

Sponsorship, Endorsement, and Affirmation Policies

Approved 5-03-07; revised 07-30-07, 5-01-08

General Provisions and Clarification of Terminology:

1A - For purposes of Society policies, the terms “sponsor” or “co-sponsor” are used to refer to situations where the Society either initiates the event, activity or product or is involved in it from the beginning.

1B - For purposes of Society policies, the term “endorse” is used to refer to situations where the Society is asked to express publicly its approval of (or support for) an event, activity, or product that is already substantially planned by an outside entity.

1C - For purposes of Society policies, the term “affirmation of value” is used to refer to situations where PES expresses publicly its approval of (or support for) an event, activity, or product that has been developed by an outside entity, with or without some PES involvement.

2 - No warranty or guarantee shall be conveyed by the Society’s endorsement. The Society’s endorsement shall not include the content of any presentation or materials provided at an endorsed event or, without review by the Society and a separate agreement, any report or other materials published from the event. The outside entity must agree to indemnify the Society against all claims and related costs arising from the event, activity or product endorse.

3 - Sponsorship and endorsement may (but not necessarily) involve financial or other support provided by the Society, such as marketing assistance, or they may (but not necessarily) involve return to the Society for the use of its good name or for in kind assistance provided.

4 - The outside entity requesting sponsorship or endorsement will be provided a form/checklist requesting necessary information and will be required to provide the information in a timely fashion (90 days in advance) to allow the Society to determine if the request meets the criteria set by the Society in its sponsorship or endorsement policies. Once submitted to the operations management firm, the request will be referred to the appropriate committee for consideration prior to sending to Board of Directors for approval. Such consideration will be given in a timely manner insofar as possible.

5 - The sponsorship or endorsement agreement between the Society and another entity must be in writing and executed by both parties and must include all the conditions and obligations involved as well as any variations from these policies as may be approved for a specific agreement by the Board of Directors.

6 - The outside organization requesting sponsorship or endorsement of one of its activities or products must use Society-approved language when characterizing Society involvement in any publicized descriptions. (i.e., that the relationship will be characterized as sponsorship or endorsement, as determined by the Society, regardless of what terminology the requester used.)

7 - The Society Board of Directors will conduct an annual review of all ongoing sponsorship and endorsement activities and a triennial review of all endorsed or affirmed publications.

SPONSORSHIP POLICIES

Society Policies on Sponsorship Of Conferences

Characteristics and definitions of types of conferences and categories of evidence

There are four types of conferences:

1. Consensus
2. State of the Science
3. Expert Opinion Advisory Group
4. Best Practices Conferences

There are three categories of evidence:

1. Randomized controlled trials, multi-center trials, or meta-analyses
2. Published data
3. Expert opinion

The Society may sponsor all four types of conferences, the selection of which in any particular case depending upon appropriateness as determined by meeting organizers/planning committee, subject to Board of Directors approval.

Partnerships in Society-sponsored conferences

1. Whenever possible, the Society will invite related organizations to participate as deemed appropriate by the planning committee of the event, subject to Board of Directors approval;
2. Other organizations will participate with the Society with the understanding that they may withdraw their names should they not agree with the report and recommendations;
3. If the Society is requested to co-sponsor a conference organized by another organization, the Society (Board of Directors) will accept the invitation only under the following conditions (all are required):
 - a) that the Society (Board of Directors) will name its own representative(s) to participate in the event; and
 - b) that its representatives will be permitted to participate fully in the event; and,
 - c) that the Board of Directors may withdraw the name of the Society or have the option to issue a dissenting report should the Society (Board of Directors) not agree with the report or other outcomes of the event.

Approval process

1. The organization, design, participants and any documents (reports, position/white papers, recommendations, guidelines, standards, etc.) produced pursuant to a conference must be reviewed and approved in advance by the relevant Society Committee AND the Board of Directors.
2. The Pediatric Endocrine Society retains ownership of any documents/products resulting from Society-sponsored conferences and retains all publications rights.
3. Outside supporters/funders of the event will have no influence over the content of the event, the speaker/participant selection, or the content of the report or other documents produced as a result of the conference.

Conflict (Duality) of Interest Disclosure and Management

1. All conferences will follow CME-accreditation disclosure requirements for all participants even if the event does not offer CME credit;
2. All documents produced by conferences will include disclosures for all participants;
3. Participants in the event must include a majority who are individuals without conflict of interest in the matter under study;
4. Participants with conflicts of interest may participate in conferences as long as the appropriate public disclosures are made and as long as the planning committee appropriately manages conflicts of participants so as not to compromise the credibility of the event or the Society.

Funding

1. Conferences sponsored by the Society shall be funded only by one (or more) of the following three mechanisms:
 - a) Society funding; and/or
 - b) Funding provided by sister society partners or other related non profit organizations invited to participate; and/or
 - c) Unrestricted educational grants from for-profit industry funders -- provided that these funders have no influence over the content of the event, the speaker/participant selection, or the content of the report or other documents produced as a result of the event.
2. Corporate sponsors and their employees may not participate in the writing of consensus statements.

SOCIETY POLICIES ON SPONSORSHIP OF CLINICAL GUIDELINES, REVIEWS, AND SURVEYS

Desirability of developing endocrine-related clinical guidelines

1. The Pediatric Endocrine Society believes that an active role in disease management is vital to the future of the Society and to ensure excellence in clinical practice, pursuant to the Strategic Plan;
2. The Society should develop clinical guidelines for endocrinologists -- but should also pursue the development of non-endocrine-physician educational materials as priorities and funding permit.

Development of clinical guidelines

1. The Diagnosis and Therapeutics Committee (or an appropriate committee) will develop a topic in conjunction with the BOD. This Committee will then appoint a Subcommittee, the chair of which will appoint 2-3 outside experts, as deemed necessary. A manuscript will be generated by this committee.
2. The BOD will act as an internal editorial board. One member will serve as the PES Associate Editor (AE); this will ordinarily be the Secretary or a Director. This AE will select 3 expert reviewers, at least two of whom will not be members of the BOD. Upon receipt of the review, the AE will provide recommendations, based on the reviews and the principals and policies of PES, to the BOD. The decision of the BOD will be conveyed to the subcommittee. The options will be acceptance, acceptance with point-by-point revisions, or, rejection.
3. When a revised manuscript acceptable to the BOD is achieved, it will be posted on the PES web-site (members-only section) for a 30-day period of PES general membership comment.
4. The PES AE will review the received comments and submit them to the subcommittee for revision, if necessary.
5. The PES AE will then submit the manuscript to an appropriate journal on behalf of the authors with PES endorsement.
6. The manuscript will be processed according to guidelines of the journal to which it is submitted, with the PES AE undertaking final review before submission of the final document.
7. Guidelines will be published with a disclaimer, such as: "Clinical Practice Guidelines are developed to be of assistance to endocrinologists by providing guidance and recommendations for particular areas of practice. The Guidelines should not be considered inclusive of all proper approaches or methods, or exclusive of others. The Guidelines cannot guarantee any specific outcome, nor do they establish a standard of care. The Guidelines are not intended to dictate the treatment of a particular

patient. Treatment decisions must be made based on the independent judgment of healthcare providers and each patient's individual circumstance.

****Note that committees report to the Board of Directors***

Partnerships in Society-sponsored guidelines

1. Whenever possible, the Society will invite related organizations to participate as deemed appropriate by the appropriate PES committee, subject to Board of Directors approval;
2. Other organizations will participate with the Society with the understanding that they may withdraw their names should they not agree with the guideline;
3. If the Society is requested by another organization to co-sponsor a guideline, the Society (Board of Directors) will accept the invitation only under the following conditions (all required):
 - a) that the Society (Board of Directors) will name its own representative(s) to participate in the guideline development; and
 - b) that its representatives will be permitted to participate fully in the event; and
 - c) that the Board of Directors may withdraw the name of the Pediatric Endocrine Society or have the option to issue a dissenting report should the Society (Board of Directors) not agree with the guideline.

Approval process

1. The plan for the development of a guideline must be reviewed and approved in advance by the Drug and Therapeutics Committee AND Board of Directors of the Society;
2. The Pediatric Endocrine Society retains ownership of any guidelines resulting from Society-sponsored guideline development and retains all publications rights;
3. Outside supporters/funders of the guideline development will have no influence over its content, selection of participants or other documents produced.

Conflict (Duality) of Interest Disclosure and Management

1. All guidelines development will follow CME-accreditation disclosure requirements for all participants;
2. All guidelines will include disclosures for all participants;
3. Participants in the guideline development must include a majority who are individuals without conflict of interest in the matter under study;
4. Participants with conflicts of interest may participate as long as the appropriate public disclosures are made and as long as the guideline development groups appropriately manage conflicts of participants so as not to compromise the credibility of the guideline or the Society

Funding

Guidelines sponsored by the Society shall be funded only by one (or more) of the following three mechanisms:

- a) Society funding; and/or
- b) Funding provided by sister society partners or other related non profit organizations invited to participate; and/or
- c) Unrestricted educational grants from for-profit industry funders – provided that these funders have no influence over the content of the guideline, the participant selection, or other documents produced as a result.

Development of reviews and surveys

1. Reviews developed by PES committees shall undergo a review process similar to that for clinical guidelines. However, a) the requirement for PES web-site posting shall be waived and b) The author line will not mention the Committee, but a title-page footnote will state: "This review was developed by the

(appropriate) Committee of the Pediatric Society to be of educational value for practitioners. It does not indicate an official policy or guideline of the Society.

2. Products of PES-sponsored consensus conferences shall undergo a review process similar to that for clinical guidelines. However, a) the requirement for PES web-site posting shall be waived if there is acceptance by all participants to the work-product, which may include a minority report and b) a title-page footnote will state: "This conference was sponsored and endorsed by the Pediatric Society. It does not indicate an official policy or guideline of the Society."

3. Surveys developed by PES committees shall be reviewed by a subcommittee of the Board of Directors, or full Board if deemed necessary. After approval by the Board they will be disseminated on the Society web-site with a cover notice of their purpose in a manner similar to reviews.

ENDORSEMENT AND AFFIRMATION POLICIES

SOCIETY POLICIES ON ENDORSEMENT OF CONFERENCES DEVELOPED OUTSIDE SOCIETY AUSPICES

Initiation

If initiated by an entity outside the Society governance, the request will be referred to an appropriate Society committee or task force for consideration and recommendation prior to coming to the Board of Directors for approval.

Characteristics and definitions of types of conferences and categories of evidence

There are four types of conferences

1. Consensus
2. State of the Science
3. Expert Opinion Advisory Group
4. Best Practices Conferences

There are three categories of evidence

1. Randomized controlled trials, multi-center trials, or meta-analyses
2. Published data
3. Expert opinion; the evidence categories used as part of the conference must be specified

The Society may endorse all four types of conferences.

Approval process

1. Any documents (reports, position/white papers, recommendations, guidelines, standards, etc.) produced pursuant to an endorsed conference must also be reviewed and approved by the relevant Society Committee AND the Board of Directors of the Society (or its designee) prior to publication of the Society's endorsement in association with the document;
2. If the Society does not approve said documents, it has the right to remove its endorsement from the document, the specifics of the steps involved to be determined on a case by case basis;
3. Outside funders of the event will have no influence over the content of the event, the speaker/participant selection, or the content of the report or other documents produced as a result of the endorsed conference

Conflict of Interest Disclosure and Management Requirements for Society Endorsement of a Conference

1. All conferences will follow CME-accreditation disclosure requirements for all participants even if the event does not offer CME credit;
2. All documents produced by the conference will include disclosures for all participants;

3. Participants in the conference must include a majority who are individuals without conflict of interest in the matter under study;
4. Individuals with conflicts of interest may participate in the conference as long as the appropriate public disclosures are made and as long as the planning committee appropriately manages conflicts of participants so as not to compromise the credibility of the event or the Society.

Timeframe and Reciprocity

1. The completed request from an outside entity for endorsement of a conference must be received at least 90 days prior to the decision deadline in order for the Society to be able to guarantee a response;
2. The Society endorsement will normally include a provision for a corresponding advantage to the Society, to be determined on a case by case basis (e.g., complimentary registrations; travel grants awarded by the Society; provision of attendee list; complimentary exhibit space; rights to publish outcomes of the event, etc.). If marketing support is granted in addition to the “good name” of the Society, additional return to the Society may be involved.

Funding

Conferences endorsed by the Society shall be funded only by one (or both) of the following two mechanisms:

- a) Funding provided by sister societies or other related nonprofit organizations;
- b) Unrestricted educational grants from for-profit industry funders -- provided that these funders have no influence over the content of the event, the speaker/participant selection, or the content of the report or other documents produced as a result of the conference.

SOCIETY POLICIES ON ENDORSEMENT OR AFFIRMATION OF CLINICAL GUIDELINES AND REVIEWS DEVELOPED OUTSIDE SOCIETY AUSPICES

Initiation

If initiated by an outside entity, the request will be referred to the appropriate committee* for consideration and recommendation prior to coming to Board of Directors for approval.

****Note that Committees report directly to the Board of Directors***

Desirability of developing endocrine-related clinical guidelines and reviews

1. The Pediatric Endocrine Society believes that an active role in disease management is vital to the future of the Society and to ensuring excellence in clinical practice, pursuant to the Strategic Plan;
2. Endorsement of clinical guidelines or reviews developed by an outside entity is one of the mechanisms by which the Society may take an active role in disease management;
3. Affirmation of clinical guidelines or other products developed by an outside entity is a mechanism by which the Society is alerted to pertinent information relevant to disease management.

Endorsement of guidelines or reviews developed by other societies/organizations

1. PES will *consider* endorsement of clinical guidelines or reviews produced by another organization(s) under the following conditions:
 - a) If the evidence categories utilized in the development of the guideline are clearly identified;
 - b) If evidence was reviewed and/or evaluated by either a federal agency (i.e., AHRQ) or an outside research consultant as well as by speakers/participants in the event;
 - c) If the guideline is periodically reviewed according to a published schedule;
 - d) If appropriate conflict of interest disclosure and management procedures were followed, i.e., if appropriate public disclosures are made and as long as the conflicts of participants are managed so as not to compromise the credibility of the guideline or the Society;

- e) If the guideline development was funded either by one or more of the endocrine sister societies or other related non profit organizations; and/or unrestricted educational grants from for profit industry funders;
 - f) If outside funders have had no influence over the development process, participants or the content of the guideline;
 - g) If the Drug and Therapeutics Committee of the Society has the opportunity for full review and significant editorial input prior to publication; and
 - h) The Drug and Therapeutics Committee of the Society recommends endorsement to the Board of Directors.
2. If guidelines are not produced under conditions 5 a-f, above, the Pediatric Endocrine Society will consider affirmation:
- a) If developed according to a method approved by the Drug and Therapeutics Committee and the Board of Directors;
 - b) If published or in press; and
 - c) If reviewed and recommended by the Drug and Therapeutics Committee to the Board of Directors for affirmation.
 - d) The membership will be notified of such affirmations by an announcement, such as, "The Board of Directors of the Pediatric Endocrine Society affirms that the following publication may be of educational value to the membership."

Timeframe and Reciprocity

1. The request from an outside entity for endorsement of a guideline must be received at least 90 days prior to the decision deadline for the Society to be able to guarantee a response;
2. Society endorsement of a guideline will normally include a provision for a corresponding advantage (return, financial or non-financial) to the Society, to be determined on a case by case basis.

SOCIETY POLICIES ON ENDORSEMENT OR AFFIRMATION OF EDUCATIONAL MATERIALS, SURVEYS, OR OTHER PRODUCTS DEVELOPED OUTSIDE SOCIETY AUSPICES

Initiation

If initiated by an entity outside the Society governance, the request will be referred to an appropriate Society committee or task force for consideration and recommendation prior to coming to the Board of Directors for approval.

Permitted Outside Entities

1. The Society will consider endorsement or affirmation of products developed by endocrine-related sister societies or other related non-profit or governmental organizations.
2. The Society will consider endorsement or affirmation of surveys developed by individual members. For members seeking external peer-reviewed funding for projects involving a survey, the Society can provide a letter of support to the funding agency indicating that, endorsement will be stated in a cover letter to those surveyed once the project has received external support. For surveys already developed, the Society will, after review and approval by an appropriate committee, provide a note that includes a statement that survey design and data analysis are solely the investigator's responsibility and that replies should be directed to the investigator. A statement of endorsement will be provided if the survey is (part of) a project with external peer-reviewed funding. Otherwise, a statement will be provided that the Society affirms that this survey may be of interest to members (rather than a statement of endorsement).
3. Dissemination of such surveys will be as an e-mail attachment, upon request of the member sponsoring the survey. For surveys endorsed by the Society, a cover note will be provided by the Society that indicates endorsement. For those affirmed but not endorsed, the cover note will indicate this status and that the Society is distributing it solely as a service to the membership.

Funding

Products endorsed by the Society shall be funded only by one (or both) of the following two mechanisms:

- a) Funding provided by sister societies or other related non profit organizations;
- b) Unrestricted educational grants from for-profit industry funders -- provided that these funders have no influence over the content or the selection of participants involved in the development of the product.

Conflict (Duality) of Interest Disclosure and Management

All products will include disclosures for all participants in their development:

- a) Participants in the event must include a majority who are individuals without conflict of interest in the matter under study;
- b) Participants with conflicts of interest may participate in the development of the products as long as the appropriate public disclosures are made and as long as the planning committee appropriately manages conflicts of participants so as not to compromise the credibility of the product or the Society.

Approval Process

The Board of Directors of the Society will make all decisions regarding endorsement or affirmation of a product developed by an outside entity upon the recommendation of the relevant committee or task force.

Timeframe and Reciprocity

1. The request from an outside entity for endorsement of a product must be received by the Society at least 90 days prior to the decision deadline in order for the Society to guarantee a response;
2. Society endorsement or affirmation of a product may (but not necessarily) include marketing assistance or other support and will normally include a provision for return to the Society for the use of its good name and for other support that may be provided (such as marketing assistance), to be determined on a case by case basis (e.g., distribution rights, portion of income, publication rights, etc.)