Choose Me

There’s a fortune in them there alternative therapies, and the market is as unregulated as the wild West. What’s a consumer to do? Susan Gerhard reports.

April 1, 2000 By Susan Gerhard

This could be the magic bullet!” crows LaneLabs’ ad for MGN-3 in three-inch type across a page in the magazine Alternative Medicine. “Magic bullet”!?! A typical consumer’s BS detector registers such phrases, especially in cases like this: LaneLabs, by law, can’t specify the condition for which its rice bran– and–medicinal mushroom product is allegedly a miracle cure. Since the passage of the contentious Dietary Supplement Health Education Act (DSHEA) in 1994, which prevents the Food and Drug Administration (FDA) from banning herbs and nutritional products simply because they function differently from foods, the government has imposed strict limits on what manufacturers can tell consumers about their products. Mention of a disease is out unless the product’s research backup meets either the Federal Trade Commission’s vague “competent and reliable” standard or the FDA’s still-unspecified benchmark of “significant scientific agreement.”

These restrictions have turned labeling and advertising into a coy code that can only hint at the real benefits of supplements. Consumers are more confused than ever because there is still no easy way to find out if a product is snake oil or not—a key concern for HIVers who wonder if their favorite herbs and nutrients can be harmful or, at the very least, a waste of money. For instance, even though the two-page “Magic Bullet” MGN-3 pitch contains the government-mandated disclaimers in typically tiny type—“This statement has not been evaluated by the FDA” and “This product is not intended to diagnose, treat, cure or prevent any disease”—the ad tries to fill in the blanks with summaries of clinical research: MGN-3 augments natural killer cell activity and “shows promise as an agent for treating patients with AIDS.” Well, what does that mean?

Promise is a seductive word for HIV positive adults, 78 percent of whom use alternative treatments, according to a 1995 study. The AIDS Research Center of Bastyr University, a naturopathic medical school in Kenmore, Washington, reports that among the most popular treatments for HIVers are vitamins such as C and E; foods that double as medicines, like garlic; and herbs such as echinacea. These items, along with amino acids, minerals and other naturally derived substances, are categorized by the DSHEA as “dietary supplements.” Since the law passed, annual sales of supplements have ballooned to $14 billion. Clearly, promises are being made by the boatload. But are they being delivered? Are the supplements manufactured responsibly, with certifiable quality control? Or are manufacturers making a killing with unsubstantiated claims?

“It’s the wild, wild West show out there right now,” says Fred Bingham, executive director of Direct Access to Alternative Information Resources (DAAIR), a New York City nonprofit AIDS buyers club. He said the same thing in Washington, DC, last June at an FDA public meeting seeking input on how to better implement DSHEA. Bingham, a long-term AIDS survivor who turned to alternative therapies because his liver couldn’t tolerate pharmaceuticals, founded DAAIR in 1991 to provide PWAs with access to and information on a broad range of supplements. Since then he has been a staunch advocate of freedom of choice in medicine.

During the battle to pass DSHEA, he spoke before Congress and a national TV audience about PWAs’ need for access to alternative therapies. Now, however, Bingham wants the FDA to take more control over the industry’s often-outrageous claims by coming up with a more informative labeling system. “Even thoughtful citizens would be overwhelmed when attempting to evaluate which of these health claims have merit,” he says. And he has called on the agency to institute Good Manufacturing Practices (GMPs)—enforceable standards for production.

Bingham and his allies, however, are by no means seeking restrictions on the products: They argue that dietary supplements—derived from nature and mostly in circulation for decades, if not centuries—have proven safety records. And, they say, hundreds of studies—generally small-scale—have found that many products can at least help to prevent or treat various diseases. So besides assuring that manufacturing is done properly, the only role for the government, say advocates such as Citizens for Health (CFH), a national grassroots lobby group for access to alternative treatments, is to give consumers the best information about how to safely and effectively use these products. “That’s how informed consumers make better choices,” says Susan Haeger, CFH’s president and CEO.

On the pro-regulation side of the debate are other consumer groups such as the Ralph Nader–founded Public Citizen, which argues that DSHEA should be repealed because it gives supplement manufacturers a free ride. Larry Sasich, a pharmacist with the organization, says, “What we have now is a marketplace that’s full of fraudulent and untested products.” The FDA, he says, should not only decree GMPs, it should also ban promotions for uses that have not been confirmed by scientific consensus. “If they make a medical claim, the product must be regulated, tested and approved the same way that prescription drugs are,” Sasich says. “It’s put up or shut up.”

Many PWAs feel caught between the rock of over-regulation and the hard place of marketplace mayhem. While advocates such as Bingham call for smarter regs that protect access, expand information and ensure quality control, others—like Gregg Gonsalves, policy director of the Treatment Action Group in New York City—echo Public Citizen’s deeper frustrations with the industry. “Little clinical data supports the use of these products,” he says, adding that some even carry health risks.

What data do exist don’t always reach the public. FDA rules say that supplement makers can only make statements about how their product affects the “structure and function” of the body—as in MGN-3’s “augments natural killer cell activity”—but no claims about treating disease, without FDA

approval. For instance, the antioxidant alpha-lipoic acid can't, by law, be said to "treat liver disease," but it can "provide nutritional support for normal liver functioning." As few disease-related claims have emerged from the FDA's bureaucratic maze, supplement manufacturers offer up hyperbolic hints rather than straightforward assertions about what their products may be able to do. Prior to DSHEA, if disease claims were made for supplements, the FDA asserted the right to treat the product as a drug, threatening to yank it off the market until the manufacturer could run large, expensive safety and effectiveness trials and provide pharmaceutical-style GMP paperwork.

But the idea of giving the FDA back the power to ban supplements raises the hackles of many alternative-therapy advocates, who claim that the agency has long been hostile toward the industry. Consider the record: In the early '60s, the FDA unsuccessfully attempted to require labels on vitamins that would have denied any scientific basis for their routine use. Until the mid-'90s, FDA raids and edicts against supplement manufacturers and even alternative practitioners—accused of selling "unapproved drugs"—were not uncommon, though often later ruled illegal by the courts. In 1993, agency officials, citing "safety concerns" about untested supplements that could constitute "a class of products to compete with approved drugs," proposed a new regulatory scheme: reclassifying all amino acids and many herbal remedies as "food additives" or "drugs"—in effect, banning them. Both consumers and the industry responded with a massive lobbying campaign—more than a million letters to Congress—which led to the passage of DSHEA.

Since then the FDA has found its attempts to control supplements out of step with the courts and Congress. In January 1999, a federal judge ruled in favor of CFH and several other plaintiffs who had sued the FDA for denying approval of four research-based claims that particular nutrients could prevent particular diseases.

The judge said that such claims should be allowed if they are not false, along with a disclaimer that scientific consensus had not yet been reached. In February 1999, another federal judge reversed the FDA's effort to ban the cholesterol treatment Cholestin, which is made from Chinese rice fermented with red yeast. (The FDA is appealing.) The agency had labeled it an "unapproved drug" because it contained, naturally, an ingredient sold as a synthetic pharmaceutical by Merck. And last August, the Congressional General Accounting Office rebuked the FDA for failing to observe scientific standards when proposing to restrict sale of Ephedra (the herb ma huang), used to treat both asthma and weight loss.

In 1998, the agency moved to broaden the definition of "disease" so that even pregnancy, menopause and such related symptoms as morning sickness and hot flashes would be off-limits for dietary supplement labels. Faced with a storm of protest, the FDA backed down in January 2000.

While disease claims have been bitterly contested territory, few dispute that consumers lack guarantees that they're getting products with the potency and purity promised by the maker. A healthy skepticism rules at the PWA Health Group, a buyers' club in New York City. Its information sheet about the herb St. John's wort, for example, states, "We know next to nothing about the purity or consistency of the St. John's wort products that we carry. They are not pharmaceutical-

grade, and like many products sold at health food stores, you have only the manufacturer's assurance of good quality control."

Indeed, Consumer Reports, the Los Angeles Times and other publications have reported on tests of herbal products showing wide variations in potency. Consumer Reports' tests of 12 brands of echinacea last March, for instance, found a sixfold difference among levels of four of the herb's key compounds—though herbalists point to flaws in such tests. But no institute regularly tests even a few products, much less a cross section of the vast numbers on the market.

Unlike in Germany, where druglike supplements such as amino acids are subject to intense scrutiny—premarket review, certification of GMP compliance—in the United States, supplement makers have to meet only the same simple standards as food producers: ensure that products are unadulterated and uncontaminated. And even then there is no mandatory testing.

The 1994 law authorized the FDA to issue GMPs, but more than five years later, no such guidelines exist. In January, the agency announced that GMPs would be adopted by 2010. "That's absurd," says DAAIR's Bingham. "GMPs should be in place within two or three years." Other freedom-of-choice advocates charge that the agency has been so focused on attempts to restrict supplement marketing that it has yet to prioritize simple quality-control measures. Donald Pohl of the FDA's Office of Special Health Issues, replies, "When we've proposed GMPs before, there have been lots of disagreements about them. So we want to be upfront that it will take a while to work with everybody on these issues." In the meantime, he advises PWAs, "Buy from a reliable source, and strongly evaluate the claims being made." (See "Guide Dog," below, for specific tips.)

GMPs generally require product standardization, and while that's easy to do for vitamins, minerals and amino acids, it's more complicated when it comes to plant-based products. Most herbs have a large number of "active" ingredients that may be contributing to the desired effects. There are good reasons for standardization: to better preserve the active component, to concentrate it at a tolerable level, to eliminate undesirable plant parts and to ensure potency. But herbalists fear that producing standardized extracts—new forms of old herbs—may make them less effective or even dangerous. "Chemistry has tended to push us away from the living organic processes," say Roy Upton, executive director of American Herbal Pharmacopoeia (AHP), a group that sets quality-control standards for herbs.

Upton fears that the recent entry into herbal manufacture by Warner-Lambert, American Home Products and other big drug companies—which together account for most vitamin and mineral production—may increase the problems. "Many of these companies don't have full knowledge of how to standardize herbs," he says. Though their facilities follow GMPs for drugs, big firms may have little experience in herbal quality control, including such details as when to pick and how best to dry and prepare the plant. (Upton's AHP has published such guides for seven herbs, with more in the works.) "What the drug companies look for," Upton says, "are PhD types and pharmacists with credibility, but without training in herbs." Noting the small numbers of "experts on the finer points of herbal medicine," Upton predicts, "The drug companies are going to be dancing around this whole conversation until they figure out that they have to get closer to the plant."

Industry insiders admit that any system of self-regulation is far from fully up and running. Upton says that fewer than 1 percent of herb makers employ AHP's quality-control standards. According to Upton, most of these firms are supplement-only producers in business for decades that are members of industry trade associations. He adds that many entrepreneurs not part of such groups have recently jumped on the dietary-supplements bandwagon, delivering products to convenience stores, truck stops and even pharmacies.

But even if supplements are pure and potent, are they safe? DSHEA grandfathered in as "safe" all supplements on the market before 1994, but required those that include newer ingredients to have "history of use" and "evidence of safety" documents submitted to the FDA before being sold. Still, the agency has the burden of proving a substance unsafe—in court. Most manufacturers balk at increased safety regs, assuring consumers that their products have been tested by time. The industry relies on the record of 2,621 adverse effects of supplements reported to the FDA from 1993 to 1998—compared to two million hospitalizations and 100,000 deaths annually from the side effects of regulated drugs. What the companies fail to mention is that the reporting system for supplements is even less reliable than the inadequate one for drugs.

And while medicinal foods and herbs do have histories going back thousands of years, they are being manufactured and used in increasingly novel ways. The preventive-medicine model is giving way to that of the quick remedy; time-honored traditions break down under the weight of modern practices—extraction, new plant forms, off-label uses and unheeded dosage guidelines. DAAIR's Bingham says that "a lot of people at our buyers club use these things at treatment doses, as if they were drugs." Adds Fred Schaich, founding director of the Portland, Oregon–based Institute for Alternative Research on AIDS, "There are PWAs taking supplements who have the philosophy that 'if a little is good, a lot is great.' But some 'natural' products can actually be toxic, especially for sick people."

Almost everyone agrees that more clinical studies of supplements, especially new ones, will only help. But getting the research done remains difficult, with no guarantee that a company's investment will benefit it for a product that can't be patented. Less than 1 percent of the herb industry's sales, estimates Mark Blumenthal, director of the American Botanical Council, goes into research.
"One model we don't want," says John S. James, editor of AIDS Treatment News, "is the high-cost efficacy testing of pharmaceutical drugs, leading to exorbitant prices and delays in access. With natural products that are not very patentable, the delays could last forever." But without adequate financial incentives, the industry may never get around to more testing. And the National Institutes of Health (NIH), which is supposed to fill such research gaps, still spends very little on studies on whether supplements prevent or treat any disease—including AIDS.

Meanwhile, controversy rages over how the research should be done, at least with respect to herbs. Herbal researchers say they have a difficult time getting their research protocols recognized by mainstream scientists, who in turn complain of what they consider a lack of rigor in alternative medicine. The NIH's new Office of Dietary Supplements, established under a DSHEA mandate, is trying to bridge the gap between old science and new, sponsoring symposia to sort

through the studies that exist and promoting more.

With or without more research, DAAIR's Bingham insists that it's time for the FDA to institute Good Manufacturing Practices with teeth, as well as clarity in labeling. Without independent assurances of product quality and broad consumer access to the data, Bingham says, "PWAs are going to stay stuck between uncertainty and confusion."

GUIDE DOG

Michael Onstott leads you through the maddening maze of the alternative-treatment marketplace. Start here:

High Potency Or Low? Brand name or generic? Tablet or capsule? And that's just a start. Buyers clubs? Health-food stores? Books or Internet? Figuring out how to choose, use and pay for supplements when facing hundreds of products, an avalanche of marketing hype and few quality standards can send an HIVer back to bed. This will help you conquer the confusion.

Design a strategy: The professional advice of nutritionists and herbalists is one way to go. Such consultations can be had for free or at reduced cost for many PWAs, especially those with specialized medical coverage or access to free services through local AIDS programs and county health departments in certain states, such as California and New York. Whatever you do, be specific about what symptoms you want to treat and what you hope a supplement or herb regimen will accomplish.

Gathering Information: Several buyers clubs provide fact sheets on many supplements and treatment issues. "Buyers clubs do the research to help consumers make informed choices," says Fred Bingham, director of Direct Access to Alternative Information Resources in New York City. Books, newsletters, Internet sites, savvy PWAs and even health food stores can also provide valuable—or, for that matter, inaccurate or biased—information on vitamins and herbs. New York City treatment activist and supplement superman George Carter advises, "Maintain a healthy skepticism and an open mind."

What and How Much to Take: Once you've done some homework and had a sitdown with a practitioner (if possible), it's time to decide which supplements and dosages are best and how they fit into your regimen. Do you want to "replace" nutrients, boost immune function, reduce the side effects of HIV drugs, treat specific conditions or a combination of all of these?

Safety: Taken as directed, nutritional supplements are generally harmless. However, so-called contraindications as well as interactions with prescribed drugs—especially when using herbs—can occur. Discuss with a nutritionist or herbalist, as well as your doctor, before starting.

Caps, Tabs or Liquid: The two most important issues when deciding which form of a supplement to take are overall effectiveness and how well each product is absorbed and used by the body (bioavailability). There are no absolutes, but some forms are likely better for certain uses than

others. You may find that herbalists prefer liquid extracts or standardized tablets for long-term treatment of chronic conditions and traditionally cooked tea for acute infections. On the other hand, nutritionists might favor nutrients in soft-gel caps or regular capsules over tablets or timed-release supplements. (Note: Some top-quality multivitamin tablets are well absorbed.)

Quality: Choosing reputable brands with expiration dates on the labels—those recommended by licensed practitioners and well-respected buyers clubs—is the best way to assure quality and freshness. (Check whether the manufacturer is affiliated with the Council for Responsible Nutrition or the American Herbal Products Association, which maintain minimal standards.) One recent UCLA study of herbal supplements found that the labels were generally correct. Some druglike products (GBL, GHB), herbal stimulants, sexual energizers and bodybuilding aids are the most likely to be mislabeled, worthless or even harmful.

Seal Of Approval: Allergy Research Foundation, AMNI, Health Concerns, Herb Pharm, Jarrow, Nature’s Life, Solgar, Source Naturals, Super Nutrition and Twin Lab are all reputable brands.

Saving Money: Once you’ve chosen the products and brands you want, buyers clubs, discount health food stores, drug stores and the Internet are good sources for low-cost supplements. Be wary of extremely low-cost supplements (quality may be compromised) or bogus reasons to charge excessively high prices—such as unsubstantiated claims of product superiority, “secret” or “all-natural” formulas, and “special” or synergistic ingredients. A limited number of free supplements (often including multivitamins) are available to low-income residents of Arkansas, Connecticut, Delaware, District of Columbia, Hawaii and New York through ADAPs (AIDS Drug Assistance Programs). In addition, regional food banks may provide free vitamins.
