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June 9, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Re: Docket #03N-1043 Continued over-the-counter-status of ipecac syrup

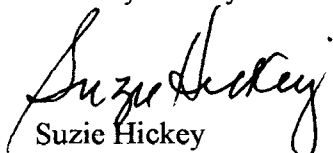
To Whom It May Concern:

Enclosed please find 3 copies of the Industry Response to the NDAC Meeting on Ipecac Syrup.

Humco Holding Group, Inc., Denison Pharmaceuticals, Inc. and Cumberland Swan Holdings, Inc. are jointly submitting this response for the committee's review.

If you have any questions, I may be reached at 800-662-3435, ext: 766.

Thank you for your attention to this matter.


Suzie Hickey

03N-0143

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Industry Response

Humco Holding Group, Inc
Cumberland Swan Holdings, Inc
Denison Pharmaceuticals, Inc

800-662-3435
903-831-7472 (fax)
shickey@humco.com

RESPONSE to NDAC Meeting on Ipecac Syrup

Industry Response:

Humco Holding Group, Inc., Texarkana, Texas

Cumberland Swan Holdings, Inc., Smyrna, Tennessee

Denison Pharmaceuticals, Inc., Pawtucket, Rhode Island

June 4, 2003

**Humco Holding Group Inc. , Cumberland Swan
Holdings, Inc. , Denison Pharmaceuticals, Inc.**

Industry Response

NDAC June 12, 2003 Safety & Efficacy of Ipecac Syrup, indicated for emergency use for continued OTC status under 21 CFR 201.308.

Major Premise

The manufacturers listed above supply ipecac syrup to major drug wholesalers, hospital buying groups, mass merchandisers and grocery chains. These channels of business provide access to ipecac syrup both over the counter and upon request from the pharmacist.

- 1) As manufacturers in the wholesale drug industry, our role is to provide safe and effective over the counter products which will be purchased by the end user at a retail location.
 - 2) Ipecac Syrup and Activated Charcoal have a history of safe and effective use in treating poison emergencies, with the direction of the Poison Control Centers across the United States. With poisoning fatalities on the rise a review of the declining use of ipecac syrup may need to be revisited from the perspective of industry and the home consumer.
 - 3) The studies cited which challenge the over the counter access of ipecac syrup provide a good check and balance to reviewing the product but give rise to concerns in regards to overreaction in making the product less or unavailable to the potential victim whose life may be in the balance.
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Response to agenda items:

1) The status of the role of ipecac syrup in gastrointestinal decontamination

- a. Of 2,267,979 human exposures reported to Poison Control Centers in 2001, 92.2% occurred at a residence. (AJEM, Volume 20, Number 5, Sept. 2002, p. 392, Review of the Data)
- b. Peak hours of reporting were between 4-10PM, with 90% of calls logged between 8AM and Midnight. (AJEM, p. 392, Review of the Data)
- c. The average number of human poison exposure consultations handled per day by all participating Poison Control Centers (59 of 64 centers nationwide) was 6,214. Higher volumes were observed in warmer months. (AJEM, p. 392, Review of the Data)
- d. National Poison Prevention Month is March, which promotes the product during National Baby Month as well. This promotional period aligns with being prepared for the higher call volume period noted above.
- e. The majority of cases reported to poison centers were managed in a non-health care facility (78%) usually at the site of exposure, the patient's own home. (AJEM, p.395)
- f. During the past 19 years the number of fatalities as a result of poison exposures, has increased 12 of the 19 years. In 2001, the total was 1,074 up from 920. Suicides accounted for 51.4% of those deaths which involved drug overdose. Industry questions the diminishing use of ipecac syrup as an agent in drug overdose cases. With the increasing use of analgesics and anti depressants and the aging population growth the risk of these exposure percentages increasing grows as well.
- g. The Consumer Products Safety Commission has recommended in publications dated 1977, 1978, and 2002 as well as in their "The Super Sitter" publication that a bottle of Ipecac should be kept in the home. The FDA concurred in the 1978 publication and there are other groups who also agree.

2) Whether the literature clearly defines the risk/benefit ratio of ipecac syrup

- a. The Committee should review the Prevention and Education Aspect of the product being readily available for household purchase. Having the product available upon request from the Pharmacist limits the opportunity for purchase due to visibility and pharmacy hours of operation thus reducing a prevention opportunity. The pharmacist should be the primary educator at point of purchase, but it is difficult to assess the likelihood of available time and complete medical reasoning for each purchasing customer. Responsible consumers will address the product labeling as well as converse with the Pharmacist at the point of purchase
- b. Industry cites these ratio of risk/benefit concerns if the OTC status of Ipecac Syrup is changed:

- i. How would this change enhance treatment and care of the victim?
 - ii. What will be the available method of obtaining the prescription product as a poisoning emergency is occurring?
 - iii. What will be the prescription writing protocol that makes the product available to the consumer, and how does this method enhance or impede the care and treatment of the victim?
 - iv. Transportation and timing are critical. A major concern is getting the product in time. There is a focus on the population who reside in rural communities, but they are not exclusive. The winter snowstorm, flat tire, poor directions, stress and anxiety in the emergency situation all create additional risk to the victim. What is the value of saving that life?
- c. Industry cautions that literature be examined from the victim whose life has been saved as well as the victim of product abuse.

3) The role of ipecac syrup in poison treatment for populations with limited access to emergency medical treatment

- a. "There may still be a limited role for the use of ipecac in a situation where a child has ingested a potentially lethal quantity of a drug and he is more than 45-60 minutes away from hospital. (http://www.icu.mcgill.ca/Toxicology/general_approach_to_acute_drug.htm)
- b. Poison Control Centers are not typically located in rural areas where emergency medical treatment may be needed.
- c. Access to hospital or emergency treatment center may be longer than 45-60 minutes in urban areas as well as rural communities due to traffic, construction, etc.
- d. The American Association of Poison Control Centers established a nationwide toll free number for immediate access to Educators and Emergency Response instruction for Poison Emergencies.
- e. Industry labeling on ipecac syrup clearly stresses the first step in responding to a poisoning emergency is to contact the Poison Control Center.
- f. The potential of making the product less accessible than it currently is reduces the value of the one life it may save.
- g. Industry is being responsible in the formulation and education of the consumer and is working to increase the awareness and guidance of the Poison Control Centers.
- h. Industry has responded to the most recent census reporting, showing Hispanics to be the largest minority group, in providing both labeling and information in bi-lingual format.

4) If there is significant abuse of ipecac syrup

- a.** The focus on keeping ipecac syrup an over the counter product should not be solely influenced by those who abuse the product as an emetic due to an existing eating disorder or Munchausen's syndrome by proxy. Those who are affected have an illness that typically is a result of an emotional disorder.
- b.** Anorexia and bulimia typically involve a mental illness such as depression or stress which cause the victim to reach a body weight or self image which is dangerously low. Munchausen's by Proxy Syndrome and these eating disorders use ipecac syrup as one tool. If ipecac syrup were not available it is industry's viewpoint that the emotional disorders are so strong alternative means to reaching the desired results will quickly take its place.
- c.** Industry cautions that the change in OTC status for ipecac syrup be reviewed not from the perspective of those with emotional disorders, but rather the effect it will have on the poison emergency victim not having ready access to the product in their home.
- d.** Consumers and Industry must act responsibly. In regards to industry products which are health related, responsibility to inform and educate as well as regulate will do only so much. Alcohol, cigarettes and all medications carry a health risk when abused. The access to Ipecac Syrup needs to be such that the responsible consumer is not restricted, causing an increase in health risk due to poisoning.

5) Alternative therapies to ipecac syrup

- a.** Activated Charcoal should be used exclusively for certain poisonings, as an alternative to ipecac syrup in certain poisonings, and may be used as an alternative rather than ipecac syrup in others.
- b.** Activated charcoal should not be administered routinely in poison management. Its efficacy after 1 hour is greatly diminished.
- c.** Alternative therapies to ipecac syrup include gastric lavage, activated charcoal, whole bowel irrigation & hemodialysis; however, no one therapy will take care of all classes of known toxic substances. According to the Baystate Health System Clinical Practice Guidelines dated 05/01, Springfield, MA, no definitive recommendation can be made on the use of syrup of ipecac, gastric lavage, cathartics, and whole bowel irrigation for all patients. If any of those modalities are used, the choice should be based on consideration of the toxic substance(s), time of exposure, and condition of the patient.
 - i.** Industry notes that these alternatives are not home remedies, and refers back to item #3. How do these alternatives prepare for the victim who is not in range of hospital treatment?
- d.** Activated Charcoal is an effective adsorbent when administered properly. The administration of Activated Charcoal is most effective in an emergency room or by an EMT.

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 - 3) The studies cited which challenge the over the counter access of ipecac syrup provide a good check and balance to reviewing the product but give rise to concerns in regards to overreaction in making the product less or unavailable to the potential victim whose life may be in the balance.
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Response to agenda items:

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- d. National Poison Prevention Month is March, which promotes the product during National Baby Month as well. This promotional period aligns with being prepared for the higher call volume period noted above.
- e. The majority of cases reported to poison centers were managed in a non-health care facility (78%) usually at the site of exposure, the patient's own home. (AJEM, p.395)
- f. During the past 19 years the number of fatalities as a result of poison exposures, has increased 12 of the 19 years. In 2001, the total was 1,074 up from 920. Suicides accounted for 51.4% of those deaths which involved drug overdose. Industry questions the diminishing use of ipecac syrup as an agent in drug overdose cases. With the increasing use of analgesics and anti depressants and the aging population growth the risk of these exposure percentages increasing grows as well.
- g. The Consumer Products Safety Commission has recommended in publications dated 1977, 1978, and 2002 as well as in their "The Super Sitter" publication that a bottle of Ipecac should be kept in the home. The FDA concurred in the 1978 publication and there are other groups who also agree


2) Whether the literature clearly defines the risk/benefit ratio of ipecac syrup

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- b. Industry cites these ratio of risk/benefit concerns if the OTC status of Ipecac Syrup is changed:

- i. How would this change enhance treatment and care of the victim?
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- c. Industry cautions that literature be examined from the victim whose life has been saved as well as the victim of product abuse.

3) The role of ipecac syrup in poison treatment for populations with limited access to emergency medical treatment

- a. "There may still be a limited role for the use of ipecac in a situation where a child has ingested a potentially lethal quantity of a drug and he is more than 45-60 minutes away from hospital. (http://www.icu.mcgill.ca/Toxicology/general_approach_to_acute_drug.htm)
- b. Poison Control Centers are not typically located in rural areas where emergency medical treatment may be needed.
- c. Access to hospital or emergency treatment center may be longer than 45-60 minutes in urban areas as well as rural communities due to traffic, construction, etc.
- d. The American Association of Poison Control Centers established a nationwide toll free number for immediate access to Educators and Emergency Response instruction for Poison Emergencies.
- e. Industry labeling on ipecac syrup clearly stresses the first step in responding to a poisoning emergency is to contact the Poison Control Center.
- f. The potential of making the product less accessible than it currently is reduces the value of the one life it may save.
- g. Industry is being responsible in the formulation and education of the consumer and is working to increase the awareness and guidance of the Poison Control Centers.
- h. Industry has responded to the most recent census reporting, showing Hispanics to be the largest minority group, in providing both labeling and information in bi-lingual format.

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- e. Activated Charcoal creates a gag reflex which makes it difficult to administer and to determine if the proper amount has entered the gastrointestinal tract.
 - f. Industry would like to communicate with the Poison Control Centers and the American Academy of Clinical Toxicology in developing additional or improved products for the treatment of Poison Emergencies.

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