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 446

SPONSOR: Governmental Oversight and Productivity Committee, Health, Aging, and Long-Term Care Committee, and Senators Margolis and Wasserman-Shultz

SUBJECT: Sale of Products Containing Ephedrine

DATE: January 22, 2003 REVISED: _____ _____ _____ _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Munroe	Wilson	HC	Favorable/CS
2.	White	Wilson	GO	Favorable/CS
3.			RC	
4.				
5.				
6.				

I. Summary:

The Committee Substitute for Committee Substitute for Senate Bill 446 amends a provision of law which currently requires a drug product containing ephedrine, the active ingredient of ephedra, to be dispensed only as a prescription drug, to require any product intended for ingestion by humans which contains ephedra or sida cordifolia to also be legally dispensed by a duly licensed pharmacist or dispensing practitioner only with a prescription. The bill requires a prescription for the sale or delivery of any product that contains any quantity of ephedrine, a salt of ephedra, a salt of ephedrine, an optical isomer of ephedrine, or a salt of any optical isomer of ephedrine, including any part of the plant genus ephedra or the plant genus sida cordifolia. Under the bill, combinations of drug products containing ephedrine in specified dosage forms will continue to be available to consumers as over-the-counter products without the need for a prescription.

Individuals or establishments that sell, purchase, receive, possess, or deliver prescription or contraband drugs in violation of the requirements of the bill relating to products containing ephedra or ephedrine may be liable for felony violations.

The bill creates the "Weight Loss and Athletic Performance Dietary Supplement Review Committee" for the purpose of evaluating the safety of ingredients contained in dietary supplements that are sold in Florida.

The bill repeals s. 501.0583, F.S., which prohibits the selling, delivering, bartering, furnishing, or giving of weight-loss pills to persons under age 18.

This bill amends section 499.033, Florida Statutes.

This bill repeals s. 501.0583, F.S., as created by section 1 of chapter 2003-24, Laws of Florida.

II. Present Situation:

Ephedra and Dietary Supplements Promoting Weight-loss and Athletic Performance

Many consumers believe that dietary supplements help to augment their diets and provide health benefits. However, 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 those with risk factors for cardiovascular conditions, as well as in previously healthy people. 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.

Other weight-loss drugs have also been linked to potential health problems. 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 conditions, 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.

Several states, including Illinois and New York have banned over-the-counter sales of any product that contains ephedra. Illinois bans the sale of ephedra, but the ban does not include any drug that contains ephedrine which is lawfully sold, transferred, or furnished over the counter with or without a prescription pursuant to the federal Food, Drug and Cosmetic Act or regulations adopted under that Act. Violation of the Illinois law carries a criminal penalty of imprisonment for less than one year and the imposition of a fine of not more than $5,000. The Illinois law has enhanced penalties for subsequent violations and imprisonment of up to 5 years and a fine of up to $20,000 may be imposed. Under New York law, ephedra products can only be sold by prescription.

Federal Regulation of Dietary Supplements

Pursuant to the 1958 Federal Food, Drug, and Cosmetic Act, the United States Food and Drug Administration regulated dietary supplements for many years 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, tablet, or liquid form;
- is labeled as a "dietary supplement;" and
- 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 the "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 (DACS) has jurisdiction over the manufacture, sale or delivery of food to ensure that it is not adulterated or misbranded. Over-the-counter pills for which the manufacturer does not make claims of medical benefits, but which are purported to have health benefits generally, fall into the broad category of dietary supplements. Dietary supplements are regulated as foods in Florida.

The DACS 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

[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>
[2] *Id.*
[3] *Id.*

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 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 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 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 DACS 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.

During the 2003 Session, the Florida Legislature adopted legislation (chapter 2003-24, Laws of Florida) that 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. This provision was codified in s. 501.0583, F.S. The law 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; or sida cordifolia. 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.

It is a defense to a charge of violating this prohibition if the buyer or recipient displays valid identification 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.

[4] See s. 500.03(l), Florida Statutes.
[5] See s. 500.174, F.S.

A first violation of the prohibition is punishable by a fine of $100; a second violation is punishable by a fine of $250; a third violation is punishable by a fine of $500; and a fourth or subsequent violation is punishable by a fine as determined by DACS, not to exceed $1,000.

Regulation of Over-the-Counter Ephedrine in Florida

During the 1994 Session, the Legislature adopted legislation which made ephedrine, the active ingredient of ephedra, a prescription drug.[6] This means that any product which contains ephedrine can only be dispensed by prescription. This legislation was enacted in reaction to the marketing of, and the growing popularity of, products that were advertised to help the user of the products to stay awake, lose weight, or enhance athletic performance. The use of ephedrine for these purposes has not been approved by the FDA. There was growing concern that the marketing of these products was misleading consumers and was encouraging abuse of ephedrine among teenaged youth. In 1995, the law was amended to authorize certain drug products such as Primatene tablets to control asthma and combinations of products containing ephedrine in specified dosage forms to be sold over the counter. Such drug products were thought to have little potential for abuse. The 1995 revisions also made it a violation of the Florida Drug and Cosmetic Act, ch. 499, F.S., for any person to advertise or label any product containing ephedrine for the indication of stimulation, mental alertness, weight loss, appetite control, energy, or any other indication not approved by the FDA.[7]

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.

Section 499.003, F.S., defines “contraband legend drug” to mean any adulterated drug, any counterfeit drug, and also means any legend drug for which a pedigree paper does not exist, or for which the pedigree paper in existence has been forged, counterfeited, falsely created, or contains any altered, false, or misrepresented matter. Under s. 499.006(10), F.S., a drug is an adulterated drug if it is a legend drug that has been purchased, held, sold or distributed at any time by a person not authorized under federal or state law to do so.

Chapter 499, F.S., provides criminal penalties for violations of the act relating to illegal activities to sell, purchase, receive, possess, or deliver prescription or contraband drugs. Any person who purchases or sells prescription drugs for wholesale distribution in exchange for currency commits a third degree felony punishable by imprisonment of up to 5 years and the imposition of a fine of up to $5,000.[8] A person who knowingly purchases or receives from a person not authorized to distribute legend drugs under ch. 499, F.S., a legend drug in a wholesale transaction commits a second degree felony punishable by imprisonment of up to 15 years and the imposition of a fine

[6] See chapter 94-309, Laws of Florida, which created s. 499.033, F.S.
[7] See s. 2, ch. 95-415, L.O.F., which added s. 499.0054(6), F.S.
[8] See s. 499.0691(2)(i), F.S.

of up to $10,000.[9] A person who knowingly sells or transfers to a person not authorized to purchase or possess legend drugs, under the law of the jurisdiction in which the person receives the drug, a legend drug in a wholesale distribution transaction commits a second degree felony punishable by imprisonment of up to 15 years and the imposition of a fine of up to $10,000.[10] A person who is knowingly in actual possession of any amount of contraband legend drugs, who knowingly sells or delivers, or who possesses with intent to sell or deliver any amount of contraband legend drugs, commits a second degree felony punishable by imprisonment of up to 15 years and the imposition of a fine of up to $10,000.

III. Effect of Proposed Changes:

The bill amends s. 499.033, F.S., which currently requires a drug product containing ephedrine, the active ingredient of ephedra, to be dispensed only as a prescription drug, to require any product intended for ingestion by humans which contains ephedra or sida cordifolia to also be legally dispensed by a duly licensed pharmacist or dispensing practitioner only with a prescription. The bill requires a prescription for the sale or delivery of any product that contains any quantity of ephedrine, a salt of ephedra, a salt of ephedrine, an optical isomer of ephedrine, or a salt of any optical isomer of ephedrine, including any part of the plant genus ephedra or the plant genus sida cordifolia. Under the bill, combinations of drug products containing ephedrine in specified dosage forms will continue to be available to consumers as over-the-counter products without the need for a prescription.

Individuals or establishments that sell, purchase, receive, possess, or deliver prescription or contraband drugs in violation of the requirements of the bill relating to products containing ephedra or ephedrine may be liable for felony violations.

The bill creates the "Weight Loss and Athletic Performance Dietary Supplement Review Committee." The committee is created for the purpose of evaluating the safety of ingredients contained in dietary supplements that are sold in Florida and that claim to promote weight loss and athletic performance. The committee membership is to consist of the following eight members: (a) the Commissioner of the Department of Agriculture, or his or her designee; (b) the Secretary of the Department of Health, or his or her designee; (c) two members, who are health care practitioners as defined in s. 456.001 or scientists and who possess expertise in the area of weight loss and athletic performance dietary supplements, to be appointed by the Secretary of the Department of Health; (d) two members, who possess expertise in the area of dietary supplement regulation, to be appointed by the Commissioner of Agriculture; and
(e) two members, who represent the weight loss and athletic performance dietary supplement industry, to be appointed by the Commissioner of Agriculture. The committee is required to submit a report to the Legislature, which summarizes its findings and provides recommendations by August 1, 2005. Administrative support for the committee is to be provided jointly and equally by the DACS and the Department of Health.

The bill repeals s. 501.0583, F.S., which prohibits the selling, delivering, bartering, furnishing, or giving of weight-loss pills to persons under age 18.

[9] See s. 499.0051(4), F.S.
[10] See s. 499.051(5), F.S.

The effective date of the bill is July 1, 2004.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

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

D. Other Constitutional Issues:

Article VI, cl. 2 of the United States Constitution sets forth the "Supremacy Clause," which provides that the United States Constitution and laws made in pursuance thereof are the supreme law of the land, notwithstanding any contrary state constitution or law. Constitutionally enacted acts of Congress are considered part of the supreme law of the land, and thus, state law may be preempted by federal law where:

- Congress, in enacting federal law, has expressed a clear intent to occupy the field exclusively;
- There is an actual conflict between the federal and state law;
- Compliance with both the federal and state would be impossible;
- Congress has regulated so pervasively that it may be inferred that Congress left no room for state supplementation; or
- The state law impedes the accomplishment and execution of Congressional objectives.[11]

In 1994, Congress enacted the DSHEA in 1994 for the purposes of: (a) making dietary supplements more readily accessible to consumers; and (b) providing the FDA with limited power to regulate dietary supplements that present a significant or unreasonable risk of illness or injury when used as directed. The DSHEA does not contain any express preemption clause; however, legal commentators have indicated that state laws that regulate dietary supplements might be preempted, as it can be argued that such impede Congress's objective of providing the public with ready accessibility to dietary supplements.[12]

[11] 16 Am. Jur. 2d Constitutional Law s. 53.
[12] Comment, *Dietary Supplements: Is Availability Worth the Risks? Proposed Alternatives to the Present DSHEA Scheme*, 33 Seton Hall L. Rev. 411 (2003).

The bill amends s. 499.033, F.S., which requires ephedrine, the active ingredient of ephedra, to be dispensed only as a prescription drug. The bill's amendments would expand existing law's prescription requirement to include any product intended for ingestion by humans, which contains ephedra or sida cordifolia. Arguably both existing law and the bill's expansion thereof could be subject to preemption challenges alleging that the state's prescription requirement impedes the public's ability to access dietary supplements containing ephedra in violation of Congressional intent for the DSHEA. Such a challenge, however, has never been litigated in Florida since the enactment of s. 499.033, F.S., in 1994.

As discussed in "Related Issues," *infra*, the FDA on December 31, 2003, announced its intent to publish a rule that would prohibit the sale of dietary supplements containing ephedra. However, as of the date of this analysis, the text of the rule is unknown. Thus, it cannot yet be determined whether existing Florida law and/or the bill's proposed amendments thereto could be subject to challenges based on conflict with the FDA's rule or other preemption arguments.

V. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

The bill, in effect, would remove dietary supplements containing ephedra or sida cordifolia from the over-the-counter market in Florida. Dietary supplement manufacturers, wholesale distributors and retail distributors who sold such products over the counter will lose revenue because they will no longer be legally able to do so in Florida.

C. Government Sector Impact:

The Department of Health will incur minimal costs to enforce the provisions of the bill requiring products containing ephedra or sida cordifolia to be dispensed with a prescription and will likely make referrals to law enforcement agencies and prosecutors.

The Department of Agriculture and Consumer Services, as the regulator of "foods" and dietary supplements, will incur minimal costs to enforce the provisions of the bill requiring products containing ephedra or sida cordifolia to be dispensed with a prescription and will likely make referrals to law enforcement agencies and prosecutors.

VI. Technical Deficiencies:

None.

VII. Related Issues:

On December 30, 2003, the FDA announced its intent to issue a rule that would prohibit the sale of dietary supplements containing ephedra. This announcement was predicated on the FDA's determination that such supplements present an unreasonable risk of illness or injury and should not be consumed.

The FDA has indicated on its website that the rule is currently under review and will be published, "[i]n the coming weeks."[13] The rule will take effect 60 days after publication.[14] As of the date of this analysis, the text of the rule is unknown. Thus, whether existing Florida law and/or the bill's proposed amendments thereto will be in accord or in conflict with the FDA's rule cannot yet be determined.

VIII. Amendments:

None.

[13] See http://www.fda.gov/oc/initiatives/ephedra/december2003/qa.html.
[14] See 5 U.S.C.A. 801-808.