



## NEWS

# Makers of tainted supplements have criminal pasts

**Alison Young** USA TODAY

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## Story Highlights

USA TODAY investigation finds wide array of supplement companies run by people with criminal histories

Supposedly natural supplements spiked with drugs account for more than half of serious drug recalls

Better enforcement needed to curb 'shadow industry' major trade groups say

Like many pills and powders sold as dietary supplements, Dr. Larry's Tranquility pills were not what they seemed.

And neither was Dr. Larry.

The pills promised insomniacs a great night's sleep with an all-natural blend of ingredients such as figwort root and licorice.

Then, earlier this summer, these particular pills — out of an estimated 85,000 supplement products on the market — happened to get tested in a lab by regulators from the U.S. Food and Drug Administration. The agency is budgeted to run just 1,000 tests a year in its limited oversight of the \$30 billion industry.

The tests showed Tranquility was spiked with two powerful prescription drugs: an anti-psychotic medication best known as Thorazine, and the anti-depressant and sleep medication called doxepin.

Research by USA TODAY shows that Larry LeGunn is a convicted criminal and not a licensed doctor. He's a former chiropractor who had to give up his Florida license in 2010 after being charged with grand theft and insurance fraud relating to his treatment of auto accident victims, according to court and licensing records. LeGunn ultimately pleaded no contest to an amended charge of misleading solicitation of payments.

Far from an isolated case, a USA TODAY investigation finds that a wide array of dietary supplement companies caught with drug-spiked products are run by people with criminal backgrounds and regulatory run-ins. Consumers buying products from these firms are in some cases entrusting their health and safety to people with rap sheets for crimes involving barbiturates, crack cocaine, Ecstasy and other narcotics, as well as arrests for selling or possessing steroids and human growth hormone. Other supplement company executives have records of fraud, theft, assault, weapons offenses, money laundering or other offenses, the investigation shows.

- Jeffrey Bolanos, who runs Beamonstar Products in Queen Creek, Ariz., has twice been convicted on drug charges, most recently in a 2008 case that notes possession of crack cocaine and a relapse with methamphetamines, court records show.

In May, his company, which has received industry awards for its sexual enhancement supplements, recalled three supposedly all-natural products after FDA tests found that two contained tadalafil, the medication in the prescription erectile dysfunction drug Cialis. The third was potentially spiked. One of Beamonstar's tainted supplements was marketed for women. Bolanos had no comment.

- Martin McDermott, president of Kilo Sports in Phoenix, was indicted in 2004 with three felony counts of dangerous drug possession involving the steroid boldenone and testosterone, and one felony count of possession of prescription drugs, specifically human growth hormone, for sale. He later pleaded guilty to a misdemeanor count of possession of drug paraphernalia and received probation.

In 2009, three Kilo Sports products were recalled for ingredients the FDA said should be classified as steroids. The company recalled another supplement in 2010 because of concerns it contained an anti-estrogen drug. McDermott didn't respond to interview requests.

- Barry Nevins, who runs DrBarrysVitamins.com, isn't really a doctor and under an agreement with prosecutors isn't supposed to represent himself as one in his vitamin store. Yet as recently as this week, his website touted "Dr. Barry" — whose only Florida health care license was as a massage therapist — as "a leading formulator, developer and manufacturer of natural pharmaceuticals."

In 2011, Nevins was charged with unlicensed practice of the health care profession, a felony, records show. While facing those charges, FDA tests found one of Barry's Vitamins & Herbs' products, Virility Max, was secretly spiked with a drug that's a chemical cousin to Viagra. Prosecutors in Palm Beach County, Fla., said they are now reviewing the website to

determine whether Nevins has violated a deferred prosecution agreement reached in March in the 2011 case. Nevins declined to be interviewed.

- Jay Cohen, CEO of IQ Formulations, was arrested on a charge of aggravated assault with a deadly weapon in 2008 for wielding a machete and striking the driver's side mirror of a teenager's car parked outside Cohen's home blaring music, police and court records show. Cohen, who told USA TODAY he was protecting his family, pleaded no contest in 2010 to assault and received probation.

In November, IQ Formulations recalled its Hydravax weight-loss supplement after the FDA told the company it contained a prescription-only diuretic drug. A company spokesman said the recall was the result of a supplier providing a tainted ingredient.

USA TODAY scrutinized about 100 companies that have been caught selling supplements secretly spiked with drugs and potentially dangerous chemicals since 2007. The examination found that at least 14 were run by people with criminal records beyond traffic infractions. The newspaper researched corporation records to identify the company executives and owners, then examined police, court and professional licensing records, ordering files from across the country to determine what they had done in the past.

There are likely many more supplement company executives with criminal records. The FDA's tainted-supplements database lists 123 companies that have been caught selling about 460 spiked products in the past six years, but the corporate records of nearly three dozen of the companies couldn't be located. For about 150 spiked products, the FDA's database doesn't list a manufacturer, in many cases because it was unclear to the agency who made them. And many companies selling sketchy products aren't listed in the FDA's database.

Supplement executives with criminal records who granted interviews generally said their pasts had nothing to do with their ability to make good supplements and they often blamed suppliers for putting drugs in their products without their knowledge.

"China will lie, just lie and tell you it's all herbal and they slip in a little trace of something," LeGunn said, adding that he no longer has supplements made there.

But most didn't respond to interview requests or refused to talk about their backgrounds.

"I'm not going to discuss anything. I have the right to remain silent," said Gisselle Lopez, a partner in Svelte 30 Nutritional Consultants LLC in Kissimmee, Fla., when a reporter asked about a 2003 theft conviction and why her staff referred to her as "Dr. Gisselle." Florida records don't show her as having a medical license. Her company recalled one of its weight

loss supplements in 2011 after FDA tests showed it was spiked with sibutramine, the active ingredient in the prescription weight loss drug Meridia that was pulled off the U.S. market because of heart attack and stroke risks.

## **'A TALE OF TWO INDUSTRIES'**

USA TODAY's ongoing investigation has shown that consumers of tainted diet supplements have paid dearly in some cases, suffering side effects ranging from severe bleeding and dangerous effects on diabetes control to liver damage, strokes and death. Athletes have had their sports careers jeopardized after testing positive for ingredients laced into sports supplements.

Dallas-based USPlabs has been linked to a recent outbreak of serious liver injury cases among people taking its OxyElite Pro weight-loss supplement. Its CEO, Jacob Geissler, has a criminal history involving anabolic steroids and has clashed repeatedly with the FDA. USPlabs recalled OxyElite Pro in November. Until recently, Geissler served on the board of trustees of the American Herbal Products Association, a major industry trade group.

Driven Sports Vice President Matt Cahill, whose pre-workout powder Craze has been found by teams of scientists to contain a methamphetamine-like compound, is a convicted felon with a history of putting risky products on the market. Craze was named 2012's "New Supplement of the Year" by Bodybuilding.com, a major online retailer of sports supplements.

"All industries are going to have people with criminal problems in their background," said Steve Mister, president of the Council for Responsible Nutrition, a supplement industry trade group that lists major corporations such as Procter & Gamble, Bayer HealthCare and Abbott Nutrition among its members.

Histories of financial fraud or violent behavior may not have much relevance when it comes to making supplements, Mister said. "But I do think when you talk about people with a history of criminal convictions with controlled substances and illicit drugs, and they are making products where they have the opportunity to bring that prior background into their product, that is concerning."

"It is unfortunately a tale of two industries. There's a mainstream, responsible industry," Mister said of the supplement business. "Then there is this sort of shadow industry, the smaller guys playing around the fringes. The problem is how we distinguish between the two."

## **WHAT CAN BE DONE ABOUT IT**

Under the Dietary Supplement Health and Education Act of 1994, known by the acronym DSHEA, the FDA must show that a product is unsafe before it can take any action to restrict its use or seek its removal from the market. Nutritional supplements such as the vitamins, minerals, protein powders and herbal blends used by more than half of Americans are treated like foods and assumed to be all-natural and safe — unless proven otherwise. Although supplements are often sold and used as remedies for various conditions, they aren't required to prove their safety and effectiveness before being put on the market, as is required with medications.

"Supplements are under-regulated by the FDA," said June Rogers, director of drug program and policy at the NFL Players Association, whose members are tested for a variety of performance-enhancing drugs. "Anyone is allowed to go out and make a supplement and basically sell it until the FDA comes knocking at your door. But before that happens, there's a lot of profits to be made."

Loren Israelsen, a top supplement industry association official who is credited as a key architect behind the DSHEA supplement law, said that 20 years ago nobody envisioned the kinds of rogue players, advanced chemistry and drug-spiked products being seen today.

"It is so counterintuitive and opposite to the really fundamental principles of what this industry is about that we probably didn't fully recognize it because it was so not a part of us," Israelsen, president of the United Natural Products Alliance, said in an interview this week.

Israelsen was convicted in 1997 of conspiracy to defraud the United States, for a scheme that involved falsifying documents to import evening primrose oil despite an FDA ban on its importation. The documents falsely declared that the shipments were such things as "Vitamin E" to avoid seizure and sought to conceal that Health Products International was the company importing the material, federal records show.

During the conspiracy, Israelsen was a vice president and general counsel at Health Products International, which he described as the manufacturing arm of Nature's Way, where he also was a top executive. He said his actions should be viewed in the context of a time when the industry felt the FDA was taking overzealous and unjustified actions against natural products.

"I was much younger and breathing more fire," he said. "In retrospect, would we do it that way again? No."

Israelsen said there's a difference between standing up for evening primrose oil and supplement company executives fighting the FDA over substances with questionable chemical origins. He said recent media coverage of supplement makers like Cahill and Geissler and their potentially dangerous products has altered the way the industry views calls for additional regulation.

"It has been fundamental. Things have changed. That's a reality," Israelsen said. "We have to just look at where we are and what needs to be done to best address it — because it's in our best interest to address it."

In what could be considered an important conciliation for his industry, Israelsen said he's open to having discussions about whether new tools are needed to make it easier and faster for the FDA to take action.

In the past, the industry has opposed and defeated legislation that would require supplements to be registered with the FDA, arguing that criminals wouldn't register and that good companies would be overly burdened.

But Israelsen says he now thinks it's possible that requiring registration could give the FDA a "faster, easier way to say they're not in compliance."

A bill reintroduced this summer by Sen. Dick Durbin, D-Ill., and Sen. Richard Blumenthal, D-Conn., would require supplement firms to register products with the FDA within 30 days after being marketed, including providing a description of each product, its ingredients and a copy of the label.

Other supplement industry trade groups emphasize that better enforcement would address the industry's bad actors. Under existing laws, any person who markets a supplement that violates the law can be found guilty of a misdemeanor punishable by up to a year in jail and \$1,000 in fines, notes the Council for Responsible Nutrition.

Such criminal cases appear to be rare, however, and they can take years and can involve more complex felony charges. The FDA has so far not provided data, requested under the Freedom of Information Act, on how often the agency has sought criminal prosecution of supplement makers.

"More executives should be subject to these misdemeanor cases," said Mister, who heads the council. "That would send a very strong message to the industry."

Supplement makers also can be subject to individual and corporate fines of up to \$500,000 for a series of violations in a case, Mister noted. "If you don't have a cop watching the speed limit, people will speed."

Daniel Fabricant, director of the FDA's dietary supplements division, said: "We're doing all we can with the tools we have." He noted that limited resources at the agency are a factor, along with competing priorities among the many food and medical products regulated by the agency.

In some recent cases, the FDA has used its authority to detain and seize adulterated or misbranded dietary supplements, as it did this year with supplements made by USPlabs and Hi-Tech Pharmaceuticals that contained the controversial stimulant DMAA. The FDA has the authority to order a recall of supplements if a manufacturer refuses to do so, and the agency threatened this in a letter to USPlabs that prompted the company to recall OxyElite Pro last month.

But the FDA still should do more, argues Patrick Arnold, who was convicted in 2006 as the Illinois steroid chemist in the "Balco" scandal that involved distributing performance-enhancing drugs to high-profile athletes.

"Obviously, we want to avoid regulatory interference as much as we can because it never ends up being a good thing," Arnold said. But without better FDA oversight, Arnold said, it will become increasingly difficult for supplement makers to compete without spiking their products.

He pointed to the lack of any public action by the FDA to address repeated findings by independent labs — including by the U.S. Anti-Doping Agency in June 2012, and various teams of international researchers — of undisclosed amphetamine- and methamphetamine-like compounds in Craze. This week, another peer-reviewed journal article reported tests showing similar findings in additional samples of Craze, as well as in Detonate. Driven Sports says the tests are wrong; Gaspari officials have not responded to interview requests.

"When stuff like this happens with Craze and Detonate, that just makes people so pissed off that they're ready for some regulation," Arnold said. "That's so unfair to competitors and it's a public health issue."

Arnold pointed out that there have been people with criminal backgrounds making supplements as long as he's been in the business. "When I first got started in the 1990s, just

about every major supplement owner was an ex-steroid dealer," he said. "You make money selling steroids, then start your supplement company."

With the Internet, he said, it doesn't take much to start selling the pills and powders. "It's a very low barrier of entry," Arnold said. "And you don't have to be that smart. You just pretend that you know science."

Arnold says prison time, his notoriety and the increased scrutiny his products have drawn from regulators have changed the way he does business. But his products still have pushed into gray areas. In 2009, two of his products — Ergopharm's 60-OXO Xtreme and 6-OXO — were the subject of a recall after the FDA said they contained substances that should be classified as steroids. In recent years, Arnold has taken credit for being the first supplement maker to put the controversial stimulant DMAA into his products. He says he removed it after the FDA crackdown and after more scientific evidence emerged raising questions about whether it's naturally in geraniums.

## **HIDING DANGEROUS INGREDIENTS IN PLAIN SIGHT**

The problem of supplement adulteration is significant, whether it occurs with criminal intent or is the result of lax quality control and insufficient oversight of suppliers.

Just over half of all Class 1 drug recalls in the USA from 2004 to 2012 — those that could cause serious health problems or death — involved supposedly all-natural dietary supplements that were spiked with hidden pharmaceuticals, according to research published this year in the scientific journal *JAMA Internal Medicine*. Of the 237 supplements recalled for hidden drugs, 40% were sold for sexual enhancement; 31% for bodybuilding and 27% for weight loss, the researchers said.

But hidden drugs have been found in other categories of supplements as well, including diabetes and arthritis remedies. This summer, Purity First Health Products recalled various lots of Vitamin B50 capsules, Vitamin C capsules and multi-mineral capsules after FDA tests indicated the presence of steroids.

With minimal testing being done by the FDA, a growing number of private companies are doing their own tests to identify problems that aren't being detected and addressed by regulators.

The U.S. Anti-Doping Agency tests and reviews labels of supplements of interest to athletes, and maintains a list of "high-risk" supplements, many of which have not been subject to FDA action.



Sometimes troubling ingredients hide in plain sight on the products' labels under names most consumers would never recognize.

"At least 200 different names are being used for testosterone," said David Black, founder of Aegis Sciences Corp. in Nashville, which has created a database of supplements to help clients at 140 universities, the NFL Players Association and other sports organizations. A mobile Aegis Shield app has recently been made available to the public.

While there are about 2,475 ingredients in the products in the Aegis database, more than 35,000 aliases are used for the ingredients on their labels. For example, there were 167 aliases for marijuana and 82 aliases for methylhexanamine, better known as DMAA.

Aegis also found other ingredients that might make consumers think twice, including "Wu Ling Zhi" — which is flying-squirrel feces, and "Putrescine," which is also known as the foul odor of decomposing flesh.

"In our experience, we've seen so many products out there that are not what they're represented to be," Black said. "If a product has a great claim and actually does what it claims to do, it probably has an ingredient that shouldn't be in there."

And the people who pay the price, ultimately, are those who — knowingly or unknowingly — indulge. U.S. Olympic Committee athlete ombudsman John Ruger noted in an e-mail to USA TODAY this week that "despite our aggressive efforts to educate them on the potential pitfalls, the harsh reality is that we will have athlete(s) who miss the Olympic Games because they take a supplement that includes a banned substance."

To read more articles in USA TODAY's Supplement Shell Game series, go to: [supplements.usatoday.com](https://supplements.usatoday.com)

To report an adverse health event involving a dietary supplement, contact the FDA's MedWatch program online or call 800-332-1088.

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