



Here's To Your Health!

A Phoenix Fire Department Health Center Publication

www.phoenixfirehealth.com



April
2008

Supplements are big business and high profile these days. The following article explains what the ordinary consumer may not know and the dangers associated with supplement use. Talk to your doctor prior to taking supplements. The Health Center promotes a healthy lifestyle and recognizes the difference between looking healthy and being healthy. Enjoy the article.

Beyond Balco: The Untold Dietary Supplement Scandal By Jeff O'Connell, Men's Health

WARNING: If you think only home-run kings juice it before they jack it, try this on for size: Your muscle supplements might contain designer steroids, too.

DIRECTIONS: Before you pop another pill or mix another protein shake. Take a close look at the label for what manufacturers are hiding — in plain sight. You don't need a Ph.D. to formulate a best-selling supplement. In fact, Derek Cornelius did it with an undergraduate biology degree.

In the late 1990s, Cornelius, president of the supplement company Syntrex Innovations, released a fat-loss product called Triax Metabolic Accelerator. The pills worked by pegging your metabolism in the red zone, the company claimed. Sales soared.

But Cornelius's cash cow was cooked in November 1999, when several people filed complaints with the FDA, reporting they had required medical attention for abnormal thyroid function after taking Triax. It turned out the active ingredient in the supplement was tiratricol, a naturally occurring chemical that's structurally similar to a powerful thyroid hormone.

"When used as a drug, tiratricol can actually inhibit your body's ability to make its own thyroid hormone, slowing down your metabolism," says Barry Marc Forman, M.D., Ph.D., the Ruth B. and Robert K. Lanman Chair of gene regulation and drug discovery at City of Hope National Medical Center in Duarte, California. "It also has the potential to bind to thyroid receptors in your heart, which can lead to an elevated heart rate, palpitations, and other potentially harmful cardiovascular side effects."

Asked why he would risk FDA scrutiny and a slew of lawsuits to make a supplement, Cornelius seems surprised by the question. "That was the last thing I thought the FDA would target," he says. "To me, it appeared to be well within the parameters set by the federal government. It was naturally occurring, and studies showed it was safe."

And it has been shown to be safe — when it was prescribed by European physicians to treat an overactive thyroid. So not surprisingly, the FDA concluded that the active ingredient in Triax was indeed a drug, not a dietary supplement, leading the agency to pull Triax from the market in 2000. Syntrex later reached several seven-figure settlements in response to class-action lawsuits, but did not admit to wrongdoing.

Under a Microscope

Dietary supplements are the ultimate merger of self-improvement and free enterprise, with the promises and pitfalls of both. The best supplements can help us stay strong and healthy, but the industry selling them can be a maze of good products and junk, honest companies and hucksters, sound rules and misguided regulations (none of which can be enforced easily). So when you purchase that bottle of pills or canister of powder, you may be walking out with a useful concoction or the equivalent of sawdust — or something truly harmful. *Con't. page 2*

"One of every four supplements we've tested had some problem," says Tod Cooperman, M.D., president of ConsumerLab.com, a company that's tested more than 1,900 dietary supplements for quality and purity. For example, Cooperman's team analyzed Nature's Plus Ultra Chondroitin 600, a joint-health supplement that claims to be "the highest potency, most concentrated chondroitin supplement ever developed." But the lab results showed that the product didn't contain even trace amounts of chondroitin. In fact, eight of 11 chondroitin supplements failed to deliver on label claims. You can't even count on multivitamins: 52 percent of those didn't make the grade in ConsumerLab.com testing. Worse, many of these multis contained excessive amounts of lead, prompting the nation's second-largest supplement retailer, Vitamin Shoppe, to pull one of its multivitamin formulations from store shelves last January.

In many cases, the problem starts at the supplier. "Most of the small manufacturers don't test raw materials coming through the door," says Jeff Feliciano, formerly the director of research and quality assurance for Weider Global Nutrition. Instead, these firms rely on paperwork called a certificate of analysis. This is a supplier's written promise of an ingredient's quality and purity. Unfortunately, it's just that: a promise. "There's an old saying: Anyone with a printer can produce a certificate of analysis," says Warren Majerus, an auditor with a nonprofit organization that inspects supplement plants worldwide.

To avoid the risk of putting damaged or worthless goods on retailers' shelves, many larger supplement companies have voluntarily adopted a policy of either testing raw materials in-house or sending them out to a reliable third party. "It's the only way to truly protect the reputation of your product and your customers' health," says Feliciano.

But to raise standards industry-wide, the FDA issued new guidelines in June, declaring that all dietary supplement manufacturers are now responsible for having product ingredients tested. "Manufacturers obviously can still receive a certificate of analysis, but we're saying, 'Now, you must confirm it,'" says Vasilios Frankos, Ph.D., the director of the division of dietary-supplement programs at the FDA. Enforcing the guidelines could be difficult, however, considering that while the number of supplement makers increased between 2003 and 2006, the number of FDA investigators declined by 16 percent. To further complicate matters, the quality of raw materials isn't the only question mark — sometimes it's their identity.

Spiking Your Shake

"Random batch spiking" has a long history in the supplement business. It works like this: "The manufacturer sprinkles an illegal substance into an over-the-counter dietary supplement," says Feliciano. "The legal ingredients are claimed on the label, but they don't disclose the drug."

Chris Lockwood, formerly the senior category director of diet, energy, food, and beverage at the supplement retailer GNC and now a doctoral candidate in exercise physiology at the University of Oklahoma, recalls taking a popular protein powder in the early 1990s: "When I first took it, I got great gains. I felt great. I got strong. I got lean. But then something happened to it." Years later, he related his experiences to one of the product's formulators who confirmed for him that the powder had been spiked with Clenbuterol, an asthma drug that supercharges your metabolism.

"Drugs like this don't typically show up on lab tests, unless someone's looking for them," says Lockwood. "The idea is to use them to quickly build a customer base and steal market share by making a product that works 'better' than its competitors."

That sales strategy is still in evidence. In May, the FDA advised consumers to discontinue the use of two "male-enhancement" supplements: True Man and Energy Max. In a chemical analysis, the FDA discovered that both products contained "undeclared analog ingredients." An analog is defined by the FDA as a chemical that has a similar structure to a prescription drug. True Man contained an analog of sildenafil, the active ingredient in Viagra; Energy Max contained an analog of vardenafil, the active ingredient in Levitra. (America True Man Health, which distributes and packs both products, hadn't responded to our queries as of our press date.)

While it may sound appealing to get more than you paid for, the physical cost of a spiked supplement may be quite high. "It's like randomly taking a drug with no forethought about proper dosage, negative side effects, or the way it may interact with other medications you're taking," says Dr. Forman.

Even if all the ingredients are safe (and listed), you still may not be swallowing what you expected. "Fairy dusting" is the name of this industry trick, says Lockwood. Say the hot item of the moment is whey-protein isolate, which is a more pure form of protein than the less expensive whey-protein concentrate. The marketing department at Company X tells its R & D team, "This new product has to contain whey-protein isolate. That's what consumers are buying." But when the formulators crunch the numbers, they realize they can afford to use only 1 gram (g) of isolate for every 40 g concentrate. To keep the whey-protein isolate from standing out as the bottom entry in the ingredients list, they bunch the huge amount of concentrate and the tiny amount of isolate together into a "proprietary protein blend" whose collective heft places it near the top of the list. "This creates the impression that the canister is loaded with something that's really only present in near-trace amounts," says Lockwood.

One recent example of possible fairy dusting — or perhaps simply the same net effect due to poor formulation — comes from a ConsumerLab.com test of Muscle Marketing USA ATP Creatine Serum. The manufacturer claimed one serving provided 250 milligrams (mg) of a "proprietary creatine phosphate complex." But Dr. Cooperman and his colleagues determined it contained only 26 mg actual creatine. "To put that in perspective, a single dose of most products promises and delivers 5,000 mg creatine," says Dr. Cooperman. GNC ProPerformance, MuscleTech CellTech, and EAS Phosphagen, among others, all met their label claims. (Through e-mail correspondence, Muscle Marketing USA claimed that their product's trade secret formula is too complex for ConsumerLab.com to accurately determine its creatine content.)

Of course, many people simply fall prey to bogus marketing copy. Last January, marketers of four diet products — Xenadrine EFX, CortiSlim, One-A-Day WeightSmart, and TrimSpa — agreed to settle charges of false advertising made by the Federal Trade Commission, and paid \$25 million in claims. For instance, investigators found that before-and-after subjects had lost weight by dieting and exercising, not by popping to the FTC, this company's own research showed that members of a placebo group lost more weight than the supplement takers did. Consider this more confirmation that when it comes to losing your gut, there's no substitute for working out and eating right.

A Tale of Two Industries

If a quarter of all dietary supplements failed to match label claims when tested by ConsumerLab.com, that means three-fourths did live up to their promises. "There's not a single brand with a broad product line that I can think of that always tests out well," says Dr. Cooperman. "But among multivitamins, Centrum and One-a-Day tend to fare well when we test them. For joint supplements, Nutramax and Schiff are among the most reliable. Nature Made and Nature's Way also have a good track record." Among lower-priced brands, Dr. Cooperman says, Wal-Mart's Spring Valley brand and Puritan's Pride, a catalog brand, generally offer solid products.

Indeed, many U.S. companies make high-quality dietary supplements. According to Majerus, the FDA's new guidelines were met or surpassed pre-emptively by companies such as Schiff and GNC (which makes its own house brand). "Big companies like that refuse to participate in any of this renegade activity," says Feliciano. "They have all sorts of defense systems in place. You'll often find four or five Ph.D.'s working in quality control, and these are big-money positions. When they sign off on something, they're legally responsible." Both experts say the middle third of U.S. supplement companies, while not as far along as the top tier, are already in the ballpark when it comes to playing by the new FDA rules.

The problem is the bottom third of what is a huge industry, one whose fringe products are the spawn of amateur chemistry experiments using pharmaceutical-strength ingredients. "There are guys tarnishing the reputation of the whole industry because they're making potentially dangerous products in their home kitchens," says a former researcher at Yale University school of medicine, who requested anonymity since he now consults with supplement companies on product formulations. What's more, these lower-tier manufacturers often thrive on loopholes in the Dietary Supplement Health and Education Act (DSHEA).

The DSHEA, passed in 1994, doesn't require supplement companies to prove their products are safe and effective before bringing them to the market. Instead, supplements are allowed to be stocked on shelves as long as (1) the product label doesn't claim the supplement diagnoses, treats, cures, or prevents any disease, and (2) its ingredients are naturally occurring. The second stipulation is a bit deceptive. It means that if a natural compound can be chemically synthesized in a lab and isn't classified as a controlled substance, it can legally be used as an ingredient and sold over the counter. That's no problem when the active ingredient is vitamin E. But if it's a steroid-like substance, the loophole can be exploited.

One of the first chemists to do just that was Patrick Arnold, the man best known for synthesizing "The Clear," the designer steroid given to Barry Bonds by the Bay Area Laboratory Co-Operative (BALCO).

In the mid-1990s, Arnold discovered — or rather, rediscovered — the active ingredient in androstenedione, the infamous Mark McGwire supplement. This ingredient can be found in the bark of Scotch pine trees, so it's naturally occurring, and at the time it wasn't a controlled substance.

Arnold knew that "andro," which falls into a category called pro-hormones, was just one chemical step removed from the hormone testosterone. "The concept is that if ingested, you'll provide your body with more compounds that can be converted to testosterone," says Lockwood. "But these hormone precursors could just as easily be converted to estrogen."

In January 2005, the Drug Enforcement Agency added specific pro-hormones to its list of anabolic steroids classified as Schedule III controlled substances. These legal definitions, however, are cast narrowly, in the form of a list containing the names of specific molecular structures. The result: more loopholes.

Underground chemists take advantage of the gap between the chemical and legal definitions of a steroid. So they set out to tweak molecules that are still anabolic and still steroids, yet haven't been categorized as such on DEA stationery. "The legislators can't possibly know every single variation of the molecule," says Thomas Incledon, M.S., R.D., who served as the scientific advisor for the NFL Players Association's player safety and welfare program.

These new substances are often referred to as pro-steroids. "It's more accurate to consider these types of products to be 'junk steroids,' " says Feliciano. "They're put on the market without toxicology tests, human studies, or concern for consumers' health."

And although these products may imply or even state that they contain drug-like agents for which you don't need a prescription, you can be sure these claims have never been proved — and just as unsure about the supplement's true contents.

The Logical Approach

You can't buy a magic bullet in a vitamin store. And no matter how alluring a package looks or the sales pitch sounds, there's a simple truth about supplements: They work best when they augment, not replace, a healthy diet. (Hence the name.) Well-formulated multivitamins, protein powder, fish oil, and creatine, for instance, have all been proved safe and effective, but none can outweigh or even counterbalance a steady diet of junk food.

Which leads, perhaps, to an obvious strategy: "Before you invest in a supplement that promises dramatic physique changes or amazing health benefits," says Lockwood, "first ask yourself if you're doing everything else right."