



THE PLAIN DEALER

Whatever happened to . . .

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1940s to 1970s:

Amphetamines were first approved for treatment of obesity in 1947. By 1967, doctors were writing 23 million prescriptions a year, 80 percent of them for women. In 1973, the FDA concluded that they were "effective" as an adjunct to diet and exercise. Because they are addictive, they are recommended only for short-term use. In recent years, amphetamines have fallen into disfavor because there's no evidence they contribute to long-term weight management.

1960s and 1970s:

Remember Ayds? This vitamin-fortified chocolate, butterscotch or caramel candy was taken with a cup of hot tea before meals as an appetite suppressant. It was one of the top-selling over-the-counter diet aids in the 1960s and 1970s until the AIDS virus was discovered in the early 1980s. Use this link to access a radio spot for Ayds candy from the 1960s: www.bayarearadio.org/blog/2005/07/how-to-lose-weight-1982-edition.html.

1950s through the '70s:

Metracal was the first weight-loss shake product, adapted from baby formula by Mead Johnson Nutritionals. It was wildly successful. The company also marketed Metracal cookies. Metracal is now off the market.

1990s:

Phen-Fen was not a dietary supplement but a combination of two prescription drugs, phentermine and fenfluramine. In 1997, the FDA withdrew fenfluramine (Pondimin) and dexfenfluramine (Redux) after linking the two drugs to heart-valve problems. Phentermine is still on the market.

1990s and 2000s:

Herbal phen-fen was marketed as a safer alternative to phen-fen. The active ingredients were ephedra and St. John's Wort, an anti-depressant. There is little evidence that St. John's Wort is effective in weight loss. This formulation was taken off the market when ephedra was banned in 2004.

1990s:

Phenylpropanolamine (PPA) was the active ingredient in over-the-counter weight-loss products such as Dexatrim and Acutrim. In 2000, PPA was linked to hemorrhagic stroke. The FDA requested that all drug companies discontinue marketing products containing PPA and warned consumers to read labels and avoid products containing it. Both Dexatrim and Acutrim have been reformulated to exclude PPA.

2000s:

Remember when you couldn't turn on the radio without hearing some disc jockey describe how he peeled off the pounds as he slept, without diet or exercise. The secret? Body Solutions. The Federal Trade Commission was not amused. It sued Mark Nutritionals, the manufacturer, for false and unsubstantiated advertising claims. In a settlement in 2003, Mark was barred from any future business

activity.

2000s:

Citing evidence linking ephedra (also known as ma huang) to potentially deadly conditions such as heart attack and stroke, the Food and Drug Administration banned ephedra in 2004. Many products that contained ephedra, such as Metabolife and Hydroxycut, have been reformulated using other weight-loss ingredients.

Late last year, Unilever signed an agreement with Phytopharm to develop and market foods containing hoodia. Unilever makes SlimFast weight-loss shakes as well as cholesterol-lowering spreads containing plant sterol esters, a chemical derived from plants that's been shown to lower blood cholesterol. Unilever predicts it will take three years to complete safety and effectiveness testing. Trevor Gorin of Unilever UK says that at this point it is unknown whether hoodia will be marketed in bars, shakes or other products.

Does it work?

If hoodia works, there's little scientific research to back it up. In 2001, Phytopharm reported that in a three-day trial of 18 overweight males - nine of whom were on hoodia - P57 reduced caloric intake and body fat in nine overweight males. There was no mention of weight loss, and the study has never been published. The only published study I could find focused on biochemical changes when P57 was injected into rat brains.

Mark Blumenthal of the American Botanical Council, an independent member-based nonprofit organization to promote herbal medicine, suspects that Phytopharm doesn't publish its research so competitors can't use it. "They know that others would use their data to justify the safety of competing products."

David Grotto is a Chicago dietitian with 25 years of experience in the natural-foods business. Grotto is unconvinced by the evidence on hoodia. "The bottom line is that we need to see it used in a long-term study to see what are the side effects and its possible effectiveness in managing weight."

Wendy Goldstein works in the supplements department of Mustard Seed Market, a natural-foods store in Solon. She likes to try what is hot in the market so she can advise customers. She used hoodia for about three weeks.

"I didn't notice anything dramatic," she reports. "I didn't say to myself, 'Wow, this is making me not eat.' " Although she didn't lose weight on hoodia, she has customers who swear that it worked very well for them.

"Everybody's body is different," Goldstein says. "What works for some people may not work for others."

Is it safe?

Hoodia enthusiasts point to its long history of use by the San people as evidence of its safety. Others are more cautious.

"It has a history of traditional use, but we are choosing to use it in a higher dose and in different ways," says Dr. Robert Bonakdar of the Scripps Center for Integrative Medicine in LaJolla, Calif. "So many supplements have not panned out or have been shown to be unsafe."

What kind of research would be convincing? The gold standard is a randomized trial with follow-up to show long-term efficacy and safety. But not many supplements have this kind of research behind them.

Although Phytopharm has patented the use of hoodia extract as a weight-loss supplement, natural plant material is not patentable. Says Bonakdar, "It's hard to patent an herb and put it in a product that's profitable enough to pay for the research. But you can still do good pilot data to show safety at some level."

The FDA is unimpressed. In a response to a New Dietary Ingredient Notification by Awareness Corp., a dietary supplement manufacturer, the FDA said, "The information in your submission does not provide an

adequate basis to conclude that your product containing Hoodia gordonii powder will reasonably be expected to be safe." FDA goes on to say that products containing hoodia might be considered to be adulterated and prohibited in interstate commerce.

Yet hoodia is everywhere. I asked FDA spokeswoman Kim Rawlings how that could be. Says Rawlings, "We haven't found that [hoodia] is unsafe for its intended use, but the applications haven't shown that it is safe." The burden is on the FDA to prove that a product is unsafe after it's on the market through reports of adverse effects.

Is it really hoodia?

Under current regulations, no government agency oversees the accuracy of ingredient labeling on dietary supplements. Hoodia is a slow-growing endangered desert shrub that is difficult to propagate. Therefore, there's a real question whether many of the hoodia supplements on the market contain any hoodia at all.

In its story, the BBC reported that it tested the best-selling hoodia supplement and found it contained no hoodia. Unilever's Gorin says they have analyzed many of the hoodia products on the market and found they contained little, if any, plant material. A class-action suit was filed Feb. 23, 2004, in the New York Supreme Court against the makers of the dietary supplement, Trimspa, asserting that it does not contain P57, the active appetite suppressant ingredient.

"It's the Wild, Wild West out there," says Grotto. "It's just not a very well-regulated industry."

Supplement manufacturers who act responsibly might be at a disadvantage. Says Unilever's Gorin, "Consumers are being misled by claims that offer help for weight control which is not being delivered. If products like this are found to be disappointing, it's that much harder to persuade people when our product comes on the market."

Do you have questions?

This article launches a series in which I'll discuss other popular weight-loss supplements and offer advice on supplement safety. Is there a dietary supplement you are curious about? Have you had an experience, positive or negative, with weight-loss supplements? Write to me at Nutri-News via food@pd.com.

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