



LIVER FAILURE Jareem Gunter says he landed in the hospital, just days from death, after taking a supplement to improve his athletic performance.

Dangerous supplements

What you don't know about these 12 ingredients could hurt you

W E AMERICANS do love our dietary supplements. More than half of the adult population have taken them to stay healthy, lose weight, gain an edge in sports or in the bedroom, and avoid using prescription drugs. In 2009, we spent \$26.7 billion on them, according to the Nutrition Business Journal, a trade publication.

What consumers might not realize, though, is that supplement manufacturers routinely, and legally, sell their products without first having to demonstrate that they are safe and effective. The Food and Drug Administration has not made full use of even the meager authority granted it by the industry-friendly 1994 Dietary Supplement Health and Education Act (DSHEA).

As a result, the supplement marketplace is not as safe as it should be.

• We have identified a dozen supplement

ingredients that we think consumers should avoid because of health risks, including cardiovascular, liver, and kidney problems. We found products with those ingredients readily available in stores and online. (See "Twelve Supplements You Should Avoid," page 18.)

• Because of inadequate quality control and inspection, supplements contaminated with heavy metals, pesticides, or prescription drugs have been sold to unsuspecting consumers. And FDA rules covering manufacturing quality don't ap-

Unsafe products can easily be found online and in retail stores.

ply to the companies that supply herbs, vitamins, and other raw ingredients.

• China, which has repeatedly been caught exporting contaminated products, is a major supplier of raw supplement ingredients. The FDA has yet to inspect a single factory there.

The lack of oversight leaves consumers like John Coolidge, 55, of Signal Mountain, Tenn., vulnerable. He started taking a supplement called Total Body Formula to improve his general health. But instead, he says, beginning in February 2008, he experienced one symptom after another: diarrhea, joint pain, hair loss, lung problems, and fingernails and toenails that fell off. "It just tore me up," he said.

Eventually, hundreds of other reports of adverse reactions to the product came to the attention of the FDA, which inspected the manufacturer's facilities and tested

the contents of the products. Most of the samples contained more than 200 times the labeled amount of selenium and up to 17 times the recommended intake of chromium, according to the FDA.

In March 2008 the distributor voluntarily recalled the products involved. Coolidge is suing multiple companies for compensatory damages; they have denied the claims in court papers. His nails and hair have grown back, but he said he still suffers from serious breathing problems.

The dirty dozen

Working with experts from the Natural Medicines Comprehensive Database, an independent research group, we identified a group of ingredients (out of nearly 1,100 in the database) linked to serious adverse events by clinical research or case reports. To come up with our dozen finalists, we also considered factors such as whether the ingredients were effective for their purported uses and how readily available they were to consumers. We then shopped for them online and in stores near our Yonkers, N.Y., headquarters and easily found all of them for sale in June 2010.

The dozen are aconite, bitter orange, chaparral, colloidal silver, coltsfoot, comfrey, country mallow, germanium, greater celandine, kava, lobelia, and yohimbe. The FDA has warned about at least eight of them, some as long ago as 1993.

Why are they still for sale? Two national retailers we contacted about specific supplements said they carried them because the FDA has not banned them. The agency has "the authority to immediately remove them from the market, and we would follow the FDA recommendation," said a spokeswoman for the Vitamin Shoppe chain.

Most of the products we bought had warning labels, but not all did. A bottle of silver we purchased was labeled "perfectly safe," with an asterisked note that said the FDA had not evaluated the claim. In fact, the FDA issued a consumer advisory about silver (including colloidal silver) in 2009, with good reason: Sold for its supposed immune system "support," it can permanently turn skin bluish-gray.

Janis Dowd, 56, of Bartlesville, Okla., says she started taking colloidal silver in 2000 after reading online that it would keep her Lyme disease from returning. She says her skin changed color so gradually that she didn't notice, but others did. "They kept saying, 'You look a little blue.'"

Laser treatments have erased almost all

the discoloration from Dowd's face and neck, but she said it's not feasible to treat the rest of her body.

Under the DSHEA, it is difficult for the FDA to put together strong enough evidence to order products off the market. To date, it has banned only one ingredient, ephedrine alkaloids. That effort dragged on for a decade, during which ephedra weight-loss products were implicated in thousands of adverse events, including deaths. Instead of attempting any more outright bans, the agency issued warnings, detained imported products, and asked companies to recall products it considered unsafe.

No scientific backup required

Of the more than 54,000 dietary supplement products in the Natural Medicines Comprehensive Database, only about a

third have some level of safety and effectiveness that is supported by scientific evidence, according to a review by NMCD experts. And close to 12 percent have been linked to safety concerns or problems with product quality.

Consider the path to market of Go Away Gray, a product that is claimed to "help stop your hair from turning gray." Cathy Beggan, president of the supplement's maker, Rise-N-Shine, based in New Jersey, said that her company has not had to provide product information to the FDA. Nor did it conduct any clinical trials of the supplement, which includes a natural enzyme called catalase, before putting it on sale. Beggan pointed us to a study by European researchers published in the July 2009 issue of the Federation of American Societies for Experimental Biology Jour-

Your 'all natural' supplement might contain drugs

Consumers might be attracted to dietary supplements because they're "all natural" and don't contain the synthetic chemicals found in prescription drugs. But they might be getting fooled.

In the past two years, according to the Food and Drug Administration, manufacturers have voluntarily recalled more than 80 bodybuilding supplements that contained synthetic steroids or steroid-like substances, 50 sexual-enhancement products that contained sildenafil (Viagra) or other erectile-dysfunction drugs, and 40 weight-loss supplements containing sibutramine (Meridia) and other drugs.

Unwitting purchasers

"We're talking about very serious risks and injuries that can happen to people—and often young people—who do not understand that they're taking prescription drugs and steroids," Joshua M. Sharfstein, M.D., the FDA's principal deputy commissioner, told the U.S. Senate's special committee on aging in May 2010.

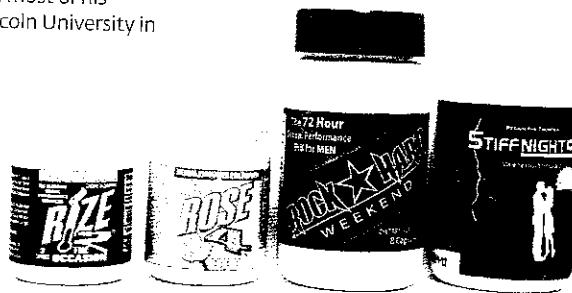
In 2005, eager to make the most of his baseball scholarship at Lincoln University in Jefferson City, Mo., Jareem Gunter started taking a supplement he found online that promised to improve his athletic performance and claimed to be "legal," he recalls. But he soon began feeling fatigued, and when the whites of his eyes turned yellow,

he said, he went to the hospital.

"I woke up in the morning and the doctor was sitting by my bedside," Gunter said. "He told me, 'Your liver's failed. You only had a couple of days left to live if you hadn't come in.'" The supplement turned out to contain a synthetic steroid, which cost Gunter his scholarship, he claimed in a lawsuit that was settled before the trial date, according to public court documents. He's now 27 and living in Oakland, Calif. His health is much improved and he is working for a charitable organization and playing baseball in his hometown league.

Use with caution

Hazardous ingredients have been known to turn up in dietary supplements marketed for weight loss, bodybuilding, and sexual enhancement. And in light of the potentially serious health risks—including dangerous changes in blood pressure, serious liver injury, kidney failure, heart attack, and stroke—we think consumers should be extremely cautious with those categories of products or avoid them.



RISKY HELPERS These products contain a Viagra-like drug, the FDA said.

nal. The study found that gray hair had lower-than-normal levels of catalase but did not prove that taking that enzyme by mouth would stop hair from turning gray. "We are working on getting an actual clinical trial going because the results have been so amazing, and it would just be good to have some concrete data behind it," Beggan said.

In the dark about dangers

In March 2008, Marques Parke, 29, a plumber from Janesville, Wis., took a

weight-loss supplement called Hydroxycut because he wanted to lose 5 pounds, he said. Within weeks he was stricken with acute hepatitis and jaundice. He is suing the manufacturer and others. An attorney representing the defendants said they intended to contest the claims.

The FDA had received its first adverse-event report about Hydroxycut in 2002, long before Parke started taking it. In May 2009, by which point Parke's liver was already damaged, the agency warned consumers to stop using Hydroxycut, and the

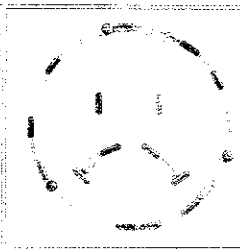
manufacturer, Iovate Health Sciences, voluntarily recalled some of its products, its attorney said.

The company had frequently reformulated the product, according to the FDA, which said it didn't know which ingredients produced the liver toxicity. The FDA said that Hydroxycut presented "a severe, potentially life-threatening hazard to some users" and had been linked to two reported deaths. Hydroxycut has been reformulated and is on the market again. An FDA representative told us the agency

Twelve supplements you should avoid

These supplement ingredients are among those linked by clinical research or case reports to serious side effects. We worked with the Natural Medicines Comprehensive Database, an independent research group that evaluates the safety and effectiveness of

nutritional supplements, to develop this list. We think it's wise to avoid all the ingredients on it. Unless otherwise noted, there's insufficient evidence to rate their effectiveness for their purported uses. Dangers listed are not meant to be all-inclusive.



NAME (also known as)	PURPORTED USES	POSSIBLE DANGERS	COMMENTS
ACONITE (aconiti tuber, aconitum, radix aconiti)	Inflammation, joint pain, wounds, gout.	Toxicity, nausea, vomiting, low blood pressure, respiratory-system paralysis, heart-rhythm disorders, death.	Unsafe. Aconite is the most common cause of severe herbal poisoning in Hong Kong.
BITTER ORANGE (aurantii fructus, Citrus aurantium, zhi shi)	Weight loss, nasal congestion, allergies.	Fainting, heart-rhythm disorders, heart attack, stroke, death.	Possibly unsafe. Contains synephrine, which is similar to ephedrine, banned by the FDA in 2004. Risks might be higher when taken with herbs that contain caffeine.
CHAPARRAL (creosote bush, Larrea divaricata, larreaatata)	Colds, weight loss, infections, inflammation, cancer, detoxification.	Liver damage, kidney problems.	Likely unsafe. The FDA advises people not to take chaparral.
COLLOIDAL SILVER (ionic silver, native silver, Silver in suspending agent)	Fungal and other infections, Lyme disease, rosacea, psoriasis, food poisoning, chronic fatigue syndrome, HIV/AIDS.	Bluish skin, mucous membrane discoloration, neurological problems, kidney damage.	Likely unsafe. The FDA advised consumers about the risk of discoloration on Oct. 6, 2009.
COLTSFOOT (coughwort, farfarae folium leaf, foalswort)	Cough, sore throat, laryngitis, bronchitis, asthma.	Liver damage, cancer.	Likely unsafe.
COMFREY (blackwort, common comfrey, slippery root)	Cough, heavy menstrual periods, chest pain, cancer.	Liver damage, cancer.	Likely unsafe. The FDA advised manufacturers to remove comfrey products from the market in July 2001.
COUNTRY MALLOW (heartleaf, Sida cordifolia, silky white mallow)	Nasal congestion, allergies, asthma, weight loss, bronchitis.	Heart attack, heart arrhythmia, stroke, death.	Likely unsafe. Possible dangers linked with its ephedrine alkaloids banned by the FDA in 2004.
GERMANIUM (Ge, Ge-132, germanium-132)	Pain, infections, glaucoma, liver problems, arthritis, osteoporosis, heart disease, HIV/AIDS, cancer.	Kidney damage, death.	Likely unsafe. The FDA warned in 1993 that it was linked to serious adverse events.
GREATER CELANDINE (celandine, chelidonii herba, Chelidonium majus)	Upset stomach, irritable bowel syndrome, liver disorders, detoxification, cancer.	Liver damage.	Possibly unsafe.
KAVA (awa, Piper methysticum, kava-kava)	Anxiety (possibly effective).	Liver damage.	Possibly unsafe. The FDA issued a warning to consumers in March 2002. Banned in Germany, Canada, and Switzerland.
LOBELIA (asthma weed, Lobelia inflata, pukeweed, vomit wort)	Coughing, bronchitis, asthma, smoking cessation (possibly ineffective).	Toxicity; overdose can cause fast heartbeat, very low blood pressure, coma, possibly death.	Likely unsafe. The FDA warned in 1993 that it was linked to serious adverse events.
YOHIMBE (yohimbine, Corynanthe yohimbi, Corynanthe johimbi)	Aphrodisiac, chest pain, diabetic complications, depression; erectile dysfunction (possibly effective).	Usual doses can cause high blood pressure, rapid heart rate; high doses can cause severe low blood pressure, heart problems, death.	Possibly unsafe for use without medical supervision because it contains a prescription drug, yohimbine. The FDA warned in 1993 that reports of serious adverse events were under investigation.

Source: Natural Medicines Comprehensive Database, Professional Version, June 2010

1,500

U.S. supplement manufacturers (estimated)

55

FDA inspections for good manufacturing practices (estimated)

170+

Supplements found to have hidden drugs or steroids since 2008

33%

Supplements in Natural Medicines Comprehensive Database with scientific evidence of efficacy that are likely safe

Source: Food and Drug Administration, May 2010

considers the new version acceptable.

Amazingly, for the first 13 years after the enactment of the DSHEA, supplement makers didn't have to inform the FDA if they received reports of serious adverse events, an obligation that's required for prescription drugs. A law that took effect in December 2007 closed that loophole, and in 2008 and 2009 the FDA said it received 1,359 reports of serious adverse effects from manufacturers and 602 from consumers and health professionals. But even with the new law, consumers can't easily find out which products are involved because the FDA doesn't routinely make those reports available to the public.

Overblown sales pitches

It's against the law for companies to claim that any supplement can prevent, treat, or cure any disease except some nutrient-deficiency conditions. But in the past two years, the Federal Trade Commission has filed or settled 30 cases against supplement marketers, charging that they made exactly those kinds of claims. It reached a \$7.5 million settlement with the QVC home-shopping channel. And the FDA has recently taken legal action against a few supplement manufacturers that claimed their products could prevent or treat a disease.

Undercover investigators from the Government Accountability Office, posing as elderly consumers, caught salespeople on tape dispensing potentially harmful medical advice. In one case, a salesperson told an investigator that a garlic supplement could be taken in lieu of high blood pressure medicine.

What you can do

The FDA and Congress have recently taken some action to strengthen the agency's oversight, such as passing the law requiring that companies report serious adverse events. But much more needs to be done to keep consumers safe. (See Viewpoint,

page 6.) In the meantime, here are steps you can take to make sure the supplements you use are safe and beneficial.

Consult your doctor or pharmacist.

Even helpful products can be harmful in some situations, such as when you're pregnant or nursing, have a chronic disease, or are about to have elective surgery. And some supplements might be fine on their own but interact with certain prescription drugs. Your doctor or pharmacist can steer you away from such problems only if they know what supplements you're taking or plan to take.

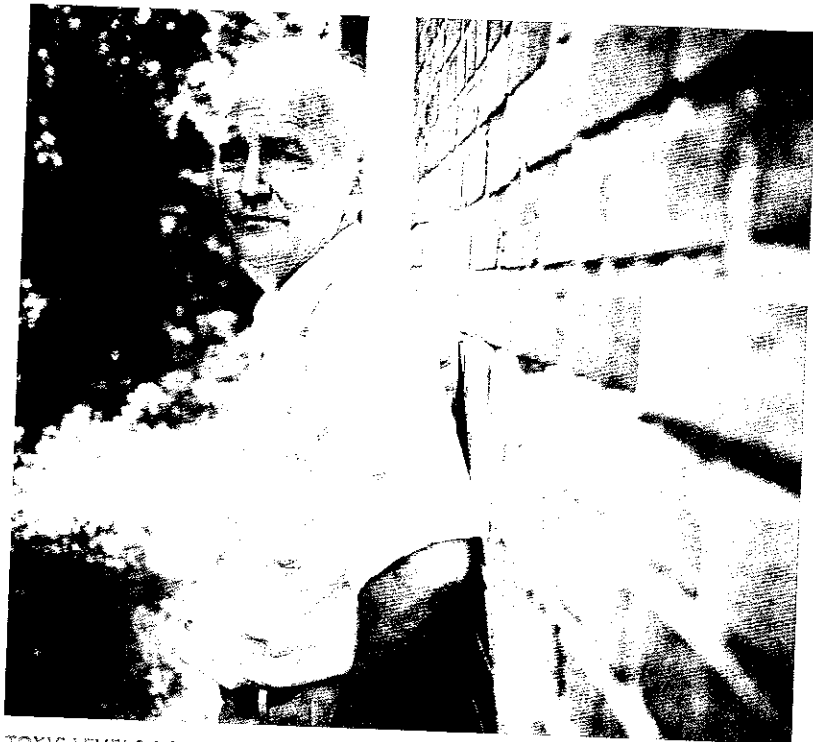
Beware of these categories. Supplements for weight loss, sexual enhancement, and bodybuilding have been problematic, the FDA said, because some contain steroids and prescription drugs. Lose weight through diet and exercise, get

fit through training, and consult your doctor if you need help in the bedroom.

Look for the "USP Verified" mark. It indicates that the supplement manufacturer has voluntarily asked U.S. Pharmacopeia, a trusted nonprofit, private standards-setting authority, to verify the quality, purity, and potency of its raw ingredients or finished products. USP maintains a list of verified products on its website, at www.uspverified.org.

Don't assume more is better. It's possible to overdose even on beneficial vitamins and minerals. Avoid any product that is claimed to contain "megadoses."

Report problems. Let your doctor know if you experience any symptoms after you start taking a supplement. And if you end up with a serious side effect, ask your doctor or pharmacist to report it to



TOXIC LEVELS John Coolidge of Signal Mountain, Tenn., says he took a supplement that turned out to contain hazardous amounts of chromium and selenium.

the FDA, or do it yourself at www.fda.gov/medwatch or by calling 800-332-1088.

Research in the right places. Be skeptical about claims made for supplements in ads, on TV, and by sales staff. If a claim sounds too good to be true, it probably is. Instead, try these sources:

- The National Institutes of Health's Office of Dietary Supplements, at ods.od.nih.gov.
- The FDA, for alerts, advisories, and other actions, at www.fda.gov/food/dietarysupplements.
- Consumer Reports Health, at www.ConsumerReportsHealth.org, where, for a \$19 annual subscription to the site, you can

search for information about dietary supplements and other natural health products by type, brand, or ingredient. You can also view ratings of product effectiveness for various conditions and check interactions between those supplements and certain drugs.

Eleven supplements to consider

These popular supplements, listed in alphabetical order, have been shown to likely be safe for most people and possibly or likely to be effective in appropriate doses for certain conditions. Talk to

your doctor or pharmacist before starting any supplement. Most supplements haven't been studied in pregnant or nursing women. The list of interactions and side effects is not all-inclusive.



NAME (also known as)	EFFICACY FOR SELECTED USES	SELECTED POTENTIAL SIDE EFFECTS	SELECTED DRUG INTERACTIONS
CALCIUM (calcium carbonate, calcium citrate, calcium gluconate)	Likely effective in combination with vitamin D in preventing and treating bone loss and osteoporosis. Taken daily, appears to reduce some PMS symptoms.	Belching, gas.	Calcium can decrease the effectiveness of certain antibiotics, osteoporosis drugs, and thyroid drugs.
CRANBERRY (American cranberry, large cranberry, cranberry extract)	Possibly effective for preventing recurrent urinary-tract infections.	Large amounts can cause stomach upset, diarrhea.	Might increase the effects of the blood thinner warfarin.
FISH OIL (EPA/DHA, omega-3 fatty acids, PUFA)	Effective for reducing triglyceride levels. Likely effective for decreasing the risk of heart attack, stroke, and progression of hardening of the arteries in people with existing heart disease.	Fishy aftertaste, upset stomach, nausea, loose stools. High doses can increase levels of LDL (bad) cholesterol in some people or increase the chance of bleeding.	Might increase the effect of blood-thinning drugs and high blood pressure medications.
GLUCOSAMINE SULFATE (G6S, glucosamine sulfate 2KCl, glucosamine sulfate-potassium chloride)	Likely effective treatment for reducing symptoms of osteoarthritis of the knee. Might also help slow progression of osteoarthritis.	Nausea, heartburn, diarrhea, constipation, headache.	Might increase the blood-thinning effect of warfarin and cause bruising and bleeding.
LACTASE (beta-galactosidase)	Likely effective for reducing gastrointestinal symptoms in lactose-intolerant people when used before consuming lactose or when added to milk.	No reported side effects.	None known.
LACTOBACILLUS (acidophilus, acidophilus lactobacillus, probiotics)	Possibly effective for preventing diarrhea while taking antibiotics.	Gas. People with poor immune function should check with their doctor first.	Might cause infection in people taking immunosuppressant drugs.
PSYLLIUM (blond plantago, blonde psyllium, plantago, isabgola)	Effective as a bulk laxative for reducing constipation or softening stools. Likely effective for lowering cholesterol in people with mild to moderately high cholesterol.	Gas, stomach pain, diarrhea, constipation, nausea. Some people can have a serious allergic response that requires immediate medical attention.	Might decrease the effectiveness of carbamazepine, an antiseizure drug; digoxin, a heart drug; and lithium, for bipolar disorder. Might cause low blood sugar when taken with some diabetes drugs.
PYGEUM (African plum tree, African prune, <i>Prunus africana</i>)	Likely effective for reducing symptoms of an enlarged prostate.	Nausea, abdominal pain.	None known.
SAME (ademethionine, adenosylmethionine, S-Adenosyl-L-Methionine, sammy)	Likely effective in reducing symptoms of major depression, reducing pain, and improving functioning in people with osteoarthritis.	GI symptoms, dry mouth, headache, mild insomnia, anorexia, sweating, dizziness, and nervousness, especially at higher doses. It can make some people with depression feel anxious.	Might lead to a toxic reaction when taken with the cough suppressant dextromethorphan, certain antidepressants, or narcotic pain relievers. Might worsen symptoms when taken with the Parkinson's drug levodopa.
ST. JOHN'S WORT (<i>Hypericum perforatum</i> , Saynt Johannes Wort, SJW)	Likely effective for improving symptoms of some forms of depression.	Insomnia, vivid dreams, anxiety, dizziness, headache, skin rash, and tingling. It can cause skin to become extra-sensitive to the sun.	Can decrease the effectiveness of a wide range of drugs, including birth-control pills, heart medications, HIV/AIDS drugs, and warfarin. Might also increase the effects or side effects of certain antidepressants.
VITAMIN D (Cholecalciferol, vitamin D3, ergocalciferol, vitamin D2)	Likely effective when taken with calcium to help prevent osteoporosis. Might help reduce falls in people with vitamin D deficiency and bone loss in people taking corticosteroids.	Extremely large amounts might cause weakness, fatigue, headache, and nausea, though side effects are rare.	Might reduce the effectiveness of some medications, such as atorvastatin (Lipitor), other heart medications, birth-control pills, HIV/AIDS drugs.

Source: Natural Medicines Comprehensive Database, Professional Version, June 2010