

108TH CONGRESS
1ST SESSION

S. RES. 260

Expressing the sense of the Senate that the Secretary of Health and Human Services should take action to remove dietary supplements containing ephedrine alkaloids from the market.

IN THE SENATE OF THE UNITED STATES

NOVEMBER 6, 2003

Mr. DURBIN (for himself and Mr. MCCAIN) submitted the following resolution; which was referred to the Committee on Health, Education, Labor, and Pensions

RESOLUTION

Expressing the sense of the Senate that the Secretary of Health and Human Services should take action to remove dietary supplements containing ephedrine alkaloids from the market.

Whereas a RAND Corporation study commissioned by the Department of Health and Human Services found no evidence for long-term efficacy of ephedrine alkaloids for weight loss and that there is no credible science showing that ephedrine or dietary supplements containing ephedrine alkaloids, as those products are used by the general population, improve athletic performance;

Whereas ephedrine alkaloids can—

- (1) increase heart rate and blood pressure;
- (2) stimulate the central nervous system; and

(3) lead to strokes, seizures, psychosis, cardiac arrhythmia, heart attacks, and deaths;

Whereas the Food and Drug Administration has received approximately 16,500 adverse events reports for consumers who have used dietary supplements containing ephedrine alkaloids, including approximately 155 reports of death;

Whereas the Inspector General of the Department of Health and Human Services has noted with concern that about 60 percent of persons suffering adverse events related to the use of dietary supplements containing ephedrine alkaloids are under the age of 40;

Whereas a study published in the Journal of Neurology found that there may be an association between the use of more than 32 milligrams per day of ephedra and an increased risk of hemorrhagic stroke, but the daily dose recommended by the dietary supplement industry is about 3 times that much;

Whereas a study published in Mayo Clinical Proceedings found that in 36 out of 37 serious cardiovascular events associated with ephedrine alkaloids examined, the patient had consumed doses of a dietary supplement containing ephedrine alkaloids at or below the dose recommended by the manufacturer;

Whereas a study commissioned by the Food and Drug Administration to review reports of ephedrine alkaloid-related adverse events (including serious adverse events such as seizures, strokes, and death), which resulted in publication in the New England Journal of Medicine of an article in 2000, found that 31 percent of the reports were definitely or probably related to ephedrine alkaloid

use and an additional 31 percent were possibly related to ephedrine alkaloid use;

Whereas a study published in the *Annals of Internal Medicine* concluded that—

(1) the risk for an adverse reaction after the use of ephedra is substantially greater than with other herbal products; and

(2) the sale of ephedra as a dietary supplement should be restricted or banned to prevent serious adverse reactions in the general population;

Whereas approximately 30 members of the United States Army have died after taking a dietary supplement containing ephedrine alkaloids, and the Department of Defense has banned the sale of dietary supplements containing ephedrine alkaloids from military commissaries worldwide because of safety concerns;

Whereas the American Medical Association has called on the Secretary of Health and Human Services to ban the sale of dietary supplements containing ephedrine alkaloids;

Whereas the National Football League, the International Federation of Football Associations, the National Collegiate Athletics Association, the Commissioner of the National Association of Baseball with regard to the Minor Leagues, Major League Soccer, the National Basketball Association, and the International Olympics Committee have banned the use of ephedrine alkaloids by their athletes;

Whereas 3 States, representing 65,000,000 Americans, have banned dietary supplements containing ephedrine alkaloids;

Whereas major drug store chains representing 17,300 stores nationwide have pulled ephedrine alkaloid-containing dietary supplements from their shelves; and

Whereas the largest specialty retailer of dietary supplements in the country, which has 5,300 stores nationwide, has pulled ephedrine alkaloids from its shelves: Now, therefore, be it

1 *Resolved by the Senate (the House of Representatives*
2 *concurring)*, That it is the sense of Congress that—

3 (1) the Secretary of Health and Human Serv-
4 ices has authority under subsections (a) and (f) of
5 section 402 of the Federal Food, Drug, and Cos-
6 metic Act (21 U.S.C. 343) to determine that dietary
7 supplements containing ephedrine alkaloids—

8 (A) present a significant or unreasonable
9 risk of illness or injury;

10 (B) pose an imminent hazard to public
11 health or safety; or

12 (C) contain poisonous or deleterious sub-
13 stances that may render dietary supplements
14 injurious to health;

15 (2) there is sufficient evidence to make such a
16 determination; and

17 (3) the Secretary should take immediate action
18 to remove dietary supplements containing ephedrine
19 alkaloids from the marketplace.