Date Effective: January 9, 2010

ACADEMY OF BREASTFEEDING MEDICINE (ABM)

POLICIES FOR INTERACTION WITH COMMERCIAL AND NON PROFIT ORGANIZATIONS

The Committee on Ethics

I. INTRODUCTION

1. Purpose of Statement

The Academy of Breastfeeding Medicine has joined more than 30 other US professional organizations in adopting the uniform "<u>Code for Interacting with</u> <u>Companies</u>" developed by the Council of Medical Specialty Societies (CMSS). The following statement explains the specific and unique organizational principles and policies of ABM. This statement should be considered as an expansion of the CMSS US Code and, as such, details the implementation process of maintaining and protecting the desired ethical standards of ABM.

A second purpose is to confirm and expand upon the ABM endorsement of the WHO Code of Marketing of Breast-milk Substitutes and subsequent WHA resolutions, referred to as the WHO Code, hereafter.

The Academy of Breastfeeding Medicine (ABM) acknowledges that its officers, Board members, and its management staff will have interactions with for-profit commercial and not-for-profit enterprises, henceforth known as *organizations*, from time to time as part of its normal operations. This statement provides a set of policies, procedures, and recommendations to ensure all interactions with other organizations are consistent with the <u>ABM Mission Statement</u>, and avoid any potential conflict of interest The following interfaces with organizations are included:

- a. Advertising in publications, websites and other distributed materials.
- b. Vendor displays and other marketing efforts at ABM conferences.
- c. Solicited and unsolicited donations and grants to ABM.
- d. Evaluations and endorsements of commercial products.
- e. Lectures and demonstrations that may have commercial interfaces.

f. Officer and Board member and other key member (see definition of key members in CMSS Code) relations with organizations.

2. Underlying Ethical Principles

a. The Academy of Breastfeeding Medicine's foremost goal is to educate physicians worldwide and, in support of this goal, to provide evidencebased guidance (protocols) for physicians in breastfeeding medicine. Therefore, the credibility, reputation and intellectual independence of ABM is essential and must be protected through financial independence. To this end, ABM must not be obligated financially or

philosophically to any other organization. Information must be given for the well-being of patients and not for product promotion or financial gain. Professional judgement must not be influenced by commercial bias, profit motives or conflict of interest.

- b. ABM adopts the CMSS "Code for Interacting with Companies"
- c. ABM's guiding principles include the World Health Organization's International Code of Marketing of Breast-milk Substitutes for the promotion, protection and support of breastfeeding and human lactation.
- **d.** Although the principles and recommendations contained in this document may give guidance to individual physician practice, its primary intention is to provide guidance to the Academy of Breastfeeding Medicine and its leaders, representatives, and associated publications.

II. <u>Organizations to Consider When Assessing Potential</u> <u>Conflicts of Interest</u>

- 1. Manufacturers of infant formula and their non-profit affiliate companies
- 2. Pharmaceutical manufacturers
- 3. Producers and distributors of products for breastfeeding mothers and infants
 - a. Bottles, nipples and pacifiers, cups, spoons
 - b. Infant beds, supports, pillows, etc.
 - c. Breastfeeding-specific clothing for mothers and infants
 - d. Breast pumps and related equipment

e. Foods and other nutritional products for mothers sold as breastfeeding support products (i.e., intended to increase or assist lactation); replacement or complementary foods marketed for infants younger than 6 months old.

- 4. Publishers and authors of breastfeeding educational materials
- 5. Manufacturers of human milk derived products (fortifiers, etc.)
- 6. Commercial and not-for-profit milk banks
- 7. Companies providing management services on behalf of ABM or other medical or scientific societies

III. CONFLICTS OF INTEREST WITHIN ABM

1. Revelation of Conflict

Board members, officers, committee chairs and protocol committee members, and management must reveal, in writing, on an annual basis, any and all commercial interests with organizations delineated in Section II. Conflicts may include, but are not limited to: ownership of stock; membership on a company's board or committee; any receipt of financial or other compensation; listing as a company speaker; role in evaluation of a product or service; any professional or personal consultation with the company, formal or informal or receipt of grants within the previous five years. Membership or leadership in a not-for-profit organization for which there may be a conflict of interest with ABM principles and activities must be revealed. Similar information regarding the involvement of spouses/partners must also be revealed.

Conflicts of interest must be reviewed by the ABM Board of Directors. Conflicts of interest will preclude participation in deliberations with implications in that area of conflict. A major conflict of interest could preclude a leadership position within ABM. All leaders and representatives of ABM take into account the possibility of a conflict of interest and make efforts to avoid such conflicts and even the appearance of such an ethical violation.

2. Handling of conflicts of interest by board members and officers

Individuals with an alleged conflict of interest may contest the ABM Board's decision by appealing to the Ethics Committee for further investigation. Alternatively, the Board may request an initial Ethics Committee review of all reported conflicts. The ultimate oversight and decision remains the Board's responsibility.

3. Acknowledgement regarding conflicts of interest

All identified conflicts of interest by Board members, officers, committee chairs and protocol committee members, as well as the management and spouses/partners shall be acknowledged on the ABM Website.

4. Gifts, travel and meals

Board members, officers and management staff, while in these roles, may not accept any gifts of merchandise, travel costs, cash or other financial equivalents from any organization (as defined in Sections II and III.1 above). Samples of products related to activities of ABM may be accepted only for purposes of evaluation. Board members, officers and management staff should pay for their own meals that occur in conjunction with a meeting with representatives of commercial enterprises. Organizations may not underwrite any parties, receptions or other social events that ABM or its Board, officers or management representatives may hold for themselves or for ABM members or guests. Board members, officers and management staff should not accept desk, office or patient care materials that contain advertising related to infant nutrition on them (e.g. pens, pads, etc.). Educational materials from organizations that contain company names or logos are acceptable for use by the physician, but not for locations in which patients and their families would see them.

5. Grant Support

Board members, officers and management staff may apply for and receive grants from organizations in support of research or educational efforts related to ABM or independent of ABM. All such support must be acknowledged in writing to the ABM Board at the time of application and again at the time of receipt of the grant. Research design, execution, and publication must be entirely under the control of the recipient. If a conflict of interest is identified within the context of a grant award, the grant recipient will not be eligible to vote on any similar or related issue; however, the individual may participate in pertinent discussion provided they have disclosed the conflict of interest to all involved.

IV. ROLES OF ORGANIZATIONS AS THEY RELATE TO BREASTFEEDING

Organizations may have both positive and negative relationships to breastfeeding. ABM must clearly identify the organization's activities in order to develop an appropriate relationship. Organizations with programs that actively support breastfeeding should be

recognized and encouraged. ABM should not enter into relationship with organizations whose activities or programs negatively impact breastfeeding.

1. Determination of Compliance with the WHO International Code of Marketing of Breast-milk Substitutes and Subsequent WHA Resolutions

A. In recognition of the requirement of the ABM By-Laws that all organizations with which ABM has official relationships or that exhibit at ABM meetings shall be compliant with the WHO International Code of Marketing of Breast-milk Substitutes and subsequent resolutions (WHO Code), it is incumbent upon ABM to also fully comply with the WHO Code and subsequent resolutions, and to have a mechanism for assessment of compliance.

B. The ABM Ethics Committee shall be the review body for Code compliance issues based on all updates as to the WHO Code policies, resolutions and review process

C. Review of the compliance with the Code for an outside organization or ABM shall be instituted by the ABM Ethics Committee when the ABM Board requests such review based on allegations of non-compliance, or when the issue is raised by membership.

D. The review shall utilize the following procedures:

- a. Request that the organization with alleged violations state whether they consider themselves compliant with the Code and the basis for that statement of compliance.
- b. Request all marketing materials, product documents, advertising materials, labels and other relevant materials from the organization under review, as well as a statement of their marketing policies and activities.
- c. Request statements and other evaluations of the organization under review from agencies and individuals who have evaluated the organization and who are considered experts on matters of Code compliance.
- d. Request an opinion or additional information on compliance from the available resources
- e. An organization, or an ABM group or product, against which a charge of Code violation has been made will be afforded a reasonable opportunity to respond to the preliminary conclusions and recommendations of the ABM Ethics Committee prior to the finalization of the committee recommendation.
- f. Prepare a statement summarizing the findings and the basis for the recommendation as to whether the organization is or is not compliant with the code. The Ethics Committee should submit its conclusions and recommendations only after a majority of the committee members have voted in favor of its submission to the ABM Board.

- g.The summary statement and recommendation shall be forwarded to the ABM Board of Directors for their review and endorsement or rejection of the recommendation. The organization under review shall then be informed of the decision in writing by the ABM Board or its Executive Committee.
- h.If the ABM Board should be the ABM group in question, the findings will be made known to membership.

V. DONATIONS, CONTRIBUTIONS & UNDERWRITING FROM ORGANIZATIONS

1. Solicitation

Support of ABM activities may be solicited from outside organizations. While willing to support ABM, the organization's underlying motivation may reflect their own interests and must be ascertained prior to negotiating a relationship. Company motivations may include the following:

- a. Direct financial benefit through increased sales and services simply by association with the ABM: a subtle form of endorsement
- b. Altruistic donation by a breastfeeding related organization to enhance shared breastfeeding promotion/education goals
- c. Organizational image building for companies without direct relationship to breastfeeding, including significant recognition by ABM.
- d. Altruistic donation by company with direct relationship to breastfeeding.

Whatever the motivation may be, prior to ABM's acceptance of support, the organization must disclose its intentions and expectations regarding future acknowledgment of its relationship to ABM. The specific relationship must be clearly defined and stipulated in the documents accompanying the donation.

2. Acceptability

ABM should seek to solicit or accept approaches only from organizations which have either a positive or a neutral relationship to breastfeeding* (Note: Breastfeeding is defined in the ABM position statement as "the mother/child act of milk transference, "breastmilk feeding" as the provision of the mother's milk to the infant, and "human milk feeding" as the feeding of human milk from any other individual or pooled milk.) Approaches from organizations that have clearly negative relationships to breastfeeding and/or breastmilk feeding or human milk feeding, or have violated or are non-compliant with the **WHO International Code of Marketing of Breast-milk Substitutes** should be categorically rejected.

3. Relationship of Donor to Program

Whether solicited by ABM or by the US and WHO Code compliant organization, unless specified in the terms of the agreement and agreed upon by the Board, the donor should not be involved in the development of the program it supports or the decisions on how the program will be run. All decisions on the activity should be made by ABM and

its independent designated agents, all of whom should be without any relationship to the donor organization or the donor's agents.

4. Relationship of ABM to Organizations

ABM should avoid all involvement that may appear to support the development or promotion of a specific product or service, or imply its approval by governmental authorities (e.g. FDA). Similarly, key ABM members in positions of authority (Board member, officer, program chair, committee chair or member, founders, etc.) should avoid all involvement with commercial enterprises that are providing any form of support to ABM. However, ABM may act as an independent consultant on a product or service, as long as its independence and objectivity is assured and acknowledged and the organization is not providing donations or other underwriting of ABM programs

5. Acknowledgements

a. Location of acknowledgement

Acknowledgements of financial or "in kind" support should have a unique location in all publications or websites, without links to specific ABM activities. If the donor desires more specific acknowledgement linked to the supported activity, a separate acknowledgement section with a link to the ABM activity may suffice. If the donor insists upon acknowledgement within the content of the supported program or presentation, it must be in smaller type than that of the title, authors, presenters, etc. and a less prominent location in the order of activities. ABM reserves the right to refuse support from any organization that requires linked acknowledgement in a manner deemed inappropriate or not meeting ABM standards

b. Wording of acknowledgement

The acknowledgement should simply be a statement of the organization title and division, if appropriate. No product identification or product logo should be included.

c. Disclaimers

Depending on the nature of the supported program or activity, it may be necessary and appropriate to include a disclaimer within the acknowledgement, making it clear that the donor had no involvement in the program's development or choice of speakers or topic, research project design, data analysis, or conclusions.

6. Relationship to ABM budget

To minimize the risk that ABM could become financially dependent upon donations from other organizations that would interfere with and potentially damage its independence and credibility, it is recommended that ABM should establish a limit as to how much external total support of either its general budget or its annual meeting budget will be acceptable. This may be as small as 5% or as large as 25%, from an individual organization, but it should always be an amount that is small enough that the organization can continue to operate *without* such underwriting. Targeted donations for full support of ad hoc programs or meetings are acceptable.

ABM accounting documentation should be entirely transparent and should list all donors and the size of each donation. Publication of the names of all donors and the size of each donation is recommended.

7. Endorsement of Products

ABM does not endorse specific commercial products or commercial organizations. This principle should be clearly stipulated to every commercial donor, including warnings against subtle uses of the ABM name in association with promotional activities on behalf of any product or service.

8. Research and Educational Support

a. *Terms for acceptance of external funding by type of research:* All proposed project funding must be approved by the ABM board and clearly relate to ABM goals. Acceptable research or educational projects must include design, implementation, reporting and review by scientist/educators independent of the funding organization. Projects designed solely to enhance a company's sales or services would not be acceptable. The same rules may not apply for vendor presentations at meetings. If neither the chair nor a member of the Ethics committee sits on the Board, a liaison will be established.

b. ABM membership: organizational access and use for research purposes

US and WHO Code compliant organizations requesting permission to use or survey ABM membership for research may be acceptable provided the project is in concert with ABM goals and is not intended to primarily benefit an organization's marketing efforts. A full description and intended purpose of the study must be submitted and reviewed/approved by the ABM Board of Directors who retains the right to refuse final publication or distribution of such project if deemed unacceptable. Charging a fee for access to ABM membership is a sound, ethical practice and need not be discouraged, however, consideration of a discounted fee for ABM members will be considered.

c. Review of all research protocols and approval by an Institutional Review Board

Research undertaken by ABM that involves patient or professional staff participation whether funded by commercial enterprises, governmental agencies, not-for-profit agencies or is unfunded must be reviewed by an approved Institutional Review Board (IRB) and by the ABM Board of Directors.

VI. ORGANIZATION INVOLVEMENT WITH ABM MEETINGS

1. Principles

The principles outlined in the previous section as well as the sections of the CMSS Code's guidelines for Society meetings apply also to organizational underwriting and other support of activities at all meetings of ABM. These include annual, regional, special or ad hoc meetings, as well as Board of director and committee meetings **2. Speakers**

2. Speakers

All speakers must reveal conflicts of interest as well as absence of conflicts of interest at the beginning of each ABM meeting presentation. While such conflicts of interest may preclude inclusion in an ABM program, acknowledgement in the program and prior to the presentation may be an acceptable avenue for inclusion. Individuals who are members of a Speaker's bureau and/or with current employment in a company that violates the WHO Code should not be selected as speakers for an ABM program.

3. Underwriting and other contributions

a. General support

The acceptability of an organization for general or specific support should follow the principles provided in the previous section, including acknowledgements.

b. Specific projects (lectures, awards, travel grants, etc.)

Organizational support for lectures, travel, and other meeting-specific activities is acceptable as long as the donors are not-for-Profit Organizations and therefore not in a position to profit from the lecture. For-profit organizations, by definition, could gain advantage from the activity they are supporting and this would not be acceptable. ABM should retain full independence in all decisions regarding the program or activity. No promotion or advertising material should be permitted in association with any such activity. Ideally, all such funding should be placed in a single account and acknowledgements of support should not be linked to a specific speaker, traveler, topic or meeting component. This isolation of the funding from the meeting activity minimizes any possible obligation that such support may place on the recipient.

4. Exhibits

All exhibitors must represent commercial enterprises that are compliant with the *WHO Code of Marketing and subsequent resolutions*. The ABM Board of Directors shall appoint a subcommittee of the Program Committee to review all applications for exhibits and approve them for inclusion at the meeting. The exhibits at all ABM meetings must be clearly defined as organizational marketing efforts. All such activities shall be restricted to the designated exhibit area. Access to the meeting room(s) without requiring passage through the exhibit area should be provided wherever possible. The acceptability of organizations for the exhibits shall follow the same criteria used above for solicited donors. An ABM member shall be designated by the Board to review all exhibits at the beginning of the meeting to be certain there are no violations of the principles by exhibitors. Violations must be removed promptly. The Ethics Committee may be called upon if there is a lack of clear decision.

5. Gifts at Meetings

Organizations may not give gifts to any ABM members or non-member attendees except for small samples and educational materials offered to members and guests as a component of their exhibit.

6. Advertising on announcements, badges, etc.

Badges, certificates, announcements, portfolios, and other materials distributed by ABM shall be free of all commercial advertising or other associations with products or services, including corporate names. The meeting program may have advertisements in it, providing they are in a separate section and not on the front or inside front cover.

7. Receptions and other social gatherings

Receptions, meals, snacks and social gatherings shall not be underwritten or supported in any way by organizations that are not compliant with the US CMSS or WHO Code. Exhibitors and other business associates may be present at such activities, but they must not promote their commercial interests during these activities.

8. Location of Meetings

ABM meetings are generally held at commercial hotels. ABM should use only hotels and hotel chains that have policies favorable to breastfeeding and will ascertain the policies prior to recommendation of site to ABM board. In addition, prior to recommendation, the hotel must agree to provide an area for milk expression by attendees.

VII. ORGANIZATION INVOLVEMENT WITH AN ABM JOURNAL

ABM Board desires that its official journal, Breastfeeding Medicine, adhere to the practices of refusing advertising from any entity that violates the WHO Code of Marketing of Breast-milk substitutes in any country worldwide.

VIII. COMMUNICATIONS FROM ORGANIZATIONS TO ABM MEMBERS

1. Control and access to membership lists

In specific instances, ABM may make its membership lists available to organizations and may charge a fee for such access. However, this may be done only after full review and approval by the ABM Board, and if there is any question, by the Ethics Committee, of the material content to be sent to ABM members. The use of the mailing list shall be restricted to the material specifically approved for this purpose. Any other use shall be a violation of the approval.

2. Use of ABM Website

The ABM Website and Listserv shall not be used for **any** commercial purposes, including promotion of specific books or other publications. Members may not use the Listserv to promote their own financial interests (e.g. their own publications or publications of others) or to advertise their services. This does not restrict the advertising and sale of ABM's own publications or other ABM materials on the website.

3. Linkages from ABM Website

Linkages listed on the ABM Website shall only include not-for-profit Code compliant organizations and educational enterprises.

IX. CONCLUSIONS

Developing relationships with other organizations is a complex endeavor for ABM. Despite this challenge, however, external support can facilitate ABM's financial success and, in turn, create broader support for breastfeeding. Every relationship must be carefully and comprehensively evaluated to insure that the benefit outweighs the potential risk.

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X. <u>References</u>

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3. American Medical Association. *Gifts to Physicians from Industry*. In: Code of Medical Ethics of the AMA: current opinions with annotations. Chicago, IL 2006

4. Pharmaceutical Research and Manufacturers of America. *Code on interactions with healthcare professionals*. Washington, DC PHRMA 2002. Available at: http://www.pharma.org/files/PhRMA%20Code.pdf.

5. Kassirer, J.P. On the Take. How America's Complicity with Big business Can endanger Your Health. Oxford University Press, New York 2005

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XI. This document has been prepared by the Ethics Committee of the Academy of Breastfeeding Medicine

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XII. Review or Revision Dates

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