Complex Standards for a Complex Industry
By Ann Armbrecht

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The food industry understands that quality is cultural and is learned. It is no longer only blemishes and bruises on fruits and vegetables that customers reject. There is now specialized branding for niche commodities like coffee and chocolate, salt and cheese—where it is clear that you get what you pay for in terms of taste and care, and possibly in terms of ethical practices, sustainability, and nutritional value. As Josef Brinckmann of Traditional Medicinals told me when we interviewed him for *Numen*, "There's a difference between a microbrewery's India Pale Ale and a bottle of Budweiser. There's a difference between a Snickers bar and a Swiss chocolate bar. And it's really the same with herbs. You can get the Snickers bar or the Bud or you can get the microbrew or the Swiss chocolate bar or anything in between." (Josef is considered one of the foremost thinkers and leaders on sustainability and the botanical supply chain. I didn't know it at the time, but this was to be the first of many conversations he and I would have over the next thirteen years.)

Quality standards in the dietary supplement industry are regulated under the Dietary Supplement Health and Education Act of 1994 (DSHEA). The act officially defines dietary supplements, which include herbs as well as vitamins and minerals. Under DSHEA and in particular under the Good Manufacturing Practices that were subsequently implemented by the FDA over ten years later, quality is defined in specific steps to ensure the "identity, purity, strength, and composition" of each ingredient and product.

More rigorous and detailed quality standards are found in recognized pharmacopeias, like the United States Pharmacopeia (USP), the American Herbal Pharmacopoeia, European Pharmacopoeia, and others. Though companies can choose to source only pharmacopeial grade plants, herbal products that are not formally approved as botanical drugs do not need to meet the requirements listed in the USP. These products are regulated as a food category, rather than as drugs. This is the primary reason why there is such variation in quality produced by different companies. More on this below.

Discerning quality with herbal products is more complex than it perhaps seems and has to do with more than regulatory frameworks. For example, I can tell the difference between a good and a bad apple, a field-ripened tomato and one that was grown out of season. But when I first started working with medicinal herbs, the signs that indicated good quality weren't obvious to me. It was self-evident that dried herbs that are still vibrant green are better quality than dried herbs that are brown and lifeless. Beyond that, I had to learn what to look for and how to interpret what I saw. Quality also includes correct identification. That seems obvious but it isn't. When I was a beginning herb student, any two jars of dried herbs looked exactly alike to me, like green pieces of dried leaves. And there was no way I could discern by taste or appearance whether a liquid extract made with a combination of herbs actually included all the plants listed on the label or some others entirely. Nor could I tell whether something potentially harmful was present, such as pathogenic microbes, pesticide residues, arsenic, or lead. Or whether the plants had been harvested at the correct time and handled in the ways that are known to retain the constituents.

What's needed is knowledgeable buyers making sure they are sourcing high-quality raw material. Yet that knowledge about herbs and identification was lost in the US, Steven Foster said. Unlike countries such as Europe, India, China, and Russia—almost every other country where the tradition of using plants as medicine didn't fade—in America the complex grading systems for discerning quality in manufacturing botanical medicine were lost when the Eclectics died out. Without this deeper understanding of how to identify high-quality raw material, buyers have had nothing to go on but price. And so in the 1970s and '80s, the US quickly became known as the price-buying market.

Many European phytomedicine and other botanical companies are at least one hundred years old. Two, three, and four generations of family members are involved, and knowledge about sourcing and processing of medicinal plants is passed through the generations. In the US the leading companies weren't even established until the late 1960s. And the founders of those companies had no strong tradition to turn to for guidance. When botanical medicines died out in the early 1900s in the United States, the traditional networks of trade and manufacturing fell away. The scientific field of pharmacognosy began to die out as well. Plant knowledge was integral to the curriculum in US pharmacy schools from the late 1800s to the 1930s when herbs were part of mainstream care. But by around the 1970s and 1980s, pharmacy schools began dropping medicinal plant study from their curricula and eventually closed their pharmacognosy departments, often subsuming the subject under medicinal chemistry. The USP and the National Formulary dropped most monographs of crude drugs, including echinacea, black cohosh, and other mainstays of botanical medicine, between 1930 and 1950. (Many of these have been or are in the process of being readmitted.) In contrast, European and Australian pharmacopeias continued to list one hundred crude drugs and required companies to follow these pharmacopeial standards. This was not required in the 1950s in the United States. Pharmacists stopped preparing plant medicines, and so they no longer needed the tools to determine the identity and quality of crude drugs purchased from botanical supply houses. Plant medicines "fell away not because they had been shown to be ineffective," Steven Dentali wrote in a 2010 journal article. "They just fell out of fashion."

As the focus of pharmacognosy shifted from the containers (plants) to their contents (chemicals), the "smeckers and leckers" (smellers and tasters)—those who could identify plants organoleptically (with their sense organs) and who knew common adulterants and bad-quality herbs—gave way to the "grinders and finders" who were looking for active compounds to be used to formulate new drugs. "Smellers and tasters" evaluated the plant as a "cultural message," Steven Dentali wrote, and were replaced by those operating under the model of drug discovery.

Though much of the back-to-the-land movement focused on folk remedies and kitchen medicine you could prepare with common weeds, it also helped create a renewed interest in information about plants and botanical identification. Even so, in the early days, the herbal renaissance in the United States lacked the scientific rigor found in the European phytopharmaceutical industry or clinical herb programs. Steven Dentali guessed that few herbalists had the technical knowledge needed to productively read a scientific journal, just as few scientists had heard of the medicinal uses of echinacea. Things had gotten so bad that by the late 1970s, noted pharmacognosist Norman Farnsworth had a stamp made that said, SAVE THE ENDANGERED SPECIES: PHARMACOGNOSY.

Without any knowledge about how to evaluate quality and maintain it through the supply chain, those who were sourcing herbs for herb companies tended to make decisions based on price alone. For US companies that weren't purchasing pharmacopeial-grade herbs, there were no systems for ensuring the quality of the imported herbs. "Few people were testing or tasting. They were just buying," Roy Upton told me. And they were simply ordering plants from a list of names and prices printed on a piece of paper. They were not, as in other countries with established systems of trade, examining samples and setting specifications or, better yet, visiting the sources. This led to many sorts of problems in the supply chain, not just for US companies and consumers, but for the international market sourcing raw materials from the US.

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The regulations concerning herbal products proved to be one of the most confounding aspects of my research for this book, especially the implications of these regulations on the practice of herbal medicine. The events leading up to and following passage of the Dietary Supplement Health and Education Act of 1994 (DSHEA) are far beyond the scope of this book. The key point is that before the regulations passed, herbal products were in a regulatory no man's land. In the 1970s, companies that sold herbal products risked being shut down by the FDA because there were no clear standards. Drake recalled a visit by an FDA officer who had a bag of Smooth Move tea and told Drake that the company was selling the tea as a drug, which was illegal.

Peggy Brevoort was president of the American Herbal Products Association at the time that DSHEA was passed. One of her goals as president of AHPA was to work with Congress and with the FDA. "We got a lot of

pushback. There were deep disagreements. 'We can't work with them!'" Brevoort said. "There were people who felt if you didn't collect the plants from the woods, your business wasn't legitimate. You had to keep it small and pure. There were those who said if you didn't make it in your kitchen, it didn't count. And there were those who said if you *did* make it in your kitchen, it didn't count." Former Healthnotes, Inc., CEO Skye Lininger, who has been active in the natural products industry for almost forty years, said that organizing around the FDA was the first time the left and right came together in the health food industry. "The left, the old hippies, wanted their natural products, and the right, the libertarians, didn't want anyone telling them what to do. And so that formed an unusual alliance." DSHEA was passed in part as a result of the biggest letter-writing campaign ever by constituents to Congress other than that expressing opposition to the Vietnam War. It was considered an unprecedented victory for a renegade industry and a shocking defeat for the FDA.

Under DSHEA, companies did not have to legally prove that herbs were safe and effective for treating specific diseases, so long as they did not make drug claims (claims of disease prevention, treatment, mitigation, or cure) on product labels. This legal definition meant that companies did not have to go through the lengthy and expensive drug approval process (which typically cost $230 million for each drug even at that time).

Mark explained the regulations to me as follows. Companies are allowed to make so-called structure/function claims—claims on how the product can affect the structure and/or function of the human body—but they cannot make claims related to how the product might be able to prevent or treat a disease. Such claims are limited to FDA-approved drugs. Structure/function claims must be truthful and not misleading and must be supportable or substantiated by a reasonable level of scientific evidence. Also, disease-related claims based on traditional use—no matter how compelling—are not allowed. This prohibition against providing such educational information on product labels separated the products from the traditions from which they arose. "Without being able to say what an herb was used for, we have herbs without herbalism," K. P. Khalsa, then head of the American Herbalists Guild, told herbalist and doctor Anne Dougherty during an interview. Or as David Hoffmann said, "The inherent empowerment of herbal medicine was given away. You are only empowered if you buy a product."

DSHEA was a defensive position against the FDA's efforts to prevent access to herbal medicines and dietary supplements, Roy Upton explained to me. He acknowledged that it wasn't perfect, but given FDA pressure, the regulation was what he and others believed was possible and was considered a victory for both the natural health consumer and the dietary supplement industry.

The impact was immediate. Because companies were no longer threatened by closure, DSHEA opened the floodgates for herbal products. The *Wall Street Journal*, *Boston Globe*, and *Detroit News* all featured articles on echinacea in 1997. Dan Rather visited Nature's Way, a supplement company in Utah, to record a news segment on the use of echinacea to prevent the common cold. The following day Nature's Way—and most companies that made echinacea products—were sold out. The market for botanical medicines was estimated at approximately $1.6 billion in annual retail sales in 1994. In 1998 sales were purported close to $4 billion. Companies that had been averaging $22,000 a year in sales were realizing sales as high as $8 million a year by the late 1990s. In 1994 (the year that DSHEA was passed) roughly four thousand products were on the market. By 2017, twenty-three years later, fifty to eighty thousand products were on the market. That huge increase in production brought a whole host of intended and unintended consequences, especially because many of the products depended on plants collected from the wild.

Many people entered the market to cash in, gathering herbs wherever they could—harvesting echinacea growing wild along roadsides in the Midwest, for example—likely paying little attention to the impact of overharvesting or the guidelines governing the harvest or handling of medicinal plants in systems of traditional medicine. Boom-and-bust cycles always wreak havoc on supply chains, and herbs were no exception. *HerbalGram* columnist Peter Landes reported on the oscillations in supply: "The scramble began. Prices for even low-quality goods skyrocket and companies end up paying high prices for poor material. Next, lots of specious or basically valueless material comes on the market and even that is scooped up by unsophisticated users. Growers/gatherers are encouraged by the extremely high prices and seemingly limitless demand and good material is oversupplied just as consumers move on to the next 'hot' herb. (By the way, is there anyone out there not growing echinacea?)" The following year Landes reported: "In many instances inappropriate, carelessly

harvested plant parts have been marketed (the whole damn plant instead of just the rootlets or the flowering tops) or whole fields with delicate ecologies have been decimated."

The market reportedly reached a high of $3.87 billion in 1998. And then it began to drop. Mid-year sales in 2000 were down 12 percent. By 2001, they were down 15 percent. Companies planned their growth based on projections that customers would be repeat buyers. But many first-time customers never returned. Products sat on shelves; herbs sat in warehouses. Peter Landes wrote in *HerbalGram*, "Over-projection of sales was easy and obvious just a few months ago; companies that saw a 30 or 40 or 50 percent increase in sales over a couple of months simply projected a continuation of that happy trend, forgetting that every consumer in America would have to buy their second bottle of St. Johnswort or kava to make the projection prove out. This didn't happen that quickly and companies that have made commitments for property, merchandise, equipment, etc., and planned to finance that expansion from projected sales increases and profits may find problems instead if sales (and collections) don't pick up soon."

Product quality was a key factor. Assays of ginkgo, for example, showed that six of thirty products tested did not meet the specifications on the label. Tests of valerian indicated that some of the products did not contain valerenic acid (which is considered an active constituent) "and therefore were probably a different species or a different plant altogether."

Inconsistent quality wasn't the only problem. Just as knowledge about sourcing and producing botanical medicines had been lost, understanding of how to treat health conditions with herbal medicine had been lost. Consumers who bought and took products without guidance from a skilled practitioner didn't know, for example, what the expected time frame would be for the herbal medicine to work its effect.

As ethnobotanist and herbalist James Duke (who passed away in 2017) explained when we interviewed him in 2007 for *Numen*, "Contrasted with pharmaceuticals, which tend to hit you real hard, I believe that the more gentle herbs give you a whole menu of phytochemicals and your body selects from that menu." Those chemicals have different effects in the body: Some chemicals warm the tissue, others cool the tissue, working together to reestablish a healthy balance. As with most natural remedies, plants don't work fast, but their effect is sustainable as they slowly bring a body back to wellness.

Aspirin, which begins working to ease pain in thirty minutes, conditioned consumers to expect quick results. And so in the 1990s when customers first tried taking St. Johnswort (SJW) for depression and felt no noticeable effect within a few days, they stopped taking it. The bottles of SJW sat on the store shelves. Tons of SJW stored in warehouses around the world in anticipation of repeat orders became moldy. Processing facilities built exclusively to extract SJW sat idle.

This enormous waste is just one example of what can result from the separation of the plants from the source—the human and ecological communities where they grew and were harvested and processed and the systems of medicines that codified their use. All that mattered was selling a product and making a profit, regardless of its impact on the wellness of the individual taking the supplement or of the ecosystem, human and environmental, from which the plant was sourced.

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