ACADEMY OF BREASTFEEDING MEDICINE (ABM)

CODE AND 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 over 30 professional organization in adopting the uniform "Code for Interacting with Companies" developed by the Council of Medical Specialty Societies (CMSS) (see attached). The following statement spells out the specific and unique organizational principles and policies of ABM. This statement should be considered as an expansion of the CMSS code and, as such, details the implementation process of maintaining and protecting the desired ethical standards of ABM

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 preserve ABM principles, goals, and objectives, 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 and to provide evidence based guidance (protocols) for physicians who are patient advocates. 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'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.
- c. 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 and representatives.

II. ORGANIZATIONS THAT MAY RELATE TO BREASTFEEDING AND ABM

- 1. Manufacturers of infant formula
- 2. Pharmaceutical manufacturers
- 3. Producers and distributors of products for breastfeeding mothers and infants
 - a. Bottles, nipples, 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 mother sold as breastfeeding support products; complementary foods for infants and children.
- 4. Publishers and authors of breastfeeding educational materials
- 5. Manufacturers of human milk derived products (fortifiers, etc.)
- 6. Commercial milk banks
- 7. Media (radio, television, Internet, newspapers, magazines)
- 8. Not-for-profit educational, research or service organizations
- 9. 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 committee members (including protocol committee and its members), and management must reveal, in writing, on a annual basis, any and all commercial interests that bear any possible relation to breastfeeding, lactation, or infant, child and maternal nutrition or to products or services potentially related to breastfeeding, lactation or infant, child and maternal nutrition. These 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. Similar information regarding the involvement of first order relatives need be revealed only if such a relationship can be construed as a potential conflict of interest. Membership or leadership in a not-for-profit organization for which there may be any possible conflict of interest with ABM principles and activities must be revealed.

The revelations of potential conflicts of interest must be reviewed by the ABM Board of Directors. Potential 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 must practice awareness of the possibility of a conflict of interest and make every effort to avoid such conflicts and even the appearance of such an ethical violation. ABM leaders and representatives are personally responsible for avoiding both real and perceived conflicts of interest as they constitute serious ethical violations.

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 committee members, as well as the management 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. Meals that occur in conjunction with meetings by Board members, officers and management staff with representatives of commercial enterprises should be paid by each party. 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 or use 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. Grant design, execution, and publication must be entirely under the control of the recipient. The funder must not control any aspect of the funded operation. 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 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 (Code), it is incumbent upon ABM to have a mechanism for assessment of such compliance.
- B. The ABM Ethics Committee shall be the review body for Code compliance issues and shall be cognizant and updated as to the WHO Code policies, resolutions and review process
- C. Review of an organization for compliance with the Code shall be instituted by the ABM Ethics Committee when the ABM Board requests such review based on allegations of non-compliance.

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 against which a charge of Code violation has been lodged 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.

V. <u>Donations, Contributions & Underwriting From</u> Organizations

1. Solicitation

Support of ABM activities may be solicited from outside organizations. Though organizations may be willing to support ABM activities per se, their motivations may also reflect their own interests. Thus in the course of negotiating such a relationship the underlying motivations should be identified. Company motivations may include the following:

- a. The organization may benefit financially, through increased sales and services, or simply by its association with ABM: a subtle form of endorsement. Therefore, prior to ABM's acceptance of support, the organization must disclose its intentions and expectations regarding future acknowledgement of its relationship to ABM. Specifically, ABM needs to determine and clarify with the organization how it will acknowledge the donation (see section below).
- b. Despite the organization producing a product related to breastfeeding, the company does not intend to utilize the relationship with ABM to promote their products or services. This altruistic relationship should also be clearly defined and stipulated in the documents accompanying the donation.
- c. The organization has no relationship to breastfeeding, but sees support of ABM as organizational image building. They intend to acknowledge their contribution in their promotional materials. They also desire significant recognition by ABM. These actions by both parties need to be clearly defined and stipulated in the documents accompanying the donation.
- d. The organization has no business related to breastfeeding and is not seeking a means of enhancing their corporate image through this association. This pure altruistic motivation is also to be 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. Approaches from organizations that have clearly negative relationships to breastfeeding or have violated or are non-compliant with the WHO International Code of Marketing of Breast-milk Substitutes should be categorically rejected.

Restrictions on advertising and editorial content in the official journal of ABM (*Breastfeeding Medicine*) should follow the same principles and standards as those for all other activities of ABM and as outlined in this document. The Editor and Editorial Board of Breastfeeding Medicine will be directly responsible for monitoring and reviewing the content of the advertising in conjunction with the Journal publishers

3. Relationship of Donor to Program

Whether solicited by ABM or the organization, 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, 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. Ideally, ABM would not consult for organizations providing donations or other underwriting of ABM programs, since this could be seen as a potential conflict of interest..

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. Articles in Breastfeeding Medicine reporting on activities and/or research supported by an outside source must be acknowledged by a full disclosure statement

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:

Organizational funding of an ABM research or educational project is considered acceptable if design, implementation, reporting and review of the project are governed entirely by scientists/educators completely independent of the funding organization. Furthermore, the project must clearly relate to the goals of ABM. ABM's acceptance of proposed funding of the project must be approved by the ABM Board. Any funded project primarily designed to enhance sales of a company's products or services would not qualify for ABM acceptance or involvement. This does not relate to accepted vendors' presentations at designated areas at our annual meeting

b. ABM membership: organizational access and use for research purposes
From time to time, an organization may request permission to survey or otherwise use ABM membership for its own research project. Such a project must be in concert with ABM's goals. While such access to membership may be acceptable, it is critical that such research not be primarily intended to collect data solely for the benefit an organization's marketing efforts. To be acceptable, the organization must submit full descriptions of the study details and its intended purpose. These materials must be reviewed and approved by the ABM Board of Directors. Charging a fee for access to ABM membership is a sound, ethical practice and need not be discouraged. Because the ABM name will be associated with such a project, the Board retains the right to review and approve any and all final reports related to the research project. ABM may ultimately refuse to allow distribution or publication of the results if it wishes to make this a condition of involvement.

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 apply also to organizational underwriting and other support of activities at various meetings of ABM. The sections of the CMSS Code regarding guidelines for Society meetings are applicable to ABM. Additional issues related to ABM activities are noted below:

2. Types of meetings

Meetings of ABM include the annual meeting and any regional or special meetings that may be established, whether regularly recurring or ad hoc. In addition, "meetings" also cover those of the Board of Directors, the Executive Committee and all other committees.

3. Speakers

All speakers at ABM meetings must be asked and must reveal all conflicts of interest including those defined above under Conflicts within ABM. While it is possible that such conflicts would preclude the individual's inclusion in the program, it is generally acceptable to acknowledge the speaker's organizational involvement in the published program and during the speaker's introduction. Absence of a conflict of interest in relation to the lecture or demonstration should also be acknowledged at the beginning of the presentation and in the program.

4. 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 in a position to gain advantage from the activity they are supporting and that ABM retains 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.

5. Exhibits

All exhibitors must represent commercial enterprises that are compliant with the *WHO Code of Marketing*. 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 the annual and any other meetings of ABM must be clearly defined as organizational marketing efforts. All such activities shall be restricted to the designated exhibit area and shall not be allowed in the meeting hall. 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. Commercial and not-for-profit enterprises may

be mixed and appear in the same area or they may each have separate areas. 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.

6. 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.

7. 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 or on the back cover. Advertisements or other commercial identifications may not be on the front cover, inside front cover or first page of the program.

8. Receptions and other social gatherings

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

9. 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 are absent of any policies that restrict breastfeeding for employees or guests. ABM management should make every effort to ascertain hotel policies on breastfeeding before presenting a recommendation to the ABM Board.

10. Satellite Meetings

ABM shall abide by the guidelines of the CMSS Code.

VII. ORGANIZATION INVOLVEMENT WITH AN ABM JOURNAL

This section covers any journal or other publication which bears the name and/or logo of the Academy of Breastfeeding Medicine. The CMSS Code guidelines (section 8) are applicable

1. Advertisements

a. Who can advertise?

Advertisements are generally accepted from organizations that sell or promote legitimate products or services relevant to the readership of the journal; specifically: child and/or maternal care, pediatric or obstetrical medical issues, products in direct support of breastfeeding, etc. The legitimacy of the organization can be determined from general knowledge or by requesting specific information from the organization. To ensure all journal advertising is supportive of the ABM mission, the Journal Editor and designates should review the content of the advertising including text and images. Ideally, the outside organization's own policies should be breastfeeding supportive; however, the only absolute

requirements for advertising are a neutral or positive position toward breastfeeding and no violations of the WHO Code on Marketing. b. *Who can not advertise?*

Organizations who are currently in violation of the WHO Code of Marketing, as confirmed by the Board of ABM, or who produce a product or service which is deemed by the Journal Editor and staff likely to discourage breastfeeding should not be accepted for advertising in the journal. Organizations that submit advertisements considered inappropriate should receive a letter explaining the rationale for rejection and steps the organization can take to create acceptable advertising.

c. Review of advertising content

These criteria for the acceptability of advertising should be published in the ABM Website, in the journal and also made available to all potential advertisers.

d. Placement of advertisements

Every effort should be made to avoid any appearance of endorsement of a product by ABM or journal article authors. As per the CMSS Code, placement of advertising adjacent to an article or editorial content which relates in any way to the product or service being advertised is prohibited. While interleaving of advertisements with editorial materials is common in many journals, it is best if advertising materials are in a section separate from editorial content. The front cover should never be used for advertising materials or company logos. The back cover and inside covers may be acceptable locations for advertisements. e. *Inserts and tear-outs*

Most readers dislike inserts and tear-outs because they interfere with the readability of the journal. However, there is no ethical concern about such advertising materials providing they meet all other criteria for acceptance. They should be reviewed by the advertising review committee.

2. Support of articles by organizations

a. Research support

Research that is supported by a commercial, governmental or not-for-profit organization must be fully acknowledged on the first page of the journal article. Funders must not have had any editorial review or involvement in the writing or preparation of the article. Other involvement by a funder must be acknowledged in the article (e.g. supplying a drug or tested product).

b. Editorial support

The journal may accept financial support or underwriting from an organization as long as the support is unrestricted and does not require editorial or management restrictions in any way. Such support should be acknowledged on an inside page. Acknowledgement of support from a commercial organization should never be adjacent to editorial content.

c. Refusal to publish based on commercial support

The journal editorial staff must retain the right to refuse publication of an article if there is evidence that an organization has compromised the scientific validity of the study or report, or has exercised prior editorial review of the paper.

3. Distribution of journal content by organizations

If an organization wishes to distribute an entire issue of a journal or a specific article, journal management must approve or deny the request after appropriate evaluation. This evaluation must include how and to whom this material will be distributed as well as physical presentation of all accompanying materials to be sent. This request and all of the submitted material should then be reviewed by the advertising review committee to be certain that this action does not compromise ABM's goals and standards.

4. Conflicts of Interest

On a regular basis, authors, reviewers and editors must reveal, in writing, any and all organizational interests with any possible relation to breastfeeding, lactation or to any associated products or services. These 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 an organization speaker; role in evaluation of a product or service; and any professional or personal consultation with the organization, formal or informal. Similar information regarding the involvement of first order relatives need be revealed only if such a relationship can be construed as a potential conflict of interest. These revelations of potential conflicts of interest must be reviewed by the Editor of the journal. Potential conflicts of interest will preclude acting as a reviewer or editor of an article, but does not preclude authorship of an article providing the conflict is fully revealed on the first page of the article.

The publisher of the journal may also have a potential conflict of interest either through commercial investment or management or through involvement with another publication. Such potential conflicts must be revealed to the Editor, the Editorial Board and the ABM Board of Directors to determine whether such a conflict compromises the integrity of the journal or ABM.

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 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. ABM ACTIVISM

1. Awards to Organizations

ABM may formally recognize and award an organization for programs or policies which support breastfeeding. This recognition may be part of a regularly recurring program or may be an ad hoc event. It is essential that such recognition be free of any organizational endorsement, real or perceived. The award or recognition must be specific to the activity or program positively impacting breastfeeding. These awards may recognize breastfeeding supportive advertising, workplace programs or development of a new product or service. In the case of an award for a new project or service, however, the ABM must make it clear it is not endorsing the product as safe or effective. Recognition may be in the form of an announcement, a certificate, a ceremony, or even a financial award. ABM must not accept or solicit any financial support or other benefit from the award recipient.

2. Identification of poor practices by commercial organizations

Occasionally, ABM may wish to notify its members or the public of a specific practice or program that negatively impacts breastfeeding. While generic identification of poor practices is usually without risk, classification of an organization or program as having poor or harmful practices can lead to legal claims against ABM. Such actions in the media or other public sites should be very carefully undertaken only if there is adequate supporting evidence of wrong-doing. Even notification of ABM membership may be considered libelous unless well documented. Legal consultation is advisable. The safest method is to contact the violating company privately. Reporting adverse practices to a governmental agency (FDA, HHS, Department of Health, etc.) is another alternative that may safely and ethically address the problem.

X. 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.

XI. <u>References</u>

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XII. This report has been prepared by the Ethics Committee of the Academy of Breastfeeding Medicine

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