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Natural Products Insider

June **2023**

The business of *botanicals:*

From discovery and quality to making claims—and magic!

Contributors include:

Mark Blumenthal Chris Kilham Michael McGuffin Roy Upton David Winston

Paul Altaffer Ann Armbrecht Steven Dentali Stefan Gafner

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Language loss is the biggest threat to botanicals

The loss of herbal knowledge codified in vanishing languages begs for more attention from stakeholders in the botanical ingredients field. There are no ready solutions, but inaction all but guarantees much of this heritage will be lost.

As the human population nears 8 billion, ever more information is available—yet the cultural richness of that trove has appeared to wane as cultural homogeneity comes to the fore.

Among the things that are getting pushed to the wayside are thousands of indigenous languages, many of which are spoken by only a few thousand people at most. Some of those languages teeter on the brink of extinction with only handfuls of speakers.

As tragic as that is for the diversity of human culture, it's a looming disaster for the development of new botanical ingredients. As a 2021 paper published in the Proceedings of the National Academy of Sciences made clear, a startling amount of global medicinal plant knowledge is codified in indigenous languages.

In the three regions surveyed—North America, the Amazon Basin and New Guinea—the vast majority of mentions of medicinal plant knowledge are in one language only.

The keys to those codes are being lost. The same study noted that only 58% of the present generation in Papua New Guinea is fluent in indigenous languages, compared to 91% of their forebears.

The same study showed that only 6% of the medicinal plants used around the world for medicinal purposes have been screened in modern labs. This means only that portion of that overall trove of knowledge can be said with certainty to have been codified in a modern language.

As big as this industry is, it's hardly a rounding error within the global economy. Even so, companies are rightly proud of changes made to cut energy usage or to shift to lower carbon footprint packaging. They make these changes not only because they help them connect with motivated consumers, but because they believe them to be the right things to do.

An additional commitment to help support the preservation of indigenous languages and cultural traditions is called for. As mentioned, no ready solutions to this problem exist, but journeys that never begin never conclude. As a first step, botanical industry stakeholders should commit to bringing this topic to greater awareness. Consumers can't be motivated to care about a problem they don't know exists.

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How plants serve both pharma and supplements

by Steven Dentali

Drugs are found in nature—living beings have relied on medicinal botanicals since time immemorial.

In society, drugs have existed as single herb "simples" or herb mixtures determined by sophisticated medical systems. Botanical drugs, as such, are still widely used by the Earth's population, although they have fallen out of official favor in the U.S.

The discovery of highly active constituents (think alkaloids like morphine, cocaine, caffeine and other -ine ending compounds) drew attention to what plants contained versus the whole of what they offer—the contents instead of the container. This powerful, game-changing perspective led away from whole plant medicines to predictably acting single chemicals, as evidenced by the 1950s shift away from official USP (U.S. Pharmacopeia) botanical monographs. As scientific fashion went, so did the country. Drug discovery from nature followed a similar reductive approach, often employing something called bioassay-directed botanical research.

As the name implies, bioassay-directed botanical research relies on simple systems, such as cells in a laboratory, that can measure biological responses. For example, anti-cancer activity may be tested by seeing if plant extracts kill tumor cells. If a "hit" is discovered, then the extract is separated—typically using solvents—into fractions that are also tested, with the hopeful result that one or more concentrate the activity of the parent extract, thereby focusing the research direction onto particular fractions.

These active fractions are further separated using techniques involving chromatography (literally meaning "color separating" but it applies to more than colors) into subfractions that are then tested via the bioassay. In some cases, this approach has resulted in the isolation of very potent compounds like vincristine from Madagascar periwinkle (*Catharanthus roseus*, formerly known as *Vinca rosea*), found while screening for anti-diabetic drugs but still used in cancer treatments today.

The molecular approach to single compound botanically derived drugs requires their isolation and purification (slight impurities are sometimes the real actor, not the major isolated constituent!) and then identification as to their exact molecular structure. Structural elucidation may involve different analytical instruments employing techniques designed to tease out telltale molecular properties.

For example, high-resolution mass spectrometry can provide a precise molecular weight of a compound so that its chemical formula (the number of atoms, like carbon, hydrogen and oxygen, in a single molecule) can be exactly known. NMR or nuclear magnetic resonance (aka MRI "magnetic resonance imaging" machines in medicine) simply use harmless radio waves to literally get spinning

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> Botanicals are more complex—and interesting!—than single constituents.

atoms to flip upside down like little tops that have had too much to drink. The frequency at which they flip is characteristic of certain molecular features. Perhaps more relatable is IR or infrared spectroscopy that literally warms molecules with infrared light to see how they "dance" because different atomic bonds wiggle, stretch and sway in revealing ways.

IN COMPLEXITY IS STRENGTH

A singular focus on one herbal constituent among literally thousands is all well and good when either it really does account for the desired effect from a botanical ("entourage effects" notwithstanding) or interest lies with having just a single chemical to worry about. The advantage of knowing the active compound in a botanical extract (having only one recognized active is rare) is that the biological effect—the potency, if you will—can be standardized by controlling the strength (amount) of that constituent in the extract. You know exactly what is important for activity and can directly control it.

These types of extracts are the only ones referred to as standardized by European regulators. The predictability and controllability of single constituents is attractive both for herbal drugs and pharmaceutical chemicals, and helps explain the drug industry's preference for single compounds over botanical extracts.

But botanicals are more complex—and interesting!—than single constituents. Beyond manufacturing carbohydrates, protein and oil, known as primary metabolites, herbs also synthesize a broad array of secondary metabolites with recognized bioactivities. Often such constituents are known to contribute to, but not fully account for, health promoting and medicinal effects. They may be called out as part of so-called quantified extracts (by European standards), like withanolides in ashwagandha (*Withania somnifera*) extracts, of which there are dozens with varying strengths and potencies. Rather than a single chemical, the whole of the root or root extract is appropriately considered as the active material, which makes the whole of the agricultural practices and processing relevant to a finished product.

Complex botanical ingredients are not as uniform as single pure compounds, but with proper management and handling they can be manufactured into reasonably consistent finished products deserving of a place in modern Western foods, dietary supplements and medicines. ✦

Steven Dentali, Ph.D., is a botanical industry consultant at Dentali Botanical Sciences, where he provides strategic advice on raw material sourcing and processing, claims and safety substantiation, with a focus on botanical ingredient integrity and authenticity. He serves as a volunteer expert for the U.S. Pharmacopoeia (USP), among other nongovernmental organizations. Dentali has worked in botanical development, research and validation for Herbalife, Rexall Sundown and the American Herbal Products Association (AHPA).

MY FAVORITE HERB

SAGE

Sage is the versatile genus of the mint family with more than 900 species and a name that references its historical and holistic properties. Its scientific name *Salvia* comes from the Latin word *salvare*, which translate as "to save or heal." Every species has different phytochemicals, and therefore different uses. Saving yourself from bad vibes? Burn white sage (*S. apiana*). Saving your brain power? Check out the up-and-coming research on Chinese sage (*S. miltiorrhiza*). Looking to smell spicy and fresh? Enjoy the aroma of clary sage (*S. sclarea*). Super plant sage may just be able to save the day.

Charlotte Traas
TopGum Gummiceuticals

Monographs link ingredient specs with product effectiveness

by Roy Upton

When a consumer buys an apple, she can immediately determine it is an apple even if it is mistakenly placed in the bin containing oranges. With a high level of confidence, she can see the apple is clean, whole, fresh, is not filled with worms or dirt, and is fit for consumption.

And when a consumer or health practitioner chooses an herbal product, she assumes the product will deliver a specific benefit based on traditional or scientific knowledge. While the assumption of quality—and therefore effectiveness—is ever present, seldom does anyone, except for the most geekish of herb nerds, understand how quality is achieved.

That's because identifying quality botanicals in the industry is a lot more difficult than buying an apple in a grocery store. Yes, small-scale herbalists making products typically have a relatively close connection with the starting herb material and are working with whole or semi-whole roots, barks, leaves, etc. But many of those in the botanical industry routinely trade in chopped, powdered or extracted herbal ingredients, and seldom actually see the plant that went into making the product. Once chopped, powdered, juiced or processed, even ingredients as culturally familiar as an apple are unrecognizable. For determining the quality of botanicals such as echinacea, a specialized skill set is required.

Federally mandated good manufacturing practices (GMPs) require that specifications be established to ensure the identity, purity, strength and composition of dietary supplements, along with limits of contaminants that may adulterate or lead to adulteration of finished dietary supplements. At face value, this is relatively straightforward: Make sure you have the right stuff, it is clean, contains the ingredients that contribute to its claimed benefit, and is free of stuff that may make someone sick or result in an ineffective product. Unfortunately, many in the botanical products industry don't understand how quality specifications should be developed and verified.

MONOGRAPHS ARE THE ANSWER

Historically, specifications for establishing the identity, purity, composition, quality and testing of ingredients are outlined in pharmacopoeial monographs. Throughout most of the world, with the exception of the U.S., compliance with pharmacopoeial monographs is required. In America, regulations require that industry set its own standards according to the specific needs of its products.

This has advantages and disadvantages. The primary advantage is that it allows for the application of appropriate quality control (QC) standards for a vast diversity of herbal products versus the limited number proscribed in pharmacopoeial monographs. The primary disadvantage is that a manufacturer can choose

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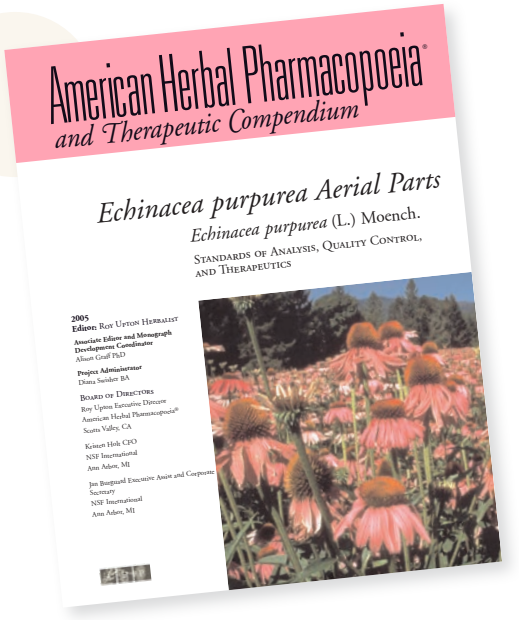

Monographs take the guesswork out of what an analyst or product development team needs to know.

inappropriate standards that result in the manufacture and marketing of products that do not deliver the expected benefits.

Pharmacopoeial monographs identify the species, plant part, quality purity and testing parameters that must be met. This takes the guesswork out of what an analyst or product development team needs to know. The primary advantage of following pharmacopoeial standards is that such standards are determined by experts to be most appropriate for delivering the intended health benefit.

AHP MONOGRAPHS

Most pharmacopoeial monographs outline a set of tests required for ensuring quality of a botanical ingredient, typically focusing on the quantification of a particular compound(s).

However, the true quality of an ingredient cannot be assessed through quantification of a single compound. The true quality of an ingredient begins with the source of the material, where and how it is grown, when it is harvested and how it is subsequently dried and processed.

Such knowledge was codified in old texts within materia medica and pharmacognosy and was established at a time when the majority of therapeutic products (drugs) were of botanical origin. Today, chemistry dominates as the primary surrogate for establishing quality and does not inherently ensure the quality of the botanical.

Monographs of the American Herbal Pharmacopoeia (AHP), like other pharmacopoeial monographs, were designed to provide the suite of tests for ensuring the basic quality of botanical ingredients. Additionally, they were designed to reintroduce the botanical products industry to the specialized knowledge of herbal quality assessment by bringing together the expanse of traditional and scientific knowledge regarding all aspects of herb quality—from the soil in which the plants are grown, to optimal times of harvest, drying and processing.

This breadth of information can be used to inform R&D, purchasing and QC departments, and can also guide regulators as to how botanical products should be assessed. ✦

Roy Upton has been working professionally as an herbalist since 1981. He is trained in ayurvedic, Chinese and Western herbal traditions, as well as North American and Caribbean ethnobotany. Upton is president of the California-based nonprofit American Herbal Pharmacopoeia (AHP) and director of Planetary Herbals.

MY FAVORITE HERB

SCHISANDRA

My favorite herb is the adaptogen *Schisandra chinensis*, otherwise known as the five-flavor fruit. It's an ambitious go-getter, being a vine-climber bearing red fruit, always reaching and climbing upward toward the sky. But, even more important, once you taste it, you will never forget it. It naturally contains all five flavors: sweet, salty, bitter, pungent and sour, to fully engage your palate. How could you not love such a special adaptogenic herb that fully engages one's senses?

Wilson Lau, Nuherbs

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Where there is commerce, there is adulteration. Discuss.

by Stefan Gafner and Michael Levin

In his elegant and well-referenced book "Brief History of Adulteration of Herbs, Spices, and Botanical Drugs," the late Steven Foster wrote, "Since the beginnings of civilization, once commerce develops, adulteration follows. Adulteration, falsification, substitution, and sophistication of willful intent or wanton neglect have evolved."

In 1862, the U.S. Congress established a Department of Agriculture, which included a Division of Chemistry that became the focal point for all "food protection activities." In 1883, the very first specific food protection law in the U.S. concerned a botanical: a prohibition against importation of adulterated tea, which was followed by more food regulations and the growing realization of the need for a "truly comprehensive and national regulatory statute governing the food supply." Other countries followed a similar path with regard to food regulation.

Today, three leading botanical groups have banded together to create the Botanical Adulterants Prevention Program (BAPP). The three groups are the American Botanical Council (ABC), the American Herbal Pharmacopoeia (AHPA) and the University of Mississippi's National Center for Natural Products Research (NCNPR).

The BAPP mission is to promote the responsible and safe use of herbs. Keenly aware of botanical adulteration issues, we have, as of this writing, published more than 80 peer-reviewed articles to educate and empower responsible members of the herb industry and others to protect themselves against economically motivated botanical adulteration.

Our focus is predominantly on issues of identity, substitution, and the use of optimal analytical methods to properly authenticate botanical ingredients and detect adulteration schemes. Many leading companies have used our documents to upgrade their ingredient specifications to guard against adulteration.

Adulterated ingredients might contain illegal adulterants, exceed limits for hazardous chemical and biological contaminants that cannot be removed, or be spiked with undeclared prescription drugs. So, what happens when such unlawful ingredients cannot be lawfully remediated for any use, anywhere? Sometimes, these "irreparably defective articles" (IDAs) are returned to suppliers, which re-sell the IDAs to the next customer in the hopes the new one does not have the same diligent QA/QC systems in place to catch the damaged goods.

TAKING PROACTIVE MEASURES

BAPP is committed to finding an industry solution to this vexing problem. The solution consists of carefully worded contract language templates and a standard operating procedure (SOP) template, along with supporting documents, that buyer and sellers can use to stop the resale of IDAs.

This solution applies to all dietary ingredients (botanical and nonbotanical), components, foods,

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> Adulterated ingredients might contain illegal adulterants, exceed limits for contaminants or be spiked with Rx drugs.

cosmetic ingredients, etc. It has been vetted through two arduous rounds of public comments, with subject matter experts in law, manufacturing, sourcing, analytical labs, chemists and others contributing their valuable time. The idea is to fairly protect buyers and sellers as a consumer protection effort. The contract language templates and SOP for the disposal/destruction of IDAs have been endorsed by leading consumer-focused organizations and industry members.

BAPP SOP primary author Michael Levin and all the other BAPP management members feel deeply indebted to the scores of subject matter experts who contributed to this important objective to address a real issue that was otherwise not sufficiently addressed in regulatory programs in the U.S. and abroad.

As with all BAPP publications, these documents are freely available to all through the contributions of BAPP underwriters. Check out the website to contribute or access free BAPP content, including news, breaking bulletins, adulteration reports, laboratory guidance documents and additional QC resources.

Underwriters and endorsers of this solution will be publicly recognized in the future. We invite and encourage you to join the list of hundreds of supporters and endorsers.

We want to hear from you! Please email your comments, questions, suggestions and concerns to BAPPSOP@herbalgram.org.✦

Stefan Gafner is CSO of the American Botanical Council and director of BAPP. Prior to working for ABC, he served as a director of analytical chemistry in the R&D department of natural personal care products company Tom's of Maine.

Michael Levin specializes in quality assurance and regulatory compliance of natural medicines. He is the primary author of the "BAPP Best Practices Standard Operating Procedures (SOP) for the Disposal/Destruction of Irreparably Defective Articles." His consulting practice projects include the creation of the first hospital-based Dietary Supplement Formulary Committee in North America at Cancer Treatment Centers of America.

MY FAVORITE HERB

REISHI

My favorite fungi, by far, is red reishi mushroom, *Ganoderma lingzhi*. We have a species of *Ganoderma* that grows on hemlocks called *Ganoderma tsugae*. I have marveled at these my whole life while hiking and fly fishing and have studied them more than any other mushroom. Prized by emperors and prime to the ecological health of the environment, they help my flow state and ability to maintain a calm, centered focus—especially at night when the thoughts have piled up. I can see why it's had such longevity itself.

Bill Chioffi, Nammex

How to select the best extract for a botanical formulation

by Paul Altaffer

The word "extract" on a label isn't always clear cut. The term can be confusing, especially since so many different types of extracts are available, along with a multitude of claims to accompany them.

Very basically stated, extraction helps concentrate desirable stuff and remove undesirable stuff. Extracts can range from very simple to complex. On the simple side, squeezing an orange extracts juice from the orange, and brewing a cup of tea is an extraction of the tea leaves. On the other end of the spectrum, the complex can make one's head spin. High pressure, solvents, separations, purifications and, well, a great deal of science and technology are usually involved.

Extraction is also used as a means to concentrate substances so they can be measured. This makes it easier to set an amount, serving or dose to what is being consumed. Finally, extraction can make a product safer, more tolerable, or more pleasant to consume.

EXTRACTION TYPES

From simple pressing or juicing, to brewing, to complex systems, extracts can be prepared in many ways. The two primary ways to extract are liquid to solid and liquid to liquid. Liquid to solid extraction is the most common way of extracting in food and nutraceuticals.

A great example of liquid to solid extraction is brewing. A liquid (hot water) is added to a solid (tea or coffee), which removes soluble and insoluble matter from the solid. The material in solution and suspension is the extract, and the solids left over after the extraction are called the marc (i.e., the spent tea or coffee, or the orange pomace left over after juicing).

All liquid to solid extraction comes down to this simple formula: A liquid solvent comes into contact with a solid and extracts (or removes) material that is either soluble or suspendible in that liquid.

Four primary variables control the process in liquid extracts:

- Particle size of the raw material.
- The makeup of the extraction solvent.
- The flow rate and contact time of raw material to solvent.
- Temperature.

What changes from extraction types are the process and equipment types, the solvents used, the extraction conditions (temperature, pressure, pH, etc.), and other secondary processing or purification steps.

In a tank or *vat extraction*, the botanical to be extracted is in a tank with liquid solvent running through it, exposing the botanical to the solvent and usually recirculating that solvent for a period

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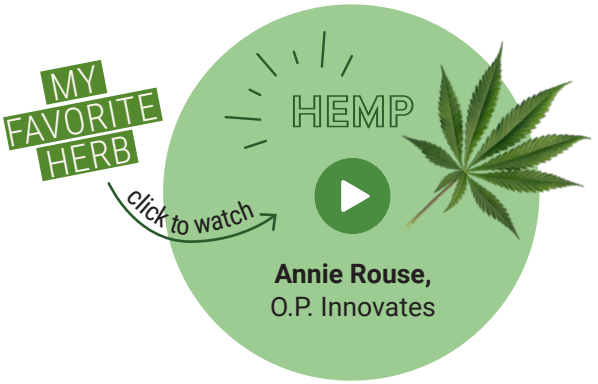

of time until the extractable solids (the "goodies") are in solution or suspension in the solvent.

Counter current extraction is similar in that a solvent runs through the botanical with the solvent moving in one direction, and typically the botanical in the opposite direction. As the liquid runs through the botanical, it concentrates naturally as it is exposed to the botanical; and once all the liquid runs through the botanical it is, in essence, "exhausted," meaning the "goodies" have all been removed from the botanical mass.

Some more complex and often more selective types of extraction include high pressure extraction, like using supercritical carbon dioxide, supercritical water or production in reactors, which bring pressure and temperature into the process.

Distillation is yet another type of extraction, which can begin with a liquid only and is oftentimes used for extracting essential oils out of products, not to mention the manufacture of distillates. The product, or byproduct, of distillation is often alcohol.

SOLVENTS

Many solvents are used in extraction, from polar to nonpolar. Polarity describes the type of solvent based on electrical charge, or lack thereof. It signals the type of compounds it is most likely to have an affinity toward, and thus be able to extract.

Water is considered the "universal" solvent as it works as the broadest extraction solvent; however, it lacks selectivity.

Alcohols—ethanol being the most well-known—and other glycols have greater selectivity, such as glycerin, gases like carbon dioxide, acids or bases, and enzymes.

Liquid to solid extraction is the most common way of extracting in food and nutraceuticals.

For many companies, achieving selectivity or purity in extraction is the goal and can be accomplished several ways. As discussed, some solvents have greater affinity for certain types of compounds and as a result, selectively extract for them. Separation through particle size filtration is another way, and fractionation in columns with specialty resins is yet another.

One of the biggest questions in extracts is whether to buy a ratio-based extract versus a standardized extract. A ratio-based extract looks at a concentration of (typically dry) plant to solvent ratio in a liquid, or plant to finished product. In a liquid, this means the amount of plant to solvent is in the final product. For powders, it means how much plant to final product it delivers.

For standardized extracts, the extract is made to have a designated amount of a specific—or a group of specific—compounds. The content of the marker compounds in the final product is more important than the concentration of extract.

3 REASONS TO SELECT AN EXTRACT

Three primary reasons drive selecting an extract. The first is that extracts typically concentrate the botanical ingredient, meaning a smaller serving of the botanical is needed to reach an active serving.

The second reason is to gain a guaranteed amount of a specific marker compound or group of compounds that have scientific support to justify their use.

The third reason is that extracts go through additional processing steps that usually lead to greater assurances of product safety and quality.

Extracts offer other features and benefits, but the considerations surrounding choice come down to what matters most to the consumer. What is more important: A holistic herbal extract or a highly standardized extract? Single marker compounds or whole product? Is a powder preferred to a liquid or an emulsion, capsules or tablets?

These days, consumers are able to choose products based on their own interests and beliefs. While science may support one option over another, and time-tested traditions may support the opposite, it ultimately comes down to choice. A great deal of choice is out there and that is good news.✦

Paul Altaffer, chief innovation officer at RFI Ingredients, has more than 30 years of experience developing, sourcing and marketing natural products. He founded Nat-Trop, a pioneer in the development of natural and nutritional ingredients from South America, which merged with RFI in 2002. Raised in Brazil, Altaffer's primary concentrations are product development, technical sales, strategic and sustainable sourcing, and managing strategic industry and association relationships.

MY FAVORITE HERB

CORDYCEPS

I was first introduced to *Cordyceps militaris* by mycologist Steve Farrar. At the time I was living in Lake Tahoe and was a big cyclist. Lake Tahoe is at 6,500 feet, so training can be challenging with lower oxygen levels. Within weeks of adding cordyceps powder to my routine, I noticed a significant improvement in my ability to train and to recover from long rides.

Cordyceps has an ability to help support respiration—and the increased availability of oxygen translates to increased endurance. Research on our M2 Ingredients *Cordyceps militaris* has shown significant results in VO2 max—a measure of cardiovascular endurance. Although I am not cycling anymore, I still enjoy taking cordyceps to give me healthy, natural energy for my long work days and busy schedule.

Sandra Carter, Ph.D.
M2 Ingredients and Om Mushroom Superfood

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Bioavailable botanicals adopt principles of nature

by Steve Hanson

If you've been in the industry a while, it's a common occurrence for someone to ask, "What supplements should I be taking?" Something that never happened in the past but is on the rise is a follow-up statement where the individual jokes about how most of what's taken never actually gets absorbed.

Consumers have become increasingly aware that bioavailability equates with absorption and effectiveness. Bioavailability is defined as the extent to which an active ingredient is absorbed and available for use by the body after ingestion. Science has shown that the body easily absorbs some compounds while others are more difficult to absorb. As a result, ingredients with enhanced bioavailability can offer improved health outcomes.

ABSORPTION ISSUES

Plants contain a broad range of phytonutrients, of which flavonoids are a significant part. More than 4,000 different flavonoids have been identified from plants, and certain flavonoids have been recognized as potent antioxidants, as well as being beneficial for human health. However, many of these flavonoids are poorly absorbed when ingested orally or from food. Common botanicals utilized in the nutrition industry known to have poor absorption include curcumin (*Curcuma longa*), boswellia (*Boswellia serrata*) and quercetin.

Inadequate absorption is linked to two main reasons:

- Limited intestinal absorption because the compounds are too large to be absorbed into the blood from the gut.
- Poor solubility where flavonoids don't mix well with oils and other lipids, inhibiting their ability to cross bio membranes.

BIOAVAILABILITY OPTIONS

Because consumers have become increasingly more aware and knowledgeable about bioavailability, it's a term widely used within the nutrition industry, especially among ingredient manufacturers. Claims made where one ingredient states improved bioavailability over a competitor are common. It's important to recognize the differences, evaluate the existing science and decide which form is best suited for the final formulation. Providing an effective product to consumers should be the primary intention.

Liposomes are sometimes utilized for aiding bioavailability. These are structures of many phospholipid molecules that enclose phytoactive molecules without forming a chemical bond. At botanical ingredient supplier Indena, scientists have created what they call Phytosomes—a unit of a few molecules weakly bonded together.

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> The number of technology platforms offering new delivery systems, improved bioavailability or more sustainable manufacturing has increased.

Certain water-phase flavonoids can be converted into lipid-compatible molecular compounds. These hybrid molecules can more easily mix with oils, thus improving bioabsorption. This means a Phytosome can carry more of each nutrient, delivering more nutrients than unformulated equivalents because of enhanced bioavailability. To date, around a dozen botanicals from Indena feature the Phytosome delivery system, including *Ginkgo biloba*, green tea, grapeseed, CoQ10, curcumin, cranberry, berberine, quercetin, boswellia, bergamot, silymarin.

BIOAVAILABLE INGREDIENTS WILL CONTINUE TO GROW AND EVOLVE

With higher standards from manufacturers and regulatory agencies requiring more clinical and safety substantiation for ingredients, the number of completely new ingredient introductions has decreased. As this has occurred, the number of technology platforms offering new delivery systems, improved bioavailability or more sustainable manufacturing has increased.

It's become apparent that both ingredient suppliers and supplement companies must look for new avenues of differentiation. One way to accomplish this is to create better-absorbed supplements and promote "improved absorption" to consumers. It's a further benefit if these supplements contain ingredients produced sustainably. Both benefits offer added value for brands and consumers. ✦

Steve Hanson is CEO and founder of Nutrasocial, a marketing and business development consultancy serving the nutrition industry. He has been an entrepreneur, executive and consultant in the nutrition industry for more than 25 years. Along with serving on executive and advisory boards for leading nutrition companies, Hanson is a marketing and ingredient branding expert who has been involved in some of the industry's most recognized success stories—FloraGLO Lutein, Ester-C and KSM-66 Ashwagandha.

MY FAVORITE HERB

CHAMOMILE

click to watch

Erik Goldman,
Holistic Primary Care – News for Health & Healing

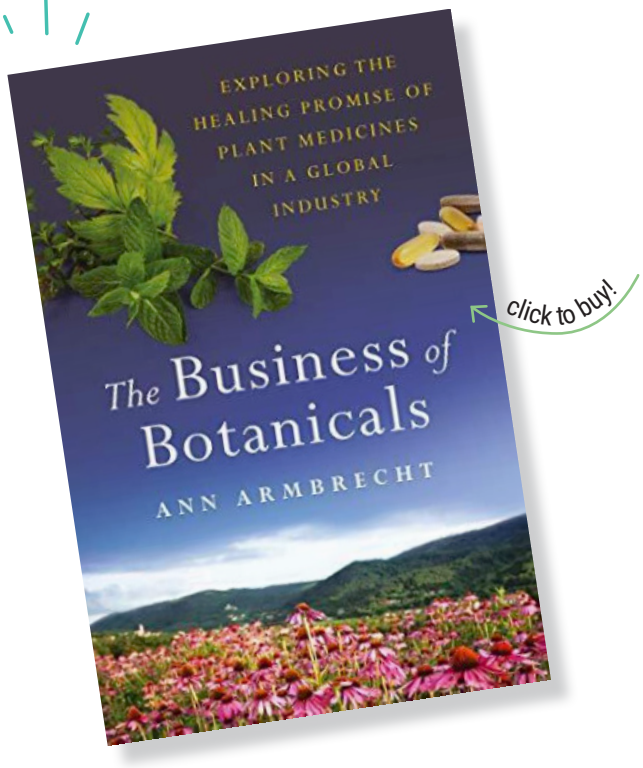
MY FAVORITE HERB

FRESH MILKY OATS

In our crazy, fast-paced and stressful world, nervines are a category of herbs that are essential. They can help relieve stress, reduce irritability, and enhance sleep. One of my favorite nervines is fresh milky oats. Yes, this is the same oat used in oatmeal, but harvested in the immature "milk" stage. During this one-week period, its chemistry totally changes; and when made into a fresh tincture or glycerine, it becomes what I call "the queen of the nervines." It is a slow-acting, mild remedy that helps to restore our emotional foundation and can be of benefit for anxiety, depression or feeling emotionally overwhelmed.

David Winston, RH(AHG),
Herbalist & Alchemist

The business of botanicals



Vexing global botanical supply issues include certifications and the power of in-person relationships. Ann Armbrecht is director of the Sustainable Herbs Program at the American Botanical Council (ABC) and author of "The Business of Botanicals." She recently chatted with Todd Runestad, Natural Products Insider's content director.

Natural Products Insider: *In your book, you wrote about the importance of intention as a means of healing—and as a way of quality. Can the life force of a plant find its way into products manufactured in a capitalist economic model society?*
Ann Armbrecht: We are disconnected from plants, and that's really what I was looking at in "The Business of Botanicals." How can we reconnect within a capitalist system? I had naïve questions at the beginning—can we manifest intention in a global supply chain? There's obviously huge amounts of herbs being shipped around the world. Attention goes with intention. When people pay attention then the quality of those herbs is going to be better. What allows us to pay attention, what allows the people who are growing the herbs and harvesting the herbs and processing the herbs to pay better attention?

Natural Products Insider: *Can we put a price on values like sustainability, quality and regenerative fair trade? Is there an ROI [return on investment] to these concepts? Will people pay more for that quality and sustainability, or is it always a race to the bottom, price price price?*
Armbrecht: There's some interesting research from Tony Booker in the U.K.; he's looked at two different supply chains and the chemical composition of turmeric. One was where the turmeric was bought in a contract and the other bought on the open market, and the prices fluctuated and farmers were storing it and the price and the quality itself didn't have the constituents needed, so all these price considerations came into play and down the line by not paying attention to the quality at the beginning. So that quality is sustainability—it's paying attention to what the farmers need to pay attention. To harvest at the right time, what they need to store it in the right way and that's why there's a contract. Getting a fair price is at play so that's fair trade. If you invest in it at the beginning then there are fewer costs down the road.

Natural Products Insider: *Is that ethos and set of practices on how you establish a quality supply chain even alive today? Can companies—instead of traveling the world over to meet farmers and everyone else on the value chain—simply use testing labs to ensure what you got is what you ordered? Are testing labs the answer?*
Armbrecht: I was talking to a trader who is invested in the community and one of the buyers was rejecting a lot of trade material they were

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buying because it didn't meet a number of markers in a lab. This trader was saying, "but this could have a huge impact on the farmers and that community." The trader was developing these fair trade supply relationships and then making decisions solely on what it says at the lab, and not going to those communities to figure out, 'How can we get (the product) to meet those marker compounds?' It's not that you throw quality out the door; it's how do you see that it's a relationship? You can't just find that in a lab. By visiting those communities—which I don't think costs that much money—you see people, you look them in the eye, you see what their challenges are; is there water nearby, how much time do they spend dealing with water, what does the water quality look like, how polluted is the air? And then when problems come up, you have that relationship and the empathy to deal with the challenges they are facing. I worked with another ingredient supplier last year and she said more buyers were dealing only with the price and on the marker compound thing, and when problems come up (and problems will come up) the buyers were unsympathetic; they were saying, "Well I'll just find another source who can sell this." So, you have to go visit.

Natural Products Insider: *I hear you saying that if you want to commit to your business, the long-term health of your business, that you do not sign a one-year contract, instead sign a three-year or a five-year contract.*
Armbrecht: Get to that source of your source so you can manage your supply chain in a more effective way. It will help you if you're on site to see those potential potholes and can build your business long term. That really is the answer.✦

MY FAVORITE HERB

KAVA

(Piper methysticum)

Dinner party in 1979 in the Boston area. After dinner a guy pulls out a jar, sticks a chopstick into it, produces this glob of black goo, says, "Try this." I say, "What's going to happen here?" He says, "It's going to make you feel good." I said, "I already feel good. Am I going to trip, or what?" He says, "No no no no no." So, I put it in my mouth. My tongue numbs instantly. In about a minute I get this wave of tranquility through my body. I turn to him and I say, "Is this legal?" He says, "Yes." I say, "What is it?" He says, "It's kava." That's stuck in my mind, never left, and when I was first hired by PureWorld, they said, "What's the first thing we should do?" I said, "You should develop kava and you should send me to the South Pacific," and they did.

Chris Kilham
The Medicine Hunter

AP-Bio™

for immune health

BacoMind™

for cognitive health

HOLIXER™

for stress & sleep management

GutGard®

for digestive health

Turmacin™

for joint health

Bringing health & happiness through our clinically tested botanicals

1 clinical study	5 clinical studies	5 clinical studies	3 clinical studies	3 clinical studies
HOLIXER™	BacoMind™	Turmacin™	GutGard®	AP-Bio™
(Ocimum tenuiflorum)	*(Bacopa monnieri)*	*(Curcuma longa)*	*(Glycyrrhiza glabra)*	*(Andrographis paniculata)*

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US regulatory barriers keep consumers uninformed

by Michael McGuffin

Many Americans make the personal choice to use herbal products to support their health. But manufacturers and marketers of herbal and other dietary supplements face legal and regulatory restrictions that often prohibit sharing truthful and not misleading information directly with consumers.

These barriers can be a detriment both to the people who use these products—that is, our families, friends and neighbors—and to those who market them.

'PHYSICALLY SEPARATE'

Since 1994, a provision of the Federal Food, Drug and Cosmetic Act (FDCA) has required certain scientific articles on dietary supplements (including their herbal and other dietary ingredients) be kept "physically separate" from dietary supplements if the publication references a therapeutic benefit related to any condition considered under U.S. federal law to be a "disease." This restriction was established when herbal and other dietary supplements were sold almost exclusively in brick-and-mortar specialty shops and health food stores.

But how does this restriction apply now that so much commerce has moved online? Regulators today still expect marketers to keep such information far from their dietary supplements, leading e-commerce sellers to ensure that articles not appear on the same webpage where they promote or sell specific products.

The irony is that most people are sophisticated enough to find the same material with a Google search, though individuals conducting their own research on herbal products may also encounter misinformation. What this ultimately means is that the party that knows the most about an ingredient or product—that is, the marketer—is restricted from providing some of the most accurate information directly to consumers.

Altogether, the "physically separate" provision no longer makes sense in today's prominent e-commerce market. The law is overdue for an amendment to remove the restrictions that prevent marketers from disseminating truthful and not misleading information about their products. And the most appropriate amendment would allow ready access to information, even if this truthful, scientific information may reference the product's or ingredient's use in treating a "disease."

CLAIMS LIMITATIONS

Another information restriction under U.S. federal law is the prohibition against making any claim that a dietary supplement can be used to cure, mitigate, treat or prevent a disease—only pharmaceutical drugs can do that. This restriction exists even if such a "disease" claim is well substantiated by scientific evidence.

Other countries, such as Canada and Australia, are not so restrictive, and they allow such claims for herbs and for other natural health products.

These international markets also have requirements that do not exist in the U.S., including mandatory product registration and premarket approval by the national regulators. Would U.S.-based companies accept such

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> Would companies accept premarket approval as a trade-off to expanding the range of claims allowed?

additional regulations as a trade-off to expanding the range of claims allowed for dietary supplements?

To date, the most vocal critics of dietary supplements tend to advocate only for more government controls—such as mandatory product listing (MPL)—but not to balance proposals for more regulations with greater freedom to inform consumers who want to use natural products for any of the current "off-limits" uses of their full therapeutic benefits.

Certainly, a better approach exists to informing the people who use herbal and other dietary supplements of their benefits, even when an intended use crosses the statutory line into the "drug" definition. In the context of the continuing interest in and discussions about amending U.S. laws that govern dietary supplements, it may be time to challenge the central tenets of the FDCA that have been in place for 85 years—including the limitations imposed by the broad definition of "drug" under the current law—to consider an appropriate expansion of the claims allowed for these dietary supplements.

TRUTH OVER MISINFORMATION

Current regulations that prohibit marketers of herbal dietary supplements from providing truthful and not misleading information—and from making claims backed by scientific evidence—are detriments to both the public and industry. The market has evolved, and consumers looking to use botanicals in their personal health regimens should have ready access to truthful information from reliable sources. As such, the American Herbal Products Association (AHPA) and its members will continue to evaluate when and how to challenge laws that place restrictions on claims and that limit what information can be directly shared with consumers.✦

MY FAVORITE HERB

AYAHUASCA

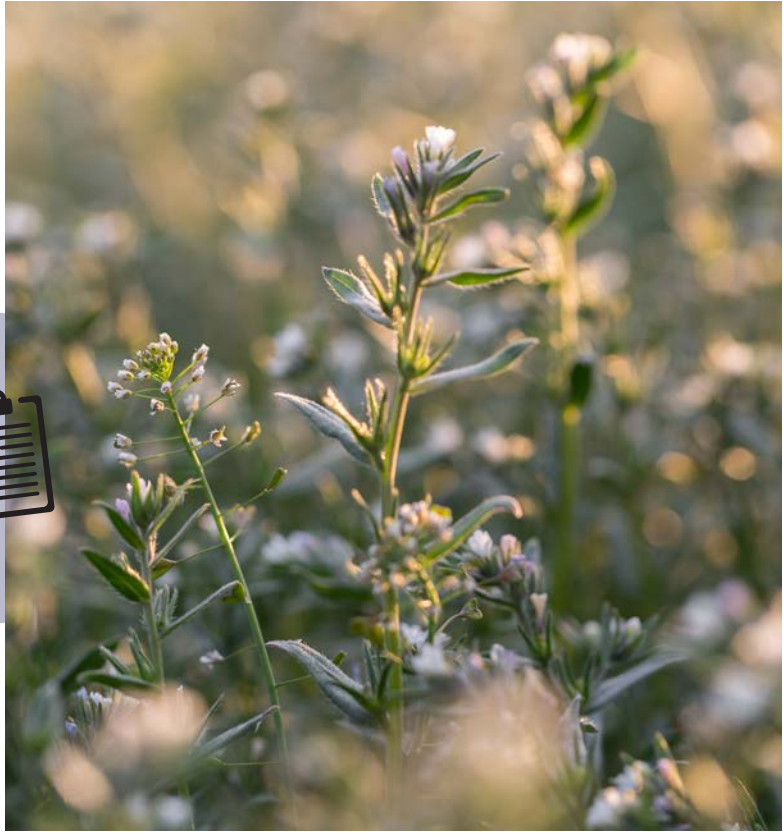
My favorite herb is a combination of two plants, *Banisteriopsis caapi* vine and *Psychotria viridis* shrub. Their decoction, called ayahuasca, is used as a shamanic medicine among the indigenous peoples of the Amazon basin and contains the powerful psychedelic drug DMT and MAO-inhibiting harmala alkaloids. People who consume it report having ego-dismantling revelations. Others describe it as 10,000 hours of therapy overnight where they work through trauma, depression, addiction, and other mental and emotional conditions.

Elan Sudberg, Alkemist Labs

Michael McGuffin has served as president of the American Herbal Products Association (AHPA) since 1999, leading the association in its mission to promote the responsible and sustainable commerce of herbal products to ensure that consumers have informed access to a wide variety of safe herbal goods. He also serves on the boards of directors of the American Herbal Pharmacopoeia (AHP) and United Plant Savers, and on the advisory boards of the USC School of Pharmacy regulatory science master's degree program and the Appalachian Beginning Forest Farmers Coalition.

Ahiflower: The making of a plant-based omega

by Andrew Hebard



More than 20 years ago when I was managing specialty oilseed crop production in the U.K., a friend, mentor and colleague, professor Keith Coupland, forecast that the demand for omega-rich dietary oils would soon outstrip the oceans' capacity to provide them sustainably.

Coupland is a world-renowned lipid chemist who co-developed the fatty acid medicine called Lorenzo's oil. His warning to me was prescient. In 2020, the UN's Food and Agriculture Organization (FAO) reported that 90% of global fisheries are exploited, fully exploited or depleted.

But back in the 1990s, Keith's example and life work developing novel plant-based lipid sources inspired me and my team to set out to find the richest-available plant source of combined omega-3 and omega-6 fatty acids that farmers could actually grow—both profitably as well as regeneratively.

We expanded our specialty oils supply business to North America in 2002. We embarked on a strategy involving agronomists, ethnobotanists, farmers and clinical researchers to search for, evaluate, learn how to grow and scientifically verify the best candidate species. We knew we would need to include new species with little or no prior history of human uses. We knew the top candidates would need to be cultivated reliably and with potential to scale to meet significant future demand.

With our U.K.-based agronomic researchers and some intrepid early grower partners, Natures Crops field-tested 200 noncommercial species of seed-producing plants whose oils contained higher quantities of omegas. Somewhat serendipitously, the winning candidate was a diminutive weed species growing in a hedgerow in Essex, only a fly fisherman's cast from the doorstep of our U.K. offices.

THE A-HI MOMENT

Sporting the Latin name *Buglossoides arvensis*, the botanical's overall omega fatty acid content and value is unrivaled in the plant kingdom. It has by far the highest levels of omega-3 stearidonic acid (SDA), which research shows the human body converts efficiently to as much omega-3 EPA (eicosapentaenoic acid) and DHA (docosahexaenoic acid) as needed for optimal wellness.

We partnered with the National Institute of Agricultural Botany in the U.K. and gathered an elite group of growers whose expert observations on this little plant's needs and growth habits could one day unlock the enormous potential we saw in it.

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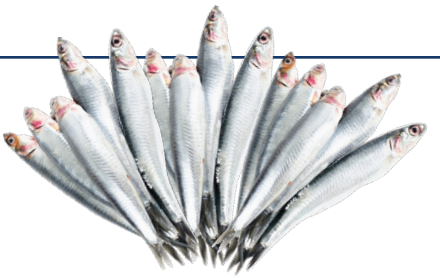
> Competitive with other specialty oilseeds, the crop can return ***twice the profitability*** for the farmer while producing as much omega-rich oil per acre as 500,000 anchovies.



By using traditional natural selection, plant breeding, persistence and long-term farming relationships, we learned how to cultivate this plant productively. It took us many years! You've heard the adage, "reap more than you sow"—well, in the first few years we reaped far less than we sowed. But we felt intuitively that this small plant could be domesticated into a high-value, biodiverse crop and provide a genuine solution to the world's omega supply challenges.

Scroll forward 20 years and today Ahiflower, our exclusive proprietary *Buglossoidies arvensis* crop and the oil from its seeds, is now grown on thousands of acres regeneratively each year in the U.K.

Regenerative farming means we put more into the soil and the environment than we take out, leveraging no-till agriculture and focusing always on soil health and resource conservation. Worms, bees, ladybirds and pollinators benefit from each Ahiflower crop farmed all over the rural U.K. landscape. And yet, because of the dedication of our growers, Ahiflower crop yields are competitive with other specialty oilseeds and can return twice the profitability for the farmer while producing as much omega-rich oil per acre as 500,000 anchovies.

COMMERCIALIZATION

Thousands of published health science papers have demonstrated that omega-3 and -6 lipids are essential nutrients supporting human and animal health. And awareness among practitioners and consumers is on the rise concerning how increasing omega-3s in the diet can help balance the overabundance of industrial omega-6 linoleic acid in the pro-inflammatory Western diet. Yet, as noted, some concern exists around potential global marine omega-3 supply and demand. We wanted to develop an alternative source.

Natures Crops has invested more than $10 million in bringing Ahiflower oil to market, including funding research, building a supply chain and developing intellectual property (IP). A major priority was to identify and then mitigate supply chain risks, so that distribution and brand

partners never have to worry about quality, quantity or continuity of supply. The ingredient also offers a desirable sensory and stability profile.

Today, many supplement brands (human and companion animal) using Ahiflower have launched in North America and Europe, with more launches coming in 2023 and 2024 in new territories like Asia-Pacific and Latin America. The ingredient is also being targeted for use in a wide variety of new foods and beverages, as well as topical skin care applications.

And in 2022, Natures Crops achieved B Corp Certification—a major milestone—signifying how passionate we are as a team about putting people and planet before profit in the quest to make omega-3 nutrition truly regenerative. ✦

MY FAVORITE HERB

STINGING NETTLES

Stinging nettles (*Urtica dioica*) embody so many functional uses—having medicinal properties in the seed, the leaf and the root (separately), and for stimulating such a powerfully effective anti-inflammatory response topically using the fresh aerial parts, and also as a nutritional fiber source. One of its traditional uses going back to medieval Italy is to alleviate joint and tendon pain by lightly brushing the skin with just a few sprigs of freshly cut leaves still on the stem. My wife Katie and I use this technique on affected joints (me: left shoulder) in the early spring when new nettles are growing close to streams or ditches. The brief stinging sensation sets in motion a powerful natural anti-inflammatory cascade in the underlying tissues that works amazingly well. Plus, I really enjoy nettle leaf tea for its energizing but nonstimulatory effects.

Greg Cumberford,
Natures Crops International

Andrew Hebard serves as president and CEO of Nature's Crops International (NCI). He founded and then led NCI's growth from a start-up in 2008 to an international leader in the growing, processing, and supply of specialty oilseed crops and specialty crop ingredients for supplements and personal care products.

The magic of herbs. Or is it plant magic?

by Mark Blumenthal

If I were expected to sum up the historical and modern value proposition regarding herbs and medicinal plants, the proposed bumper sticker would be, "Herbs Work!"

I first started using herbs on an increasingly regular basis in the late 1960s as I was learning how to responsibly supplement my diet with adequate non-meat protein. As a newly minted vegetarian in May 1968, I soon learned that the predominant public mindset about herbs and medicinal plants was frequently as folk medicine or old wives' tales.

Other dismissive terms (e.g., snake oil) reflected the lack of ways to seriously consider the growing body of scientific research on medicinal and aromatic plants. Even the term "alternative medicine" had a sense of lack of respect or legitimacy until the advent of and rise in the domain of scientific research.

I have helped document many of these efforts over half a century through the American Botanical Council's (ABC) peer-reviewed journal HerbalGram and science review service HerbClip, of which more than 9,000 have been published.

But herbs didn't begin to "work" just because researchers were able to subject them to controlled clinical trials. This new line of research simply began a process of scientific and clinical documentation, confirmation and validation of many of the therapeutic uses that for centuries had been observed via history, ethnobotany and empirical documentation.

MAGIC MAKING

Is there "magic" in acknowledging what our grandmothers learned from their grandmothers and their grandmothers? Is there "magic" in Peter Rabbit's mother giving him chamomile for an upset tummy?

Yes, the oral and written traditions are chock-full of the compelling basis for the use of medicinal and aromatic plants as medicines, especially with the increased validation of many traditional uses that are part of humankind's vast inheritance in ethnobotany.

Whenever I have encountered a skeptic about the therapeutic values of herbs, I like to point to catnip! There's no denying the almost immediate effect on felines. And then there's one of my 200 favorite herbs, aloe vera. One of the easiest ways to convince someone of the healing powers of plants is to put some fresh aloe gel (from the inner leaf of the plant) onto a kitchen burn or sunburn, or a cut or other dermal disturbance. Within seconds the effect is obvious.

Space does not permit me to employ my 40-plus year rant about the decline in education in the science of pharmacognosy (the study of drugs of natural origin, usually

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Plants have "feelings"—a polygraph showed that they reacted to injury of a plant in another room!

from plants) in colleges of pharmacy in the U.S. and worldwide, and the general lack of nutrition, nutritional biochemistry and pharmacognosy courses in conventional medical schools. What we have witnessed relatively recently is a consumer-led explosion in demand for phytomedicines, and a concomitant rise in research in medicinal botanicals.

Is this the beginning of a modern herbal renaissance? From 1977 to 2007, a British research team documented an almost 700% increase in research publications (chemistry, pharmacology, toxicology, clinical trials) on herbal medicines during these three decades.

Is there "magic" in plants? Do plants have an energy that transcends the Western reductionist model of chemistry—the search for the one main active ingredient? We know that plants are natural factories of chemical complexity, producing dozens and even hundreds of natural phytochemicals necessary for the plants' metabolism and chemical defenses. Modern pharmacological research has now begun to explore a new model of synergy where research has moved from focusing on one or more active compounds to an entire array of inherent phytochemicals acting on a variety of targets within the human body.

Many people believe in a sentient or even spiritual aspect of plants. In the 1973 book "The Secret Life of Plants," authors Peter Tompkins and Christopher Bird related the story of FBI pioneer polygraph researcher Cleve Backster, who in the 1960s "discovered" that plants have "feelings"—the polygraph showed that plants reacted to injury of a plant in another room!

But it doesn't have to be fancy or complex. Chamomile tea for an upset stomach or even for a more restful sleep? Peppermint tea for improved digestion? Aloe gel for sunburns? Where did after-dinner mints come from?

Magic? Or just amazing herbs? Or both? ✦

Mark Blumenthal is founder and executive director of the nonprofit American Botanical Council and editor-in-chief of ABC's peer-reviewed journal HerbalGram, which he has been editing for 40 years.