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Reports

DIETARY SUPPLEMENTS CONTAINING EPHEDRA

A dietary supplement is a product intended to supplement the diet, composed of one or any combination of the following substances: a vitamin, a mineral, an herb, an amino acid, or other botanicals. According to the U.S Food and Drug Administration (FDA), more than half the population in this country use "dietary supplements". While the health benefits of many dietary supplements are documented, some like ephedra have associated adverse side effects that outweigh their benefits.

What is Ephedra?

Ephedra is a naturally occurring substance derived from an herb. Its principal active ingredient is ephedrine, which is regulated as a drug when synthesized chemically. Ephedra is often used for weight loss and enhancing sports performance. It is usually available in health clubs, health stores and online. Ephedra acts as an adrenaline-like stimulant that can have potentially dangerous effects on the nervous system and heart. Despite its dangers, ephedra is still on the market with the General Accounting Office estimating that 12 million individuals were using ephedra in 1999.[1]
Benefits vs. Dangers of Ephedra

A study recently released by the Rand Corporation is one of many studies that have been conducted to determine the efficacy and adverse effects of ephedra and ephedrine. Although the study found an association between short-term use of ephedra and an increase in short-term weight loss as well as a modest effect on very short-term athletic performance, there is very little data to suggest its safety and efficacy over a long period of time.
Regulation of Ephedra

The Dietary Supplement Health and Education Act (DSHEA) of 1994 severely limits government regulation of dietary supplements. Under this Act, dietary supplements do not require pre-market approval. Once they are on the market, the FDA can only restrict their sale when they pose an unreasonable risk, based on available scientific evidence.

Sports officials, public health advocates and politicians have been calling to amend the DSHEA for years, to no avail. However, the high profile death of major league baseball player Steve Belcher, whose death was linked to a substance that contained ephedra, brought the issue to the forefront once again.

The FDA has recently proposed a warning label for all ephedra-containing dietary supplements; explaining the risks of serious side effects. In addition, the FDA has proposed a new regulation to require current good practices (CGMPs) in their manufacturing, packing, and holding. This proposed rule includes requirements for designing and constructing physical plants, establishing quality control procedures, and testing manufactured dietary ingredients and dietary supplements. It also includes proposed requirements for maintaining records and for handling consumer complaints related to CGMPs. They are also sending out warning letters to firms marketing diet supplements containing ephedrine alkaloids. These letters are being targeted at companies that claim athletic performance enhancements. The letters warn companies not to make false and misleading claims about their products capacity to boost athletic performance.

Efforts to Ban Ephedra

Suffolk County has recently passed a ban on sales of all dietary supplements containing ephedra, becoming the first county in the nation to pass such a measure. The bid to ban ephedra supplements began last summer, led by Democratic County legislator Jon Cooper. These efforts were met with intense lobbying from the dietary supplement industry, who vigorously opposed the ban.

The law is aimed at eliminating the sale of ephedra-based products in Suffolk County stores and Doctor's offices. It does not, however, affect the manufacturing of ephedra-based products in Suffolk County. First time offenders will get a warning, and fined up to \$5,000 after that. The county health department is responsible for enforcing the law, which goes into effect when it is filed with the state. That could take four to six weeks.

A number of medical and consumer organizations, including the American Heart Association and Consumers Union, have called for the banning of herbal ephedrine. Other organizations like the NFL, NCAA and the International Olympic Committee have already banned the use of ephedra.

[1]Dietary Supplements for Weight Loss: Limited Federal Oversight Has Focused More on Marketing than on Safety (Testimony, 07/31/2002, GAO-02-985T).

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