

FDA Public Meeting on Dietary Supplements

March 30, 2000

Safety Issues Associated with Dietary Supplement Use During Pregnancy

Statement of the American Herbal Products Association

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Good morning, and thank you for the opportunity to participate in this forum. The American Herbal Products Association (AHPA) was founded in 1983 by a group of companies active in the trade in botanicals, and is now the national trade association and voice of the herbal products industry. AHPA has always served its members by promoting the responsible commerce of products that contain herbs and that are used to enhance health and quality of life.

As announced in the *Federal Register* notice of February 24, 2000, this meeting provides an opportunity to comment on safety concerns regarding structure/function claims for dietary supplements used during pregnancy and on other safety issues associated with dietary supplement use during pregnancy. The primary focus of my comments will be on issues related to the use during pregnancy of botanical products that do not bear statements about the effect of the products on conditions associated with pregnancy. The agency seeks information on, among other things:

- (1) potential for harm associated with dietary supplement use during pregnancy
- (2) means to address safety concerns associated with dietary supplement use during pregnancy
- (3) specific warnings for dietary supplements used during pregnancy

Botanical Safety Handbook

The American Herbal Products Association has long understood that its responsibility includes the organization and dissemination of accurate information related to the use of botanicals. In relation to this role, AHPA published in 1997 the *Botanical Safety Handbook*, a publication on which I was proud to serve as the Managing Editor. As stated

in the Preface of that work, the goal was “to find a rational platform for the evaluation of herb safety, neither assuming that all natural substances are inherently safe, as some popular references suggest, nor blindly accepting reports of toxicity from uncritical sources.”

The *Handbook* is organized into a rating system wherein each of the over 600 herbal substances listed in the book are assigned a safety classification. Classes include:

- Class 1 – Herbs that can be safely consumed when used appropriately
- Class 2 – Herbs for which the following use restrictions apply, unless otherwise directed by an expert qualified in the use of the described substance:
 - 2a – for external use only
 - 2b – not to be used during pregnancy
 - 2c – not to be used while nursing
 - 2d – other specific use restrictions as noted
- Class 3 – Herbs for which significant data exist to recommend [labeling that restricts consumption to supervised use]
- Class 4 – Herbs for which insufficient data are available for classification

Of interest to the matter that is the subject of today’s meeting, just over 200 of the 644 botanicals listed in the *Handbook* are classified in our Class **2b**. These are herbs that are not for use in pregnancy unless otherwise directed by a qualified expert.

In July, 1998 AHPA’s Board of Trustees adopted as a trade recommendation a policy that calls upon its members to label “any products that contain herbs classified in the

Botanical Safety Handbook in Class 2b or 2c...according to the labeling classification for those classes.” The adoption of a trade recommendation establishes a condition of membership, so that all AHPA members are expected to conform to this policy.

Development of the *Botanical Safety Handbook*

At the risk of sounding like this is an infomercial for our book, I would like to spend a few minutes discussing the process by which its editors arrived at their classifications, as the development of this reference serves as a model for assessing existing expert information.

As the first stage of preparing this work, several experts in the field of botanicals convened in 1993 to discuss the concept of compiling existing knowledge about the safety issues associated with the herbs that we use. This group included 3 of the editors: Christopher Hobbs, Roy Upton and myself; Mark Blumenthal, founder and director of the American Botanical Council and editor of the English translation of *Commission E*; Steven Foster, the well-known and well-respected writer and lecturer; representatives from the naturopath community; and some of the country’s most established and knowledgeable herbalists, including Ed Smith and David Winston.

Identification of reference materials

One of our earliest tasks was to define the resources that could serve as the basis of our compilation. We arrived at a list of 29 references, from several related disciplines, that we identified as our primary sources of authoritative information. These include:

- (1) seven books specifically about poisonous plants.

- (2) actual and pending regulations related to use and/or labeling of botanicals in Canada, Australia, Belgium and Britain. We also had an early edition of the translated *Commission E*, which provided us access to the German regulatory framework.
- (3) classical texts that record the use of botanicals as therapeutic agents, such as *King's American Dispensatory*; *Hagers Handbuch*; and the 11 volume *Wealth of India*. These publications are quite different in their format and in the specific range of plants that they treat. They are, however, similar in that each of them was written by experts who were devoted to the use of plants in the promotion of health and to the preservation of all of the knowledge that has been acquired about these plants. Also, each of them includes toxicological information, if any such information is relevant to the plant's historical use.
- (4) contemporary authoritative herb usage texts, such as Leung & Foster's *Encyclopedia of Common Natural Ingredients Used in Food, Drugs and Cosmetics*, 2nd edition; Weiss' *Herbal Medicine*; Van Hellemont's *Compendium de Phytotherapie*; and Wichtl's *Herbal Drugs and Phytopharmaceuticals*. These last three were designed specifically to inform practicing pharmacists and naturopaths on the identification and use of herbs. All four of these works also include contraindications and cautions, where any are known.
- (5) the first two volumes of Dr. Peter DeSmet's *Adverse Effects of Herbal Drugs*. These provided us with in-depth analyses of 42 herbs or classes of herbs, with a special emphasis on examining appropriate use during pregnancy and lactation.

- (6) five texts that discuss different aspects of the traditional use of Chinese herbs, including known contraindications.

As you have just heard, we did not skimp in gathering together the existing authoritative references that record information on the use and relevant cautions and contraindications for the botanicals in trade in this country. We did this by identifying those references that we believed to have the same goals as we had defined for ourselves, that is: the dissemination of accurate and material information regarding the safe use of botanicals.

Establishment of Classifications

The process of establishing classifications for each of the botanicals consisted of a review by the editors of all 29 of the identified primary references for each of the botanicals listed. The agreement that we made was that if any of the primary references listed any safety concern, that fact would have to be identified in the plant's listing. Usage history was also determined as relevant to contraindicating a specific herb in pregnancy, so that any herb with an established history of use as an emmenagogue or abortifacient was automatically placed in our **2b** category.

In the course of this review of the data contained in the primary references, if there existed a preponderance of data suggesting a specific caution the editors established the appropriate restrictive classification. If a single reference was alone in stating a concern, or if there was contradictory information, the editors were obliged to identify the concern in the text and to find additional references to either support or refute the reference, and thereby make an appropriate classification. This additional requirement resulted in the development of an extensive bibliography of over 250 books and citations.

The training and professional experience of certain of the editors was also essential to the creation of an accurate reference. Roy Upton is the founder of the American Herbal Pharmacopoeia and one of the founders of the American Herbalist Guild. Christopher Hobbs holds a California license as an acupuncturist. Both Chris and Roy have significant experience and training in the hands-on use of therapeutic herbs, and this experience was of tremendous value in qualifying the safety concerns of the botanicals with which they are familiar. Finally, the entire document was reviewed by internationally recognized experts such as Drs. John Staba and Dennis Awang.

Relevance of *Botanical Safety Handbook* to FDA's safety questions

As noted earlier, the agency has posed questions regarding the use of dietary supplements during pregnancy to obtain public comment: (1) regarding potential harm from use of supplements during pregnancy; (2) to identify means to address any safety concerns for such use; and (3) to examine the use of specific warnings on dietary supplement labels regarding their use in pregnancy.

For botanical ingredients in dietary supplements, AHPA has provided authoritative answers to these three questions for the 644 plants that are examined in our *Botanical Safety Handbook*. As is obvious from our extensive references, this is not the only resource for accessing material information about safety issues, and specifically pregnancy concerns related to the use of herbs. AHPA does not, therefore, represent this work as the only valuable reference for such information, nor do we suggest that all of the information in the *Botanical Safety Handbook* is not subject to challenge. We do, however, strongly recommend that manufacturers utilize accurate resources when

designing a label that discloses all material facts related to the use of a dietary supplement.

Inappropriateness of a broad-brush approach to labeling

AHPA is aware that there is some interest in recommending that there be a requirement for providing a pregnancy caution on all non-RDI dietary ingredients, which of course includes all botanical ingredients, unless these are specifically marketed to men, children, or women who are not of child-bearing age. AHPA strongly opposes such an approach as inappropriate for botanical dietary ingredients.

Our concern about this approach is twofold. To begin with, such a requirement would essentially ignore the information that is already known, documented, and available to companies that manufacture and label herbal products. At four different points in the commentary that accompanied the Final Rule for structure/function statements published in the *Federal Register* on January 6, 2000, FDA identified its position that dietary supplements are required to include all facts that are material in light of the consequences that may result from the use of the product. The material facts as they relate to the use of botanical supplements during pregnancy cannot be generalized, and in fact are absolutely dependant upon the identity of the botanical ingredients in each supplement. AHPA believes that, in order to satisfy the need to provide material facts to a consumer, the manufacturer must access material information about a product's ingredients.

Secondly, reliance on a broad pregnancy caution on essentially all herbal supplements would so dilute the message that it would become meaningless where it is actually material. A pregnant woman encountering cautions to seek professional advice prior to use of both motherwort extract and peppermint tea is just as likely to ignore both

warnings as to somehow determine that the first is an important health message, while the second is frivolous.

Traditional use of herbs for pregnancy conditions

I will now briefly discuss, in the context of the historical use of herbs in enhancing health and quality of life in pregnant women, the agency's question regarding the potential hazards that may be associated with botanical supplements used for conditions associated with pregnancy.

Various herbs have been used for centuries and beyond to promote the health and comfort of a pregnant women. Certain of these botanicals have generally been considered as appropriate for use in pregnancy with no need for expert supervision. Other botanicals with a long history of safe use in pregnancy have most often been advised to be used only with expert supervision, for example from a midwife, a naturopathic physician, or a qualified herbalist.

The agency has asked what are the potential hazards associated with the use of dietary supplements for conditions associated with pregnancy, both to the pregnant woman and to the fetus. With regard to botanical supplements, AHPA again believes that this question can only be answered on a specific rather than a general basis. In developing further guidance to address this question, AHPA believes that the agency should utilize the existing body of knowledge about the historical safe use of herbs to promote the health and comfort of a pregnant woman, so that, whatever the outcome of any such guidance, women will continue to have access to botanicals that can be safely used during pregnancy.

I am aware that another presenter this morning, Josef Brinckmann of Traditional Medicinals, will discuss herbal products traditionally indicated for use in pregnancy. I will therefore defer to Josef for further comments on the use of botanicals for conditions related to pregnancy.

Conclusions

In summary, AHPA shares the concerns that were communicated to FDA regarding the use of supplements during pregnancy. AHPA's members are in the business of promoting health, and are committed to providing products that are properly labeled and evaluated to assure their safe use by all consumers. As is evident by the fact that nearly one out of three of the botanicals examined in our *Botanical Safety Handbook* is classified as not for use in pregnancy unless otherwise directed by an expert, we too, and the botanical traditions upon which our recommendations were made, consider pregnant women to be an especially protected population. We reiterate here today the commitment that we made with the publication of this work in 1997, a commitment to provide appropriate cautions that accurately represent the material facts that are relevant to the use of herbal products during pregnancy. We further recommend that, in whatever regulations come to govern the botanical products that have traditionally been used for specific conditions associated with pregnancy, there be not only a tolerance for but a recognition of the value that safely used botanicals can play in promoting health and comfort at this cherished phase in a woman's life.

Thank you for your attention.