

Ephedra Redux

By ACSH Staff — March 3, 2003

Yet another young man has fallen victim to the American quest for a "magic bullet." A couple of weeks ago twenty-three-year-old Steve Bechler, a Baltimore Orioles pitcher, collapsed and died of heatstroke during spring training. The weather was warm eighty-one degrees but not outstandingly hot. Why would a young, strong, athletic man succumb like that? It is quite likely that at least part of the answer is Bechler's use of an herbal weight loss/energizing product containing the herbal stimulant ephedra.

Such products are widely touted as being "natural" and therefore safe weight loss and body building aids. But natural doesn't necessarily equal safe, and no product will actually produce sustained weight loss without concomitant reduction in calorie consumption and increased calorie expenditure.

This is not to say that products containing ephedra have no effects. Indeed, a combination of ephedra and caffeine can increase the efficacy of weight loss diets. But like those other herbal products, St. John's wort and kava, ephedra's effects are not risk-free.

Ephedra stimulates the central nervous system it is similar to amphetamines in its chemical structure. It decreases nasal congestion and can relieve bronchial asthma; on the down side, ephedra increases both heart rate and blood pressure. When combined with caffeine, as is often the case with weight-loss preparations, these effects are magnified.

Reports of Negative Effects

Was ephedra responsible for Bechler's death? The toxicology reports aren't in yet, but we do know that a bottle of an ephedra-containing dietary supplement was found in his locker. News reports also indicate that he had high blood pressure and liver disease; anyone with these conditions should certainly not be using a drug like ephedra without medical supervision.

A recent study in the *Annals of Internal Medicine* (2003; 138) compared the number of reported adverse events associated with ephedra use to the number associated with other herbal products. The data for this review were derived from the 2001 annual report of the American Association of Poison Control Centers. Although ephedra-containing supplements made up less than 1% of herbal product sales, they accounted for 64% of all adverse reactions to herbs in the United States. Is this proof that ephedra is dangerous? No, not really. But that information, coupled with the fact that a recent Rand Corporation study reviewed 16,000 adverse event reports associated with ephedra-containing supplements, should be enough to make anyone think twice about using these supplements.

They would probably think twice, if they knew about such data but if people don't read the medical literature and don't follow health news, they might well rely on label information to tell them about

any problems associated the supplement. Or they might expect that such products are regulated by the government and that, like over the counter medications, they have been tested for safety and efficacy. But they'd be wrong.

Contents Unknown

Because of the 1994 Dietary Supplement Health and Education Act (DSHEA), dietary supplements are regulated like food, not drugs. This means that the manufacturer can sell them without first showing that they're safe. Sure, they're supposed to have safety data, but they don't have to make it available to the Food and Drug Administration (FDA) the way companies that make pharmaceuticals and food additives do.

Further, it is up to the FDA to show that a supplement is harmful before it can insist that it be taken off the market. Only supplements that are "adulterated" present a significant risk of injury or illness, according to DSHEA. Thus, the bar for banning a supplement is rather high, and in spite of the fact that there have been thousands of adverse effects associated with ephedra, the FDA hasn't been able to demand it be taken off the shelves.

The problem is that adverse event reporting is voluntary. A recent report in the British journal the *Lancet* calls it "an inherently weak form of surveillance." Unlike the makers of regular pharmaceuticals, supplement manufacturers don't have to collect post-marketing information on possible ill effects of their products, and they don't have to make any such reports they receive available to the FDA unless it asks for them.

Currently, the FDA, partly as a result of the widely publicized death of Steve Belcher, is considering a requirement for warning labels on dietary supplements containing ephedra. Maybe that will help consumers a little, but the main group it will help is supplement manufacturers. Such a label could indemnify them against wrongful death suits, much as the warning labels on cigarettes protected the tobacco industry for many years.

The real answer is realistic regulation of the supplement industry. Consumers should have access to herbal and other supplements if they want them, but they should also have access to *accurate* information about the safety of these products. Thanks in large part to DSHEA, they don't have that information now. Congress passed a bad law back in '94. They should fix it.

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