Since the Dietary Supplement Health and Education Act of the United States Congress in 1994 loosened the oversight of alternative health products, literally thousands of over-the-counter dietary supplements and herbal preparations have been introduced in the United States. As long as such a product is not marketed as a drug or cure for a disease or condition, and as long as it does not pose an unreasonable risk to consumers, the US Food and Drug Administration (FDA) is not allowed to regulate it. Promotions, marketing campaigns, and testimonials may be promulgated in an unrestricted manner.

Medestea Internazional of Italy manufactures Cellasene, one of the newer dietary supplements. Studied for the last 5 years and touted as a treatment for cellulite, it was introduced into the US market in March 1999 by Rexall Sundown Corporation of Boca Raton, FL, with a $6 million marketing campaign. Already, interest in the product has spawned competitive preparations such as Celluthin and Cellustop (General Health Products, Auckland, New Zealand).

The ingredients of Cellasene are as follows: (1) dried ginkgo biloba extract, which is reputed to assist in blood circulation and stimulate the metabolism of fats; (2) dried sweet clover extract, which is claimed to increase blood circulation and assist in the removal of fluid build-up; (3) grape seed bioflavonoids, thought by many to be powerful antioxidants that protect cells and blood vessels from damage; (4) dried fucus vesiculosus extract, which is reputed to stimulate metabolism and help reduce localized fats; (5) evening primrose oil and fish oil, rich in polyunsaturated fatty acids and a source of energy that may increase metabolism and help diminish saturated fatty acids; and (6) soy lecithin, which is used to help break down fats. Many naturopaths and doctors claim that the unsightly bumps and bulges of cellulite are caused by a combination of factors that include bad diet, a sedentary lifestyle, and “sluggish” blood and lymphatic circulation. These natural ingredients are purported to reduce swelling, improve the local metabolism of the adipocyte so that fat is no longer “trapped,” and improve circulation.

No side effects of Cellasene have been reported; however, the preparation contains significant amounts of iodine and should be avoided by those with thyroid conditions until they are cleared to use it by their physicians. In addition, because of the sweet clover and ginkgo biloba, the product should not be mixed with aspirin, acetaminophen, or monoamine oxidase inhibitor-containing antidepressants.

For optimal results, Cellasene proponents recommend the following adjunctive therapies to assist in cellulite reduction along with the supplement program:

1. For the sake of decreasing water retention, salt intake should be reduced.
2. Water intake should be increased to at least 6 to 8 glasses of water per day.
3. A low-fat “detoxifying” diet that includes plenty of fresh fruits, vegetables, and whole grains should be followed, and caffeine, carbonated drinks, and alcohol should be eliminated. High-fiber complex carbohydrates are essential. Simple sugars and starches, as well as animal fats, such as butter and dairy products, should be avoided, and consumption of vegetable oils and spreads should be limited.
4. To improve cutaneous blood circulation, smoking should be discontinued.
5. Application of a stimulating “essential” oil, such as basil, cedar wood, clary sage, cypress, fennel, juniper, lemon, orange, patchouli, rosemary, or thyme, is helpful before “skin brushing,” which is recommended by many to increase circulation and help the body eliminate wastes.
6. Exercise is advised as the best way to increase the metabolism and burn up stores of unwanted fat.
7. Massage for troublesome areas in conjunction with this program is recommended to help stimulate the lymphatic and circulatory systems.

One of the proposed mechanisms of the action of Cellasene, which was formulated by a pharmacist named Gianfranco Merrizi, is the selective increase of the metabolic rate in the altered adipocyte and direct stimulation of subcutaneous blood flow. However, little is mentioned about the connective tissue bands in the subcutaneous tissues. None of this is supported by peer-reviewed literature. The product has been subjected to 2 protocols, including an 8-week study carried out by the Pavia University Hospital’s Dermatological Clinic in Turin, Italy. The results of these unpublished, non-peer-reviewed clinical trials, reported at a news conference held in New York City on May 25, 1999, indicated that Cellasene decreased hip and thigh circumference in more than 90% of patients and improved the appearance of cellulite in more than 80%. One of the Italian studies was single-blind; only 25 women participated, and 15 of them received a placebo. The study did not measure changes in visual appearance and feel of fat deposits, two important clinical indicators of cellulite. In another US pilot study currently being conducted by a plastic surgeon, 10 women are being used as subjects; this study will almost certainly be too small to prove anything further. Researchers at the University of Miami have reportedly initiated another clinical trial with 200 patients; data are to be available in the fall.

It was reported in an Associated Press article published on May 27, 1999, that the US Federal Trade Commission is investigating whether the makers of Cellasene have enough evidence to substantiate their claims that an 8-week course of 3 pills daily can help rid users of cellulite. Rexall Sundown took a full-page ad in the New York Times on May 25, 1999, and has advertised in other newspapers and fashion magazines to address the “millions of women” taking the preparation. The full-page newspaper ad that touted the product as “the safe, clinically studied dietary supplement with natural herbal extracts that helps reduce cellulite” was accompanied by a footnote indicating that the statements had not been evaluated by the FDA and that the product is not meant to treat, cure, or prevent disease. Ronald M. Davis, M D, a member of the American Medical Association’s Council on Scientific Affairs, said at the June 1999 annual policy-making convention that “to make a health claim in the headline and then to say ‘We’re not really making a health claim’ is disingenuous at best, and outrageous and needful of immediate remedy by the Federal Government and the FDA.”

The following cycle sheds light on the problems encountered by doctors and their patients amidst this swirl of controversy: a very small study purports significant medical claims; a large advertising campaign generates a groundswell of public interest; enormous amounts of money are spent by patients in search of a cure; doctors hurriedly become involved in their care; closer scientific scrutiny uncovers weaknesses or inadequacies in the methodology or interpretation of the research and raises far more questions than can be answered; subsequent studies are called for; the company continues to push the product or technique; and only later is it discovered whether the product or technique is actually safe and effective. This represents scientific methodology standing on its head.

In light of these perplexing circumstances, the challenge for doctors in the practice of plastic surgery is to treat each patient on the basis of his or her individual needs and desires while exhibiting a true understanding of the difference between proven science and hearsay.

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