House
Legislative
Analysis
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REGULATE EPHEDRINE AS CONTROLLED SUBSTANCE

Senate Bill 182 (Substitute H-1)
First Analysis (9-28-99)

Sponsor: Sen. Bev Hammerstrom
House Committee: Health Policy
Senate Committee: Judiciary

THE APPARENT PROBLEM:

According to the Food and Drug Administration (FDA), ephedrine alkaloids are amphetamine-like compounds that have a powerful stimulant effect on the central nervous system. Used in decongestants and asthma medications, products containing ephedrine are also marketed as weight loss and energy enhancing aids. Because ephedrine is so powerful, especially if consumed with caffeine or alcohol, serious reactions can occur. Reported adverse effects range from insomnia, headaches, nausea and vomiting, kidney problems, and heart irregularities to seizures, strokes, heart attacks, and death. As of January 1997, the FDA had received over 800 reports of adverse effects, and it is now reported that at least 40 deaths have been associated with ephedrine use.

Ephedrine, found in Ma Huang, a Chinese herb, is used in many prescription and over-the-counter (OTC) medications for the treatment of asthma, allergies, and congestion, along with 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 use ephedrine to stay awake. Body builders use it to increase muscle mass. Since it suppresses appetite, many dieting aids contain ephedrine. Others use it 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. Unfortunately, even when used in low doses and by healthy individuals, ephedrine can result in serious, life-threatening conditions and death.

Though it is currently illegal under Michigan law to possess more than 10 grams of ephedrine alone or in a mixture, many believe that the law needs to be strengthened. Since it is inexpensive, legal, and easy to obtain by adults and children alike, many people are misled to believe that ephedrine products are safe. However, testimony given before House and Senate 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, the bill's sponsor reported that two years ago, a dozen students from a school in her district 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. In fact, a 1996 report by the Texas Department of Health told of one product marketed in that state that was labeled as having "no side effects" and that listed wild Chinese ginseng as the only ingredient. A laboratory analysis indicated that a single tablet contained 45 mg of ephedrine and 20 mg of caffeine. Dosing directions on the package instructed users to use an amount that represented 11 times the recommended OTC dosage of ephedrine contained in bronchodilator products!

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, and continues to monitor problems associated with ephedrine use. It has been proposed that Michigan adopt stricter regulations that would, among other things, complement the proposed federal regulations on ephedrine and also include a ban on sales to minors.

THE CONTENT OF THE BILL:

The bill would amend 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 that substance. Inclusion of ephedrine in Schedule 5 would not preclude prosecution under the code's current prohibition against possessing more than 10 grams of ephedrine alone or in a mixture. Products would not be included in Schedule 5 if they could lawfully be sold over the counter (OTC) without a prescription under federal law; were labeled and marketed in a manner consistent with the pertinent OTC regulations; were manufactured and distributed for

legitimate medical use; were not marketed, advertised, or labeled for an indication of stimulation, mental alertness, energy, weight loss, appetite control, or muscle enhancement; and either were in a solid dosage form and packaged as prescribed in the bill, or were anorectal preparations containing not more than 5 percent ephedrine.

A food product or dietary supplement containing ephedrine would not be included in Schedule 5 if it contained not more than 25 milligrams of ephedrine alkaloids or the maximum amount allowed by the U.S. Food and Drug Administration (FDA), whichever was less, and contained no other controlled substance; contained no hydrochloride or sulfate salts of ephedrine alkaloids; and were packaged with a prominent label that stated the amount in milligrams of ephedrine per serving or dose, the amount that constituted a serving or dose, the maximum recommended dosage of ephedrine for a healthy adult according to the FDA, and that improper use could be hazardous to a person's health.

The bill also would prohibit delivery of a food product or dietary supplement containing ephedrine to a person under 18 years of age. The bill would make exceptions for a physician or pharmacist, a parent or guardian, or a person authorized by a parent or guardian. A person could not advertise or represent in any manner that a product containing ephedrine caused euphoria, ecstasy, a "buzz" or"high", or an altered mental state, or that it heightened sexual performance or increased muscle mass. A violation relating to a food product or dietary supplement would be a misdemeanor, punishable by up to 93 days' imprisonment and/or a maximum fine of $100.

The bill would take effect 90 days after it was enacted.

MCL 333.7208 et al.

HOUSE COMMITTEE ACTION:

The House committee adopted a technical amendment to bring a section of the Public Health Code pertaining to restricted drivers' licenses into conformity with other laws that were amended earlier this year by the Repeat Offender bill package.

BACKGROUND INFORMATION

Public Health Code classification of drugs. Following federal law, the Public Health Code classifies controlled substances under one of five "schedules." Scheduled drugs must have the potential for abuse (where, in general, the abuse 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 -- must 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 opiates and opium derivatives (including heroin), schedule 1 includes hallucinogenic drugs (such as LSD and mescaline) and non-therapeutic uses of marijuana.

** Schedule 2 prescription drugs must have a high potential for abuse, a currently accepted medical use in treatment in the United States (or a currently accepted medical use with severe restrictions), and their abuse must have 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, and pethidine), and substances containing any quantity of such drugs as amphetamine, methamphetamine, methaqualone, amobarbital, pentobarbital, and secobarbital.

** Schedule 3 prescription drugs must have a potential for abuse less than those listed in schedules 1 and 2, have a currently accepted medical use in treatment in the United States, and their abuse must have 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 must have a low potential for abuse relative to those in schedule 3, have a currently accepted medical use in the United States,

and their abuse must have 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 must 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 dependence 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.

FISCAL IMPLICATIONS:

According to a fiscal note by the Senate Fiscal Agency dated 5-13-99, the bill would 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 would be convicted of dispensing, selling, or otherwise giving the ephedrine products detailed in the bill to an individual under 18 or how many people could be convicted of advertising such a product in an prohibited manner. The cost of incarceration varies by county between $27 and $65 daily. Fine revenues go to public libraries.

ARGUMENTS:

For:

Long used in prescription and OTC medications for relief from asthma and congestion, ephedrine is increasingly used by young and old alike to lose weight, stay awake, or to 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. Quite the contrary, since 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 have caused approximately 40 deaths. Reportedly, the FDA has received over 900 reports of adverse reactions just since 1995. Since many incidences go unreported, the numbers are 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 discussions are full of individuals urging others to use it with caffeine-containing products or alcohol, or bragging of the "highs" one can have with increased doses. Many of these chat room dialogues also reassure others that ephedrine products are safe because it is "natural".

Though individuals should be responsible for understanding about the effects of products they use, the government does have a compelling interest to protect the public from potentially dangerous compounds. The fact that so many other drugs and compounds are available only by prescription attests to the long precedent of the government regulating potentially dangerous products. Since the FDA has documented nation-wide problems with adverse reactions and death from OTC ephedrine products, and since even children can easily obtain these products, stricter regulation is certainly warranted.

The bill would not interfere with legitimate medicinal uses, nor would it make ephedrine a prescription-only substance. It would merely set safer dosing requirements, and would ban the sale to minors. In addition, a label could not advertise that an ephedrine product would cause euphoria, ecstasy, a "buzz" or "high", an altered mental state, or heightened sexual performance or increased muscle mass. This should in turn lessen the tendency by some to use ephedrine as an alternative to illegal street drugs and steroids. Most importantly, the bill would help to protect consumers by lowering the amount of ephedrine in each tablet to a safer level and by requiring label changes that would 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 state legislatures.

Against:

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 would greatly impede the public's access to products containing levels sufficient to give benefits. Further, there is a question as to whether the bill could violate the 1994 Dietary Supplement Health and Education Act, which was passed by Congress expressly to prevent regulation by the FDA of dietary supplements.

POSITIONS:

The Department of Consumer and Industry Services supports the bill. (9-23-99)

The Department of State Police supports the bill. (9-23-99)

H.E.A.T. (Halt Ephedrine Abuse Today) supports the bill. (5-8-99)

The Michigan Pharmacists Association supports the bill. (9-23-99)

The Michigan Osteopathic Association supports the bill. (9-23-99)

The American Herbal Products Association/Ephedra Committee supports the bill. (9-23-99)

Analyst: S. Stutzky

■This analysis was prepared by nonpartisan House staff for use by House members in their deliberations, and does not constitute an official statement of legislative intent.