

Holistic Primary Care's

# Quality Counts

A Clinician's Guide to Supplement Quality

Fall | 2020



**Natural Products & COVID-19: An Industry Rises to the Occasion**

**PAGE 2** An Industry Rises to Meet Unprecedented Challenges

**PAGE 4** Sales Surges, Supply Shortages, Stormy Seas

**PAGE 7** Words of Warning: Fed Cautions Clinicians on COVID Claims

**PAGE 9** BAPP Update: Herb Industry Meets New Threats with Renewed Vigilance

# An Industry Rises to Meet Unprecedented Challenges

By Erik Goldman | Editor in Chief

The COVID-19 pandemic has been radically disruptive to all sectors of the economy, especially those connected with healthcare. The natural products and dietary supplements industries are no exception.

Since early March, when the industry's 80,000-strong ExpoWest trade show was abruptly cancelled, the world's supplement makers and the raw materials companies that supply them have rallied to meet the myriad challenges posed by the COVID crisis.

Those challenges are significant:

- **A sudden surge in consumer demand** for health-promoting products simultaneous with equally sudden shortages of key raw materials from China and other parts of Asia;
- **Rising costs** for shipping and longer wait-times on imported materials;
- **New social distancing** and employee-protection requirements;
- **Increased scrutiny and enforcement** actions from federal agencies working to protect the public from fraudulent COVID "cures";
- **Major disruptions of distribution and sales channels** as consumers stayed home, and practitioners shifted patient visits to telemedicine platforms;
- **Cancellation of trade shows, conferences, in-office visits,** and other vital marketing and education activities.

These changes play out against extreme economic uncertainty as the pandemic drags on and millions face unemployment and financial hardship.

## Are Supplements "Essential"?

Early in the epidemic, a fundamental existential question hung over the industry: Would it be considered part of the "critical infrastructure" in a crisis like this? In other words, are dietary supplements an "essential" business?

The official answer was a solid, "Yes!"

Thanks in part to the efforts of organizations like the [Natural Products Association](#) which, in March issued [a letter to governors](#) of all 50 states, nearly all stay-at-home orders included supplement companies, ingredient suppliers, health food stores and other health-related enterprises under the "essential business" umbrella.

"Designation as a critical infrastructure industry with essential products was huge. That one decision turned the fate of the industry," [Loren Israelsen](#), who heads the [United Natural Products Alliance](#), one of the industry's major trade organizations.

**"Designation as a critical infrastructure industry with essential products was huge. That one decision turned the fate of the industry"**

—Loren Israelsen,  
*United Natural Products Alliance*

## Rapid Responses

Relieved of the threat of total shutdown, supplement makers were able to redouble their quality assurance and employee protection efforts and focus on meeting the logistical challenges of a new and chaotic marketplace.

"I think overall we've done very well," Israelsen said of the industry's adaptation to the new post-COVID reality.

He told *Holistic Primary Care* that ethical, well-reputed companies already had strict environmental control systems and personal protective equipment requirements in place as part of their standard operating procedures. They were able to respond rapidly to the new situation.

"In GMP (Good Manufacturing Practices)-compliant facilities masks and eyewear are routine. The companies that did the work and the training for compliance with the

[Food Safety Modernization Act](#), were able to immediately go to their preventive control plans. They had a good understanding of where their hazard control points were."

Many have instituted daily employee temperature checks, health screenings, and infection tracing systems. They also mandated work-from-home rules for all jobs not requiring physical presence at manufacturing and packaging facilities.

In terms of COVID caseloads, the supplements industry fared far better than other industries.

There have been a few coronavirus cases among supplement company employees. But they were quickly identified, isolated, and well-handled. There are no reports of major multi-person outbreaks within the industry, says Israelsen, one of the architects of the [Dietary Supplements Health and Education Act of 1994](#), which set the regulatory framework for supplements.

"Our worker safety record, to date, has been very good. Dietary supplement GMPs together with FSMA compliance have demonstrated that product quality and worker safety can and should be achievable, day in and day out."

Israelsen added that, "the severe outbreaks of COVID in a number of meatpacking plants confirms that proper controls and a people-first system are essential for protecting workers. This means making costly changes to systems and schedules and training. I believe this ethos is embedded in our companies and so far, reports of workplace-caused infections are very low in our industry sector."

## Shortages & Slowdowns

According to [Michael McGuffin](#), executive director of the [American Herbal Products Association](#), botanical medicine producers have been contending admirably with significant ingredient shortages.

As the pandemic interrupted international trade, many key herbs like Turmeric/Curcumin, Boswellia, Hawthorne, Ginger, Elderberry, and Gentian were suddenly in short supply. There have also been shortfalls and shipping delays for glass bottles and grain alcohol. The latter is essential for making tinctures.

"So much of the alcohol supply is going to making hand sanitizer," McGuffin says.

Some companies and contract manufacturers had to slow down production owing to the new employee safety requirements. "Where you're used to having elbow-to-elbow filling lines, and now the workers are 6 feet apart, the result is lower production per shift," McGuffin explained, adding that many companies have added more shifts to meet the soaring demand.

## Rising Demand, Intensified Scrutiny

From the earliest days, it was clear that consumers considered supplements essential during the pandemic.

Industry watchers say overall supplement sales rose by more than 50% last Spring, compared with the same period in 2019.

A survey of 1,000 US consumers by [Lonza, one of the world's largest nutraceutical ingredient suppliers](#), showed that 44% have increased their supplement use since COVID, and 16% were stockpiling products. [A consumer study by Nutrition Business Journal](#) showed that 20% of post-COVID supplement buyers had never used supplements before.

The retail surge was matched by an equally robust growth of sales via practitioners. Kyle Bliffert, President and CEO of [Atrium Innovations](#), a division of Nestle Health Sciences, says Atrium's practitioner brands (which include Pure Encapsulations and Douglas Laboratories) saw sales of 120% to 150% over predicted levels in the Spring. "In March alone, total business increased by 80%."

Not surprisingly, immune support products drove the surge: vitamin C, vitamin D, zinc, omega-3 fatty acids, N-acetyl cysteine, and immunomodulatory and anti-inflammatory herbs like echinacea, elderberry, and turmeric have been huge sellers.

These growth trends are not lost on the Food and Drug Administration and the Federal Trade Commission. Both have made it clear they will not tolerate COVID prevention or treatment claims for supplements, or for that matter, for off-label use of drugs. They've taken swift and widespread action to enforce this position (see page 7).

The agencies do not consider anecdotal evidence, *in vitro* or animal experiments, epidemiological correlations, or even human clinical studies of other viral pathogens, to be adequate evidence to support supplement claims in the COVID context.

This puts practitioners in a challenging position: patients often turn to clinicians for intelligent, informed guidance on how to reduce COVID risk, increase immune system strength, and improve overall health. Yet federal regulators want to squelch the notion that supplements might mitigate risk. They do not want practitioners publicly promoting such ideas—at least online.

## A Golden Opportunity

Despite this obstacle, the materials shortages, and the other challenges, industry leaders see COVID as a rare opportunity for the natural medicine movement and the supplement industry to move from healthcare's margins to the main stage.

Matt Schueller, Chief Innovations Officer for [Nature's Way](#), which owns the [Integrative Therapeutics](#) practitioner brand says the sweet spot for supplements is not so much in preventing or treating COVID directly, but rather "in regard to the underlying conditions and chronic diseases that predispose to COVID and raise risk of death. Integrative practitioners play a role in this area, working on prevention and root cause resolution, with a track record of safety."

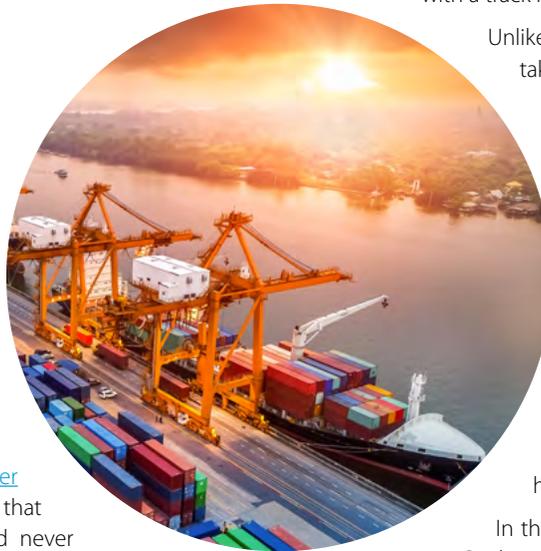
Unlike vaccines and new antiviral drugs that will take months or years to develop, integrative and functional medicine already has a wide array of readily available tools to reduce systemic inflammation, improve glucose metabolism, and improve resilience and wellbeing, all of which indirectly mitigate COVID risk.

Loren Israelsen believes the pandemic offers the supplements industry, "a unique opportunity to redefine our role in personal and public health." It is, he says, "the single best chance we've ever had to establish an expanded role in the delivery of health and wellness for generations."

In this 2020 edition of *Quality Counts: A Clinician's Guide to Supplement Quality*, we'll take a look at how key players in the industry have responded to the massive challenges of COVID, with specific emphasis on how they are assuring product quality and integrity.

We'll also explore the question of bioavailability and absorption, the potential role of liposomes and micelles to improve product efficacy, and the recent regulatory developments.

A big thank-you to our sponsors: [LONZA](#) and [Quicksilver Scientific](#). This report is only possible because of their generous support. 



Holistic Primary Care is grateful to our industry partners for their support of *Quality Counts: A Clinician's Guide to Supplement Quality*

**Lonza**

**Capsugel**



# Sales Surges & Supply Shortages: Supplement Brands Navigate Choppy Post-COVID Seas

By Kristen Schepker | Assistant Editor

Dietary supplement sales soared to unprecedented heights this year, owing to the coronavirus pandemic.

But as consumer interest spiked, major disruptions to the ingredient supply chain limited the accessibility of many botanical and nutraceutical raw materials, excipients, and packaging materials, creating major sourcing challenges for supplement companies.

## Peak, Then Plateau

A *Nutrition Business Journal* [analysis](#) posted in July projected that sales of cold, flu, and immunity supplements would hit \$5.2 billion by the end of 2020, a category growth of 51.2% over 2019. Immune health products will likely comprise nearly 10% of all US supplement sales this year.

In an earlier survey, 36% of consumers reported using more supplements now than prior to the pandemic, and 39% said they expect their elevated usage to continue, “signaling a potential halo effect for supplements beyond the immunity category.”

Roughly 20% of respondents who claimed that they “never” used supplements before COVID expect to increase their usage over the coming months.

“It’s as if Americans woke up to the fact that they have a thing called an immune system,” said Mark Blumenthal, founder and executive director of the [American Botanical Council \(ABC\)](#), an herbal medicine education and advocacy group.

“And not only that, but if you get enough sleep, and you eat well, and take supplements, you might be able to enhance that immune system’s function in ways you hadn’t done previously. There is a wider bandwidth of people pushing demand on some of these products, whether or not they are legitimately warranted for COVID prevention, treatment, or even mitigation,” Blumenthal told *Holistic Primary Care*.

By June, sales leveled off as consumers shifted from hoard-buying to cash conservation. But overall, the numbers are higher now than at this time last year.

## Soaring Demand, Short Supply

Like much of our globalized economy, the ingredient supply chain relies on vast international networks. The pandemic revealed just how vulnerable those networks were.

Between 70%-80% of all supplement raw materials come from China. For nearly three months, the entire country was shut down. Nothing was entering or leaving, said Loren Israelsen, President of the United Natural Products Alliance (UNPA). The organization, one of the industry’s major trade groups, has an office in Beijing.

When COVID hit, most US brands were reasonably well-supplied for their near-term production runs. They had ordered key raw materials months in advance. But by the summer, many faced shortages on herbs, bulk vitamins, and excipient ingredients such as the alcohol used to make tinctures. Much of the world’s ethanol output has been re-routed for hand sanitizer, reducing availability and raising prices.

China restarted its industrial engines in May, and industry watchers say ingredient output is nearly back to “BC” (Before COVID) levels. But this is not uniform across all regions of China, nor does it apply to all ingredients.

## Shipping Challenges

Then there’s the issue of shipping. Executives who spoke in a recent webinar on supply chain challenges, sponsored by *Nutritional Outlook magazine*, say they’ve been hit with 3 to 5-fold increases in shipping costs from China, as well as longer wait times.

There are several reasons for this: labor shortages at Chinese ports; reduced numbers of FDA and Customs officers resulting in longer waits for inspection; prioritization of medical equipment and personal protective equipment (PPE) on the shipping rosters.

By summer, trans-Pacific shipping resumed, but disrupted logistics chains and trade-war posturing resulted in chaotic commerce between the US and China.

“There were serious misalignments of assets,” Israelsen says.

Many common ingredients—echinacea, ginseng, amino acids, vitamins, minerals—were affected. For herbs and specialty ingredients that are somewhat tight in ordinary times, the shortages were aggravated and the costs rose.

Supplement makers have been reluctant to pass their cost increases on to consumers at a time when so many are struggling financially.

Nobody is resting easy. Sales have increased, but so have costs. And employee protection measures require supplement makers to alter the structure and scheduling of their production shifts.

## Supply-Demand Mismatches

Barring a major crop failure or sudden hot trend, it used to be fairly easy for procurement managers to match raw materials purchases with expected consumer demand. The major variables were predictable. Not anymore.

By mid-March, companies that had cash reserves faced big questions: Should they buy long? If so, how long? And for which ingredients?

“It is very much like speculating in the (stock) market,” says Israelsen. “Which ingredients do you think are going to go short, and how do you price-protect yourself? There’s a lot of financial risk, and some companies did not have cash reserves to do the longer buys. They had to put customers on ration orders. That continues in certain categories.”

## Requalifying Vendors

“In all my years, I have never seen a Whole Foods supplement shelf barren until this year’s pandemic. Not a single product was left, not even the no-name knock-off vitamin C,” said Elan Sudberg, CEO of [Alkemist Labs](#), a contract testing laboratory that provides botanical ingredient identification and quantitative analytical services to the industry’s top companies.



Ripe elderberry *Sambucus nigra*

"As a result of the early rush to buy all the immune supplements, our clients had to frantically resupply—and in some cases, that meant re-qualify vendors," he added. As one of the world's premier analytical testing labs, [Alkemist has been at the forefront of these requalification efforts.](#)

Wilson Lau, Vice President of [Nuherbs](#), a botanical ingredients supplier, said the massive swell in sales left some companies unexpectedly "needing to find new suppliers, which is difficult when you can't send someone [out] to vet them in person."

Brands that had previously "qualified multiple suppliers before the pandemic were in a stronger position" than those with smaller supply networks.

## Shortages Invite Adulteration

Ingredient adulteration—a persistent problem before COVID—has only intensified since the pandemic.

The American Botanical Council issued a [memo](#) in early April advising its members that adulterated herbs would inevitably emerge as the coronavirus spread across the globe.

"We didn't know at that time exactly what they were going to be—but we know when there is short-term dislocation of the supply of almost any botanical, there is almost always an adulteration problem," Blumenthal said. Fraudulent products invariably "jump in to try to remedy gaps in the supply."

The ABC advisory cautioned that a reduction in FDA inspections meant "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 up on their testing requirements, thus possibly facilitating the sale of adulterated material," the notice stated. But given the level of FDA and FTC scrutiny now trained on the industry, this is a bad time to get slack about quality control.

Lau similarly cautioned that "manufacturers must place more scrutiny on material they are buying," as they make changes in their supply chains. He stressed the need for "exact identity, potency, and purity testing."

"I think that [adulteration] is something we have to be very, very watchful of," says Israelsen. "The problem of supply chain irregularities is turning into more of a chronic issue—assuming that COVID-19 continues through to 2021."

## Elderberry Blues

Elderberry has long been one of the most popular herbal cold and flu remedies. This year, demand "shot through the roof because of COVID," Blumenthal reported. Other immunomodulating botanicals like turmeric, echinacea, and medicinal mushrooms have also sold briskly.

Though there are no specific COVID trials of elderberry, there is some limited evidence that it can help treat or shorten the duration of com-

mon colds and flus. Many people have taken those findings to mean elder might reduce COVID susceptibility or severity.

Unfortunately, the world does not contain an endless elderberry supply, Blumenthal said.

Elder—the tree that yields elderberries—is "not something you can just find, or just grow." Unlike other herbs such as dill or garlic, which are ready for harvest within months of planting, elder trees must grow for years before generating a usable crop.

In an ordinary year, most companies build reserves of valued botanicals like elder, based on factors like seasonal availability or growing cycles. Some brands did, therefore, have sufficient elderberry inventory at the start of the pandemic.

However, "nobody could have foreseen the rise in demand that happened starting in the end of February and beginning of March with elder," Blumenthal said.

Right on cue, as supplies dwindled, cases of botanical fraud started to climb.

"We have seen an increase in reports of material coming in, claiming to be elderberry, but according to various lab reports, it's adulterated," Blumenthal noted. "There is a lot of adulterated material on the market."

Elderberry products derive from one of two varieties: *Sambucus canadensis* (North American elder) and *Sambucus nigra* (European elder). To date, most research in the cold and flu context is on the latter.

In the early months of the pandemic, "some companies started looking for alternative sources of supply just to hedge their bets, and found that the material being promoted—primarily from China, but not only from China—was not true European elder, or even North American elderberry," Blumenthal explained.

Laboratory analyses indicate that some fraudulent products did contain the medicinal herbs they claim to, but in reduced quantity. In others, advertised botanicals are replaced with other ingredients of similar color, odor, and texture.

Anthocyanidins, a broad class of deep purple, red, and blue pigments that give fruits like cranberries, cherries, and blueberries their rich hue, are common elder adulterants.

That's because elderberries do contain anthocyanins. But Blumenthal explained that adulterated supplements often include the colorful compounds in ratios that differ from those naturally present in the elder plant. Deceitful products may also include pigments from different lower-cost berries or from unrelated plants like black soy or rice.

Added anthocyanidins are harmless, but they may or may not be bioactive. And because they're added as substitutes for the harder-to-obtain elderberry, they compromise the quality and efficacy of the products.

**"It's as if Americans woke up to the fact that they have a thing called an immune system."**

—Mark Blumenthal, Founder/Executive Director  
*American Botanical Council (ABC)*

## The PPE Challenge

Supplement ingredients are not the only things subject to alteration and shoddy manufacture these days.

The unprecedented, ongoing, global demand for face masks, gloves, and other PPE has created an open market for poorly made products. It is ironic that Wuhan province, where SARS-CoV-2 first emerged, is also home to the world's largest PPE factories.

Israelsen, who's seen the PPE trade first-hand, described the scene in China as "Kafka-esque." Buyers for all the world's national and provincial governments, major private-sector distributors, and independent speculators are all competing for slices of China's PPE output. Prices swing wildly, and the market is rife with substandard merchandise.

"I'm dubious about a lot of the masks being shipped from China. Many are not up to snuff. Everyone and their grandmothers are in the mask business now, and 99% should not be," he says, adding that the Chinese government is trying to get a handle on the situation.

"What is disappointing is that the US has not developed a more robust domestic PPE manufacturing capacity."

## A "New Normal"?

Will public demand for immune-strengthening products peak again this winter?

In part, that depends on how many Americans have enough disposable income after bare necessities like food and housing, to continue purchasing them. Given the continued shutdowns in many business sectors, the high unemployment rate, and the fragility of the economy, that's a big question.

ABC's Mark Blumenthal is bullish: "As COVID moves into our new normal, there will be millions more people using herbs and other supplements for immune and general wellness than ever before. Even if a COVID vaccine comes out, there is always the threat of another pandemic or something else coming along later."

"People are going to change their lifestyles," he added. "People are going to take more supplements. And hopefully, there's also going to be more research on the benefits of those supplements."

## Changing Channels

How people access these products has changed radically since COVID. Online sales had been rising steadily for several years now, thanks largely to the ascent of Amazon. The pandemic turbocharged that trend.

The retail sector—especially the local independent stores—was very hard-hit. After an initial flurry of panic-buying, many stores experienced perilous drops in foot traffic, as states issued stay-at-home guidelines, and people were reluctant to shop.

Big chains like [Whole Foods](#) and [Natural Grocers](#) adjusted operating hours to provide extra time for cleaning and restocking, limited the number of customers in the stores, developed new traffic flow pathways, and required masks. Most scheduled special hours for elderly and vulnerable patrons.

**"In all my years, I have never seen a Whole Foods supplement shelf barren until this year's pandemic. Not a single product was left, not even the no-name knock-off vitamin C."**

For smaller businesses, overhauls like these are physically or financially infeasible. Many mom-and-pop stores around the country simply closed their doors forever.

But even the big chains are not immune to COVID's economic fallout. The pandemic was not solely responsible for [GNC's bankruptcy filing](#) in June; the 8,400-store giant had been in dire straits for years. But the sudden drop in floor sales resulted in the closure of 40% of its stores, and likely struck the knockout blow for GNC.

In the clinical sphere, the sudden shift from face-to-face visits to screen-to-screen tele-consults stoked a concurrent surge in sales via [Fullscript](#), [Welleve](#), and other online dispensaries.

Kyle Bliffert, president of [Atrium Innovations](#), which owns [Pure Encapsulations](#) and [Douglas Labs](#), said orders from practitioner-owned clinics dropped from 75% of Atrium's total in 2017 to 62% by early summer 2020. At the same time, orders via online dispensaries rose from 25% to 38%.

Alex Keller, ND, Fullscript's medical director, says practitioners are flocking to the company's dispensing platform, which now integrates with a number of EMR systems.

Fullscript saw a 20% rise in new practitioner sign-ups since COVID, and a 30% growth in patients now getting their supplements via the online formulary.

Fullscript now has 75,000 registered practitioner accounts that represent 1.75 million patients in total. Since the beginning of the year, the company has seen a 66% increase in orders for immune system support products.

How long the increased sales will last is a big question, says Keller. Roughly two-thirds (65%) of Fullscript practitioners say some of their patients are struggling financially, and 43% say existing patients are not booking appointments. Another 38% say they are challenged to find new patients.

UNPA's Israelsen believes telemedicine and online product dispensing are both here to stay.

"This is existential in nature. It's a permanent shift. The longer COVID continues, the more structured the muscle memory is for all these changes. I'd say, for any big change in behavior, the spring-back to previous normal is 90 days. If the change goes on beyond that, the habits fundamentally change."

The COVID pandemic is well past its 90th day.

For the foreseeable future, supplement companies must continue to vector carefully between three conflicting currents

- Public hunger for products that might improve their resilience and mitigate COVID risk
- Episodic ingredient shortages
- Increased need for vigilance, quality assurance, and regulatory compliance.

The post-COVID landscape is challenging. It is forcing the natural products industry—now entering its 27<sup>th</sup> year as an officially recognized business sector—to mature and evolve. In the long run that's a very positive trend. **QC**



# Words of Warning: Fed Reprimands Clinicians on COVID Communications

By Erik Goldman | Editor in Chief

Any public health crisis creates a ripe situation for marketers promising quick cures and phony protections. With COVID-19, the huckstering began almost immediately.

So did federal regulatory actions. By the second week of March, the FDA had issued cease-and-desist [warning letters to seven companies](#) for selling COVID-19 remedies, including teas, essential oils, tinctures, and colloidal silver. The agency fired off [a second wave of warnings](#) in April. By August, FDA had [sent letters](#) to nearly 100 different companies for “selling fraudulent products with claims to prevent, treat, mitigate, diagnose or cure” coronavirus.

The FDA also sounded alarms about “rogue online pharmacies offer[ing] potentially dangerous prescription drugs.” [A catalog of internet companies operating unlawful drug-selling operations](#) is available on the FDA website.

## Coordinated Action

Working closely with FDA, the Federal Trade Commission (FTC) also cracked down on advertising of health products and services for preventing or treating COVID.

Kristi Wolff, an attorney with Kelley & Drye, LLP, a law firm specializing in nutrition industry regulation, explains that the warnings come in two basic flavors: The FDA says: “You’re making claims to treat a disease. That is not permitted for dietary supplements.”

The FTC says: “You need competent scientific evidence to substantiate the claim you’re making. We don’t believe you have it. Therefore, we believe you’re making fraudulent claims.”

None of this is surprising: the FDA and FTC frequently reprimand supplement companies, pharmacies, device-makers, and food/beverage brands that market unverified product or make unsubstantiated, misleading, or inappropriate claims.

What is unique about the agencies’ COVID response is that it targeted healthcare professionals, not just manufacturers and retailers.

## Practitioners: A New Target

Since the pandemic began, FTC has issued unprecedented warning letters to [more than 250 physicians, clinics, and companies](#) that “promot[ed] their products and services with COVID-19 prevention or treatment claims.”

Some recipients were indeed making egregious and potentially dangerous claims about unproven, or even disproven, COVID therapies. But scores of letters also went to well-meaning healers who had no idea that statements about things like vitamin C and D for immune health, or Chinese herbs based on traditional use counted as “marketing.”

The warnings contend that in making or insinuating COVID claims, these practitioners violated the Dietary Supplement Health and Education Act (DSHEA), which strictly prohibits supplement producers and marketers from making disease-related claims.

Regulators hold that disease treatment language is the inviolable province of drugs and medical devices. To state publicly that a supplement can prevent or cure any disease is to make an unapproved drug marketing claim—even if there is research to support it.

Under DSHEA, supplement brands may only make structure/function claims, with the now-familiar disclaimers that, “These statements have not been evaluated by the Food and Drug Administration” and that, “This Product is not intended to diagnose, treat, cure, or prevent any disease.”

## Are Practitioners “Marketers”?

The FDA and FTC routinely apply DSHEA to nutrition companies, but they’ve seldom invoked it to discipline practitioners. Yet in the last 6 months, many MDs, DOs, DCs, naturopaths, acupuncturists, and nutritionists have been warned about COVID-related “claims.”

Most were using e-mail, websites, and social media to share information about supplements with potential immunostimulatory effects. In many but not all, cases these practitioners also sell products via in-clinic or online formularies.

Some, including the high-profile [Joseph Mercola](#), were clearly pitching unsubstantiated claims with obvious intent to boost sales of their private label supplement lines. Others are far less famous and less commercially motivated.

Most of the warnings have been simple cease-and-desist letters informing recipients that they violated federal rules, and insisting that they remove all offending statements from all public communications within 48 hours. But the FBI was called in for at least one clinic raid, and there are reports of bank account closures of practitioners who’ve been targeted.

Michael D. Levin, a supplement industry consultant who has decades of experience in both the mainstream and holistic medical worlds, was recently included on a conference call with high-level FTC officials, to better understand the agency’s motives.

He says FTC is simply taking a very hard stance that currently there are no treatments—pharmaceutical, nutritional, herbal, or otherwise—scientifically proven and FDA-approved as effective for preventing or treating COVID-19 or the virus that causes it. Therefore, any commercial language stating or insinuating such benefits is inherently misleading, and therefore in violation of the law. Part of the FTC’s mandate is to protect the public from being misled by unsubstantiated, false, or misleading advertisements.

## A Hard Stance

This view is summed up clearly in phrasing found in many of the warning letters:

*“It is unlawful under the FTC Act, 15 U.S.C. § 41 et seq., to advertise that a product or service can prevent, treat, or cure human disease unless you possess competent and reliable scientific evidence, including, when appropriate, well-controlled human clinical studies, substantiating that the claims are true at the time they are made. For COVID-19, no such study is currently known to exist for the services identified above. Thus, any coronavirus-related treatment or prevention claims regarding such services are not supported by competent and reliable scientific evidence.”*

One troubling feature of the recent warnings is that they sometimes cite general immune system claims as de facto COVID claims, even though the actual language may comply with structure/function rules, with no mention of “COVID” or “coronavirus.”

In the post-pandemic era, apparently, any mention of the immune system is considered a proxy for COVID.

This worries many natural medicine advocates. For years, the regulators considered claims like “supports a healthy immune system” to be within bounds. Not anymore.

“We have a growing concern that the FTC is working hard to push back what has been “safe” structure/function claims territory,” said the United Natural Products Alliance in a recent bulletin. “The worst case is that this trend would now follow to other important categories, whether COVID-19 or not.”

## Concern in Congress

There’s legislative weight behind the recent regulatory moves. In July, the Senate Subcommittee on Manufacturing, Trade and Consumer Protection, headed by Sen. Jerry Moran (R-KS) held [a hearing titled, “Protecting Americans from COVID-19 Scams.”](#)

“During this time of national emergency and coordinated recovery, there are fraudsters and scam artists that seek to take advantage of consumers, especially the nation’s most vulnerable communities,” said Sen. Moran. “FTC’s Consumer Sentinel Network reports that consumers across the US have reported over 136,000 different cases of COVID-related scams totaling approximately \$90 million in total fraud losses from January 1 to July 20. These are only the reported cases. It is fair to assume that there are harmful consumer scams that have not been reported to date.”

Moran, and others in Congress, feel they have an obligation to protect Americans from, “unsubstantiated health benefits advertised for certain products, illegal robocalls pitching low-priced health insurance, fraudulent donation solicitations, or even impostors claiming to be from federal agencies collecting mandatory payments.”

Few in the natural products industry take issue with this stance, at least in principle.

Back in February, a coalition of supplement associations issued a stark warning about COVID treatment claims.

“While research supports the use of certain dietary supplements to maintain immune system health, we are not aware of clinical research that demonstrates using a dietary supplement specifically to prevent or to treat the Novel Coronavirus,” says [the position statement](#).

“Even if research is conducted and published on the topic, the law that regulates dietary supplements [DSHEA] prohibits marketers of dietary supplements in the US from promoting any dietary supplement product that makes disease prevention or treatment claims.”

## Claims vs Clinical Communication

At issue currently is whether a physician’s social media posts about the immune-boosting potential of medicinal mushrooms or oil of oregano, for example, constitute COVID-related disease claims or clinical communication.

Levin says the FTC is acting on the principle of “commercial speech”, which includes statements made on a clinic’s website, in e-mail newsletters, or on social media posts—especially if the person or company has a product or service to sell.

But he stressed that FTC has shown no interest in regulating the protected and private speech between doctors and their patients.

The commission, he says, distinguishes between one-on-one clinical conversations and public communication. Unfortunately, many practitioners do not.

Some clinicians who were blind-sided by the warning letters believed they were simply offering guidance to their audience (patients and prospective patients) for improving their resilience, mitigating risk, and supporting immune function. It was ignorance of the regulations that got them in trouble, not knowing intent.

Some health advocacy groups are concerned that the warning letters foreshadow a larger, more insidious federal effort to curtail natural health care.

“Your right to learn from your doctor about natural methods of staying healthy during the pandemic are under threat,” the Alliance for Natural Health [warned consumers in a May statement](#). “The FDA, FTC, Department of Justice, and some state attorneys general have launched a coordinated censorship campaign that prevents medical doctors and other healthcare providers from communicating their extensive knowledge about how to stay healthy... using natural medicine.”

**Since the pandemic began, FTC has issued unprecedented warning letters to more than 250 physicians, clinics, and companies that promoted their products and services with COVID-19 prevention or treatment claims.**

## Finding a Middle Path

The proliferation of fraudulent COVID cures is a real and a significant problem.

Equally significant and problematic is the restriction of open communication about potentially beneficial, readily-accessible, low-risk ways to boost resilience, reduce cardiometabolic risk, and improve overall health.

The question is how to regulate the market appropriately to protect the public from scams without penalizing practitioners who are simply trying to educate patients.

Finding that reasonable middle path will take considerable advocacy, time, and goodwill from all parties involved.

For now, Levin says practitioners would do well to learn the rules. “With COVID-19 in this digital age, medical professionals who advertise products and services must learn how to avoid regulatory landmines. Health care organizations don’t understand what’s required under advertising laws. And they don’t teach about that in medical schools.”

Several medical organizations have acknowledged the need to train members about the kinds of messages that trigger regulatory action. The American Association of Naturopathic Physicians (AANP) updated its [guidance to members](#), advising members against commercializing or marketing the natural treatment approaches they write about in any of their patient communications. Saying ‘Vitamin D boosts immunity’ on your website is free speech. Saying “Vitamin D boosts immunity and you can buy it at my store” is marketing. Regulators are unlikely to object to the first statement. They very well could target the second.

Levin is working with *Holistic Primary Care* and several integrative medical organizations to develop an online training program that will help practitioners to “stay within the bright white lines of approvable commercial speech, while maintaining their freedom of speech to heal others.” Watch for that later this Fall. **QC**

# BAPP Update: Herb Industry Meets New Threats with Renewed Vigilance



By Kristen Schepker | Assistant Editor

Intentional adulteration of herbs is not a novel threat in the dietary supplement world, but it's showing up in new ways amid the coronavirus pandemic.

In response, the industry is intensifying its efforts to detect, reject, and destroy adulterated raw materials.

The US Pharmacopeia defines Economically Motivated Adulteration as: "The fraudulent addition of non-authentic substances or removal or replacement of authentic substances without the purchaser's knowledge for economic gain of the seller."

The problem is as old as commerce itself. [Dioscorides, Pliny the Elder, Galen and other medical authors of antiquity](#) described alteration of medically valuable herbs over 2000 years ago.

Today, with public demand for immune support products at an all-time high, and disruption of international supply chains leading to raw materials shortages, the potential for fraud has grown.

"History teaches that high-value ingredients are at most risk of economic adulteration during periods of supply chain shortages and/or sudden demand increases," said Michael D. Levin, a supplement industry consultant.

## Cleaning Up the Supply Chain

Levin is an advisor to the [Botanical Adulterants Prevention Program \(BAPP\)](#), a collaboration between the American Botanical Council (ABC), American Herbal Pharmacopoeia (AHP), and the University of Mississippi's National Center for Natural Products Research (NCNPR).

BAPP tracks herbal adulteration, and sounds alarms when new incidents are identified. Last year, BAPP launched an industry-wide self-policing initiative called, "[Burn It, Don't Return It](#)" that puts direct economic pressure on raw materials suppliers to improve quality and eliminate adulteration.

Launched last October with support from major industry trade groups, the program outlines contract terms and standard operating procedures (SOPs) to be used by supplement brands in their raw materials purchasing agreements.

The terms stipulate that if a manufacturer's quality assurance officers detect "irreparably defective" raw materials—contaminants, adulterants, or substitutions that cannot be removed or lawfully rectified—those materials are to be destroyed at the supplier's expense.

Ginkgo powder containing plants other than *Ginkgo biloba*, or St. John's Wort extract containing Red Dye #2, are two simple examples.

Levin says "Burn It," which is still in early stages of implementation, fills a big hole in the FDA's regulations: the current FDA Good Manufacturing Practice (GMP) guidelines do not outline procedures for how supplement companies should handle irreparably defective ingredients. In too many cases, they simply return the rejected materials to the suppliers, who then re-sell them elsewhere.

## New Standards

Mark Blumenthal, founder and director of the American Botanical Council, which sponsors the BAPP program, hopes BAPP's forthcoming finalized contract and SOPs will aid the herbal industry in solving the perennial issue of adulteration. "We're empowering companies to take control of this part of the supply chain, to take defective material out of it."

Levin believes the model "will become a widely adopted industry standard within two years." He also foresees GMP certification programs eventually adopting the BAPP's approach "as a GMP standard."

A BAPP [memo published in early April](#) warned member companies to be watchful for pandemic-induced adulteration.

In the wake of COVID, elderberry is among the herbs most vulnerable to counterfeiting. Blumenthal says there is not yet any international scientific literature addressing elderberry adulteration. But BAPP has consulted with at least one reputable maker of elderberry products that has identified fraudulent materials in products tested in independent 3rd party labs.

BAPP is currently drafting a bulletin on elderberry adulteration to educate consumers, health professionals, and industry members.

## Vexations in Vetting

Supplement companies have responded to the adulteration challenge by ramping up ingredient analysis.

Elan Sudberg, CEO of Alkemist Labs, reports "an uptick in testing, specifically the immune system boosting herbs, which are selling like hot cakes these days."

If the pandemic continues into next year, "the supply chain will continue to be strained, while demand will continue to be high. All the tricks unscrupulous vendors may use, from plant substitution, to providing the wrong plant part, to spiking for higher potency, will be in play, which is why testing plants at a lab that knows botanicals inside and out is crucial," he urged.



After COVID hit, Alkemist received requests to analyze “a lot of duplicate samples, meaning our clients were acquiring samples and testing them as part of their process of determining what new vendor they could possibly buy key ingredients from,” Sudberg said.

“Ordinarily, that may have involved a long plane flight to countries that now won’t let Americans in, so the usual vetting process isn’t an option right now.”

In addition to doctored ingredients, some raw materials suppliers are issuing [dubious Certificates of Analysis \(C of A’s\)](#)—basically bogus lab reports—in their marketing materials. They simply copy legitimate reports from reputable labs like Alkemist or DNA4, and post them in C of A’s for batches of herbs the labs have never tested.

## FDA Enforcement Curtailed

Part of the problem is that the pandemic has significantly curtailed the FDA’s on-the-ground enforcement.

“FDA publicly stated early on that they will be unlikely to perform onsite audits for a while,” Sudberg says. The lack of oversight opens the door to more fraud. “When there are no police monitoring stop signs, people stop stopping as much. When the likelihood of adulteration being spotted by regulatory agencies goes down, the need for brands to be even more vigilant goes up.”

“Because in-person audits have all but subsided, testing your ingredients with a third-party lab is more critical than ever,” Sudberg stressed. Based on the sustained high volume of testing at Alkemist in recent weeks, he believes the industry as a whole is taking this seriously. “Testing is still up, which likely means more vendor qualification is happening.”

The spotlight has been on elderberry lately, but a number of other popular botanicals are also at risk of economically motivated adulteration:

- **Lavander:** Adulteration of lavender oil can occur in several ways, says ABC. Some products are mixed with oils from other similar plants like spike lavender; others contain synthetic components whose odor and chemistry resemble genuine lavender oil. Still others include the “undeclared admixture of non-volatile solvents such as glycols, benzyl benzoate, benzyl salicylate, triethyl citrate, or vegetable oils such as coconut oil.” BAPP recently issued a [bulletin on English lavender](#) (*Lavandula angustifolia*), the latest in its ongoing series of peer-reviewed publications on botanical adulteration.
- **Pomegranate:** is naturally high in ellagic acid. Dishonest products may contain ellagic acid from other less expensive sources like wood pulp. This raises the concentration of this key chemical constituent, but it creates a false sense of value, especially because the additive is not disclosed.

**“History teaches that high-value ingredients are at most risk of economic adulteration during periods of supply chain shortages and/or sudden demand increases.”**

—Michael D. Levin,  
*Health Business Strategies*

- **Grape seed extract (GSE):** is a natural byproduct from the wine and juice industries. BAPP has identified [GSE adulterated with peanut skin extract](#), which Blumenthal says originates largely from China. Peanut skin extract, a byproduct of the peanut industry, is less expensive and available at a much greater volume than actual GSE.
- **Bilberry:** is often adulterated with dark anthocyanidin pigments from other cheaper berries, soybean or rice hulls. Some sellers create adulterated products so sophisticated they can pass through laboratory testing undetected.
- **Saw Palmetto:** Extracts from the saw palmetto, a type of palm tree, are common in natural treatments for urinary and prostate disorders. [Saw palmetto extract \(SPE\)](#) may be substituted or blended with lower-cost vegetable oils, especially palm oils, to

achieve a similar fatty acid profile. It was the subject of, “one of the most egregious cases” of botanical adulteration, says Blumenthal.

Two years ago, [BAPP broke the news](#) of a Chinese saw palmetto supplier that obtained sheep, cow, chicken and pork-derived fat from a slaughterhouse and used it to adulterate SPE. The animal fatty acids were isolated and recombined to match fatty acid ratios indicated in the US Pharmacopeia (USP) for saw palmetto.

The mixture was so chemically sophisticated that high-performance liquid chromatography (HPLC), the widely utilized analytical method, couldn’t detect the animal-based compounds.

- **Mint oil:** In one of BAPP’s most recent victories, natural products manufacturer NOW Foods, owner of the Protocol for Life Balance practitioner brand, rejected and destroyed a shipment of mint oil from India after determining it was adulterated with safflower oil.

## Unethical? Yes. Dangerous? No.

The good news is that so far, BAPP has “found very few examples where the adulteration we’ve uncovered has any real safety concerns. Even though deplorable, even though morally objectionable—very few (of these cases) have safety implications.”

There are, however, exceptions. Consider skullcap (*Scutellaria lateriflora*) adulterated with germander (*Teucrium chamaedrys*): the two herbs look alike, but germander contains hepatotoxic compounds while skullcap does not. When the one is substituted for the other—whether accidentally or intentionally—there’s a potential for liver damage.

Most botanical adulteration is not accidental or due to human error. It is an intentional and deliberate attempt to cut costs, enhance a product’s activity or increase its value.

Sudberg recommends that clinicians “use or sell only brands that offer as much transparency as possible, and have a demonstrated and verifiable commitment to quality. Asking about their sourcing and testing practices is always a good idea, but now it’s essential.” **QC**

# Liposomes, Micelles & Nanoparticles: Major Advance or Marketing Hype?

By Erik Goldman | Editor in Chief

## Liposomal formulations have been all the rage in the dietary supplement and nutraceutical industry over the last decade

With their promises of better absorption, increased bioavailability, and improvements in efficacy, liposomal and “nanoparticle” formulas are popular with health-conscious consumers. They’re showing up with increasing frequency across the spectrum of natural products.

The “nanoparticle revolution” began with very real advances in chemistry. But as is the case with so many health trends, enthusiastic marketers jumped in, oversimplifying the science and obscuring the terminology as they tried to generate buzz.

It is a challenge to distinguish the real promise of these delivery systems from the marketing hype.

### Basic Terminology

Technically, liposomes are a subset of lipid-based drug or nutrient delivery methods that utilize tiny phospholipid spheres to encapsulate water-soluble or lipid-soluble ingredients.

The phospholipid spheres may be single-layered, with their hydrophilic heads at the surface and their lipophilic tails toward the center. If these monolayered spheres contain nothing inside, they’re known as *micelles*. If the phospholipid monolayer contains an oil core of some sort, it is known as a *nanoemulsion*.

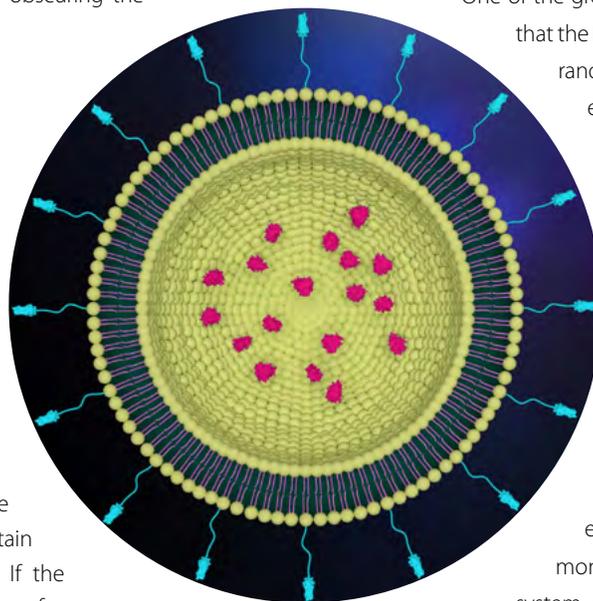
It is also possible to create bilayered phospholipid spheres that encapsulate water (and water-soluble ingredients). These are known as *liposomes*. The bilayers form concentrically: the outer layer has its hydrophilic heads at the surface with its tails toward the center, while the inner layer has its hydrophilic heads toward the center and its tails meeting those of the outer layer.

When properly made, the single and double-layered spheres should be “*nanoparticles*,” which means simply that the spheres are under 100 nanometers in diameter.

As a method for oral delivery of drugs or nutrients, nanoemulsions and liposomes have several advantages over standard tablet, capsule, or

liquid forms, at least in principle. These include:

- **Protection of bioactive ingredients** from breakdown by stomach acid
- **Higher bioavailability** compared with other oral forms, leading to potential dose-sparing and improved cost efficiency
- **Increased transmucosal and intestinal absorption and improved delivery** of bioactive compounds to target tissues
- **More adaptable** to incremental dosing regimens
- **Greater ease of use** for people who have difficulty swallowing pills or capsules



“One of the great aspects of the sub-100 nm particles is that the Brownian movement of the particles—the random vibration inherent in all substances—exceeds the force of gravity that would naturally cause lipids and water to separate, with the oils going to the top,” explained Christopher Shade, PhD, CEO and founder of [Quicksilver Scientific](#), one of the world’s leading producers and suppliers of liposomal and nanoemulsion-based nutraceuticals.

Liposomes, like other lipid particles, are cleared from the blood by the reticulo-endothelial system (RES), also called the mononuclear phagocyte system (MPS), a system of monocytes and macrophages in the lymph nodes, liver, and spleen. Shade says clearance correlates inversely with particle size: larger particles are cleared quickly; smaller ones remain in blood for longer periods.

### Old Tech, New Applications

Liposomal and nanoemulsion technology is not new. It emerged as a potential drug delivery method back in the 1970s, and it is used in the production of many consumer products, from skin creams to foods, in which fats and water-based ingredients must be brought together in shelf-stable mixtures.

Long ago, food makers figured out how to use surfactants—molecules that can interact with both water and oil—to stabilize oil in water or

vice versa. Soy-derived lecithin was among the first such surfactants, and it remains widely used. When synthetic surfactants, such as polyethylene glycols (PEGs) became available, emulsion technology grew in sophistication and breadth of application.

The technology took another evolutionary leap when high-shear processing methods, such as sonication and homogenization enabled producers to reduce the particle size of their emulsions down to the 10-200 nm range. By the late 1990s, liposomal formulations became the norm for many intravenous drugs including doxorubicin, amphotericin B, nystatin, and vincristine. Liposomes modify drug distribution in the body and mitigate somewhat the potential toxicities of these compounds.

It was only fairly recently that supplement companies became interested in liposomes. The shift was driven by research showing that many popular supplement ingredients like glutathione, B vitamins, Quercetin, Resveratrol, Berberine, Curcumin, Silymarin, and even Vitamins C and D, are not well-absorbed from standard oral tablets or capsules.

## The Glutathione Conundrum

[Dr. Shade](#), an environmental biochemist by training, says his interest in liposomes and nanoemulsions arose from a life-long concern about—and fascination with—mercury. He grew up in a Pennsylvania steel town where heavy metal pollution and mercury toxicity were all too common.

Quicksilver Scientific actually began as a testing company, providing medical practitioners with specialized tests for subspecies of mercury, based on technology that Shade patented while in graduate school.

“I was interested in the question of how different types of mercury are distributed in the body. That highlighted the problem of detoxification,” he said.

“I used myself as a laboratory. I got all my mercury amalgam (fillings) taken out, and then proceeded to do what most people did then which was to use synthetic

chelators. I used DMSA (dimercaptosuccinic acid). The idea was to get all of the mercury out of my body. But it really wasn't coming out of my body, it was just making me sicker and sicker. I started

**“Long-term stability is crucial and difficult to achieve in liposomes. Instability shows up most often in creaming, the rising to the top of free fats. On the other end of the spectrum, sedimentation is the falling out of insoluble compounds.”**

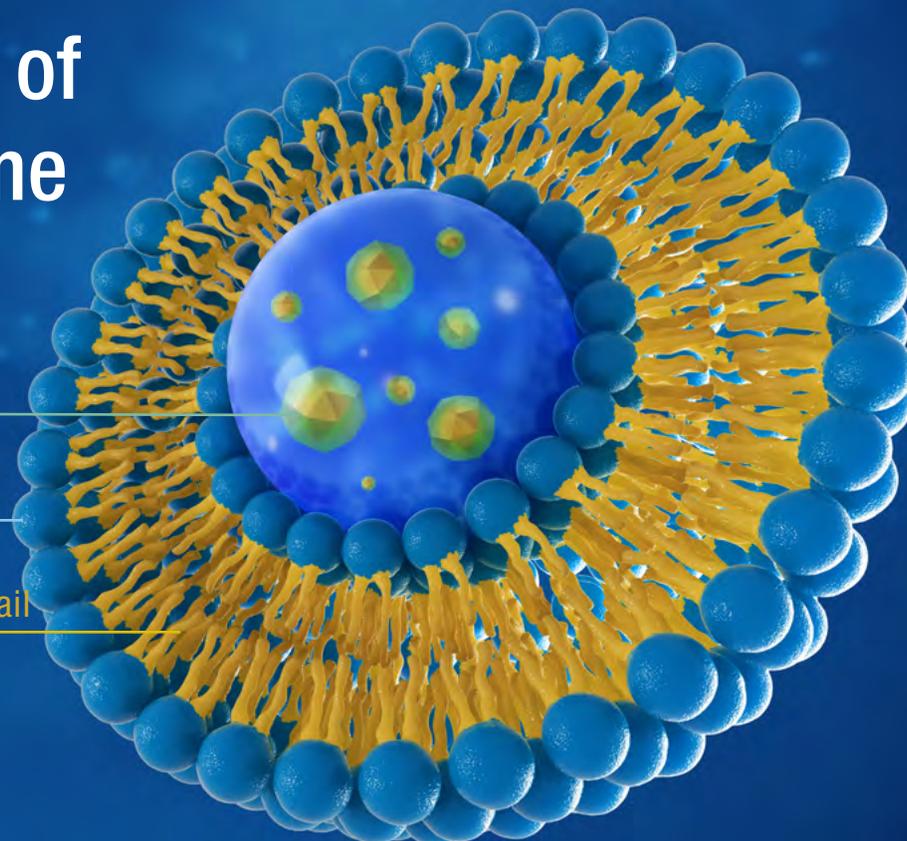
—Christopher Shade, PhD,  
Founder, Quicksilver Scientific

## Structure of a Liposome

Nutrient

Hydrophilic Head

Hydrophobic Tail



thinking more deeply about how the body is supposed to deal with mercury, how to detoxify it. And that led me to focusing on glutathione.”

Supplemental glutathione can be extremely helpful in detox protocols. But it is notoriously difficult to deliver to the target tissues. “Ordinary capsules don’t work for glutathione. There’s a bioavailability issue. The GI tract just takes apart the glutathione and you absorb the amino acids, not glutathione.”

In a search for ways to increase glutathione absorption, Shade explored nebulizer and transdermal delivery methods, which kindled an interest in liposomes.

He found a manufacturer who claimed to produce liposomal glutathione. “They sold me on the dream of liposomes, but the products didn’t deliver on the claims. They claimed to be at the nano range of under 100 nm. But I had the stuff analyzed. It was not “nano.”

Applying the old adage, “If you want something done right, do it yourself,” Shade invested in the technology to produce his own liposomal glutathione, as well as nanoemulsion forms of other low-absorption ingredients.

## Smaller is Better

The advantages of liposomal and nano-emulsion formulations are predicated on increasing both *absorption*—the amount of the desired substance that passes from the GI lumen into the bloodstream—and *bioavailability*, the amount of the active compound reaching the target tissues. At least in principle, by increasing absorption and bioavailability, one increases *bioactivity*—the net physiological impact.

Shade says a lot of companies are playing loose and fast with these terms, and not really backing up their claims with analytical studies of their own formulas. Likewise, some claim their products to be “liposomal” or “nano” when in actuality they are not.

The improved absorption happens when the phospholipid spheres are under 100 nm in size. But some so-called liposomal formulas contain particles in the 400-1000 nm range.

In a lab setting, researchers use a method called Dynamic Light Scattering (DLS), also called photon correlation spectrometry to assess particle size. This makes use of the scatter patterns made by a laser beam as it passes through the liquid sample. Absolute particle size and shape are confirmed with electron microscopy. Shade says Quicksilver invested in 3 DLS machines to constantly test its own formulas.

“Long-term stability is crucial and difficult to achieve in liposomes. Instability shows up most often in creaming, the rising to the top of free fats. On the other end of the spectrum, sedimentation is the falling out of insoluble compounds.” Either of these indicates a deterioration of the emulsion and loss of the potential benefits.

## Seek Transparency

Fortunately, there’s a simple no-cost way for practitioners and patients to get a reasonably accurate sense of whether a product is truly “nano” or not: transparency.

An emulsion with consistent particle size under 100 nm will appear completely transparent to the naked eye. That’s because the particles are smaller than the shortest wavelength of visible light, which is around 400 nm, so they do not block passage of light.

A “nano” or “liposomal” solution that appears cloudy, milky, or opaque contains particles that are 400 nm or greater, which puts them out of true nano range.



Stability of the emulsion and even distribution of the phospholipid particles are also important quality variables, says Shade.

“This needs to be factored into the expiration date of these products. It’s not just the expiration of, say the glutathione itself, but also the life expectancy of the liposomes. Typically, this is in the range of 1-3 years.”

For some ingredients, the liposomes themselves last longer than the active compound inside them. This is true of glutathione, and nicotinamide mononucleotide (NMN), which only lasts for about a year.”

Shade says Quicksilver has invested heavily in its analytical testing capabilities.

“We are the only company that puts particle size range information for each batch on the Certificates of Analysis. We measure particle size first, during the manufacturing process. Particle size is what determines stability, consistency, absorption, and efficacy.”

Quicksilver also runs routine pharmacokinetic analyses on its nanoemulsions, using classic “Area Under the Curve” methods that compare blood levels of the nanoemulsion formulations against curves tracing blood levels from intravenous dosing of the same compounds.

“We invested a quarter of a million dollars in a Liquid Chromatography/Mass Spectrometry triple quad system, which is a fancy way of finding a compound by measuring its mass in blood.”

There’s no question that true liposomal or nanoemulsion formulas will be more expensive than standard tablet or capsule formulations of the same ingredient.

If nanotechnology in the supplement industry is to deliver on its promises of better absorption and improved efficacy, and not devolve into an empty marketing gimmick, the companies producing these products must make the investments in production technology and product testing to ensure the integrity of their products.

Educated practitioners who understand the potential of liposomal and nanoemulsion formulas can play an important role in taking supplement brands to task on their “nano” claims. **QC**

# “We Had To Remain Open”: A Global Supply Giant Affirms Its Core Mission

By Erik Goldman | Editor in Chief

“As the major supplier of the world’s hard-capsules for both pharmaceutical and nutraceutical applications, we understood from the start that we had to remain open, no matter what.”

It is no small feat for a global corporation with 24 offices and production facilities on four different continents to respond effectively to a fast-moving pandemic like COVID-19.

For nutritional and pharmaceutical ingredient manufacturer, Lonza, the challenges posed by COVID were a fundamental test of the company’s core mission: “providing solutions that improve quality of life by preventing illness, enabling healthier lifestyles and supporting a safe environment.”

Like many other companies in the natural products sector, the Basel-based company had to contend with a rapid surge in demand for its ingredients and its array of capsules and dose delivery technologies at the same time as the epidemic was disrupting supply chains and manufacturing procedures.

## Securing Supplies, Optimizing Safety

“From securing our supply chains, to optimizing the health and safety of our factories, to delivering quality products to our customers and ultimately to consumers and patients, globally, Lonza is continuing to work tirelessly to meet the health needs of the world during this time of uncertainty,” says Vaughn DuBow, North American manager for Lonza’s Hard Capsule, Ingredient, and Dosage Form Solutions portfolios.

Among the company’s top-selling branded ingredients are [Carnipure™](#) L-carnitine, the arabinogalactan and flavonoid-rich [ResistAid™](#) and [UC-II®](#) undenatured collagen. Through its [Capsugel](#)



brand, the company also manufactures literally billions of [capsules of diverse forms](#) and materials for the global supplement and pharmaceutical industries.

“Lonza recognizes its essential role during this crisis and fully embraces its responsibility to provide,” said DuBow. “As the major supplier of the world’s hard-capsules for both pharmaceutical and nutraceutical applications, we understood from the start that we had to remain open, no matter what. Lonza’s people have tirelessly dedicated their time to ensuring that we could continue to deliver on the world’s healthcare needs, and that our people remain safe and healthy while doing so.”

He said the response efforts centered on three main objectives: ensuring the safety of Lonza’s workforce, securing the company’s vast supply chains, and providing its client companies with real-time market data on the evolving pandemic so they could make more informed and intelligent business decisions.

## Mitigating Viral Spread

Like most major corporations, Lonza quickly instituted protocols to mitigate spread of the virus. These included:

- **Indefinite restrictions** on employees’ local and international business travel, and replacement of meetings with virtual alternatives to the greatest possible extent.
- **Encouraging office-based employees to work from home** whenever possible.
- **Advising employees on minimizing the risk of infection** both at work and at home via frequent e-mail updates and reminders of health and safety services.
- **Requesting that any employees experiencing symptoms inform their line managers and self-quarantine for 14 days.**
- **Increasing safety measures** in factories, offices and distribution centers.
- **Providing sick pay** for those who contract the virus, and paying all hourly and salaried staff affected by temporary work stoppages in full for a minimum of twelve weeks.

In the manufacturing facilities, Lonza's managers implemented a host of special measures to safeguard employee health and safety:

- **Creation of Site Operational Zones** that assign cohorts of employees to specific operation zones. When employees arrive to work, they report directly to their zones and work in those zones for the duration of their shifts. Employees are not allowed to visit other zones. Restricting employee movement around the facilities reduces potential for exposure and transmission.
- **Mandatory temperature screenings:** From the beginning of the pandemic, Lonza instituted frequent temperature and symptom checks prior to employees starting their work.
- **Mask Mandates:** Lonza employees are required to wear face masks at all times while in the workplace.
- **Social Distancing:** Employees must maintain 6-foot (1.8 M) distances between colleagues and practice social distancing while at work.
- **Frequent disinfection of work spaces**
- **Wide Distribution of Hand Sanitizer Stations** in all Lonza facilities.
- **Mandates to Stay Home When Ill:** Employees are encouraged to stay home from work if they are feeling even minor symptoms suggestive of COVID-19.

Everyone in the business sector is trying to understand how the pandemic is playing out in different communities across the globe, how it is affecting consumer behavior, and how it is impacting the various sectors of the economy.

## Consumers Seek Resilience

Beginning in March, Lonza's Americas Region marketing team began a series of four surveys to gauge the consumer landscape relative to

COVID-19. They gathered data from 1,000 consumers via [Suzy](#), a real-time market research platform.

Participants were between the ages of 18 and 72. At the time they were surveyed, they were current consumers of immune supplements, sports supplements, RX/OTC products, or some combination thereof.

The data indicate that three-fourths of consumers have increased their immune supplement use over the course of the pandemic, and 50% had increased their immune supplement purchases between May and June compared to March through April.

- **44% increased their purchases** because they are fearful that immune support products may be less available in the near future
- **45% are concerned about a second wave of COVID** and want to protect themselves and their family members
- **74% are seeking continued or enhanced immune support**

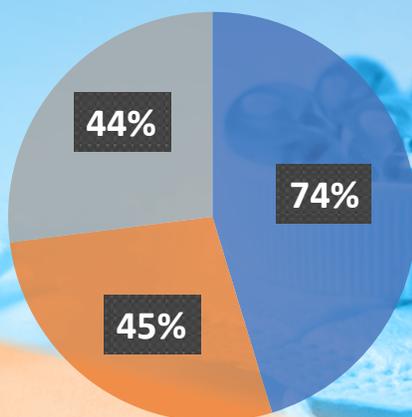
Lonza's AMER marketing team discovered that nearly half of consumers have had no change at all in their sports nutrition supplement regimens in the past 6 weeks while 46% have increased their usage and 8% have decreased their usage.

Regarding OTC products, one-third of respondents indicated that they have increased their usage/purchases in the past 6 weeks while 7% have decreased their consumption. This category included drugs like Tylenol (acetaminophen), Advil/Aleve (ibuprofen), and allergy drugs like Claritin and Allegra.

What was truly striking was the finding that nearly 20% of respondents believe that taking drugs like Tylenol and Advil will support their immune systems and help to protect them against COVID, says DuBow.

That belief, spurious and unscientific as it may seem, reflects the high level of concern about COVID within the general population, and the strong desire people feel to take extra measures to protect themselves. **QC**

# Purchase Choices Reflect Consumers' Concerns



In a recent survey, 1000 supplement users gave reasons for their recent immune product purchases

- **Continued/enhanced immune support during COVID-19**
- **Concern of second wave of COVID-19 negatively impacting my/family members' health**
- **Fearful of immune support products being less available in the near future**

HPC is grateful to our industry partners for their support of  
*Quality Counts: A Clinician's Guide to Supplement Quality*

**Lonza**

**Capsugel**



**QUICKSILVER**  
S C I E N T I F I C<sup>®</sup>



**Holistic Primary Care**

**NEWS FOR HEALTH & HEALING<sup>®</sup>**

Erik Goldman  
Co-Founder - Editor

Meg Sinclair  
Co-Founder - Publisher

[www.holisticprimarycare.net](http://www.holisticprimarycare.net)

