

FEB 27 1997

Place On Calendar

S-3/13/97 Judiciary  
S-3/25/97 Do Pass  
S-4/10/97 Unfinished Business Calendar  
**384**

HOUSE FILE  
BY COMMITTEE ON JUDICIARY

(SUCCESSOR TO HSB 136)

(P.587)

Passed House, Date 3-13-97 Passed Senate, Date 4-16-97 (p.1197)

Vote: Ayes 100 Nays 0 Vote: Ayes 48 Nays 0

Approved April 23, 1997

A BILL FOR

1 An Act to include certain products containing ephedrine as  
2 schedule V controlled substances.

3 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

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HF 384

1 Section 1. Section 124.212, Code 1997, is amended by  
2 adding the following new subsection:

3 NEW SUBSECTION. 5. EPHEDRINE. Unless specifically  
4 excepted in paragraph "b" or listed in another schedule, any  
5 material, compound, mixture, or preparation which contains any  
6 quantity of the following substance, including its salts,  
7 optical isomers, and salts of such optical isomers:

8 a. Ephedrine.

9 b. The following drug products containing ephedrine, its  
10 salts, optical isomers, and salts of such optical isomers are  
11 excepted from this schedule, if they may lawfully be sold over  
12 the counter without a prescription under the federal Food,  
13 Drug and Cosmetic Act; are labeled and marketed in a manner  
14 consistent with the pertinent over-the-counter tentative final  
15 or final monograph; are manufactured and distributed for  
16 legitimate medicinal use in a manner that reduces or  
17 eliminates the likelihood of abuse; and are not marketed,  
18 advertised, or labeled for the indication of stimulation,  
19 mental alertness, weight loss, muscle enhancement, appetite  
20 control, or energy:

21 (1) Solid oral dosage forms, including soft gelatin  
22 capsules, that combine active ingredients in the following  
23 range for each dosage unit of not less than twelve and five-  
24 tenths milligrams but not more than twenty-five milligrams of  
25 ephedrine and not less than four hundred milligrams of  
26 guaifenesin packaged in blister packs of not more than two  
27 tablets per blister.

28 (2) Anorectal preparations containing less than five  
29 percent ephedrine.

30 EXPLANATION

31 This bill adds certain substances containing ephedrine to  
32 the list of schedule V controlled substances. Also listed are  
33 those substances containing ephedrine which are specifically  
34 excluded from schedule V. Under Iowa Code section 124.308  
35 schedule V controlled substances do not require a

1 prescription, but are not to be distributed other than for a  
2 medical purpose. The distribution of schedule V substances is  
3 regulated by pharmacists. Schedule V substances must be kept  
4 off public access shelves and require the signature of the  
5 purchaser prior to distribution.

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Veenstra, Chr.  
Grundberg  
Mareland

HSB 136  
JUDICIARY

Succeeded By  
SENATE/HOUSE FILE IF 384  
BY (PROPOSED DEPARTMENT OF  
PUBLIC SAFETY BILL)

Passed Senate, Date \_\_\_\_\_ Passed House, Date \_\_\_\_\_  
Vote: Ayes \_\_\_\_\_ Nays \_\_\_\_\_ Vote: Ayes \_\_\_\_\_ Nays \_\_\_\_\_  
Approved \_\_\_\_\_

**A BILL FOR**

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7 optical isomers, and salts of such optical isomers:

8 a. Ephedrine.

9 b. The following drug products containing ephedrine, its  
10 salts, optical isomers, and salts of such optical isomers are  
11 excepted from this schedule, if they may lawfully be sold over  
12 the counter without a prescription under the federal Food,  
13 Drug and Cosmetic Act; are labeled and marketed in a manner  
14 consistent with the pertinent over-the-counter tentative final  
15 or final monograph; are manufactured and distributed for  
16 legitimate medicinal use in a manner that reduces or  
17 eliminates the likelihood of abuse; and are not marketed,  
18 advertised, or labeled for the indication of stimulation,  
19 mental alertness, weight loss, muscle enhancement, appetite  
20 control, or energy:

21 (1) Solid oral dosage forms, including soft gelatin  
22 capsules, that combine active ingredients in the following  
23 ranges for each dosage unit:

24 (a) Not less than one hundred milligrams but not more than  
25 one hundred thirty milligrams of theophylline and not less  
26 than twelve and five-tenths milligrams but not more than  
27 twenty-four milligrams of ephedrine.

28 (b) Not less than sixty milligrams but not more than one  
29 hundred milligrams of theophylline, not less than twelve and  
30 five-tenths milligrams but not more than twenty-four  
31 milligrams of ephedrine, and not less than two hundred  
32 milligrams but not more than four hundred milligrams of  
33 quaifenesin.

34 (c) Not less than twelve and five-tenths milligrams but  
35 not more than twenty-five milligrams of ephedrine and not less

1 than two hundred milligrams but not more than four hundred  
2 milligrams of quaifenesin.

3 (d) Not more than eight milligrams of phenobarbital in  
4 combination with the ingredients of subparagraph subdivision  
5 (a) or (b).

6 (2) Liquid oral dosage forms that combine active  
7 ingredients in the following ranges for each five milliliter  
8 dose:

9 (a) Not more than forty-five milligrams of theophylline,  
10 not more than thirty-six milligrams of ephedrine, not more  
11 than one hundred milligrams of quaifenesin, and not more than  
12 twelve milligrams of phenobarbital.

13 (b) Not more than five milligrams of phenylephrine, not  
14 more than five milligrams of ephedrine, not more than two  
15 milligrams of chlorpheniramine, not more than ten milligrams  
16 of dextromethorphan, not more than forty milligrams of  
17 ammonium chloride, and not more than five one-thousandths of a  
18 milligram of ipecac fluid extract.

19 (c) Anorectal preparations containing less than five  
20 percent ephedrine.

21 EXPLANATION

22 This bill adds certain substances containing ephedrine to  
23 the list of schedule V controlled substances. Also listed are  
24 those substances containing ephedrine which are specifically  
25 excluded from schedule V. Under Iowa Code section 124.308  
26 schedule V controlled substances do not require a  
27 prescription, but are not to be distributed other than for a  
28 medical purpose. The distribution of schedule V substances is  
29 regulated by pharmacists. Schedule V substances must be kept  
30 off public access shelves and require the signature of the  
31 purchaser prior to distribution.

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TERRY E. BRANSTAD, GOVERNOR

LSB 1104DP

DEPARTMENT OF PUBLIC SAFETY  
PAUL H. WIECK II, COMMISSIONER

Members of the General Assembly  
77th Iowa General Assembly  
State Capitol

Subject: Control of Ephedrine Products

This proposed Department of Public Safety bill addresses (1) the diversion of ephedrine-containing products for unlawful purposes and (2) the abuses of ephedra and ma huang products.

The manufacture and use of methamphetamine is at a critical point in the state. Methamphetamine manufacture is an extremely hazardous, explosive, and environmentally damaging process. It threatens the safety of children, neighbors, and the environment. Due to the ease of manufacture, the activity can be conducted almost anywhere, as in a recent case, from the trunk of a motor vehicle. Ephedrine is easily obtained and is the chemical precursor to the clandestine manufacture of methamphetamine.

In addition, ephedra or ma huang based products, such as "Ritual Spirit," "Herbal Ecstasy," and "Magic Mushroom," are advertised as a "natural" alternative to illegal drugs and tout such effects as enhanced vision, "illegal highs", mood-altering states, increased heart rate, weight loss, heightened sexual awareness and enhanced athletic performance. Their advertised claims have made the drugs desirable to many young people and have led to mis-use and abuse, including adverse reactions and death. The FDA believes they should be treated as drugs.

This proposal will place these products in Schedule V as a controlled drug. Schedule V is the lowest level of control and does not require a prescription. However, products included would be regulated by a pharmacist, would be taken off public-access shelves, and would require the purchaser's signature.

Submitted by: Iowa Department of Public Safety

HOUSE FILE 384

(2) Anorectal preparations containing less than five percent ephedrine.

AN ACT  
TO INCLUDE CERTAIN PRODUCTS CONTAINING EPHEDRINE AS  
SCHEDULE V CONTROLLED SUBSTANCES.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

Section 1. Section 124.212, Code 1997, is amended by adding the following new subsection:

NEW SUBSECTION. 5. EPHEDRINE. Unless specifically excepted in paragraph "b" or listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substance, including its salts, optical isomers, and salts of such optical isomers:

a. Ephedrine.

b. The following drug products containing ephedrine, its salts, optical isomers, and salts of such optical isomers are excepted from this schedule, if they may lawfully be sold over the counter without a prescription under the federal Food, Drug and Cosmetic Act; are labeled and marketed in a manner consistent with the pertinent over-the-counter tentative final or final monograph; are manufactured and distributed for legitimate medicinal use in a manner that reduces or eliminates the likelihood of abuse; and are not marketed, advertised, or labeled for the indication of stimulation, mental alertness, weight loss, muscle enhancement, appetite control, or energy:

(1) Solid oral dosage forms, including soft gelatin capsules, that combine active ingredients in the following range for each dosage unit of not less than twelve and five-tenths milligrams but not more than twenty-five milligrams of ephedrine and not less than four hundred milligrams of guaifenesin packaged in blister packs of not more than two tablets per blister.

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RON J. CORBETT  
Speaker of the House

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MARY E. KRAMER  
President of the Senate

I hereby certify that this bill originated in the House and is known as House File 384, Seventy-seventh General Assembly.

Approved *April 23*, 1997

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ELIZABETH ISAACSON  
Chief Clerk of the House

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TERRY E. BRANSTAD  
Governor