unofficinal Preparations* published in 1888 was based on those unofficial (preparations not included) articles of the *USP 1880* that were in the most frequent demand, to

**Figure 3.** Documentation of the revision history of *USP VII*, 1890. Source: USP





**Figure 4.** An 1882 record of the ballot for approval of a standard. Source: USP



**Figure 5.** A comparative picture of the USP Committee of Revision and the officers of the Convention in 1910 (upper right) and the corresponding Council of Experts in 2017 (lower right). Source: USP

provide formulas that would enable pharmacists to prepare them to a uniform standard.[19]

Rice also established the first subcommittees and pioneered the use of revision circulars (Figure 3). This gave each member of the USP's Committee of Revision equal influence in the revision process by implementing a voting and commenting system, the framework of which is still in use today (Figures 4 and 5).

Joseph P. Remington (1847-1918) (Figure 6) was a distinguished Philadelphia pharmacist who succeeded Rice as the chair of the USP's Committee of Revision. Rice served as chair from 1880 to 1901 and Remington from 1901 to 1918. Remington was a member of the APhA Pharmacopeial Committee that was appointed specifically to provide APhA's input for the pharmacopeia. By the start of the 20th century, pharmacists began to dominate the revision of the pharmacopeia and make it more relevant to the times.

Admission of articles to the *NF* was based on extent of use rather than therapeutic value. The *NF* did not include monographs of botanical raw materials until 1916. "In listing a botanical drug, for example, the *NF IV* (1916) provided specifications of the species and part of the plant to be utilized, permissible percentage of foreign matter, odor, taste, and color, a description of the macroscopic and microscopic appearance, in addition to other characteristics," wrote Higby.[20] There was a dramatic increase with two-thirds more articles than the previous revision of the *NF,* resulting from increasing recognition of uncompounded botanical and chemical ingredients for the first time. Depending on the *USP*'s admission criteria, a monograph developed for the *NF* could appear in the *USP*, and those dropped from the *USP* could be admitted into the *NF* if there was widespread usage, even if the therapeutic value had not been proven.

As shown in Table 1 on page 58, the two compendia borrowed from each other in terms of organization, and thus monographs in the two became similar. According to Higby:

> The general thrust was to harmonize the *NF* with the activities and the character of the *USP*, while preserving the traditional conceptual difference between the two books — the *USP* setting specifications for drugs of first choice therapeutically, the *NF* for other drugs whose extent of use justified development of a monograph.... Of equally durable interest was a question about which drugs should be recognized by the *NF* and dealt with in the monographs. The [*USP*] had stuck by its original concept of scope, recognizing only drugs of first choice in each therapeutic category, as determined by representatives of organized medicine. This left a majority of the medicaments open for selection by the *NF*, and left ample room for differences of opinion. The pharmacist's journals reflected this interest at least until industrialization removed drug manufacture and most compounding from the local pharmacy.[20]

In the *NF V* (1926), at the end of a botanical monograph, a list of preparations that included it as an essential ingredient was published. Many botanical drugs were deleted (omitted) in the *NF IX* (1950).

## Federal Recognition

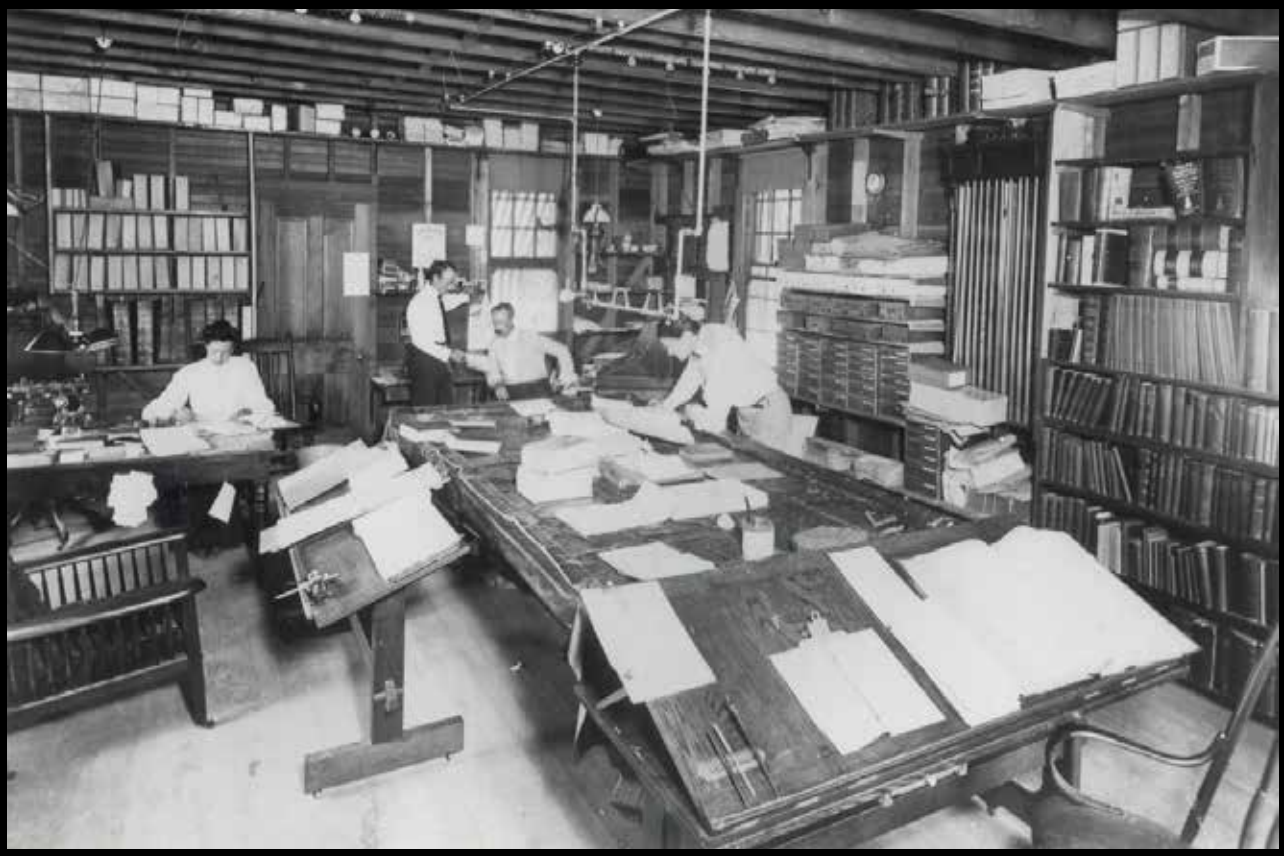
Long before the Federal Food and Drug Act of 1906, the 1848 Drug Importation Act was enacted to control the number of spurious and adulterated articles coming into the United States. New York City was the major port of entry for drugs, and since the 1830s, inspectors were seeing imports that were not of consistent quality. In an article titled "Good Enough for America," Professor Dennis B. Worthen wrote: "Six articles dealing with adulteration or questionable identity of calomel, rhubarb,** morphine, colocynth, and quinine were published in 1835, four by NYCCoP [New York City College of Pharmacy]."[21] The NYCCoP and many others, including Dr. Montgomery J. Bailey, an examiner in the NY Customs House, had also cataloged adulterated and counterfeit drugs coming through New York City. The bill passed quickly through the House of Representatives and Senate and was signed into law by President James K. Polk. In the Act, *USP* was mentioned along with other pharmacopeias and it was stipulated that articles that originated from England, Scotland, France, and Germany had to adhere to their respective pharmacopeias, and any others had to comply with the *USP*.

*USP* and *NF* standards were recognized in the Food and Drug Act of 1906, which provided a definition for drugs and misbranding and established the importance of standards. During the same time period, the chemical industry was growing, while the use of medicines derived from natural products was declining. This changed the pharmacopeial structure, with the inclusion of many more chemical medicines than botanicals. The Federal Food, Drug, and Cosmetic Act (FD&C Act), first enacted in 1938, defined the term "official compendium" as the official *USP*, the official *NF*, the official *Homeopathic Pharmacopoeia of the United States*, or any supplement to these publications.

To eliminate duplication of the same standards in different publications, the *USP* acquired the *NF* in 1975, and the combined volumes then became *USP–NF*.[16] In the United States, compliance with a *USP–NF* monograph, if one exists, is mandatory for botanical drugs for the drug's nonproprietary name, identity, strength, quality, purity, packaging, and labeling. Thus, *USP–NF* standards play a role in the prevention of adulteration and misbranding provisions of the FD&C Act.

** Regarding the adulteration and identity of the laxative drug rhubarb (*Rheum palmatum*, Polygonaceae) root, while it was included in the *materia medica* of *USP I* (1830), along with several monographs for preparations made from it (Rhubarb Pills, Infusions, Syrups, Tinctures, and Wines), the *US Dispensatory* (1833, p. 528) monograph dedicated pages of discussion on the uncertainty of the origin and botanical identity of rhubarb articles of commerce at that time, noting that "the question yet remains unsettled from what precise plant it is derived. The remoteness of the region where it is collected, and the jealous care with which the monopoly of the trade in this drug is guarded, have prevented any accurate information on the subject." They did not know then that the medicinal rhubarb of commerce was, and still is for the most part, wild-collected in the high-altitude Qinghai-Tibet Plateau and Hengduan Mountains of China.

**Figure 6.** Dr. Joseph P. Remington at his library; note the innovative use of the pool table for document review.
Source: American Institute of the History of Pharmacy



In 1994, the Dietary Supplement Health and Education Act (DSHEA) amendment to the FD&C Act recognized voluntary compliance with the "official compendia of United States" for dietary supplements. The amendment provided that a dietary supplement may be deemed misbranded if it is covered by a monograph in an official compendium, and is represented as conforming to this monograph, but fails to so conform. The dietary supplement must be represented as conforming to a *USP–NF* dietary supplement monograph for the compendial standards to apply. This contrasts with pharmaceutical products, for which conformance to the monograph is mandatory whether or not the product claims to conform.[22] This means that a dietary supplement is not required to meet *USP* standards unless the label includes a *USP* quality claim. Many dietary supplement products do not claim to conform to *USP* standards. When public standards are not mandatory, as in the case of dietary supplements, products that may be traded under identical names may possess vastly dissimilar attributes, and thus may be dissimilar in quality, benefits, and safety for consumers.

In 1995, a resolution at the USP Convention passed by its member delegates recognized the need for standards for dietary supplements and provided the mandate to USP to contribute in this area. Consistent with the regulatory recognition, the structure of the *USP–NF* publication introduced a separate section for dietary supplements.

### Notable Inclusions and Omissions since *USP 1820*

The preface to the first edition of *USP* stated: "It is the object of a Pharmacopoeia to select from among substances which possess medicinal power, those, the utility of which is most fully established and best understood." Faithful to this principle, and also in association with the rise in government regulation of both drugs and new drug claims, *USP* has evolved over time. Starting out as a compendium of complex botanicals whose pharmacology and composition were not well established or understood, *USP* has evolved in favor of including more of the simple small molecules for which the pharmacological mechanisms and composition were much clearer. In the early 20th century, analytical technology was not sufficient to enable a clear understanding of the composition of the complex mixtures used in traditional medicines, much less the underlying pharmacological mechanisms that involve multiple synergies and compensating interactions among constituents. Fortunately, this situation is changing rapidly, as new knowledge and analytical technologies emerge that can appropriately characterize botanicals.

THE PREFACE TO THE FIRST EDITION OF *USP* STATED:

"It is the object of a Pharmacopoeia to select from among substances which possess medicinal power, those, the utility of which is most fully established and best understood."

Examples of important botanicals that were published in the pharmacopeia after *USP 1820* and omitted in subsequent revisions, but later reintroduced or are presently in the process of being included, are American ginseng (*Panax quinquefolius*, Araliaceae) root and cannabis (*Cannabis sativa*, Cannabaceae) female (pistillate) inflorescence.

The American ginseng trade began in Québec, New France, in the early 18th century, and the article was initially defined in the *Dictionnaire de l'Académie Française.* Later, it entered the 1827 edition of *Pharmacopée française, ou Code des médicaments*, which included the Iroquois common name "*Garent-Oguen"* (meaning "resembles man" or "a man's thigh") among others under the entry "Panax De La Chine."[23] While initially appearing only on the Secondary List of *materia medica* of the second revision of the *USP 1840*, "Panax" (described as the root of *Panax quinquefolium*, now *P. quinquefolius*) had a short pharmacopeial life. Secondary



American ginseng (*Panax quinquefolius*) plate from the 1818 *American Medical Botany* by Jacob M. Bigelow, one of the authors of *USP 1820*. (*American Medical Botany*, vol. 2, 1818, pl. XXIX)

List drugs were articles deemed to be of secondary importance; they were on probation toward dismissal or toward promotion to the Primary List, but were not for use in officinal preparations.[24] *Panax* root was dismissed 40 years later from the *USP VI* (1880). After a 122-year hiatus, American ginseng root reentered the *USP*, published in the *USP 26* in 2002,[23] this time as a dietary ingredient along with monographs for processed forms, such as powder and dry extract, and in dietary supplement dosage forms, namely capsules and tablets.

Cannabis, under the entry "Extractum Cannabis. *Extract of Hemp.* An alcoholic extract of the dried tops of *Cannabis sativa*—variety *Indica*," first appeared in the Secondary List of *USP III* (1850). It was subsequently elevated to the Primary List in *USP IV* (1860). Interestingly, *USP V* (1870) included monographs for both "Cannabis Americanae" (flowering tops of *C. sativa* cultivated in North America) and "Cannabis Indicae" (flowering tops of female *C. sativa* var. *indica* from India), as well as monographs for their respective preparations, "Extractum Cannabis Americanae" and "Extractum Cannabis Indicae." In 1888, both "Extract of Indian Cannabis" and "Tincture of Indian Cannabis" were included as components of several multi-ingredient preparations monographed in the first issue of *NF*.[13,25] Cannabis extract remained in *USP* until the twelfth decennial revision (*USP XII*, 1940), published in 1942.

In recent years, there has been active and growing interest in cannabis inflorescence for medical purposes. In light of the unique regulatory status of cannabis, USP published a Stimuli Article for public comment in 2016 on the topic of the advisability and feasibility of developing new USP quality standards for medical cannabis. As a result of legalization of the medical use of cannabis in numerous US states and in other countries, and in the absence of modernized quality standards such as monographs (i.e., other than the extensive but unofficial *Cannabis* monograph published by the American Herbal Pharmacopoeia in 2014), USP was asked to develop such standards.[26] The USP Cannabis Expert Panel was established, comprising scientific experts in areas of cannabis testing, procedure development and validation, and compendial procedures. The USP Cannabis Expert Panel has recommended specifications for fit-for-purpose analytical methods and to limit contaminants such as toxic elemental impurities, pesticides, microorganisms, and fungal toxins. Multiple complementary tests are included to provide an exhaustive quality characterization. The Expert Panel also highlighted the importance of naming, definition of chemotypes based on the cannabinoid profile, use of reference materials, and packaging/storage conditions. In April 2020, the USP Cannabis Expert Panel published a peer-reviewed article in the *Journal of Natural Products* describing quality attributes for cannabis inflorescence.[27] USP also submitted public comments to the US Food and Drug Administration (FDA) and US Department of Agriculture (USDA) regarding the need for quality standards for cannabis and cannabis-related compounds.

While *USP 1820* listed 145 botanical drugs in its Primary List, many more were admitted in the subsequent decennial revisions throughout the remainder of the 19th century. *NF* provided for the continuance of official standards for drugs

Illustration of cannabis (*Cannabis sativa*) from *American Medicinal Plants: An Illustrated and Descriptive Guide to the American Plants Used as Homeopathic Remedies: Their History, Preparation, Chemistry and Physiological Effects* by Charles F. Millspaugh (1887). Image courtesy of Steven Foster



deleted from the *USP* during periodic revisions. Table 1 provides a list of selected notable articles of botanical origin admitted through *USP VIII* (1900), along with their year of dismissal and eventual readmission (including those that are expected to be readmitted). Additional information on the regional types and geographic origins of each botanical species is included in the table, although such data were generally not included in the *USP*. Inclusion in the table indicates significant current use in herbal foods, herbal dietary supplements, botanical drugs, and other natural health products in North America. In the 20th century, when an article was dismissed from the *USP*, it was generally admitted to the next edition of the *NF*. Furthermore, most botanicals were eventually dismissed from the *NF* as well. Thus, the Dismissed column of Table 1 shows dismissals from the USP and, in most cases, subsequent dismissal from the *NF*. Many of the dismissed botanicals in Table 1 that subsequently entered the *NF* and left the *NF* eventually

**TABLE 1. NOTABLE ADMISSIONS AND DISMISSALS OF *USP* ARTICLES OF BOTANICAL ORIGIN**

| Admitted | Article | Native | Dismissed | Readmitted |
|---|---|---|---|---|
| *USP* (1820) | Black cohosh [then black snake root] (then *Cimicifuga serpentaria*, now *Actaea racemosa*) root | Canada and USA | *USP* XI (1930); *NF* IX (1950) | *USP* 31 (2008) |
| *USP* (1820) | (Ceylon) Cinnamon (then *Laurus cinnamomum,* now *Cinnamomum verum*) bark | Asia (Sri Lanka) | *USP* X (1920); *NF* XII (1965) | In process |
| *USP* (1820) | (Chinese) Cassia (then *Laurus cassia*, now *Cinnamomum cassia*) bark | Asia (China) | *USP* VIII (1900) | In process |
| *USP* (1820) | Garlic (*Allium sativum*) bulb | Asia | *USP* VIII (1900); *NF* VI (1936) | *USP* 23–*NF* 18, 8th Suppl. (1998) |
| *USP* (1820) | Ginger (*Zingiber officinale*) root | Asia | *USP* XIV (1950); *NF* XIII (1970) | *USP* 23–*NF* 18, 7th Suppl. (1997) |
| *USP* (1820) | Licorice (*Glycyrrhiza glabra*) root | Europe and Asia | *USP* XXII–*NF* XVII (1990) | *USP* 25 (2001) |
| *USP* (1820) | Saffron (*Crocus sativus*) stigma | Europe | *USP* VIII (1900); *NF* VIII (1946) | Not yet planned |
| *USP* (1820) | Slippery elm (then *Ulmus fulva*, now *Ulmus rubra*) inner bark | Canada and USA | *USP* XI (1930); *NF* XI (1960) | *USP* 23–*NF* 18 (1995) |
| *USP* (1820) | Turmeric (*Curcuma longa*) root | S. Asia (India) | *USP* VI (1880) | *USP* 32 (2009) |
| *USP* (1820) | Valerian (*Valeriana officinalis*) root | Europe | *USP* XII (1940); *NF* IX (1950) | *USP* 23–*NF* 18, 8th Suppl. (1998) |
| *USP* 1 (1830) | Dandelion (then *Leontodon taraxacum*, now *Taraxacum officinale*) root | Europe | *USP* X (1920); *NF* XII (1965) | In process |
| *USP* 2 (1840) | (American) ginseng (then *Panax quinquefolium*, now *P. quinquefolius*) | Canada and USA | *USP* VI (1880) | *USP* 26 (2002) |
| *USP* 2 (1840) | (German) chamomile (*Matricaria chamomilla*) flower | Europe | *USP* X (1920); *NF* IX (1950) | *USP* 23–*NF* 18, 9th Suppl. (1998) |
| *USP* 2 (1840) | (Lemon) balm (*Melissa officinalis*) leaf | Europe, W. Asia | *USP* VIII (1900) | Not yet planned |
| *USP* 3 (1850) | Cannabis extract (alcoholic liquid extract of the dried flowering tops of *Cannabis sativa* var. *indica*) | S. Asia | *USP* XII (1940) | Work in progress[27] |
| *USP* 4 (1860) | Goldenseal [then hydrastis] (*Hydrastis canadensis*) root | Canada and USA | *USP* XI (1930); *NF* XI (1960) | *USP* 27 (2003) |
| *USP* 4 (1860) | Skullcap (*Scutellaria lateriflora*) herb | Canada and USA | *USP* IX (1910); *NF* VIII (1946) | Not yet planned |
| *USP* 4 (1860) | Yarrow (*Achillea millefolium*) leaves & flowering tops | Europe, W. and C. Asia | *USP* VI (1880) | In process |
| *USP* 5 (1870) | American hemp (*Cannabis sativa* cultivated in North America) flowering tops | N. America | *USP* VII (1890) | In process |
| *USP* 5 (1870) | American hemp (alcoholic liquid) extract | N. America | *USP* VI (1880) | In process |
| *USP* 5 (1870) | Indian hemp (female plant of *Cannabis sativa* var. *indica*) flowering tops | S. Asia (India) | *USP* XII (1940) | In process |
| *USP* 5 (1870) | Oregano (*Origanum vulgare*) herb | Europe, N. Africa, Asia | *USP* VII (1890) | In process |
| *USP* 6 (1880) | Calendula (*Calendula officinalis*) ligulate flowers | Europe | *USP* IX (1910); *NF* VIII (1946) | Not yet planned |
| *USP* 6 (1880) | Guarana (then *Paullinia sorbilis*, now *P. cupana*) dried paste prepared from the crushed or ground seeds | S. America (Brazil) | *USP* X (1920); *NF* VIII (1946) | *USP* 43–*NF* 38, 1st Suppl. (2020) |
| *USP* 7 (1890) | Saigon cinnamon (then an undetermined species of *Cinnamomum*, now *Cinnamomum loureiroi*) bark | Vietnam | *USP* XV (1955); *NF* XVII (1990) | Not yet planned |
| *USP* 8 (1900) | Saw palmetto [then sabal] (*Serenoa repens*) fruit | USA | *USP* X (1920); *NF* IX (1950) | *USP* 23–*NF* 18, 9th Suppl. (1998) |

reentered the merged *USP–NF* in the late 20th century, or are again prioritized for readmission in the early 21st century. In 1995, the use of Roman numerals ceased, replaced with Arabic numerals starting with *USP 23–NF 18*.

Introduction of bioassays in *USP IX* (1910) marked a notable method for testing the potency of some botanicals. Optional bioassay methods were introduced for digitalis (*Digitalis purpurea*, then Scrophulariaceae, since moved to Plantaginaceae) leaf, squill (then *Urginea maritima*, now *Drimia maritima*, Asparagaceae) bulb inner scales, strophanthus (*Strophanthus kombe* or *S. hispidus*, Apocynaceae) ripe seed, and aconite (*Aconitum napellus*, Ranunculaceae) tuberous root. A bioassay requirement was also introduced for cannabis and its preparations. The bioassay for cannabis is based on the symptoms of incoordination in dogs and then adjusting the strength by comparison with a standard preparation. This requirement was omitted by *USP XI* (1930), possibly due to the challenges with bioassays (large variability) and a preference for replacing bioassays with chemical assays, as evidenced by a paragraph in Anderson & Higby's (1995) *Spirit of Voluntarism* stating concerns with bioassay reliability and reproducibility.[28]

Over the last two centuries, the Pharmacopeia's content has evolved dramatically, from simple descriptions to comprehensive monographs with specifications for identity, assays, impurities, and characterization of quality, as well as detailed requirements for storage, packaging, and labeling.

## Current Status of *USP* Botanical Standards

Over the last two centuries, the Pharmacopeia's content has evolved dramatically, from simple descriptions to comprehensive monographs with specifications for identity, assays, impurities, and characterization of quality, as well as detailed requirements for storage, packaging, and labeling. An elaborate description of the current monograph specifications has been published[16,29] with examples by both Schiff et al. (2006) and Ma et al. (2018) (see also the section *A Walk Through a USP Monograph*, available in the full-length paper). The number of monographs has increased substantially from a few hundred in 1820, which consisted mostly of botanicals and minerals, to nearly 5,000 in 2020, which are mostly chemical medicines but also include about 300 botanical ingredients, botanically derived compounds, and their dosage forms (see Table 2 in the full-length paper).

Depending on the manufacturer's claims and intended use(s), botanical articles described in the *USP* can be considered drugs, dietary ingredients, or excipients. The monographs in the *USP–NF* compendium are organized into different sections. When an article of botanical origin can be legally used as a drug, the monograph that describes the article's quality attributes would appear in the main section of the *USP*. When the article is used to supplement the diet, not intended to diagnose, prevent, treat, or cure a disease, it would appear in the dietary supplements section of the *USP*. If the botanical article is intended as an excipient, it would appear in the *NF*. Some articles may be used legally across these categories, thus their monographs may appear in multiple sections of the compendium, at times with different names pursuant to the nomenclature guidelines of the *USP*[30] or as cross references.



**Belladonna** *Atropa belladonna*
Photo ©2020 Steven Foster

***USP* botanical drugs.** The current edition of the *USP* includes 60 botanical drugs (see Table 3 in the full-length paper), most of which are legacy articles included in early editions of the *USP* (e.g., belladonna [*Atropa belladonna*, Solanaceae], digitalis, and podophyllum) and botanical drugs of more frequent use that are available over the counter (OTC), such as senna, psyllium (*Plantago ovata*

or *P. arenaria*, Plantaginaceae) husk, and capsicum oleoresin. Botanical drugs that are developed according to the recent FDA guidance for "botanical drugs," such as sinecatechins, a partially purified extract of green tea (*Camellia sinensis*, Theaceae) leaf, and crofelemer, a preparation of dragon's blood croton (*Croton lechleri*, Euphorbiaceae) latex, could be admitted to *USP* as botanical drugs, but are not yet listed.

> "The value of the Pharmacopoeia depends upon the fidelity with which it conforms to the best state of medical knowledge of the day."
>
> – Jacob Bigelow, MD (1820)

***Herbal Medicines Compendium* (*HMC*).** Recognizing the need for and the gap in standards for herbal medicines, USP published a Stimuli Article in 2012 to seek comments on the development of a specialized compendium of herbal medicines.[31] The Stimuli Article reviewed regulatory approaches in the United States and other countries, as well as the rationale for USP's development of standards for traditional medicines. After the public comments were received and considered, the *HMC* was developed as an online resource that provides standards for herbal ingredients used in herbal medicines.[32] Articles that are approved by a national authority for use as ingredients of herbal medicines, or are included in a national pharmacopeia, and are also deemed appropriate for inclusion in the *HMC* by a USP Expert Committee, are admitted into the compendium.

Through the *HMC*, USP created a forum for advancing standards for herbal ingredients used in traditional medicines around the world. The *HMC* publication, which is available in electronic form, contains only articles that are recognized as ingredients of herbal medicines in other countries and jurisdictions. Given that a botanical may be used as both a traditional medicine and a dietary ingredient, some of the *HMC* monographs overlap with the USP's dietary supplement monographs, although their nomenclature would be different because of the different nomenclature guidelines for the two compendia. Currently, more than 45 monographs in the *HMC* are at the Final Authorized stage, and 25 monograph proposals are open for public comment. The expert volunteers of regional Expert Panels, for example the South Asia Expert Panel and East Asia Expert Panel, prioritize and recommend the standards for adoption. *HMC* provides the avenue to set standards for botanicals such as *Polygonum multiflorum* (syn. *Reynoutria multiflora*, Polygonaceae) and *Cullen corylifolium* (Fabaceae) that do not qualify for admission into the *USP*. In these two cases, the USP Dietary Supplements Admission Evaluations Joint Standard-Setting Subcommittee decided not to proceed with monograph development due to safety concerns if used as dietary supplements. However, the *HMC* is an appropriate home for such botanicals when used within their traditional medicine contexts with specific indications and posology.

**Botanical dietary ingredients.** A major advance toward including botanicals in *USP–NF* came after the 1994 passage of DSHEA, which defined dietary supplements as including herbs and other botanicals and extracts thereof, among other substances. The USP adopted a resolution in 1995 that "encouraged the USP to explore the feasibility and advisability of establishing standards and developing information concerning dietary supplements." This resolution enabled USP to develop new monographs for this category of articles, including botanicals within the *NF* section until 2002, after which a separate section for dietary supplements was created in the *USP*. Since then, USP has steadily added new monographs of plant materials used as dietary ingredients with due diligence in the prioritization and admission of the ingredients for standards development.[16]

***Dietary Supplements Compendium* (*DSC*).** In 2009, USP published a separate compendium dedicated to dietary supplements named the *Dietary Supplements Compendium* (*DSC*). By 2019, the *DSC* transitioned to an online-only publication with annual updates. The *DSC* includes all the monographs for dietary supplements and dietary ingredients published in *USP–NF*, plus other monographs for dietary ingredients that are included in the *Food Chemicals Codex* (*FCC*) and monographs for other non-dietary ingredients published in the *NF* that can be used to formulate dietary supplements. The *DSC* also includes supplemental information of interest to the dietary supplements industry, such as FDA guidance documents pertaining to dietary supplements (e.g., dietary intake tables) and supporting material for the monographs, such as sample chromatograms and micrographs.

**Botanical excipients.** Botanicals and botanically derived excipients have always been included in the *NF,* but if an excipient is also used as a pharmaceutical active ingredient in an FDA-approved product sold in the United States, its monograph will appear in the *USP* section instead. That is because some botanicals may function as excipients at non-therapeutic dosage levels but as active ingredients when used at therapeutic dosage levels. The criterion for inclusion of botanical excipients in *NF* is based on whether the article is used as an ingredient in one or more FDA-approved drugs or legally marketed as an excipient in the United States. The article must be included in the FDA Inactive Ingredient Database, referenced in the FDA approved drug label, or included in a drug awaiting approval by the FDA.[33,34] Thus, USP works closely with the FDA to prioritize new monographs to be developed for excipients.[35]

**Reference Standards (RSs).** *USP* monograph tests for identification and quantitation of active principles or marker compounds require well-characterized materials. The USP RSs for botanicals are thoroughly characterized for use in qualitative tests (such as identification by fingerprint tests, system suitability tests, or chromatographic peak markers) and quantitative tests (such as assays for ingredients and formulations, assays for composition of major constituents, limit tests, or control tests). These RS are intended for use in specific analytical tests in monographs in which properties of the product under examination are compared with those of the relevant RS. Depending on the intended purpose, the botani-

cal RSs may be represented by a powdered plant material (e.g., USP Powdered Ginger RS), a dry extract (e.g., USP Powdered Asian Ginseng [*Panax ginseng*] Extract RS), a purified fraction (e.g., USP Ginkgo [*Ginkgo biloba*, Ginkgoaceae] Terpene Lactones RS), or a pure compound (e.g., USP Valerenic Acid RS). USP RSs are authentic specimens that have been collaboratively tested and approved for use as comparison standards in *USP–NF* or *HMC* tests and assays. USP RSs are provided for legal metrology purposes (the practice and process of applying regulatory structure and enforcement to metrology, which is the science of measurement) and can help ensure the comparability of results and traceability to the SI or metric units. Additional information regarding USP RSs is presented in the general chapter *USP Reference Standards* <11> ("chapter 11"). These RSs help to determine whether an article meets the monograph acceptance criteria to be deemed a USP-grade material.[36]

**USP guidance documents.** USP has developed several guidance documents that explain aspects of the monograph development process. The Admission Evaluation guidance describes the prioritization, selection, and evaluation of information in admitting a monograph to the *USP* monograph development process.[37] The Nomenclature guidance explains how monograph titles and article names are constructed.[30,38] Additional guidance documents, available on the USP website, address how to define the quality parameters for submission of monograph proposals.[39]

**General chapters.** General chapters (found in every *USP* revision) are documentary standards that cover general requirements for tests and assays, and general information on analytical procedures. The most relevant general chapters pertaining to herbal medicine ingredients and botanical dietary supplements are:

- *Articles of Botanical Origin* <561>
- *Identification of Articles of Botanical Origin* <563>
- *Botanical Extracts* <565>
- *High-Performance Thin-Layer Chromatography Procedure for Identification of Articles of Botanical Origin* <203>
- *Residual Solvents* <467>
- *Chromatography* <621>
- *Water Determination* <921>
- *Identification of Articles of Botanical Origin Using High-Performance Thin-Layer Chromatography Procedure* <1064>
- *Microbial Enumeration Tests-Nutritional and Dietary Supplements* <2021>
- *Microbial Procedures for Absence of Specified Microorganisms-Nutritional and Dietary Supplements* <2022>
- *Elemental Contaminants in Dietary Supplements* <2232>

## EVOLUTION OF BOTANICAL MONOGRAPHS

*"The value of the Pharmacopoeia depends upon the fidelity with which it conforms to the best state of medical knowledge of the day."*— Jacob Bigelow, MD (1820)

The monographs in *USP–NF* undergo periodic revision to ensure that the pharmacopeial standards remain state-of-the-art in terms of the methods and technologies they describe, so they help meet the regulatory requirements. While the publications in the early 19th century did not include quality parameters to address the purity of chemicals (i.e., chemical formula, identifications, or assays, which are hallmarks of a modern pharmacopeia), the monographs were periodically revised and modernized in the 20th century to update the standards in line with the state of the science.

The revision history of the valerian monographs is presented here to illustrate the major changes over time. The first edition of *USP* in 1820 included monographs for Valerian, Infusion of Valerian, Tincture of Valerian, and Ammoniated Tincture of Valerian (Figure 7). The monograph for the plant material provided a compendial name for the botanical and defined the part of the plant. The monographs for the tea infusion and tincture provided a method to compound the plant mate-




**Figure 7.** Valerian monographs in *USP 1820*.

VALERIANA. Valeriana officinalis. *W.* I. 177.
*Valerian.* Radix. *The root.*

INFUSION OF VALERIAN.

Take of Valerian, two drachms.
Boiling water, half a pint.

Infuse for an hour in a covered vessel, and strain.

TINCTURE OF VALERIAN.

Take of Valerian, four ounces.
Diluted alcohol, two pints.

Digest for ten days, and filter.

AMMONIATED TINCTURE OF VALERIAN.

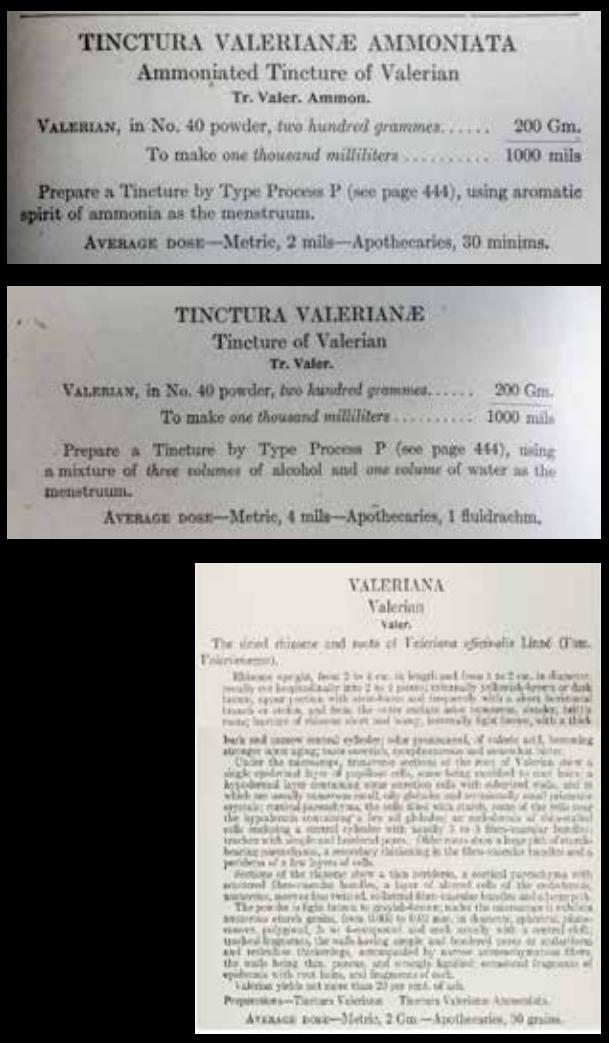
Take of Valerian, four ounces.
Ammoniated alcohol, two pints.

Digest for ten days, and filter.

rial into a standardized form. These monographs did not include methods to analyze the active principles or marker compounds or limits for contaminants.

Revisions of valerian monographs over time expanded the description of the morphological characteristics and included detailed methods for preparing the extract and tinctures. Shown in Figure 8 are the valerian monographs in *USP IX*, 1910.

**Figure 8.** Valerian monographs in *USP IX*, 1910.



TINCTURA VALERIANÆ AMMONIATA

Ammoniated Tincture of Valerian

Tr. Valer. Ammon.

VALERIAN, in No. 40 powder, *two hundred grammes*..... 200 Gm.

To make *one thousand milliliters*..... 1000 mils

Prepare a Tincture by Type Process P (see page 444), using aromatic spirit of ammonia as the menstruum.

AVERAGE DOSE—Metric, 2 mils—Apothecaries, 30 minims.

TINCTURA VALERIANÆ

Tincture of Valerian

Tr. Valer.

VALERIAN, in No. 40 powder, *two hundred grammes*..... 200 Gm.

To make *one thousand milliliters*..... 1000 mils

Prepare a Tincture by Type Process P (see page 444), using a mixture of *three volumes* of alcohol and *one volume* of water as the menstruum.

AVERAGE DOSE—Metric, 4 mils—Apothecaries, 1 fluidrachm.

VALERIANA

Valerian

Valer.

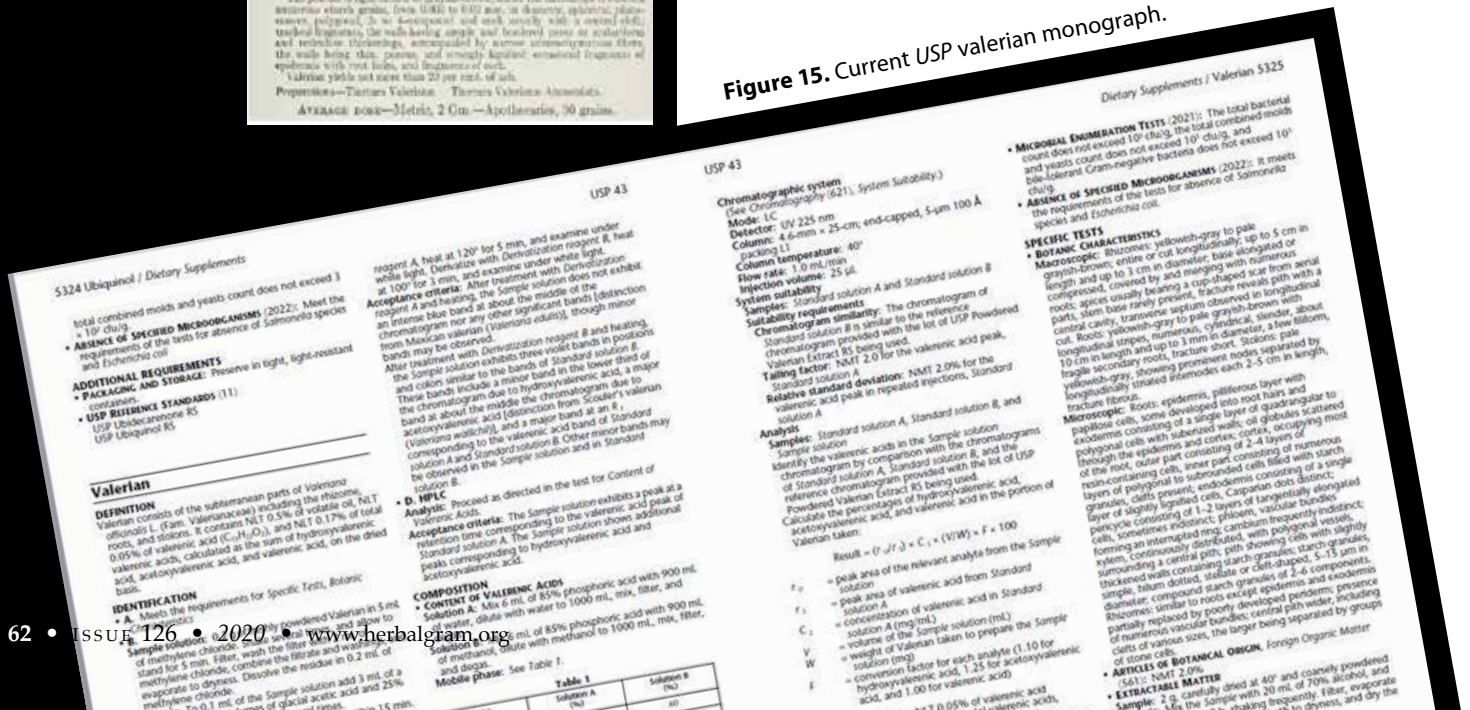
AVERAGE DOSE—Metric, 2 Gm.—Apothecaries, 30 grains.

Monographs for the valerian family were omitted from *USP XII* (1940) and *NF IX* (1950), apparently due to the decreased use of botanical remedies in the 1940s. The passage of DSHEA in 1994 provided a framework for botanical dietary supplements, and thereafter the standards for botanical dietary supplements were introduced in the *NF* portion of the *USP–NF* where they resided until 2002. Accordingly, the monographs for valerian were reintroduced in the *USP 23–NF 18*, 8th Suppl. (1998) as *NF* monographs. With the creation of a separate Dietary Supplements section within the *USP* portion of the *USP–NF*, all dietary supplement monographs and related general chapters were migrated to this new section as of *USP 27–NF 22* (2004). As of January 2020, these monographs for *Valeriana officinalis* are official in *USP 43*:

- Valerian
- Powdered Valerian
- Valerian Tablets
- Valerian Tincture
- Valerian Root Powdered Capsules
- Powdered Valerian Extract
- Valerian Root Dry Extract Capsules

The current monographs for valerian provide detailed descriptions of quality parameters in alignment with the state of the science and regulations (see *A Walk Through a USP Monograph* in the full-length paper). Modern monographs in the *Dietary Supplements Compendium* include illustrations of macro- and microscopic features with photographic material to aid the analysts. Identification tests are based on characteristic chromatographic fingerprints using high-performance thin-layer chromatography (HPTLC) and high-performance liquid chromatography (HPLC). The content of relevant constituents is typically determined by chromatographic methods such as HPLC. Detection of adulterants and contaminants is a major concern, and modern monographs now typically include provisions in the identification tests to rule out potential confounders, as well as modern purity tests to detect contaminants such as heavy metals by inductively coupled plasma (ICP) or pesticides by advanced chromatography.

**Figure 15.** Current USP valerian monograph.



5324 Ubiquinol / Dietary Supplements

USP 43

Valerian

DEFINITION

IDENTIFICATION

Dietary Supplements / Valerian 5325

SPECIFIC TESTS

ASSAY




**Figure 9.** Subterranean parts of valerian.

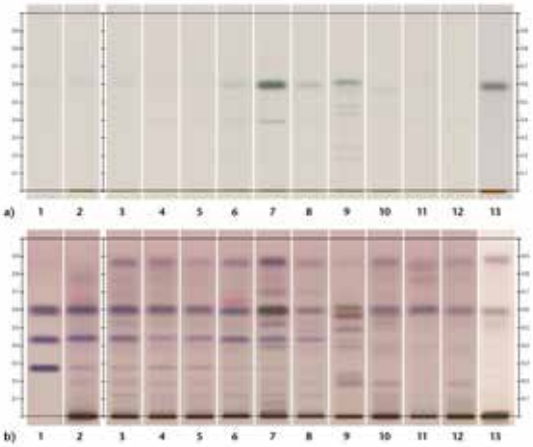


**Figure 13.** Typical valerian HPTLC chromatogram.

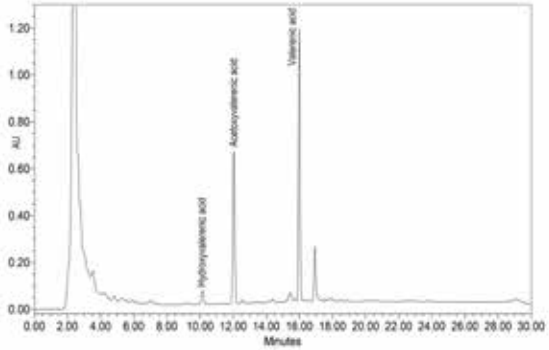



**Figure 14.** Typical chromatogram of USP Powdered Valerian Extract.



**Valerian** *Valeriana officinalis*
Photo ©2020 Steven Foster

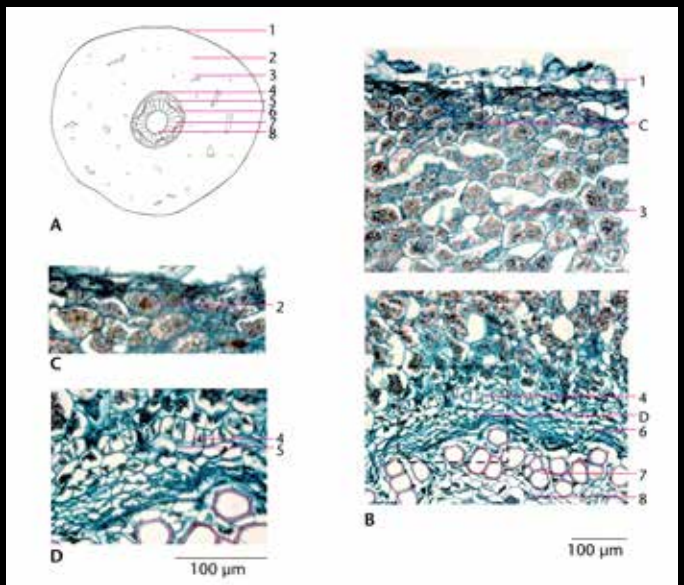



**Figure 10.** Microscopic characteristics of valerian.

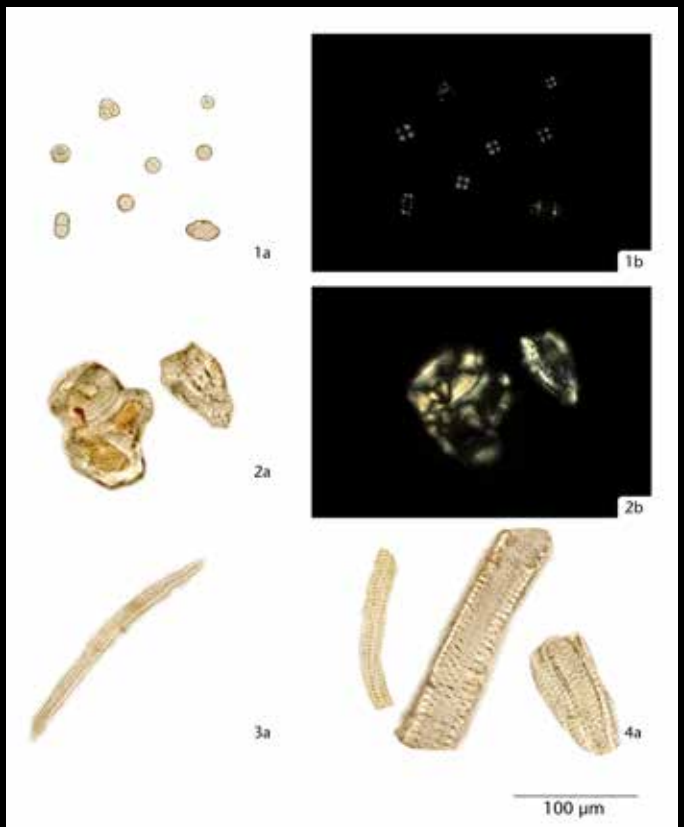



**Figure 11.** Microscopic characteristics of valerian root powder.

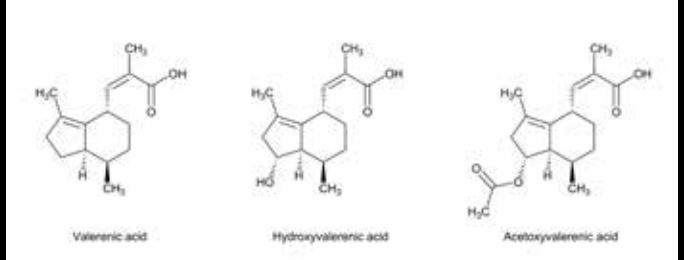



**Figure 12.** Chemical components of valerian.

Figures 9-15 illustrate the comprehensive requirements of current *USP* monographs for valerian, reflecting the current state of science.

## AN OUTLOOK FOR THE FUTURE

**Up-to-date and modernized standards.** USP is committed to keeping its monographs up to date by following the principles articulated for the valerian monographs. Another aspect of the evolution is reflected in the fact that print editions of *USP–NF* are being phased out. *USP* is moving from print media in the form of published books to digital and visual media in the form of databases of standards and knowledge accessible electronically. This new format creates opportunities for users of the pharmacopeia to access a reference repository of data linked to monographs for comparison. For example, chemometric approaches to identification of botanicals could be introduced in the modernized monographs with links to digital databases to provide an avenue to compare the phytochemical profile of a test sample with that of several samples from multiple locations and growing conditions. This approach could further refine the monograph acceptance criteria.

**New technologies.** USP recognizes the value of new technologies with greatly improved analytical sensitivity, but also knows they are likely to pose an undue burden on users familiar with older methods. To address this dilemma, USP formed a Modern Analytical Methods Joint Subcommittee to evaluate the full breadth of available approaches for including modern technologies in both the development of monographs and the establishment of reference materials. The subcommittee is a collaborative effort led by the Botanical Dietary Supplements and Herbal Medicines Expert Committee (EC) in conjunction with the Non-Botanical Dietary Supplements EC and the Food Ingredients EC. New research and innovation projects related to botanicals include DNA analysis for the identification of herbal/botanical articles and the use of quantitative nuclear magnetic resonance (qNMR) spectroscopy and liquid chromatography-mass spectrometry (LC-MS) procedures in dietary supplement monographs. As an example, it may be possible to use qNMR as a simultaneously selective and universal screening tool. The qNMR and LC-MS methods also have the potential to enhance pharmacopeial efforts in sourcing suitable reference materials. USP also recognizes new trends in pharmaceutical manufacturing such as "continuous manufacturing technologies." It remains to be seen as to how these new trends will be adopted for herbal medicine production and the impact of these approaches on future pharmacopeial standards.

Considering the constant challenge of economically motivated adulteration, there is an unmet need for non-targeted methods that can detect such adulteration (e.g., adulteration of dietary supplements with prescription drugs and their unapproved drug analogs, as well as with other dietary supplements and natural product articles with unapproved drug admixtures). LC-MS procedures could serve as non-targeted approaches to detect adulteration with synthetic drugs or drug analogs.

Considering the constant challenge of economically motivated adulteration, there is an unmet need for non-targeted methods that can detect such adulteration.

**Science of standards beyond monographs.** USP ECs and staff engage in several activities to support the standard-setting work and move the science forward. EC members and USP staff have published several articles in peer-reviewed journals on the topics of quality, safety, and nomenclature.[29,40-42] Besides the use of *Pharmacopeial Forum* as a primary portal for seeking stakeholder input, new avenues such as Stimuli Articles and roundtable discussions are used for seeking public input on issues such as rational limits for pesticide residues, DNA methods for botanical identification, and standards for cannabis and cranberry (*Vaccinium macrocarpon*, Ericaceae) fruit. Focused Expert Panels have been formed on topics such as standards for cannabis, development of multi-criteria decision-based modeling approaches to assess safety of multi-ingredient dietary supplements, and evaluating the potential hepatotoxicity of green tea extract. USP Expert Panels are convened when additional specialized expertise beyond the EC is needed.

**Novel ingredients.** As the supply chain for botanicals becomes increasingly global — both in terms of adoption of traditional herbs from other cultures by American consumers and increased use of botanicals as a part of health systems around the world — USP prioritization and admission criteria are playing an important role in admitting botanicals into the compendia by focusing on the botanicals that provide maximum public health impacts of USP's standard-setting work.

## Conclusions

USP's public health mission has remained steady and consistent from the organization's inception in 1820 to the present, and it is reflected in the current mission statement: "to improve global health through public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods." To remain relevant as science advances, timely adoption of the innovative ways of manufacturing and quality assurance is essential. In tune with the fast-paced technological developments and novel challenges, and to maintain its relevance and usefulness as a pharmacopeia, USP is rapidly adapting, and in some cases leading, in modernizing public standards with the introduction of new, fit-for-purpose technologies and modalities. Trust in quality standards is more important now than ever before, given that standards drive quality across the global supply chain. Based on its 200-year legacy of making contributions to botanical standards, USP is poised to continue its public health mission for the future. HG

## Author Declarations

Four of the seven authors are employees of USP, which is a nonprofit organization that sells documentary and physical reference standards to sustain its activities. The views presented in this article do not necessarily reflect those of the organizations for which the authors work. No official support or endorsement by these organizations is intended or should be inferred.


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# Herbal Companies Brace for Supply Chain Impacts of COVID-19

**By Karen Raterman**

***Editor's note**: This article reports on market conditions as of mid-April 2020 for herbal ingredients and products. The American Botanical Council (ABC) is not recommending any of the mentioned botanical ingredients as remedies to prevent or treat coronavirus disease-2019 (COVID-19).*

On March 11, 2020, the World Health Organization (WHO) declared the outbreak of the novel coronavirus, SARS-CoV-2, a global pandemic. By the end of March, about one-third of the world's population was under some form of quarantine or public lockdown, and the virus has prompted a tsunami of disruptions to the global economy.[1]

The pandemic has had ripple effects across every economic sector, as companies and workers have halted travel and adapted to the new reality of "nonessential" business closures, supply chain interruptions, and nationwide stay-at-home orders. It is an unprecedented event for most people and has the potential to forever change life and business.

For the herbal products industry, the impacts are no less profound. The early stages of the crisis have been a roller coaster ride of trying to interpret and anticipate potential disruptions to the herbal supply chain, which is dependent to a significant degree on China, the early epicenter of the outbreak. This has been further complicated by more recent impacts on other key herbal supply regions, such as India and Europe. As alarm about the virus grew, so did the demand for herbal immune enhancers, wellness formulas, traditional medicines, and botanical ingredients ranging from echinacea (*Echinacea* spp., Asteraceae) and elderberry (*Sambucus nigra*, Adoxaceae) fruit to turmeric (*Curcuma longa,* Zingiberaceae) root and rhizome. The result may be a perfect storm for the herbal industry and could have lasting impacts on how and where product manufacturers source their botanical ingredients.

As of this writing, companies are striving to calmly look forward, get ahead of the curve, and prepare for what's next as the impacts of the global pandemic escalate. It is a rapidly changing situation, but many herbal and dietary supplement company representatives believe that things will likely get worse before they get better.

"As we know, the herbal industry is very much dependent on global supply chains, and especially the botanicals that are trending with consumers and growing at a fast pace," said Ajay Patel, founder and CEO of Verdure Sciences, an Indianapolis, Indiana-based supplier of botanical extracts that are manufactured in India (email, March 26, 2020). With the COVID-19 disruptions in regions like China, India, and Europe, he said, "it has already become evident

that suppliers are not able to cope with the current demand, let alone future demand, which is expected to grow considering current market feedback and sales data.

"Additionally, since COVID-19 is a global issue, and demand for botanicals are already growing in those source countries, it is expected that the overall demand will outweigh the supply," Patel added, "and as a result it will not only become difficult to source certain botanicals, but in addition, the prices will escalate."

BI Nutraceuticals in Rancho Dominguez, California, which is now part of the Martin Bauer Group North America, obtains raw materials from 45 different countries, according to Rupa Das, vice president of global quality and compliance for the company (oral communication, March 17, 2020). "Certain herbs grow only in certain regions, so because we are dependent on the world for supply, we will be very much affected," she said.

Wilson Lau, vice president of Nuherbs, a San Leandro, California-based importer of Chinese herbal formulas, described the situation as "very fluid" (oral communication, March 17, 2020). "What we know is that pain is coming," he said.

## Unprecedented Demand

According to sources, herbal industry companies need to address three primary issues related to the crisis: disruptions to the supply chain, changes in domestic production, and the spike in demand for herbal products, all while keeping their workers safe and maintaining productivity.

As the ripple effects of the coronavirus continue to affect the global economy, consumers have been stockpiling nonperishable food items, soaps, and health products, including herbal dietary supplements. "Currently, many consumers are purchasing supplements to fortify their immune systems against infection, as there is no vaccine or [proven] treatment [for the coronavirus]," said Guy Woodman, general manager of Euromed S.A., a producer of standardized herbal extracts based in Barcelona, Spain (email, March 23, 2020).

Early on, Beth Lambert, CEO of Herbalist & Alchemist, a Washington, New Jersey-based manufacturer of herbal extracts and formulas, took proactive measures to deal with the emerging virus. "When we first started hearing about the coronavirus in China, we ordered all the Chinese herbs we thought we would need for the year," she explained (email, March 30, 2020). "Everything changed when it became apparent that the US and Canada would be facing similar epidemics; we saw an abrupt increase in orders, driven primarily by our practitioner customers."

Woodman noted a spike in demand for herbal extracts typically used in immune-enhancing supplements, including extracts of echinacea, olive (*Olea europaea*, Oleaceae) leaf, and rosemary (*Rosmarinus officinalis*, Lamiaceae). "Euromed has experienced increased demand for these extracts in response to brisk sales of our customers' immune health formulations," Woodman said.

Verdure's Patel agreed, noting increasing demand for immune-building herbs and botanicals, as well as adaptogens and antioxidant-containing herbs, for which he expects to see more demand. These include botanical ingredients like turmeric, ashwagandha (*Withania somnifera*, Solanaceae)



**Rosemary** *Rosmarinus officinalis*
Photo ©2020 Steven Foster



**Elderberry** *Sambucus nigra*
Photo ©2020 Steven Foster



root, tinospora (*Tinospora cordifolia,* Menispermaceae) stem, holy basil (*Ocimum tenuiflorum*, Lamiaceae) leaf, ginger (*Zingiber officinale*, Zingiberaceae) root and rhizome, boswellia (*Boswellia serrata*, Burseraceae) gum, shatavari (*Asparagus racemosus*, Asparagaceae) root, and andrographis (*Andrographis paniculata*, Acanthaceae) leaf, to name a few, he said. "Many of our customers are seeking additional supportive information to target immune health and support," Patel added.

A number of these herbs are already in high demand in the United States. According to data from *HerbalGram*'s 2018 Herb Market Report, herbal supplements marketed for immune-health benefits experienced some of the greatest sales growth (by percentage) from the previous year in both mainstream and natural retail channels.

A number of these herbs are already in high demand in the United States. According to data from *HerbalGram*'s 2018 Herb Market Report, herbal supplements marketed for immune-health benefits experienced some of the greatest sales growth (by percentage) from the previous year in both mainstream and natural retail channels.[2] The recent increases may be especially problematic for herbs that are already in high demand. This includes herbs like echinacea, a well-studied immunomodulator,[3,4] which saw more than $120 million in sales in 2018 and double-digit growth from 2017 in both channels; turmeric, for which in vitro antiviral properties have been reported,[5] which saw a combined $144.5 million in sales in both channels and growth of 30.5% from 2017 in the mainstream channel; and elderberry, increasingly recognized for its immune-support benefits,[6,7] with combined sales of $76 million in 2018 in both channels and growth of 138% in the mainstream retail channel and 94% in the natural channel.

Natural products industry publications and market research firms, such as *Nutrition Business Journal* (*NBJ*) and SPINS, reported unprecedented spikes in sales from late February through March 2020 for cold and flu formulas and immune-support products, including herbal formulas and single-herb products.[8] According to data from Amazon.com compiled by *NBJ* and presented in an April 2, 2020, webinar, more than half of surveyed Amazon customers said they increased their use of supplements during the previous week. Kathryn Peters, executive vice president of SPINS also reported in the webinar that immune-health products overall had seen sales increases in March and herbal formulas and single-herb products specifically doubled in unit sales per store across the month. While elderberry products showed one of the most significant spikes in the cold and flu category, Peters also noted an increase, although not as large, in immune-support formulas and predicted that there will likely be continued growth for products besides those related specifically to immunity and respiratory health.

Chinese herbal formulas also are seeing increasing interest. According to Subhuti Dharmananda, PhD, founder and director of the Institute for Traditional Medicine in Portland, Oregon, "general panic has set in among practitioners of Chinese medicine, and they are trying to buy up anything that is supposed to enhance immune functions or treat [viral infections]. Everyone is running out of those, and it takes time to resupply, not because of disrupted supply chains, but getting things from China normally takes some time, including delays by regulators at the ports" (email, March 20, 2020).

The demand for Chinese herbs is escalating as news reports from China have featured current treatment standards for COVID-19 from the central government of China that include herbs used in traditional Chinese medicine (TCM), with a breakdown of specific formulas used for different stages of disease.[9] One recent literature review, published in English in the *Chinese Journal of Integrative Medicine*, concluded that while more rigorous population studies are needed, Chinese herbal formulas could be an alternative approach for prevention of COVID-19 in high-risk populations.[10]

"Our business is up, as it is in most of the supplement industry," Lau noted, "and that includes orders from TCM practitioner customers. Most of the herbs that have been highlighted as being effective for COVID-19 patients *in* China are also *from* China," (email, March 27, 2020). While access to these herbs isn't really an issue, since the supply chain is flowing from China again, he said, "the prices may increase, largely because of shipping costs, with sea cargo space less available and in high demand, but for the most part the supply is accessible."

Lau noted that the increased interest is not surprising because well-trained clinical herbalists and TCM physicians reportedly are treating various serious health conditions successfully with Chinese herbs. "Some hospitals in China, such as Beijing Hospital of Traditional Chinese Medicine, are effectively treating coronavirus using TCM integrated with conventional medicine," he said. But, he added, it is important to keep in mind that those patients are being monitored by medical staff.

Many of the formulas noted in Chinese literature have been based on the *wen bing* ("warm disease") theory in Chinese medicine, according to an article by Eric Brand, PhD, LAc, a Chinese medicine practitioner, who has been following the impact of the coronavirus on the herbal supply chain for his company Legendary Herbs in Boulder, Colorado, a company which specializes in Chinese herbs. This theory has prompted a high demand for "heat clearing" herbs in China's top-tier hospitals and shortages of, for example, *ban lan gen*, the root of a flowering plant called woad (*Isatis tinctoria*, Brassicaceae); *jin yin hua*, the flower of Japanese honeysuckle (*Lonicera japonica*, Caprifoliaceae); and *huang qin*, the root of skullcap (*Scutellaria baicalensis,* Lamiaceae).

While numerous traditional Chinese herbs are considered anti-pathogenic, Dharmananda cautioned that "there is not specific information pointing to any of them as being effective for COVID-19." The well-known formula *Yin Qiao San*, which includes *jin yin hua* and *lian qiao* (the fruit of forsythia [*Forsythia suspensa*, Oleaceae]), is used traditionally to treat infections. "This has sold out promptly," he said.

The rush for these herbs has pushed companies to address shortages as best they can. "Demand for herbal supplements, immune-support herbs in particular, escalated rapidly for most of our customers, who are now reordering from us in high volume," Lau said. "Every manufacturer we have talked to is a week or more behind their usual schedule in filling orders, just as we are. Our customers are not just herbal product manufacturers. We also supply TCM practitioners with teapills, classical formulas, and other items they use in their practices, and their orders are far larger than usual as well. Everyone is trying their best at a difficult time."

While the business growth is encouraging, Euromed's Woodman thinks that the overall spike may be short-lived. "Over time, the economic impact associated with loss of employment will reduce discretionary purchases of herbal dietary supplements," he said.

## Supply Chain Concerns

Predicting how the crisis will impact the supply chain over the long-term may be more difficult. Herbal supply issues are complex and precede the pandemic. Historically, the natural products industry, in general, depends on China for up to 80% of its ingredient supply, noted Loren Israelsen, executive director of the United Natural Products Alliance (UNPA), in a recent webinar on the supply chain crisis.[11] Heavy reliance on China has been an increasingly critical issue for herbal companies because of the trade war between China and the United States that began in 2018.[12]

The situation for supplement manufacturers has become more daunting because of trade tariffs, according to Nuherbs' Lau. In a mid-March 2020 statement, Lau wrote that tariffs on dried herbs were still at 25%, and other ingredients such as herbal extracts were being tariffed at 15% and then rolled back to 7.5%.[13]

The tariff issue caused uncertainty and difficulty for many companies, but also prompted some firms to monitor the China situation early on. "We have been watching COVID-19 developments closely since early January," Lau said. "We're China experts who have been doing this for decades, so before the Chinese New Year holiday [on January 25, 2020] we had a large amount of stock arrive at our northern California warehouse, and the rest of the 2019 harvest we purchased from our farmers was processed to our specifications and ready to ship as needed."



**Forsythia** *Forsythia suspensa*
Photo ©2020 Steven Foster



Suppliers that acted early experienced few shortages in mid-March, as the crisis began to escalate globally. Verdure, with its global affiliations and network, especially in Asia, has been following the COVID-19 outbreak since January, Patel said. "Since then, we have been extremely proactive with our supply chain partners and expedited bringing in additional inventory to carry us forward several months, in the event the situation escalated in other parts of the world. Sure enough, in addition to Europe and the United States becoming the next epicenters after China, prompting various shutdowns, India went into a total shutdown ... with no movement of persons or commercial goods, including a shutdown of airports and ports, paralyzing logistics."

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Indena USA also ordered additional materials for key products in advance of the pandemic, "just in case," said Greg Ris, vice president of sales for the Milan-based supplier (email, March 18, 2020). As northern Italy became a hotspot, he noted that some shipments from Milan were delayed but not alarmingly so, although the US Food and Drug Administration (FDA) was taking extra time to clear the materials at the ports of entry.

BI Nutraceuticals/Martin Bauer also was prepared for early supply issues, according to Das, who said the company had no initial shortages and was well stocked for customers' immediate requirements. That said, she added that the company is looking at other source locations for herbs with the same medicinal effects from Europe or India, in anticipation of future shortages.

By late March, however, depleted inventories were becoming more common. "From what I hear, most manufacturers are experiencing out-of-stocks, just like we are," said Herbalist & Alchemist's Lambert. "It's a combination of supply chain disruption and rapidly increased demand. But so far our suppliers have been responding to our orders." In a statement on its website, the company noted temporary out-of-stocks for many immune-support products, with the company focusing on replenishing products it believes are most essential, including immune-, kidney- and cardio-support products as well as the "Lung Relief™ Hot/Dry" formula, nervines, and adaptogens.[14]

## Logistical Complications

Suppliers also face the evolving challenges of altered logistics. China, where the economy is currently emerging from lockdown, is a good case study of how this might play out. Factories are resuming production, but progress toward getting back to normal is slow. "Factories are reopening," Das said, "but because of restricted movement of the public, they can't reach the factories, so it has been difficult to get them back up to speed. They also need to be sanitized."

Transportation of goods is another obstacle. "Because everyone has a backlog, things are congested," Das added. "Road transportation and boats are overwhelmed, and ports are closed or ships are not stopping at specific ports." Outgoing raw materials must also be inspected, she noted, so there are administrative delays and significant congestion. "There is raw material in China, but to get it here [into the United States] is a huge deal."

Lau echoed similar concerns. These are not normal times, he said. "Shipping is still disrupted from China, being essentially shut down for weeks. Air freight shipment is faster than cargo but because of the expense, approximately 10-15 cents per kilo for container sea freight versus $4 to $9 per kilo for air shipment, it's a short-term solution. It is made worse by the tariffs."

Another factor for herbal companies is the backlog of goods from many industries that must rely on the limited number of cargo ships, Israelsen noted in the webinar. And a hierarchy determines how this will go, he explained, noting that China's domestic consumption comes first, followed by high-value cargo such as information technology and automobile materials. Natural products ingredients will be fairly low in the queue.[11] UNPA estimated that the supply of a significant number of China-sourced supplement ingredients would be critical by late April and that disruptions could continue through mid-year.

The changes have now expanded well beyond China, with lockdowns in countries around the world from India and Malaysia to Colombia and Argentina.[1] Delivery logistics for suppliers from Europe have currently become the most challenging issue for Herbalist & Alchemist, Lambert said.

These quarantines and lockdowns have triggered confusion about what industries are considered essential and will be allowed to remain open and in operation. For example, in Malaysia, many dietary supplement companies were confused about whether they were allowed to operate after the government's Movement Control Order on March 18 that left them wondering how they would keep up with product supply as pharmacies remained open and online purchasing continued.[15]

## Adulteration Concerns

If the availability of raw materials continues to decline along with the ability of companies to manufacture products, it could also amplify an already-significant industry concern about adulterated ingredients and products. Verdure's Patel said he is concerned about the potential of companies taking advantage of shortages over the short-term to make quick financial gains. Especially since a majority of raw materials come from China and India, "it is very likely that brand owners are having to scramble for raw materials to keep their pipeline filled, and, as a result, are diverting to suppliers that may not be qualified or trusted," Patel said.

Lau explained that the situation will require due diligence from ingredient suppliers and manufacturers. "Any time there is a shortage of material, or prices go up, or buyers go outside their usual supplier network," Lau said,



**Japanese honeysuckle** *Lonicera japonica*
Photo ©2020 Steven Foster



"We would rather be out of a product than compromise quality. Our customers need to know they will receive products with the same consistent quality."

"manufacturers have to be far more suspicious of material they are buying. The only solution is robust testing for identity, potency, and purity using reputable labs."

Elan Sudberg, CEO of Alkemist Labs, agreed that adulteration is a concern right now as companies are dealing with the combined challenges of a strained supply chain due to the trade war, COVID-19 disruptions, and increased demand (email, April 7, 2020). "Then, we have the FDA's temporary halt to inspections during this health crisis, and that's a perfect storm for adulteration," he said. "Robust testing is the only insurance that the products [contain] what the labels say they [contain]."

These concerns were echoed by Mark Blumenthal, founder and executive director of the American Botanical Council and founder and director of the ABC-AHP-NCNPR Botanical Adulterants Prevention Program (BAPP): "In more than 45 years in the botanical industry, I have seen cases in which supply shortages of specific botanicals led to an increase in adulterated material in the US and global markets." He added that BAPP's website includes 57 peer-reviewed documents that provide industry members and analytical labs with guidance to avoid adulterated raw materials, extracts, and essential oils.

Some companies won't allow the crisis to change their values. "Herbalist & Alchemist is very fortunate to have such close and longstanding relationships with our ingredient suppliers, farmers, and wildcrafters," Lambert said. "And we contacted all labs we work with to discuss their availability and backup plans. We will not change any of our identity specifications or procedures. We would rather be out of a product than compromise quality. Our customers need to know they will receive products with the same consistent quality."

### Safety on the Home Front

As the spread of the pandemic prompted lockdowns and shelter-in-place orders across the world, herbal companies began dealing with the challenges presented by these new protocols while also addressing the safety of their employees. Dietary supplement industry associations in the United States immediately began making statements to clarify the importance of member companies during these work stoppages. A statement from the American Herbal Products Association (AHPA), for example, cited that dietary supplement and herbal product companies are tied to the food and agriculture categories, making them essential businesses that support grocery stores, pharmacies, and other retailers that sell food and beverage products.[16] AHPA further noted that this designation is implied by several regulatory agencies and explicit in California.

Some industry associations and companies sought further clarity to be sure that manufacturers and retailers in the category would not be closed by government directives.[17] For example, the Natural Products Association (NPA), in a letter to the White House, requested that the administration take action to ensure that these types of businesses remain open and that access to essential dietary supplement products continues.[18] As of April 3, 2020, Nevada, one of the states specifically petitioned in this effort, has included health food stores among the businesses that would be closed.[19]

People are now working from home, schools are closed, and parents are staying home with their kids. "This will have a big impact on productivity," Das said. "Our first concern is the personal safety of our employees and second is supply chain safety." She noted that the team has contingency calls everyday to address ongoing supply chain issues and people who can work remotely are doing so. "We had time to plan and for now we have backup, so if one person is out sick or needs to be with a family member, we have other ways of taking care of the work."

Because Nuherbs supplies products to multiple channels including health care, it has been exempted from work stoppages and shelter-at-home orders that began early in the San Francisco Bay Area. Lau didn't rule out the possibility of a future closure and noted that the company is taking precautions to ensure the safety of its employees. "Our employees' wellbeing is our top priority," he said. "We are, of course, adhering to CDC [US Centers for Disease Control and Prevention] guidelines…, and our warehouse is large, giving people distance from each other. Our staff that has to take public transportation has been given time off, so that they don't have to be exposed while traveling to work."

Some people also are concerned about how long the virus can last inside production facilities. "One of the first questions our QC manager wanted answered was how long can it remain on different surfaces," noted Lambert. "We needed to assure ourselves we could [adopt] safe procedures based on science." On March 17, *The New England Journal of Medicine* reported that while the virus can be detected on some surfaces for up to a day, the levels tend to drop off quickly.[20] "The virus's half-life (how long it takes the viral concentration to decrease by half) on stainless steel was 5.6 hours and plastic 6.8 hours…. So, we added work instructions such as to either not touch incoming packages for 72 hours and/or wear gloves when unpacking or immediately wash hands after handling. We discussed cleaning procedures with UPS and had frank discussions with delivery people and dispatch personnel."

These scenarios are playing out in companies around the world. "My colleagues in Milan are managing the best that they can under these lockdown conditions," Ris said. "Many are working from home and thus far production has been operating on regular hours."

Similarly, at Euromed, "Staff that do not need to be onsite are working from their residences," Woodman said. "Customer communications are being performed

by conference call rather than in-person meetings. Non-essential employee travel has been prohibited." In addition, Euromed's extraction facilities in Spain are working split shifts to segregate personnel with facility sterilization between shifts. "Our laboratory staff are following a similar protocol," Woodman added. "We have alternative sources of raw material in the event of a supply chain disruption."

## The Long View

Looking further ahead, however, the consequences for companies and their supply chains are more difficult to predict. In the supply chain webinar, Israelsen predicted that the pandemic will force companies to ultimately better understand their supply chain's weaknesses and diversify their ingredient sources.

Many companies agree. "I do anticipate it will change where we source," said Das. "Now, some products you can get from only China, but after this, there will be a shift from being totally dependent on China. Europe has a lot to offer. So, we are developing strategies on how to deal with this."

But the changes companies make must be considered carefully, Patel noted, which is a topic the Verdure team has been debating internally. It is particularly critical, he said, for an industry dealing with "botanicals and nature where the traditional source countries/regions have a very important role to play from a standpoint of soil and growing conditions, traditional knowledge of growing, harvesting, and processing, [and] sustainability and consistency of output ... to name a few. In addition to all of this, one needs to ensure that the economies of scale are managed."

Moving away from China to source in other countries may also create additional challenges such as maintaining compliance with the FDA Food Safety Modernization Act's Foreign Supplier Verification Program and ensuring that new sourcing partners are the original supplier and not supplying sub-components from other entities.[11]

Beyond changes to daily life, Patel said, the pandemic underscores that the botanical and dietary supplement industries will have an even greater need in the future for risk mitigation and contingencies in their supply chains, inventory management, business continuity planning, and sustainability. But Patel also sees potential opportunities as the world recovers from the crisis. While things may be different, he said, "this is a great opportunity for the dietary supplement industry in which the acceptance of and demand for many botanicals and herbal preparations is expected to grow as consumers divert more toward natural alternatives that have been proven in traditional medicine to support immune systems and keep people healthy long-term using a more proactive approach."

Das sees the potential to learn from past mistakes. "My fear is that after all of this, it [goes] back to the same old same old, where we are faced again with the need to clamp down and find alternatives in a crisis." She noted that this is an opportunity for the industry to put competition aside, work together to develop studies on alternative ingredients that might be cost-prohibitive for a single company, and have experts within the industry dedicated to this rather than every company doing their own thing. "Every company should not have to reinvent the wheel," she said.

While the effects of the pandemic may be disruptive to the industry for a long time, Lambert was also optimistic overall, noting that the close relationships many people within the herb industry have will help all get though the resulting challenges. "There is this shared passion for and



**Holy basil** *Ocimum tenuiflorum*
Photo ©2020 Steven Foster



"There is this shared passion for and commitment to the benefits provided by what we all do, and we will continue to help each other deliver those. Some of our suppliers are concerned about the impact on the growers and wildcrafters. Their health through this crisis might be the most important factor in the long-term health of herbal supplies."

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For now, even with the challenges, some are taking comfort in the small things. "I am hopeful," Lambert added. "This morning I received confirmation of shipment from one of our European suppliers with the note, 'feeling lucky for ourselves and our kids to live in the countryside rather than being locked up inside. At least they can play in the garden.'" And that is a hopeful thing for herbalists everywhere. HG

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FRANKINCENSE
Essential Oil
5 mL (0.17 fl. oz.)
Certified Organic
BLUE
CHAMOMILE
Essential Oil
5 mL (0.17 fl. oz.)

***The Sensory Herbal Handbook: Connect with the Medicinal Power of Your Local Plants*** by Fiona Heckels, Karen Lawton, and Belle Benfield. ISBN: 9781786782113. Softcover, 272 pages. New York, NY: Watkins Publishing; 2019. $22.95.

**By Chanchal Cabrera, MSc, FNIMH, RH (AHG)**

My library shelves are almost collapsing under the weight of herbal medicine books. They cover a wide range of subjects: plant chemistry, folk uses, medicine making, plant identification, and more. I reference them constantly and certainly get a lot more satisfaction from looking things up in a book than any amount of internet searching. You can imagine, then, the joy of diving into *The Sensory Herbal Handbook* by Fiona Heckels, Karen Lawton, and Belle Benfield — also known as the Seed Sistas.

This book is written by herbalists for herbalists, but also for anyone with a love of plants and the wild woods. As a practical guide for connecting to the plant spirits and the cycles and rhythms of nature, and as an informative guide to self-care with plants, this book draws the reader into a wonderful world filled with plant wisdom.

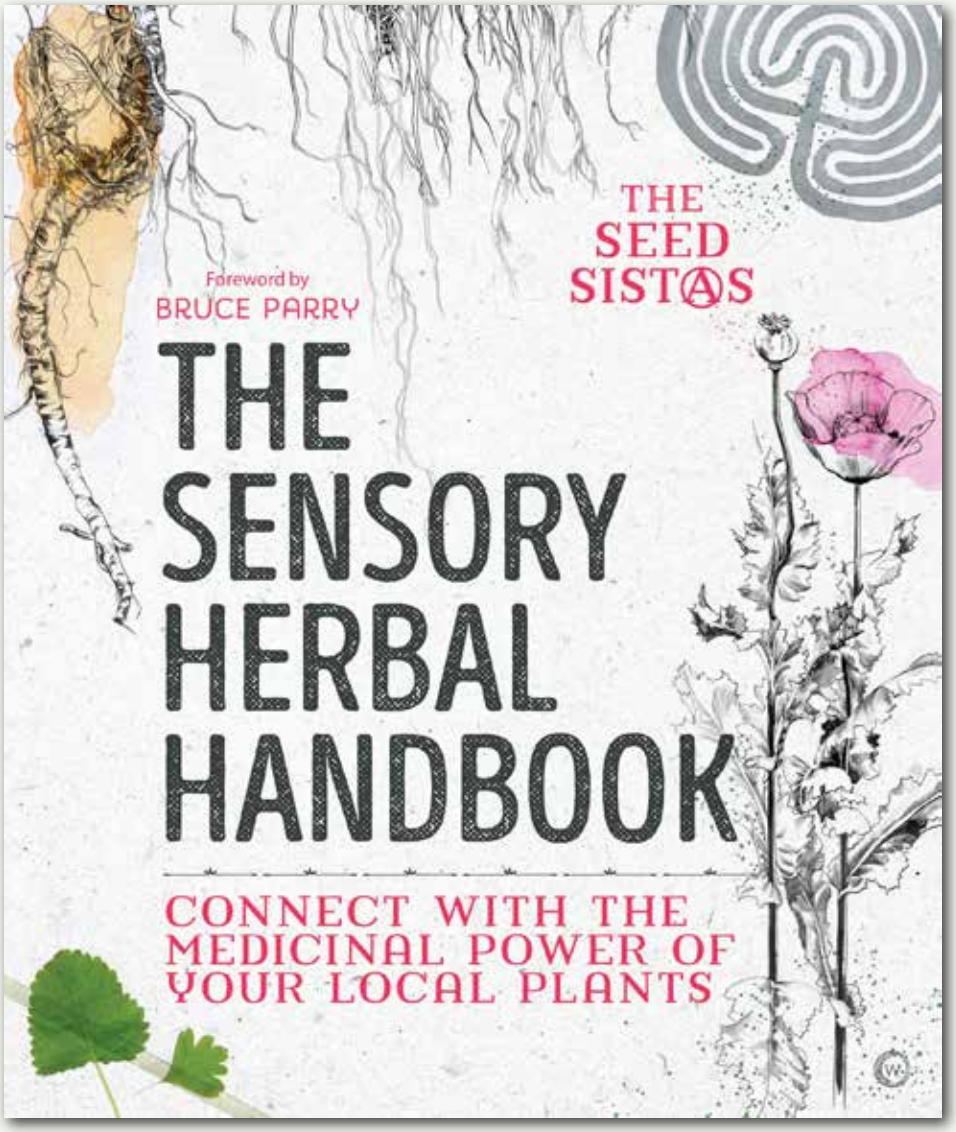
*The Sensory Herbal Handbook* teaches five core tools for deepening readers' understanding of plants: sensory observation, enhancing intuition, interpretation of the intuitive experience, divining the plant characters and personalities, and using rituals, recipes, and poetry (what the authors call the "plant dream") to express these findings. The book is structured to follow the seasons and explores herbs, related health conditions, seasonal rituals and practices, harvesting, and even cooking with herbs.

Instead of trying to cover every known constituent and every known action of dozens of herbs, filling the book with factoids and abstract references, the authors have chosen to focus instead on a handful of herbs, 16 in total, and demonstrate how to understand them deeply, and then how to apply that learning model to any other herb. This is an empowering approach with a focus on experiential learning and deep knowledge.

There are so many standouts in this book. The table of tastes, associated elements, chemical constituents, and indications for use is especially helpful. The plant meditation practices are profound. The poetry is inspiring. The recipes sound delicious. And all of this is illustrated lovingly with lush photography, beautiful line drawings, and clear diagrams.

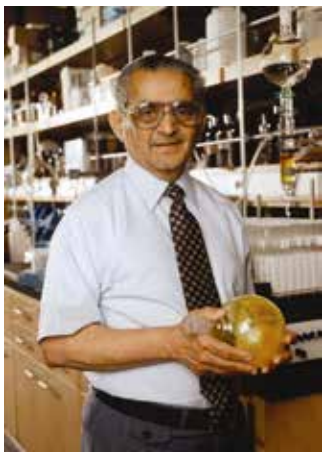
Truly, this is a book to inspire, cherish, share, and use. Herbalists and plant lovers the world over will find simple and practical techniques for enhancing their understanding of herbs. Artists, poets, gardeners, and cooks, as well as herbalists, will all find much of interest in this lovely volume. I highly recommend it. HG

***Chanchal Cabrera*** *is a medical herbalist in clinical practice in British Columbia, Canada, and the director of the Innisfree Farm and Botanic Garden.*



# Mansukh C. Wani 1925–2020

**By Nicholas Oberlies, PhD**



Mansukh C. Wani, PhD, died from natural causes on April 11, 2020, at age 95. To the natural products community, he is most well-known for discovering the natural compound paclitaxel (Taxol®; Bristol-Myers Squibb; New York, NY) with his colleague of nearly 40 years, Monroe E. Wall, PhD (1916-2002). Taxol, one of the best-selling cancer drugs ever manufactured, was first isolated from the bark of the Pacific yew tree (*Taxus brevifolia*, Taxaceae). If that singular achievement were not enough, he and Wall also discovered camptothecin, a compound from the Chinese happy tree (*Camptotheca acuminata*, Nyssaceae). That discovery led to two chemotherapeutic agents: topotecan and irinotecan, which are analogues that circumvent the solubility problems of isolated camptothecin.

It is difficult to fully quantify either of those discoveries. They led to the development of multibillion-dollar drugs that have been used to treat millions of patients with cancer. Wani's original publications on paclitaxel and camptothecin have prompted thousands of research projects. They are evidence of the value of nature to help mitigate human disease. In fact, Taxol is also used to coat stents, mitigating heart disease by preventing restenosis (the recurrence of abnormal narrowing) in arteries.

I had the distinct honor of working with Wani for more than two decades, often traveling with him to meetings and conferences. While he was always proud of those discoveries, he was also extremely humble. He loved to talk about the many challenges associated with the research that ultimately led to those compounds being advanced into drugs. Yet he was quick to point out the numerous players along the way, from botanists, to bench scientists, to pharmacologists, to leading oncologists, all of whom played critical parts.

Wani was born in Nandurbar, Maharashtra, India, on February 20, 1925, and received his bachelor's and master's degrees from the University of Bombay. He came to the United States in the late 1950s to pursue his PhD at Indiana University. He was an older student, in his 30s, with a previous career in India as a chemistry lecturer. He was drawn to the pursuit of knowledge, which was evident until his death, as he still had an office, traveling there by Uber when he could no longer drive, just so he could read up on the literature and correspondence.

He completed his PhD in about two and a half years and moved to the University of Wisconsin for a short postdoctoral stay. Then, he began working at the newly formed Research Triangle Institute (RTI), which is now called RTI International, in North Carolina in 1962.

At first, Wani did not work directly with Wall, who led the chemistry efforts at RTI. After Wani had worked there for about two years, Wall developed a notion that Wani had almost "magic" hands when it came to generating crystals suitable for x-ray crystallography — and even when I joined their team in 1998, Wall still held that belief. Wani was moved to a project to help develop a crystal for their work on camptothecin, which he achieved in about six months and led to their first seminal paper. From that point forward, he always worked with Wall, both on the isolation and structure elucidation of natural compounds and on the development of analogues thereof, mostly to improve solubility and potency. In fact, at the time of Wall's death, they were still working on camptothecin analogues, having registered more than 20 patents in that regard over the years.

Wani loved to tell the story of the discovery of Taxol. The structural work on Taxol took much longer than camptothecin, and on more than one occasion, Wall told Wani to stop working on that project, because they had many other priorities, including ongoing studies on camptothecin. Wani instead received permission to do the work on a low-priority basis, which, he would smile and say, meant working on evenings and weekends. Even when he had determined what he believed was the correct structure of Taxol, Wani continued experimenting, trying to enhance the compound's potency. However, the chemical reactions were not working as planned, and that flummoxed him for several weeks until he realized that his initial structural hypothesis was wrong. If it were not for those extra experiments, he said, Wall and Wani would not be famous for the structure of Taxol, but rather would be infamous, or perhaps even a footnote, for publishing it incorrectly. Wani once confided in me that he breathed a great sigh of relief when the total synthesis of Taxol was reported in the early 1990s, independently confirming that the structure was correct.

Wani, in his humble way, would emphatically point out that determining the structure of Taxol was only the beginning of the story: Susan Horwitz, PhD, performed critical pharmacology experiments to determine the mode of action, followed by the development efforts of the US National Cancer Institute, followed by the circumvention of supply issue problems by Robert Holton, PhD, etc. The abbreviation "etc." does not do it justice, however, as thousands of people were involved, leading to US Food and Drug Administration approval to treat ovarian cancer (1992) and then breast cancer (1994). Clinicians who are old enough can point to the days before Taxol and after Taxol, as it had that large of an impact on cancer chemotherapy.

The medicinal plant world has lost a pioneer, scientist, mentor, and inspiration. Wani is survived by his wife Ramila, son Bankim, daughter-in-law Darshana, and grandson Nilesh. HG



# Berkley Bedell
# 1921–2019

**By Hannah Bauman**

Former US Representative Berkley Bedell died on December 7, 2019, at age 98, following complications from a stroke. Bedell championed the use of alternative medicine and worked with Senator Thomas Harkin to introduce a bill in 1991 that established the Office of Alternative Medicine (OAM) at the US National Institutes of Health. The office is now known as the National Center for Complementary and Integrative Health (NCCIH).

Bedell was born on March 5, 1921, in Spirit Lake, Iowa. As a teenager, he earned money tying and selling fishing flies and tackle. Eventually, he rented an attic office space to expand his fledgling business, which he called Berkley and Co. Bedell attended Iowa State University from 1940 to 1942, and then enlisted and served in the army during World War II as a first lieutenant and flight instructor. After the war, he re-started Berkley and Co., which expanded rapidly, employing more than 800 people by the time he sold the business to his children in 1984. In 1964, President Lyndon B. Johnson bestowed the first "Small Businessman of the Year" award to Bedell.

Bedell's political career began in 1974, when he was elected as a Democrat representative of Iowa's sixth congressional district. He served in the House of Representatives for 12 years, focusing on issues that were important to his largely rural constituency, such as agricultural production controls, waterway usage, and small business protections. In 1986, he contracted Lyme disease from a tick bite and did not seek re-election due to related health problems. Exploring treatment options for his chronic disease brought him into contact with alternative therapies, and this would mark the beginning of his advocacy for complementary and integrative medicine.

Despite his illness and retirement, Bedell remained active in the political sphere as a lobbyist. Perhaps his most notable accomplishment was the formation of the OAM. With an initial budget of $2 million in 1992, the OAM funded research on complementary and alternative medicine, including clinical trials, and also promoted and funded training, outreach, and career development in these areas. In 1998, the office was elevated to a center with an increased budget, then called the National Center for Complementary and Alternative Medicine; the name was changed to NCCIH in 2014. For the fiscal year 2020, NCCIH was granted $151.9 million to continue and expand its work.

Bedell served on the advisory board of the OAM and continued to support alternative medicine research by co-founding the National Foundation for Alternative and Integrative Medicine with his wife, Elinor Healy Bedell, in 1998. The organization later changed its name to the Foundation for Alternative and Integrative Medicine in 2009 to reflect its global reach and goals. Bedell hoped to identify and validate cost-effective traditional treatments, so that the greatest number of people around the world could enjoy good health and wellness.

Bedell continued his political activism until his death, campaigning for Democratic candidates and advocating for increased voter turnout among youth, ways to battle climate change, and reducing student loan debt. He was also active in many private endeavors, including his local church and school board, and as a Boy Scout troop leader. Additionally, he served as the president of the American Fishing Tackle Manufacturers Association and the Iowa Manufacturing Association (now called the Iowa Association of Business and Industry), and on the Board of Trustees of Morningside College, American University, and Claremont School of Theology. In 1998, Bedell and Elinor donated 80 acres of land to create the Elinor Bedell State Park in his hometown of Spirit Lake. He was inducted into the Iowa Business Hall of Fame in 2005 and the Bass Fishing Hall of Fame in 2018.

Berkley Bedell is survived by his children, Ken Bedell (Kathie) of Westminster, Colorado, Tom Bedell (Molly) of Bend, Oregon, and Joanne Quinn (Mike) of Loveland, Colorado; eight grandchildren; and 12 great grandchildren. He was preceded in death by Elinor, his wife of 73 years, who died in 2017; his brother, Jack Bedell; and his parents, Virginia and Walter Bedell. A memorial celebration is planned for July 2020 in Spirit Lake. HG

## 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, P.O. Box 696, Ashfield, NSW 1800, Australia.

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Captured with a Canon EOS 80D, 100mm lens at f/2.8

# Common Barberry
## *Berberis vulgaris*, Berberidaceae

Common barberry is a hardy shrub native to central and southern Europe, northwestern Africa, and western Asia and has been naturalized around the world. Because it thrives in disturbed areas, displaces native species, and is a carrier of black stem rust, which can spread to and threaten cereal crops, barberry is considered an invasive or noxious weed in some areas of the United States and Canada.[1] Barberry fruits are acidic and widely used in Persian cuisine. In Native American traditional medicine, preparations of the astringent fruit have been used to stimulate the appetite and treat acne and gastrointestinal ailments. Barberry roots and twigs contain the alkaloid berberine, which has documented lipid-lowering effects, among other benefits. In clinical trials, barberry fruit has been associated with decreased serum glucose and cholesterol levels in patients with dyslipidemia.[2] HG

**References**


1. *Berberis vulgaris* L. Native Plant Trust website. Available at: https://gobotany.nativeplanttrust.org/species/berberis/vulgaris/. Accessed April 21, 2020.
2. Hadi A, Arab A, Ghaedi E, Rafie N, Miraghajani M, Kafeshani M. Barberry (*Berberis vulgaris* L.) is a safe approach for management of lipid parameters: A systematic review and meta-analysis of randomized controlled trials. *Complement Ther Med*. April 2019;43:117-124.



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