SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

BILL: CS/CS/SB 1626

SPONSOR: Criminal Justice Committee, Health, Aging, and Long-Term Care Committee and Senator Margolis and others

SUBJECT: Weight-Loss Pills

DATE: April 15, 2003 REVISED: _____ _____ _____ _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Munroe	Wilson	HC	Fav/CS
2.	Erickson	Cannon	CJ	Fav/CS
3.			RI	
4.				
5.				
6.				

I. Summary:

The CS makes it unlawful to sell, deliver, barter, furnish, or give, directly or indirectly, a weight-loss pill to a person under 18 years of age. The CS defines "weight-loss pill" to mean a pill that is available without a prescription, the marketing, advertising, or packaging of which indicates that its primary purpose is for facilitating or causing weight loss. The term includes, but is not limited to, a pill that contains at least one of the following ingredients: ephedra species; ephedrine alkaloid-containing dietary supplements; Sida cordifelia or any similar ingredient. However, the term does not include a pill containing one or more of such ingredients which is marketed or intended for a primary purpose other than weight loss. The CS provides a defense to the prohibited delivery of a weight-loss pill to a person under 18 years of age.

Each establishment at which weight-loss pills are sold at retail must display in a conspicuous place at each location within the establishment at which purchases may be made a sign with the following statement in red letters at least half an inch high on a white background: "It is a violation of Florida law to sell weight-loss pills to persons under 18 years of age."

A first violation of the offenses created in the CS is punishable by a fine of $500. A second violation is punishable by a fine of $1,000. A third or subsequent violation constitutes a second degree misdemeanor.

This CS creates one undesignated section of law.

II. Present Situation:

Weight-loss Drugs

The side effects of dietary supplements are difficult to monitor in the United States because these products do not need to be approved before sale, and there is little information about their content and safety. A product that claims to be "natural" or "herbal" is not necessarily safe. These products are not usually tested scientifically to prove that they are safe or that they work. Some herbal or other natural products may be unsafe to use with other drugs or may harm people with certain medical conditions.

Ephedra, also known as ma huang, ephedrine, sida cordifolia, and epitonin, is virtually the same ingredient as the pseudoephedrine found in many over the counter decongestants. Ephedra affects the cardiovascular and central nervous systems, and may cause cardiac arrhythmias, heart attacks, strokes, seizures and sudden death in previously healthy people as well as in those with risk factors for cardiovascular conditions. The American Medical Association recently called for a ban on the weight-loss supplement ephedra, and a top maker of the supplements said the industry should be more closely regulated.

Benzphetamin, diethylpropion, and phentermine are in a class of drugs that decrease appetite and cause stimulation, elevation of blood pressure, and faster heart rates. These weight-loss drugs are used as a short-term drug along with diet and behavior modification to treat obesity. Phenylpropanolamine (PPA) was used as an ingredient in many over-the-counter medications for colds, sinus, allergy, and coughs, and diet and appetite suppressants. In 2000, PPA was linked to increased risk for strokes by a U.S. Food and Drug Administration advisory panel.

Federal Regulation of Dietary Supplements

Many consumers believe that dietary supplements help to augment their diets and provide health benefits. Pursuant to the 1958 Federal Food, Drug, and Cosmetic Act, the United States Food and Drug Administration regulated dietary supplements as foods and evaluated the safety of all new ingredients, including those used in dietary supplements. On October 25, 1994, the Dietary Supplements Health Education Act of 1994 (DSHEA) amended the 1958 law to provide that dietary ingredients used in dietary supplements are no longer subject to premarket safety evaluations that are required of other new food ingredients or for new uses of old food ingredients.[1] A "dietary supplement" under DSHEA is:

- a product (other than tobacco) that is intended to supplement the diet that bears or contains one or more of the following ingredients (vitamin, mineral, herb, amino acid, a dietary substance for use by man to supplement the diet by increasing the total daily intake, or a concentrate, metabolite, constituent, extract, or combination of these ingredients);
- is intended for ingestion in pill, capsule, table, or liquid form;
- is labeled as a "dietary supplement;" and

[1] See "Dietary Supplement Health and Education Act of 1994" U.S. Food and Drug Administration, December 1, 1995, <http://www.cfsan.fda.gov/~dms/dietsupp.html>

- includes products such as an approved drug, certified antibiotic, or licensed biologic that was marketed as a dietary supplement or food before approval, certification, or license.[2]

Under DSHEA, a dietary supplement is adulterated if it, or one of its ingredients, presents a significant or unreasonable risk of illness or injury when used as directed on the label, or under normal conditions of use in the absence of directions.[3] Claims may not be made about the use of a dietary supplement to diagnose, prevent, mitigate, treat, or cure a specific disease under DSHEA. Appropriate health claims authorized by FDA may be made in supplement labeling if the product qualifies to bear the claim. Manufacturers may describe the supplement's effects on "structure or function" of the body or "well-being" achieved by consuming the dietary ingredient. To use these claims, manufacturers must have substantiation that the statements are truthful and not misleading and the product label must bear the statement:

> This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

Unlike health claims, nutritional support claims need not be approved by the FDA before the manufacturer can market products bearing the statement.

Regulation of Food in Florida

Under the Florida Food Safety Act, the Department of Agriculture and Consumer Services has jurisdiction over the manufacture, sale or delivery of food to ensure that it is not adulterated or misbranded. Over-the-counter pills which do not make claims of medical benefits but purport to have health benefits generally fall into the broad category of dietary supplements. Dietary supplements are regulated as foods in Florida.

The department is charged with the administration and enforcement of ch. 500, F.S., in order to prevent fraud, harm, adulteration, misbranding, or false advertising in the preparation, manufacture, or sale of articles of food. "Food" is defined to include articles used for food or drink for human consumption; chewing gum; articles used for components of such articles; and articles for which health claims are approved by the Secretary of the U.S. Department of Health and Human Services, and which are not considered drugs solely because their labels or labeling contain health claims. The term "food" includes any raw, cooked, or processed edible substance, ice, any beverage, or any ingredient used or intended for use, or sold for human consumption.[4]

The Department of Agriculture and Consumer Services (DACS) has "stop sale" authority to seize adulterated or misbranded articles of food. Any article of food that is adulterated or misbranded under the provisions of ch. 500, F.S., is subject to seizure and condemnation by DACS or by its duly authorized agents designated for that purpose in regard to foods. Whenever DACS or its duly authorized agent finds cause, or has probable cause to believe that grounds exist for the seizure of any food as set out in ch. 500, F.S., an agent of the department must affix to the article a tag, stamp or other appropriate marking, giving notice that the article is, or is

[2] *Id.*
[3] *Id*.
[4] See s. 500.03(l), Florida Statutes.

suspected of being, subject to seizure under ch. 500, F.S., and that the article has been detained and seized by the department.[5] The department must warn all persons not to remove or dispose of the article for sale, until permission of the department, or of the court of competent jurisdiction, is given. It is unlawful for any person to remove or dispose of the detained or seized article by sale or otherwise without permission of DACS or of the court in such cases and any person who violates this prohibition is subject to a second degree misdemeanor punishable by jail up to 60 days and the imposition of a fine up to $500. The department may petition a court for an order of condemnation or sale for any item seized or condemned as an adulterated or misbranded "food."

The Department of Agriculture and Consumer Services has been actively involved in the regulation of products containing ephedra/ephedrine. All ephedra (sometimes identified as ma huang) products are dietary supplements. The department has maintained an on-going surveillance of these products since the mid-1990s, and may seize products containing ephedrine alkaloids of concentrations more than 25 mg per dose/serving or more than a total daily dose/serving of 150 mg/day.

Florida Drug and Cosmetic Act

The Department of Health is responsible for regulating and enforcing the Florida Drug and Cosmetic Act, ch. 499, F.S. Chapter 499, F.S., provides regulatory oversight of the manufacture and distribution of drugs, devices, cosmetics and ether within Florida. The Department of Health does not regulate dietary supplements, but has authority to take regulatory action if drugs are misbranded or adulterated.

III. Effect of Proposed Changes:

The bill defines "weight-loss pill" to mean a pill that is available without a prescription, the marketing, advertising, or packaging of which indicates that its primary purpose is for facilitating or causing weight loss. The term includes, but is not limited to, a pill that contains at least one of the following ingredients: ephedra species; ephedrine alkaloid-containing dietary supplements; Sida cordifelia or any similar ingredient. However, the term does not include a pill containing one or more of such ingredients which is marketed or intended for a primary purpose other than weight loss.

The bill makes it unlawful to sell, deliver, barter, furnish, or give, directly or indirectly, a weight-loss pill to a person under 18 years of age. It is a defense to a charge of violating this prohibition if the buyer or recipient of the weight-loss pill displayed to the person alleged to have committed the violation a driver's license or identification card issued by Florida or another state, a passport, or a United States armed services identification card that indicated that the buyer or recipient was 18 years of age or older and the appearance of the buyer or recipient was such that a prudent person would reasonably believe that the buyer or recipient was not under 18 years of age.

[5] See s. 500.174, F.S.

Each establishment at which weight-loss pills are sold at retail must display in a conspicuous place at each location within the establishment at which purchases may be made a sign with the following statement in red letters at least half an inch high on a white background:

It is a violation of Florida law to sell weight-loss pills to persons under 18 years of age.

A first violation of the offenses created in the CS is punishable by a fine of $500. A second violation is punishable by a fine of $1,000. A third or subsequent violation constitutes a second degree misdemeanor, punishable by up to 60 days in jail or the imposition of a fine of up to $500.

The CS provides an effective date of July 1, 2003.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this CS have no impact on municipalities and the counties under the requirements of Article VII, s. 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of this CS have no impact on public records or open meetings issues under the requirements of Art. I, s. 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this CS have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

V. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

To the extent that minors avoid unanticipated bad health outcomes associated with the use of weight-loss products, they will benefit.

C. Government Sector Impact:

The Department of Agriculture and Consumer Services will incur costs to enforce the CS's requirements for signage and training of employees regarding the prohibited sale of weight-loss pills to minors. The department estimates it will need to hire an OPS position for about 950 hours/year. The associated programming costs, supplies, office space, filing fees, etc. will total $44,031 in fiscal year 2003-2004 and $41,442 in fiscal year 2004-2005. The department estimates that it will impose administrative fines and collect

revenue of $44,870 in fiscal year 2003-2004 and $42,187 in fiscal year 2004-2005 and subsequent years.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Amendments:

None.