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SFA BILL ANALYSIS

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Senate Bill 182 (as enrolled) **PUBLIC ACT 144 of 1999**
Sponsor: Senator Bev Hammerstrom
Senate Committee: Judiciary
House Committee: Health Policy

Date Completed: 2-25-00

RATIONALE

According to the United States Food and Drug Administration (FDA), ephedrine alkaloids are amphetamine-like compounds that have a powerful stimulant effect on the central nervous system. Ephedrine, found in Ma Huang, a Chinese herb, is used in many prescription and over-the-counter (OTC) medications for the treatment of such common maladies as asthma, allergies, and congestion. It also can be found in approximately 100 products marketed as energy boosters and weight-loss aids that are widely distributed in drug stores, gas stations, and health food stores. Truck drivers and students reportedly use ephedrine products to stay awake. Body builders have been known to use it to increase muscle mass. Since it suppresses appetite, many dieting aids contain ephedrine. Ephedrine also has been used as a substitute for "speed", "ecstasy", and other euphoric but illegal street drugs. Because it is an herb, many believe it to be a safe, natural ingredient. Even when used in low doses and by healthy individuals, however, ephedrine can result in serious, life-threatening conditions, especially if consumed with caffeine or alcohol. Reported adverse effects include insomnia, headaches, nausea and vomiting, kidney problems, heart irregularities, seizures, strokes, heart attacks, and even death. Reportedly, the FDA had received over 800 reports of adverse effects as of January 1997, and at least 40 deaths have been associated with ephedrine use.

In recent years, several states have banned the sale of ephedrine products or have tightened regulations. Further, the FDA proposed rules in 1997 to create stricter regulation of ephedrine products that would include warning statements on labels outlining adverse effects. The FDA continues to monitor problems associated with ephedrine use. Though it already was illegal under Michigan law to possess more than 10 grams of ephedrine alone or in a mixture, some people believed that Michigan should adopt stricter regulations to complement the proposed Federal regulations and include a ban on sale to minors, among other things.

CONTENT

The bill amended the Public Health Code to include as a Schedule 5 controlled substance ephedrine, a salt of ephedrine, an optical isomer of ephedrine, a salt of an optical isomer of ephedrine, or a compound, mixture, or preparation containing ephedrine, a salt of ephedrine, an optical isomer of ephedrine, or a salt of an optical isomer of ephedrine.

The bill specifies, however, that a product containing ephedrine or a salt, an optical isomer, or a salt of an optical isomer of ephedrine is not included in Schedule 5 if the drug product may lawfully be sold over the counter without a prescription under Federal law; is labeled and marketed in a manner consistent with the pertinent over-the-counter tentative final or final monograph; is manufactured and distributed for legitimate medical use in a manner that reduces or eliminates the likelihood of abuse; is not marketed, advertised, or labeled for an indication of stimulation, mental alertness, energy, weight loss, appetite control, or muscle enhancement; and is either an anorectal preparation containing not more than 5% ephedrine, or a solid dosage form, including but not limited to a soft gelatin caplet, that combines as active ingredients not less than 400 milligrams of guaifenesin and not more than 25 milligrams of ephedrine per dose, packaged in blister packs with not more than two tablets or caplets per blister.

A food product or a dietary supplement containing ephedrine also is not included in Schedule 5, if it meets all of the following criteria:

-- It contains, per dosage unit or serving, not more than 25 milligrams of ephedrine alkaloids or the maximum amount of ephedrine alkaloids provided in applicable FDA regulations, whichever is less, and contains no other controlled substance.
-- It contains no hydrochloride or sulfate salts of ephedrine alkaloids.

-- It is packaged with a prominent label securely affixed to each package that states the amount in milligrams of ephedrine in serving or dosage unit; the amount of the food product or dietary supplement that constitutes a serving or dosage unit; that the maximum recommended dosage of ephedrine for a healthy adult human is the lesser of 100 milligrams in a 24-hour period or the maximum recommended dosage or period of use provided in applicable FDA regulations; and that improper use of the product may be hazardous to a person's health.

In addition, the bill prohibits a person from dispensing, selling, or otherwise giving to a person under 18 years of age a food product or dietary supplement containing ephedrine that is excluded from Schedule 5 under the above criteria. The prohibition does not apply, however, to any of the following:

-- A physician or pharmacist who prescribes, dispenses, administers, or delivers a food product or dietary supplement to a person under 18.
-- A parent or guardian of a person under 18 who then delivers the food product or dietary supplement to that person.
-- A person authorized by the parent or legal guardian of an individual under 18 who dispenses or delivers the food product or dietary supplement to the individual.

In the course of selling, offering for sale, or otherwise distributing a food product or dietary supplement containing ephedrine that is excluded from Schedule 5 under the bill, a person may not advertise or represent in any manner that the food product or dietary supplement causes euphoria, ecstasy, a "buzz" or "high", or an altered mental state, or that it heightens sexual performance or, because it contains ephedrine alkaloids, increases muscle mass.

A violation of the bill's provisions relating to a food product or dietary supplement containing ephedrine that is excluded from Schedule 5 is a misdemeanor, punishable by up to 93 days' imprisonment, a maximum fine of $100, or both.

MCL 333.7208 et al.

BACKGROUND

Following Federal law, the Public Health Code classifies controlled substances under one of five "schedules". Scheduled drugs must have the potential for abuse (that, in general, is associated with a stimulant or depressive effect on the central nervous system) and are either a) illegal and without any medically accepted use in the United States (all Schedule 1 drugs), or b) prescription drugs with medically accepted uses in the United States that have a potential for psychological or physical dependence in addition to the potential for abuse (Schedules 2, 3, 4, and 5).

Schedule 1 drugs, all of which are illegal, have a high potential for abuse and no accepted medical use in treatment in the United States or lack accepted safety for use in treatment under medical supervision (MCL 333.7211). In addition to some opiates and opium derivatives (including heroin), Schedule 1 includes hallucinogenic drugs, such as LSD and mescaline, and nontherapeutic uses of marijuana.

Schedule 2 prescription drugs have a high potential for abuse and a currently accepted medical use in treatment in the United States (or a currently accepted medical use with severe restrictions), and their abuse has the potential to lead to severe psychic or physical dependence (MCL 333.7213). Schedule 2 includes opium and any of its derivatives (including codeine and morphine), coca leaves and derivatives (including cocaine), other opiates (such as fentanyl, methadone, pethidine), and substances containing any quantity of such drugs as amphetamine, methamphetamine, methaqualone, amorbarbital, pento barbital, and secobarbital.

Schedule 3 prescription drugs have a potential for abuse less than those listed in Schedules 1 and 2 and currently accepted medical use in treatment in the United States, and their abuse has the potential to lead to moderate or low physical dependence or high psychological dependence (MCL 333.7216). Schedule 3 includes any substance with any quantity of a derivative of barbituric acid and drugs containing limited quantities of codeine, opium, or morphine.

Schedule 4 prescription drugs have a low potential for abuse relative to those in Schedule 3 and a currently accepted medical use in the United States, and their abuse has the potential to lead only to limited physical or psychological dependence relative to Schedule 3 drugs (MCL 333.7217). Schedule 4 includes such drugs as barbital, chloral hydrate, lorazepam, meprobamate, diazepam (brand name Valium), phenobarbital, and Rohypnol.

Schedule 5 prescription drugs have a low potential for abuse relative to those in Schedule 4, have a currently accepted medical use in the United States, and have limited physical or psychological dependence relative to the substances listed in Schedule 4 (or the incidence of abuse is such that the substance should be dispensed by a practitioner). Schedule 5 includes codeine, Loperamide, ethylmorphine, and diphenoxylate and

atropine sulfate compounds.

ARGUMENTS

(Please note: The arguments contained in this analysis originate from sources outside the Senate Fiscal Agency. The Senate Fiscal Agency neither supports nor opposes legislation.)

Supporting Argument

Long used in prescription and OTC medications for relief from asthma and congestion, ephedrine has been used increasingly by the young and old alike to lose weight, stay awake, or enhance body building. It often is packaged as a dietary supplement in brightly colored foil packages, is relatively cheap (about $1 for several tablets), has no restrictions on the age of purchasers, and often has misleading or inaccurate labeling. As a result, many are led to believe that there are no adverse effects or dangers associated with ephedrine use. On the contrary, ephedrine, even at relatively low doses, can affect heart rate, raise blood pressure, and cause seizures. Sustained use or higher doses have resulted in kidney stones, heart attacks, and strokes, and evidently have caused approximately 40 deaths. Reportedly, the FDA had received over 800 reports of adverse reaction as of January 1997. Since many incidents go unreported, the actual number of adverse reactions is probably much higher.

Ephedrine products are currently widely available in drug and convenience stores, gas stations, and health food stores, as well as sold over the Internet. Though medical literature warns against mixing ephedrine with caffeine or alcohol, Internet chat room discussion participants reportedly have urged others to use it with caffeine-containing products or alcohol, or bragged of the "highs" one can have with increased doses. Many of these chat room dialogues apparently assure others that ephedrine products are safe because ephedrine is "natural".

Although individuals should be responsible for understanding the effects of products they use, the government does have a compelling interest to protect the public from potentially dangerous compounds. Since the FDA has documented nationwide problems with adverse reactions and death from OTC ephedrine products, and since even children can easily obtain these products, stricter regulation is certainly warranted.

Without interfering with legitimate medicinal uses, or making ephedrine a prescription-only substance, the bill sets safer dosing requirements, and bans the sale to minors. In addition, a label may not advertise that an ephedrine product causes euphoria, ecstasy, a "buzz" or "high", an altered mental state, heightened sexual performance, or increased muscle mass. This should reduce the tendency by some to use ephedrine as an alternative to illegal street drugs and steroids. Most importantly, the bill will help to protect consumers by limiting the amount of ephedrine in each tablet to a safe level and by requiring label changes that better educate consumers as to safe dosing levels and proper use.

Response: If government regulation is warranted, it would seem to be the responsibility of the FDA rather than the State.

Supporting Argument

Lax labeling requirements mislead users of ephedrine products to think the products are safe, when, in reality, they may be hazardous. Testimony given before Senate and House committees revealed that a 24-year-old Novi man died of a heart attack after ingesting an ephedrine product that he bought at a gas station in order to stay awake while driving. In addition, it was reported that, about two years ago, a dozen students from one school overdosed on ephedrine during the lunch period. These two examples underscore that individuals are greatly exceeding recommended doses, in part because of inaccurate product labeling. Reportedly, one product marketed in Texas was labeled as having "no side effects" and listed wild Chinese ginseng as the only ingredient, but a laboratory analysis indicated that a single tablet contained 45 milligrams of ephedrine and 20 milligrams of caffeine. Dosing directions on the package apparently instructed users to take an amount that represented 11 times the recommended OTC dosage of ephedrine contained in bronchodilator products. The bill brings much needed regulation to the labeling and distribution of products that contain ephedrine.

Opposing Argument

Ephedrine is a natural ingredient derived from Ma Huang, a Chinese herb that has been safely used in medicinal compounds and as a dietary supplement for over 5,000 years. The bill will greatly impede the public's access to products containing levels sufficient to give benefits. Further, ephedrine is protected from Federal regulation by the Dietary Supplement Health and Education Act of 1994, which Congress passed in order to prevent the FDA from regulating dietary supplements unless they are proven unsafe.

Response: The Federal law is not preemptive and does not prevent states from enacting stronger restrictions. Also, the fact that a substance may occur naturally does not necessarily make it safe to ingest. Opium, heroin, cocaine, and marihuana all are plants or are derived from them.

Legislative Analyst: P. Affholter

FISCAL IMPACT

The bill will have an indeterminate fiscal impact on local government for the costs of incarceration and/or the receipt of fine revenue. There are no data available to indicate how many people will be convicted of dispensing, selling, or otherwise giving the ephedrine products detailed in the bill to an individual under 18 or how many people might be convicted of advertising such a product in an prohibited manner. The cost of incarceration varies by county between $27 and $65 daily and fine revenues go to public libraries.

Fiscal Analyst: K. Firestone

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