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FTC vs. Supplement Fraud

By ACSH Staff — June 17, 2004

Yesterday's report that the United States Federal Trade Commission is going after [1] the maker of Pedia Loss [2] and Pedia Lean [3] is good news, no doubt.

The FTC charged the ironically-named Utah-based company Basic Research L.L.C. with making "Dramatic, unsubstantiated weight and fat loss claims," said Howard Beales at the FTC. "It's particularly disturbing, however, when marketers peddle such pills and potions for children without adequate substantiation."

Perhaps less disturbing, but more important, is the fact it is the FTC, not the better-qualified Food and Drug Administration, which oversees these types of products. No, it doesn't take an expert team of scientists to "challenge as unsubstantiated claims that...Tummy Flattening Gel causes rapid and visibly obvious fat loss in areas of the body to which [it is] applied."

But recall the last time the Food and Drug Administrated had the legal authority to similarly challenge a product.

I addressed that issue in a January 9 column about the law sponsored by Orin Hatch (R-UT), the Dietary Supplement Health and Education Act (DSHEA) following the FDA's announcement of its intention to ban weight loss or "athletic performance enhancing" products containing ephedra:

> *It took over 100 deaths, including that of a major league baseball player, over 10,000 recorded complaints, and countless scientific studies for the FDA to ban this dangerous supplement. Because of the 1994 DSHEA, which limited FDA's authority to regulate dietary supplements, the FDA still can't be sure that it has met the regulatory burden to enact the ban; manufacturers are likely to sue.*
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> *Ephedra should have been banned a long time ago. If it had been considered a pharmaceutical product and thus subject to the same scientific standards, ephedra would not have made it to market in the first place. However, as a supplement regulated under the DSHEA, ephedra was marketed without any proof of efficacy or studies showing that the supplement is safe. In fact, under DSHEA, the government, not the manufacturer, shoulders the burden of proving a product is dangerous (rather than the manufacturer proving it is safe, as is the case with pharmaceuticals). There is in place a double standard for dealing (harshly) with pharmaceuticals and food additives vs. dealing (leniently) with supplements, and this is intolerable. The DSHEA is handcuffing the FDA's efforts to protect public*

health and the only ones benefiting from the law are manufacturers who cannot present scientific data about the safety (let alone efficacy) of their "natural" products.

Why the disparity in treatment between synthetic pharmaceuticals and "natural" supplements? Dietary supplements (products you might expect to find in a "health food" store, not a pharmacy) are assumed to be safe unless chemically altered or adulterated in some form. The misconception lies in the notion that anything present in nature must be healthy and anything synthetic must be dangerous. But as the country has found with ephedra, this is not necessarily the case.

Even when the FDA attempts to act within its powers, little may be done. In 1997 when the FDA first attempted to regulate ephedra by requiring warning labels and dosage restrictions, the move to protect public health was blocked. Why? Because the FDA had not met the excessive burden of proving that there was "significant or unreasonable risk of injury" associated with the use of ephedra. Is it possible that the death of the Baltimore Orioles pitcher Steve Belcher in 2003 and the pain and misfortune of many other ephedra users could have been avoided? That is a question DSHEA's congressional authors will surely struggle with.

The regulations the FDA is attempting to enact will only affect the sale of ephedra, not the regulatory system itself or the problems that allowed ephedra to remain on the market for so long. If the ban on ephedra is enacted, it may serve as a good precedent for proceedings against other supplements, but it will not grant the FDA the broader power necessary to protect the public health from dangerous supplements.

As the nation becomes increasingly health-conscious but also vulnerable to "quick fixes," Americans are turning more and more to so-called "natural" remedies, including some dangerous supplements. Sixty percent of Americans take some sort of dietary supplement every year, and consumers need realistic and accurate information about the supplements they take. It is time that Congress rewrote the law to allow the FDA to better do its job and protect consumers from dangerous supplements.

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[1] http://www.ftc.gov/opa/2004/06/dietsupp.htm
[2] http://www.prescriptionlife.com/pedia-loss.html
[3] http://www.a1nutritionproducts.com/buy/Klein_Becker/pedia_lean