

Pressure builds to ban dietary supplement DMAA

June 7 2012, By Julie Deardorff

Joseph Perez used to gear up for his intense workouts by taking ephedra-based dietary supplements. When they were banned because of safety concerns, Perez turned to an even more potent stimulant called DMAA.

Like ephedra, the DMAA supplements often left Perez feeling warm, energized and mentally focused. "It's kind of like taking three cups of coffee," said the 35-year-old competitive bodybuilder and event promoter, who lives in Joliet, Ill. "It doesn't give you superhuman strength. It just gives you more mental drive to get you into the gym and get the job done."

But regulators and other critics are increasingly alarmed about DMAA's popularity as a pre-workout [energy booster](#) and "fat destroyer." Though it is often marketed as a [natural substance](#) derived from geraniums, critics say there is no good evidence that is true.

Instead, they say, the chemical is the latest and most blatant example of a pharmaceutical compound masquerading as a [natural ingredient](#), prompting calls for tighter federal oversight of dietary supplements.

The compound, also known as 1,3-dimethylamylamine or methylhexanamine, was patented as a nasal decongestant decades ago and is similar in structure to ephedrine and amphetamine. It is now found in more than 200 products sold under brand names like Hemo Rage Black and Jack3d.

In people's bodies, DMAA acts like adrenaline, which is normally produced in times of stress, said Dr. Pieter Cohen, an assistant professor at Harvard Medical School and general internist at Cambridge Health Alliance.

"It's a potentially dangerous ingredient, and manufacturers' claims that it is naturally derived are unsubstantiated," said Cohen. In a recent commentary published in the [Archives of Internal Medicine](#), Cohen called on suppliers to take all DMAA supplements off the market.

In late April, the U.S. [Food and Drug Administration](#) issued warning letters to 10 companies, saying the agency does not consider synthetically produced DMAA to be a "dietary ingredient" such as a vitamin, mineral or herb and that the companies had not provided evidence it is safe.

In fact, the FDA said, DMAA can narrow blood vessels and arteries, which can increase blood pressure and lead to shortness of breath, a tightening in the chest or heart attack.

The agency would not comment on whether it will formally ban the chemical in supplements. Cohen said he suspects the agency wants to remove DMAA from the market using the "easiest, least costly and least prolonged" path. "I think they recognize that it's an unsafe ingredient," he said.

Already, concerns over the source, safety and legality of the once-forgotten drug have led some manufacturers to reformulate their products. But some manufacturers and at least one major retailer - General Nutrition Centers, or GNC, - stand by products containing DMAA.

Supporters say DMAA is safe when used as directed, with manufacturers

frequently citing a handful of short-term studies by University of Memphis researchers. Other than finding a sharp rise in systolic blood pressure similar to the effect of drinking two or three cups of coffee, the lab tests haven't turned up anything that would alarm a health professional, said Richard Bloomer, director of the Cardiorespiratory/Metabolic Laboratory at the University of Memphis and a lead investigator on several of the studies.

"No one knows the true long-term health consequences of using products that contain this ingredient at a dosage used by the manufacturer," Bloomer added. "It hasn't been studied."

Unlike drugs, which must be proved safe and effective before they hit the market, the FDA does not "approve" supplements; the agency can take action against an unsafe product only after it reaches consumers.

The FDA banned the sale of ephedra dietary supplements in 2004 after a decadelong battle. Supplements containing the herb had been linked to thousands of adverse event reports and to serious conditions including sudden death, heart attack and stroke. Its active components stimulate the brain, increase heart rate, constrict blood vessels and expand the bronchial tubes, which is why it has been used medicinally for thousands of years to treat colds, asthma and hay fever.

DMAA was patented by Eli Lilly and Co. in 1944 as a nasal decongestant called Forthane, but the drug was quietly withdrawn in the 1970s, a time when medications were beginning to face increased regulation.

The drug spent decades in obscurity before beginning to appear in sports dietary supplements about eight years ago, often as a replacement for ephedra, though it isn't always listed on product labels.

Champaign, Ill., -based chemist Patrick Arnold, who developed the designer steroids at the heart of the professional sports doping scandal that snared athletes such as Barry Bonds and Marion Jones, trademarked methylhexaneamine or DMAA as Geranamine. Arnold, who declined to comment for the story, now develops products for a sports nutrition company called Epharm.

The fact that an obscure drug can be widely marketed as dietary supplement makes DMAA "the poster child for how laws regulating supplements are not working," said Cohen. "Synthetic copies of ingredients from plants should be regulated like drugs, not supplements," he said. "If we continue with the status quo, in this environment where supplements are assumed to be safe, we will remove one potent drug from the market and likely replace it with another."

Sales of DMAA supplements topped \$100 million last year, according to Nutrition Business Journal. The products became popular with athletes, and in 2009 the World Anti-Doping Agency added DMAA to a list of banned substances.

"Adding a stimulant to someone who already has an accelerated heartbeat and is exercising can have particularly dangerous effects," said Travis Tygart, CEO of the U.S. Anti-Doping Agency, which has also banned DMAA.

In 2010, DMAA shot to the top of the world agency's banned-stimulant list with 123 athletes testing positive, making up 21.4 percent of all cases in the stimulants class. "It's the fastest moving drug on that list I've ever seen," said Don Catlin, chief science officer of the Anti-Doping Institute, a nonprofit research and testing lab.

For an ingredient to be legally sold as a dietary supplement, it must exist in a naturally occurring substance and have a documented history of use

before 1994, the year the Dietary Supplement Health and Education Act was passed.

The bulk of the evidence that DMAA is a compound found in geranium plants, as manufacturers claim, hinges on a single Chinese study unearthed by Arnold that was published in 1996 in a now-defunct journal. That study didn't actually "find" DMAA in geranium oil, said Cohen, who reviewed it. Instead, the authors thought there might be DMAA in the oil but did no confirmatory tests. Since then, at least half a dozen peer-reviewed reports have been unable to confirm the finding, he said.

Last summer, Canada's national health agency, Health Canada, ruled that DMAA was not a natural part of the geranium plant and banned the chemical from all supplements.

The American Herbal Products Association now prohibits member companies from labeling DMAA or methylhexanamine as "geranium" on product labels. And the American Botanical Council doesn't recognize DMAA as an herbal preparation, citing a lack of credible evidence that the material is found in a plant.

"DMAA is not the hill you want to die on," said the council's founder and executive director, Mark Blumenthal. "The DMAA issue is nondefensible as a dietary supplement."

In the wake of the FDA's letters, at least five class-action lawsuits against the companies have been filed. Though GNC still sells DMAA products, they've been removed from Amazon.com.

Nutrex, a supplement manufacturer that in 2003 replaced ephedra with DMAA in products such as Lipo 6 Black, said it "vigorously disagrees" with the allegations that its product is unsafe and cites the Chinese study

as evidence the chemical comes from a plant. But like many of the companies that received warning letters, it told the FDA it would reformulate its product.

Perez, a tradesman and "natural" bodybuilder who said he avoids steroids or other illegal substances, is miffed that DMAA will be harder to obtain. For two years, he said, he has taken DMAA supplements five to six days a week without any adverse effects. He gets two physicals a year, along with heart and blood tests, and reports a clean bill of health.

"Before I found DMAA I used to stop at the gas station and get either two (Monster Energy Drinks) or two Red Bulls," he said. "How healthy could that have been? It was like drinking buckets of sugar."

Then, echoing a common sentiment found on bodybuilding blogs and forums, he offered the FDA some unsolicited advice. "If they want to ban something, they should start with cigarettes, booze or, heck, McDonald's," he said. "And leave us fitness junkies alone."

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