HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #:HB 953 w/CSWeight-loss PillsSPONSOR(S):Roberson and othersTIED BILLS:None.IDEN./SIM. BILLS: SB 1626 (s)

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR	
1) Health Standards (Sub)	<u>6 Y, 1 N</u>	Mitchell	Collins	
2 <u>) Health Care</u>	<u>17 Y, 3 N w/CS</u>	Mitchell	Collins	
3)				
4)				
5)				

SUMMARY ANALYSIS

HB 953 prohibits the sale 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 punishments for violations of either the requirement to post a notice or prohibited sale to minors. A first violation is punishable by a fine of \$500. A second violation is punishable by a fine of \$1,000. A third or subsequent violation 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 includes, but is not limited to, pills that contain the herbal supplement ephedra, ephedrine alkaloid, or Sida cordifolia, a plant which also contains ephedra alkaloids.

These products are not regulated as drugs. They are herbal supplements that are regulated in Florida by the Department of Agriculture and Consumer Services.

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 Federal Drug Administration 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.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. DOES THE BILL:

1. R	educe government?	Yes[]	No[X]	N/A[]
2. Lo	ower taxes?	Yes[]	No[]	N/A[X]
3. E	xpand individual freedom?	Yes[]	No[X]	N/A[]
4. In	crease personal responsibility?	Yes[]	No[]	N/A[X]
5. Ei	mpower families?	Yes[]	No[]	N/A[X]

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:

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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 adverse physiological consequences of dieting and weith-loss.

Ephedra is an herbal stimulant, often combined with caffeine, and used mainly for weight loss or bodybuilding. According to the Consumer's Union website, ephedra, also known by its Chinese name "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.

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.

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.

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:

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

On March 19, 2003, the Subcommittee on Health Standards adopted two amendments to address concerns raised about the original provisions of the bill.

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

Amendment #2 made a technical change that removed the word "gift" from the title.

On March 26, 2003, the Health Care Committee adopted the amendments recommended by the subcommittee and reported the bill favorably with a committee substitute.