

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 953 Weight-loss Pills
SPONSOR(S): Roberson and others
TIED BILLS: None. **IDEN./SIM. BILLS:** SB 1626 (s)

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Standards (Sub)	6 Y, 1 N	Mitchell	Collins
2) Health Care			
3)			
4)			
5)			

SUMMARY ANALYSIS

HB 953 prohibits the sale, gift, or other delivery of nonprescription "weight-loss" pills to minors. The bill requires retail establishments selling such pills to post notice that such sale to minors is unlawful. The bill provides that violation of either the requirement to post a notice or prohibited sale to minors is a second-degree misdemeanor punishable by fine of up to \$500 and imprisonment of up to 60 days. The bill provides a defense to a charge of unlawful sale or other delivery if the buyer or recipient produced identification indicating that he or she was of age and his or her appearance was such that one could reasonably believe that he or she was 18 or older.

The bill defines "weight-loss pill" as a pill that is available without prescription and is marketed, advertised or packaged to indicate that its primary purpose is for facilitating or causing weight loss. The bill specifically identifies six ingredients found in "weight-loss" pills and provides for inclusion of any similar ingredient. The six identified ingredients are: phenylpropanolamine (formerly a common ingredient of over the cold counter medications that has been removed from the market); phentermine; phendimetrazine; benzphetamine; and diethylpropion (which are prescription medications); and ephedra (an herbal supplement regulated as a consumer product not as a medication). The bill provides for any similar ingredients to be included.

These products are not regulated as drugs. The manufacturers and distributors of the "weight-loss pills" addressed by this bill make no claims that they are to be used for weight loss purposes. Such claims would require FDA regulation as a drug. Federal law forbids most regulation of dietary supplements unless the FDA proves danger. The products addressed by this bill only identify their intended use through such names as "slim-eaze," etc., which imply they are used for weight loss purposes. These products are regulated in Florida by the Department of Agriculture and Consumer Services.

The effective date of the bill is July 1, 2003.

On March 19, 2003, the Subcommittee on Health Standards adopted two amendments. (See Section IV. for explanation of the amendments.)

This document does not reflect the intent or official position of the bill sponsor or House of Representatives.

STORAGE NAME: h0953a.hc.doc
DATE: March 21, 2003

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. DOES THE BILL:

- | | | | |
|--------------------------------------|------------------------------|--|---|
| 1. Reduce government? | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> | N/A <input type="checkbox"/> |
| 2. Lower taxes? | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> |
| 3. Expand individual freedom? | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> | N/A <input type="checkbox"/> |
| 4. Increase personal responsibility? | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> |
| 5. Empower families? | Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> |

For any principle that received a "no" above, please explain:

The bill creates a new provision to prohibit the sale of weight-loss pills to persons under age 18 and provides criminal penalties for establishments selling these pills to a person under 18 years of age.

B. EFFECT OF PROPOSED CHANGES:

HB 953 prohibits the sale, gift, or other delivery of nonprescription "weight-loss" pills to minors. The bill defines "weight-loss pill" as a pill that is available without prescription and is marketed, advertised or packaged to indicate that its primary purpose is for facilitating or causing weight loss. The bill specifically identifies six ingredients found in "weight-loss" pills and provides for inclusion of any similar ingredient. The six identified ingredients are: phenylpropanolamine (formerly a common ingredient of over the cold counter medications that has been removed from the market); phentermine; phendimetrazine; benzphetamine; and diethylpropion (which are prescription medications); and ephedra (an herbal supplement regulated as a consumer product not as a medication).

The bill requires establishments selling such pills at retail to post notice that such sale to minors is unlawful. The bill provides that violation of either the notice requirement or prohibited sale to minors is a second-degree misdemeanor. The bill provides that it is a defense to a charge of unlawful sale or other delivery that the buyer or recipient produced identification indicating that he or she was of age and his or her appearance was such that one could reasonably believe that he or she was 18 or older.

The second degree misdemeanor violation provided in this bill is punishable by a fine of up to \$500, under s. 755.083(1)(e), F.S., and a term of imprisonment of up to 60 days, under s. 775.082 (3)(b), F.S.

The products addressed by this bill are not regulated as drugs. The manufacturers and distributors of the "weight-loss pills" this bill addresses make no claims that they are used for weight loss purposes. Such claims would require Federal Drug Administration regulation as a drug. These products fall into the category of dietary supplements and federal law forbids most regulation of dietary supplements, unless the FDA proves danger. The products addressed by this bill only identify their intended use through such names as "slim-eaze," etc., which imply they are used for weight loss. In Florida, they are regulated by the Department of Agriculture and Consumer Services.

Effects of these drugs:

The "Whereas" sections of the bill cite recent medical information reporting the correlation between dieting and the onset of eating disorders and the FDA warning that over-the-counter diet pills containing phenylpropanolamine (PPA) must contain warning labels that state, "People between 12 and 18 years of age should not try this product without consulting a doctor. Not for use by children under 12 years of age."

Micromedex, a national drug information database, provides the following information regarding the medications: Phenylpropanolamine (fen-ill-proe-pa-NOLE-a-meen), commonly known as PPA, was used as a nasal decongestant and as an appetite suppressant in many over-the-counter products, but

was withdrawn from the market because it was found to cause serious side effects (even death). In November 2000, the Food and Drug Administration (FDA) issued a public health warning regarding PPA due to the risk of hemorrhagic stroke. The FDA requested that manufacturers voluntarily discontinue marketing products that contain PPA .

Four of the ingredients identified in the bill are prescription medications for systemic appetite suppressants, Benzphetamine (benz-FET-a-meen), Diethylpropion (dye-eth-il-PROE-pee-on), Phendimetrazine (fen-dye-MET-ra-zeen), and Phentermine (FEN-ter-meen). According to Micromedex, sympathomimetic appetite suppressants are used in the short-term treatment of obesity. Studies on these medicines have been done only in adult patients, and there is no specific information comparing use of sympathomimetic appetite suppressants in children with use in other age groups. The use of these medicines by children younger than 16 years of age is not recommended. Diethylpropion and benzphetamine pass into breast milk. It is not known if other sympathomimetic appetite suppressants pass into breast milk. According to Micromedex, the medications may be habit-forming.

Ephedra, is in another class of ingredient. It is an herbal stimulant, often combined with caffeine, and used mainly for weight loss or bodybuilding. According to Consumer's Union, Ephedra, also known as "ma huang," has been associated with serious health problems including hypertension, irregular heartbeat, stroke, and seizures. Some of those problems resulted in death or permanent injury, and occurred in previously healthy people. The Food and Drug Administration recently ordered six companies to stop illegally selling synthetic ephedrine in the guise of an herb. The synthetic form of ephedrine has long been outlawed, and the FDA has sought to stop such sales, which occur mostly over the Internet. Ephedrine (E-fed'drin) is a bronchodilator and adrenergic.

Consumer's Union reports that ephedra is an ingredient in Xtreme Lean, Trim Fast, and Metabolife 356, which are some of the dietary supplements available in supermarkets and on the web.

Existing state regulation for prescription drugs does not apply to these "weight-loss" pills. The Florida Department of Health's Bureau of Statewide Pharmaceutical Services is responsible for regulating and enforcing The Florida Drug and Cosmetic Act, Chapter 499, F.S., that provides for regulatory oversight of the manufacture and distribution of drugs, devices, cosmetics, and ether, within and into Florida to safeguard public health and protect consumers from injury and merchandising deceit.

Ephedra and other such dietary supplements fall under chapter 500, F.S., the Florida Food Safety Act. Provisions of the act are administered by the Department of Agriculture and Consumer Services and include compliance with the Federal Food, Drug, and Cosmetic Act.

Limitations of the bill

The bill identifies specific ingredients that are found in weight-loss pills and provides that similar ingredients are covered under the provisions of the bill. Because the specified ingredients differ in several respects, it is not clear which "similar ingredients" may be covered. Similar ingredients may include Ephedrine and Guaifenesin. The bill also does not address the sale of non-pill forms of these products.

C. SECTION DIRECTORY:

Section 1. Creates an undesignated provision relating to selling, delivering, bartering, furnishing, or giving weight-loss pills to persons under age 18; and provides for penalties and defense.

Section 2. Provides the act shall take effect July 1, 2003.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

See Fiscal Comments.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

See Fiscal Comments.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

There will be lost revenues by businesses that sell "weight-loss" pills to minors.

D. FISCAL COMMENTS:

There would be no fiscal impact on the Department of Agriculture and Consumer Services which inspects retail establishments for food safety. Weight-loss products as well as the "sign" to be displayed in the retail establishments would be added to the items they look for during inspections.

The criminal provision in this bill is a misdemeanor and will have no impact on the need for prison beds, but may have an impact on the County Sheriff's department.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not require counties or municipalities to spend funds or to take an action requiring the expenditure of funds. This bill does not reduce the percentage of a state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenues.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The bill specifically identifies six ingredients that are included in "weight-loss" pills and provides for inclusion of any "similar ingredient." Because the specified ingredients differ in several respects, it is not

clear which “similar ingredients” may be covered. Additionally, this bill does not address the sale of non-pill forms of these products.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

On March 19, 2003, the Subcommittee on Health Standards adopted two amendments to address concerns identified in comments above.

Amendment #1 removes references to any drugs except ephedra and includes the names of common forms of ephedra---ephedrine alkaloid and Sida Cordifolia.

Amendment #2 makes a technical change that removes the word “gift” from the title.