HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 247 Sale of Products Containing Ephedrine or Ephedra
SPONSOR(S): Prieguez
TIED BILLS: None. **IDEN./SIM. BILLS:** CS/CS/SB 446(c)

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Services	10 Y, 0 N	Garner	Collins
2) Health Care			
3)			
4)			
5)			

SUMMARY ANALYSIS

Section 499.033, F.S., declares ephedrine to be a drug that may only be dispensed through a prescription of a duly licensed practitioner authorized by the state to prescribe medicinal drugs. HB 247 amends this provision of law by expanding the definition of ephedrine-based products that are considered a prescription drug, and reclassifies ephedra from a food/dietary supplement to a drug available only through a prescription.

Ephedra (also known as ma huang, sida cordifolia, and epitonin) is virtually the same ingredient as the pseudoephedrine found in many over-the-counter decongestants. It is currently widely used as an over-the-counter dietary supplement and weight-loss treatment, although its long-term efficacy for these purposes has not been proven. 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 consumption of ephedra or ephedrine alone or in conjunction with other stimulants (such as caffeine) increases the risk of these medical conditions occurring.[1]

The United States Food and Drug Administration (FDA) has been examining the effects of ephedrine and ephedra for many years and considered restricting its distribution without a prescription since 1996. Because federal laws pertaining to the regulation of dietary supplements place the burden of proof on the FDA to show adverse consequences related to ephedrine and/or ephedra consumption before they can regulate its distribution, rules and regulation preventing its distribution lingered. However, the weight of evidence suggesting a problem with the supplement increased over the last several years and in 2002 a sentinel report was issued by the Rand Corporation, Inc., demonstrating the dangers posed by this dietary supplement. As a result, in December 2003, the FDA issued a consumer alert reporting the dangers of the supplement and notified manufacturers of the products that it is developing regulations that will ban the manufacturing and sale of products containing these ingredients in the near future.

The sponsor of HB 247 is concerned that the FDA rules will be delayed and the nature of this problem requires more immediate action. In conjunction with the Senate counterpart, the sponsor is seeking to change the regulation of ephedra as a prescription drug under the regulatory authority of the Florida Department of Health.

According to the Department of Health, there would be minimal fiscal effect on the agency.

[1] U.S. Food and Drug Administration. "*Evidence on the Safety and Effectiveness of Ephedra: Implications for Regulation*." White Paper. 2003.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. DOES THE BILL:

1. Reduce government?	Yes[]	No[X]	N/A[]
2. Lower taxes?	Yes[]	No[]	N/A[X]
3. Expand individual freedom?	Yes[]	No[X]	N/A[]
4. Increase personal responsibility?	Yes[]	No[X]	N/A[]
5. Empower families?	Yes[]	No[]	N/A[X]

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

HB 247 expands the Department of Health's regulatory role over what are currently considered dietary supplements.

Some current users of dietary supplements containing ephedra may feel that this bill would restrict their ability to use alternative treatments for certain health conditions, especially weight-loss and management.

The bill removes the decision of whether to use ephedra as a dietary supplement from the consumer and supplants this personal responsibility for making the decision to use the product only with the approval of a licensed physician.

B. EFFECT OF PROPOSED CHANGES:

HB 247 expands the definition of ephedrine-based products that are considered a prescription drug, and reclassifies ephedra from a food/dietary supplement to a drug available only through a prescription. This bill prohibits the sell or delivery of any product over the counter without a prescription that contains any quantity of ephedrine or ephedra, a salt of ephedrine, an optical isomer of ephedrine, or a salt of any optical isomer of ephedrine.

PRESENT SITUATION

Herbal ephedra has been used in China to treat respiratory conditions for over 5,000 years;[2] however, the herb is not used for weight loss or physical performance enhancement in eastern medicine. Its active alkaloid, ephedrine, was first used in western medicine as an asthma treatment in the 1930s. Since then, ephedrine and other ephedrine alkaloids have been used in many over-the-counter (OTC) decongestants and cold medicines. It was not until the early 1990s that herbal ephedra and other products containing ephedrine began to be promoted as weight loss aids in the United States. At this same time, use of these products as athletic performance-enhancing supplements gained popularity. As a result of these two uses, by 1999, manufacturers of ephedra-containing supplement products estimated that three billion servings of these products were consumed in the U.S. annually.

As the use of ephedrine and ephedra supplements increased, so did questions regarding safety and efficacy. By October 1995, the growing number of adverse event reports received by the Food and Drug Administration (FDA) (over 300 at that point) caused enough concern that the FDA convened a Special Working Group to assess the potential health threat posed by the use of these supplements. The Special Working Group's outcome was a recommendation that warning labels should be required

[2] Fong H. "*Ephedra-containing compounds: Historical and pharmacologic context*." Hearings before the U.S. Public Health Service (Aug. 8, 2000).

to be placed on these products and further regulation considered. However, federal law limited the FDA's ability to regulate these supplements.

FEDERAL REGULATION OF DIETARY SUPPLEMENTS

The FDA's ability to regulate dietary supplements is limited under federal law. 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 pre-market safety evaluations that are required of other new food ingredients or for new uses of old food ingredients.[3]

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;
- ✓ intended for ingestion in pill, capsule, tablet, or liquid form;
- ✓ labeled as a "dietary supplement;" and
- ✓ a product such as an approved drug, certified antibiotic, or licensed biologic that was marketed as a dietary supplement or food before approval, certification, or license.

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. 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.

Because of these restrictions, the FDA has been limited in its ability to regulate ephedrine and ephedra supplements, despite the 300 adverse incident reports reviewed by the Special Working Group in 1996. Within a year, however, the number of adverse incident reports had doubled to over 600 reports and in August 1996, the FDA convened a meeting of its Food Advisory Committee to continue the discussion of ephedrine/ephedra supplements that started the year before.

The Committee was divided on its final recommendations. Some of its members recommended the removal of these supplements from the market, while others recommended that the FDA adopt rules that would help reduce adverse effects. The FDA decided to do the latter.

In 1997, the FDA published a proposed rule on the use of dietary supplements containing ephedrine alkaloids. The rule recommended limiting the dosage of the supplements, proposed a daily limit on its consumption, recommended that these products should not be used for more than 7 consecutive days,

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

and recommended the inclusion of warning labels on the products. The FDA received a large number of comments on the proposed rule and the U.S. General Accounting Office (GAO) conducted a study on the dosage limitations proposed in the rule. Neither the comments received nor the results of the GAO final report supported the rule, and in 2000, the FDA officially withdrew the proposed rule.

Since 2000, the controversy over whether ephedrine/ephedra products should be more stringently regulated continued. From 2000 to 2002, more than 100 individuals sued manufacturers of ephedra products, and from 1992 through 2002, more than 1,000 health problems were reported to FDA. In 2001, consumer groups petitioned the FDA to reconsider the issue, and at the same time, individual states and independent sports organizations began limiting or forbidding the use of these supplements.

Specifically, 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 not 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.

In the fall of 2001, the National Football League banned the supplements following the deaths of several high school and college athletes after alleged use of these supplements, and in January 2002, the Canadian government issued a warning against use of ephedra.

On June 14, 2002, the U.S. Department of Health and Human Services proposed an expanded scientific evaluation of the issue which included a study by the Rand Corporation, Inc. This sentinel report from Rand coupled with a yet published study by Dr. P.G. Shekelle, et al., provided enough evidence for the FDA to reconsider the issue. As a result, in December 2003, the FDA issued a consumer alert reporting the dangers of the supplement and notified manufacturers of the products that it is developing regulations that will ban the manufacturing and sale of products containing these ingredients in the near future.

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, such as those currently containing ephedra are regulated as foods in Florida.

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 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.

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 ss. 500.10 and 500.11, 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 s. 500.03, 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 s. 500.173, F.S., and that the article has been detained and seized by the department.

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."

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. 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. 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 s. 499.033, 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.

FLORIDA DRUG, COSEMTIC, AND HOUSEHOLD PRODUCT ACT

The Department of Health is responsible for regulating and enforcing the Florida Drug, Cosmetic Act, and Household Product 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.

Sections 499.005, 499.0051, and 499.0052, F.S., provide criminal penalties for violation 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. A person who knowingly purchases or receives from a person not authorized to distribute legend drugs under s. 499.0051, 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 of up to $10,000. 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 (see s. 499.0051, F.S.). 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.

C. SECTION DIRECTORY:

Section 1. Amends s. 499.033, F.S., by expanding the definition of ephedrine-based products that are considered a prescription drug, and reclassifies ephedra from a food/dietary supplement to a drug available only through a prescription. This section prohibits the sell or delivery of any product over-the-counter without a prescription that contains any quantity of ephedrine or ephedra, a salt of ephedrine, an optical isomer of ephedrine, or a salt of any optical isomer of ephedrine.

Section 2. Provides an effective date of July 1, 2004.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   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.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Manufactures and distributors of ephedrine and ephedra dietary supplements will see decreased revenue from the inability to sell the products without a prescription. The exact loss of income is unknown because some of the loss could be offset by the purchase of the compounds as a prescription.

D. FISCAL COMMENTS:

None.

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 revenue.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The Department of Health currently has rulemaking authority to implement this act.

C. DRAFTING ISSUES OR OTHER COMMENTS:

There is discussion between the Department of Health (DOH) and the Department of Agriculture and Consumer Services (DACS) over whether this provision should be placed under ch. 500, F.S., which would give the DACS the rulemaking authority and enforcement responsibilities of ephedra-based products as a prescription drug.

The provision amended by the bill currently falls under the authority of the Department of Health, so if the entire section is moved into ch. 500, F.S., it would expand the Department of Agriculture's regulatory oversight activity to some forms of over-the-counter medications that are currently regulated by the Department of Health.

Finally, if the federal Food and Drug Administration (FDA) does adopt rules banning the manufacture and sell of ephedra as a dietary supplement, Florida's law would be able to maintain its ability to regulate it as a prescribed drug if it is maintained under ch. 499, F.S.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

On February 4, 2004, the Subcommittee on Health Services adopted a strike everything amendment to the bill, and then reported the bill favorably to the Committee on Health Care. The amendment:

- Adds technical language to s. 499.033(2), F.S., to conform the subsection to the changes made in s. 499.033(1), F.S.
- Prohibits the sell or distribution of ephedrine or ephedra as a dietary supplement or other food product.
- Creates the Weight-Loss and Athletic Performance Dietary Supplement Review Committee that would evaluate the safety and effectiveness of dietary supplements sold in Florida.
- Provides $10,000 from General Revenue to support the operation of the Review Committee.
- Repeals s. 501.0583, F.S., which prohibits the sell or delivery of weight-loss pills containing ephedrine or ephedra to persons under the age of 18.