European Society for Pediatric Gastroenterology, Hepatology and Nutrition.

Policy on Conflict of Interest and Relationships with Industry and Other Organizations.

Preamble

The European Society of Paediatric Gastroenterology, Hepatology and Nutrition is an international scientific society based in Europe and founded in 1968. Paediatric gastroenterologists, hepatologists and nutritionists, as well as scientists in relevant fields, are members of the society. ESPGHAN has promoted, since its inception, medical and scientific knowledge in the fields of paediatric gastroenterology, hepatology and nutrition. Several guidelines and working group reports have been produced by committees of ESPGHAN to standardize the management of children in Europe and to give competent advice to doctors in Europe on the treatment of gastrointestinal, pancreatic and liver diseases of children and the nutrition requirements in health and disease. In addition ESPGHAN promotes scientific exchange among research groups in Europe and among trainees, young doctors and scientists working in paediatric gastroenterology, hepatology and nutrition by means of summer schools, research fora and workshops.

This policy document is designed to serve as a general guide to avoid conflicts of interest and ensure appropriate relationships with industry and other organizations are maintained at all times. In developing this document the Society affirms its commitment to adopt the NASPGHAN policy on conflict of interest and its relationship with industry (http://www.naspghan.org/user-assets/Documents/pdf/NASPGHAN_COI_Policy.pdf) and adhere to those of other organizations, the International society for Research in human milk and lactation (http://www.isrhml.org.umu.se/), American Medical Association’s “Principles of Medical Ethics” (http://www.ama-assn.org/ama/pub/category/2512.html), the “Code of Ethics of the Canadian Medical Association” (http://www.cma.ca/index.cfm/ci_id/2419/la_id/1.htm), the Canadian Medical Association’s policy statement “ Physicians and the Pharmaceutical Industry” (http://www.cma.ca/staticContent/HTML/N0/12/where_we_stand/physicians_and_the_pharmaceutical_industry.pdf).

1. Policy on Conflict of interest and Disclosure

ESPGHAN uses many methods to accomplish the society’s mission of advancing the science and clinical practice of the subspecialty, including professional education, public education and research. In order to fund such activities ESPGHAN and its members collaborate with industry (including manufacturers of devices, pharmaceuticals, products, formulas or equipment) and other organizations such as foundations, government agencies and corporations. While ESPGHAN accepts that without such collaborations it would not be possible to adequately fulfill its mission, the society realizes that these relationships can create both potential and real conflicts of interest that may affect an individual’s opinion, may appear to make that opinion self serving, or might not allow for impartial objective determinations.
ESPGHAN does not wish to exclude individuals who are expert in a given field from participation in the activities of the society merely because they have a conflict of interest. However the validity of policy statements and recommendations that emanate from the society are dependent on confidence in its integrity, and the belief by members of the society, the scientific community and the public at large, that these are unbiased and based only on concerns for the health of the patients and their families and are in the best interests of continuing education for health care professionals and the lay public. Therefore, ESPGHAN accepts the principle that it is not wrong to have a conflict of interest, but that failure to disclose such a conflict, and if necessary take steps to resolve such a conflict, is wrong and will not be tolerated by the Society. The policy outlined in this document is designed to serve as a general guide for all members of ESPGHAN to define potential conflicts of interest and address how they may affect the participation by members in the activities of the society.

1.1 Definition of Conflict of Interest

A conflict of interest is defined as a relationship with a business, industrial partner or agency that may result in a financial, fiduciary or otherwise rewarding arrangement for any active member of ESPGHAN or his/her immediate family, which may influence subsequent deliberations or actions, whether perceived or factual. It is incumbent on the member to disclose any such relationship that may be perceived as establishing a conflict of interest and, when necessary, take remedial action to resolve the conflict by removing oneself from any action (e.g. discussions or voting) that may be influenced by such conflict.

1.2 Examples of Potential Conflict of Interest

A. A conflict of interest may exist when an individual, his/her spouse, child, parent or business partner, is involved with a commercial firm or organization (for profit or otherwise) in the health care field that includes one or more of the following circumstances:

a) Consultant, scientific advisory committee member, scientific program organizer or faculty member for which an honorarium, stipend, research grant or any other form of remuneration is derived or expected within a 12 month period. An honorarium paid by a university, hospital or medical society which extends the invitation does not require disclosure. For an honorarium paid directly by a commercial firm or organization, or paid by a third party organization contracted by the commercial firm or organization to arrange the activity, disclosure is required.

b) Officer, board member, trustee, owner or employee of a commercial firm or organization.

c) A significant* financial interest as a stock or bond holder in a commercial firm or organization.

d) Stock options held in a commercial firm or organization related to the interest of the society or its commitments.

e) A patent is held or impending for a medically health related device, technology or drug with the expectation of personal economic gain.
A conflict of interest does not include a relationship with the individual’s own private practice unless that practice is doing business with ESPGHAN.

**B.** A conflict of interest may exist when an individual serves as program director, moderator or faculty member at an educational event funded by a commercial firm or organization (for profit or otherwise) and the individual also participates in the design or conduct of studies involving products manufactured or distributed by the firm or organization.

**C.** A conflict of interest may exist when an individual serves on the Governing Board of another national medical organization or society whose interests overlap with those of ESPGHAN, even if no financial benefits accrue to the individual.

The above examples do not include all possible scenarios that may lead to a conflict of interest. It is the responsibility of each individual to use their best judgment in making a decision involving a situation that may require disclosure. When in doubt, the individual should consider seeking advice from the ESPGHAN Ethics committee or council of ESPGHAN on the side of declaring a possible conflict of interest.

### 1.3. Disclosure

It is required that ESPGHAN officers, committee chairs and members, task force members, CME organizers, course directors, moderators and faculty, employees and others acting on behalf of ESPGHAN adhere to the policies outlined above and openly disclose any real or potential conflicts of interest. Candidates for any of these positions must be informed of the ESPGHAN conflict of interest policy and procedures, and agree to abide by them, before they are appointed, hired or placed on a ballot.

**Procedure**

- It is required that the ESPGHAN conflict of interest disclosure statement be signed at the beginning of any term of service and that this be updated whenever there is a change in circumstances that give rise to a potential conflict of interest, for the duration of the individual’s term of service. Even if there is no perceived change during the term of service, it is required that each individual complete a conflict of interest disclosure on an annual basis.

- A disclosure statement must be completed whether or not a conflict of interest is perceived.

- It is the individual’s duty to disclose a potential conflict of interest. If the individual knowingly fails to disclose a conflict of interest which is subsequently discovered, the Society will take action as deemed appropriate.

- All disclosure statements will be reviewed by the council of ESPGHAN.
Disclosure statements of candidates running for elected office within ESPGHAN will be included in the candidate’s biographical information for review by the membership of the society prior to the elections.

Disclosure statements of the ESPGHAN Officers and Council members will be made available for review by the society membership through a posting on the “Members Only” section of the ESPGHAN website for the duration of their tenure. In all other cases a potential conflict of interest will be disclosed on a "need to know" basis only.

When a potential or real conflict of interest exists that may affect objectivity, the chairman of the Ethics committee will notify the council and the President of ESPGHAN, committee chairperson, course director or leader of the relevant ESPGHAN entity. A determination will then be made whether the individual who has a perceived conflict may participate in the discussion after making full disclosure of the potential conflict of interest. Any individual who has been determined to have a conflict of interest is disqualified from voting on recommendations or any ESPGHAN matter pertaining to that conflict.

In the event the President, chairperson, course director or leader believes a conflict exists, but the individual does not agree to reveal this to the other members of the committee or entity, participation by that individual in the activity concerned is not allowed.

In all cases where there is a dispute between the interested party and the President, chairperson, course director or leader as to whether a perceived conflict is relevant to the individual’s participation, the matter will be referred to the Ethics Committee for review. Following review, the Ethics Committee will make a recommendation to the ESPGHAN council who shall have the final say in the matter.

Any transgressions of the ESPGHAN Disclosure of Conflict of Interest Policy will be referred to the Ethics Committee for review. The committee will be responsible for meeting with member(s) under review and thoroughly investigating the facts pertaining to the alleged transgression. The findings of the committee will be presented to the ESPGHAN Council who shall have the final say in the matter.


Receipt of a gift from manufacturers of medical devices, pharmaceuticals, products, formulas or equipment can create perception of a conflict of interest. For this reason ESPGHAN suggests adherence to the guidelines on “Gifts to Physicians from Industry” as described in the AMA Code of Medical Ethics, Opinion 8.061. (www.ama-assn.org/go/ethicalgifts).


As a CME provider ESPGHAN must adhere to to ensuring balance, independence, objectivity, and scientific rigor in all its individually sponsored and jointly sponsored educational activities. ESPGHAN recognizes that it has many positive and beneficial relationships and collaborations with the pharmaceutical, formula and medical device industries that
further the Society's educational mission. Accordingly, ESPGHAN adopts the following guidelines that should be interpreted to be in concert with similar requirements of the ACCME (http://www.accme.org/dir_docs/doc_upload/68b2902afb73-44d1-8725-80a1504e520c_uploaddocument.pdf), which we adopt in their entirety.

3.1. Principles of Corporate Sponsorship and Partnership for ESPGHAN endorsed CME activities.

• ESPGHAN will accept support from industry and from other outside sources for educational, professional and scientific activities and publications. This support is subject to the standards and conditions outlined in this document.

• ESPGHAN, or the course/program director appointed by ESPGHAN, is responsible for the organization and content of all educational activities endorsed by the Society and there can be no control of content by any sponsoring agent.

• ESPGHAN requires that the organizer, course director, moderator, faculty members or any individual directly involved in an educational activity endorsed by the Society, complete a conflict of interest disclosure statement, and that any potential conflict of interest be declared beforehand to the participants in the educational activity or be resolved prior to the event.

• Under no circumstances will ESPGHAN explicitly endorse any product, brand, or company. The ESPGHAN logo may not be used in conjunction with the name of the product or brand and may not be used in a manner that would express or imply an ESPGHAN endorsement of the corporation or its policies unless explicit consent is given by ESPGHAN. This includes the ESPGHAN web site.

• Participation in a specific corporate arrangement does not imply that ESPGHAN will exert its influence to advance the corporation’s interests outside the substance of the arrangement itself.

• Any project or program involving commercial support must have a clear, stated scientific or educational purpose that is consistent with the mission of ESPGHAN to promote child health, advocacy, and education of physicians, health care providers and the public.

• Scholarships or payments by corporate supporters for attendance of medical students, residents, fellows and graduate students at ESPGHAN educational programs is permissible if based on objective criteria approved by ESPGHAN, and in no case on prescribing practices, device usage or other similar economic factors. Selection of awardees for these scholarships will be made by ESPGHAN or the academic/training institutions of its members.

• All principal parties must sign a Letter of Agreement that defines the relationship, its duration, and respective responsibilities.

• All publicity related to a commercially-supported event or program must be reviewed and approved by ESPGHAN prior to its distribution or dissemination. It is
acceptable to acknowledge receipt of commercial support providing only the name of
the sponsoring agent is listed without reference to any brand name product or device
manufactured or distributed by the sponsor.

• ESPGHAN prefers multiple sources of commercial support for its educational,
professional and scientific activities. Exclusivity will be by mutual agreement.

• Only individuals authorized by the ESPGHAN Council may solicit funding for
ESPGHAN programs or projects.

• ESPGHAN adopts the principle that it will not accept any support from industry
specifically allocated for the development of a ESPGHAN endorsed Clinical Practice
Guideline. It is acceptable to use funds received in the form of an unrestricted grant
from multiple sources of commercial support for this purpose.

3.1.2. Policy and Procedure.

Honoraria and Reimbursement for Expenses
• Honoraria will be provided only as agreed upon in advance by ESPGHAN and the
speaker, teacher or author. The honorarium will be disbursed only by ESPGHAN.
Any Sponsor must give the payment as an unrestricted educational grant to
ESPGHAN, who will then be responsible for direct payment to the speaker, teacher
or author.

• Reimbursement for reasonable out-of-pocket expenses will be made directly by
ESPGHAN. This may include payment for travel, hotel and meals, and registration as
well as other designated sundry fees and costs. Documentation of expenses must be
provided by the planner, speaker, teacher, or author who then may be reimbursed.

• Subsidies for hospitality should not be accepted outside of modest social events
and meals that are held as part of the conference or meeting.

3.2. Policy on Corporate Sponsorship of non-ESPGHAN endorsed CME
activities.

ESPGHAN accepts there are many industry sponsored CME activities available to
physicians, and while these are not endorsed by ESPGHAN they may be of
educational benefit to the members of the Society. Accordingly, ESPGHAN is open to
the policy of allowing industry to sponsor CME activities, such as topic symposia,
during the period the Society holds its annual scientific meeting. Although this
arrangement should not imply that ESPGHAN endorses the content of any such
activity, the Society fully accepts that this perception may exist because the event is
held in conjunction with the meeting of the Society. Accordingly ESPGHAN requires
that a corporate sponsor of any non-ESPGHAN endorsed or organized CME activity
held in conjunction with any meeting of the Society agrees to abide by the following
principles.

3.2.1. Principles of Corporate Sponsorship of non-ESPGHAN endorsed CME
activities.
• The event organizer/director must ensure there is balance, independence,
objectivity and scientific rigor of the educational activity.
• The event organizer/director may be appointed by the sponsoring company but may not be an employee of the company.

• The event organizer/director is responsible for the content of the educational activity and there can be no control by the sponsoring company.

• There must be a clear stated scientific or educational purpose for the event that promotes health care or education.

• The event organizer/director, moderator, faculty member or any other individual directly involved in the educational activity must fully disclose any potential conflicts of interest beforehand to the participants.

• There may not be promotion of any specific product, brand or device manufactured or distributed by the sponsoring company. Wherever possible only generic names of drugs should be used, or when brand names are used, mention must also be made of competing products from other companies.

• Publicity related to the event may make mention of the sponsoring company by name but not of any brand name product or device manufactured or distributed by the sponsor.

3.2.2. Policy and Procedure.

• Participant CME evaluations of the event will be reviewed by the ESPGHAN Council, or a designee appointed by the Council, to ensure the principles outlined above are adhered to. If any participant expresses a concern for non-adherence to these principles, or believes the event was unacceptably biased, this will be thoroughly investigated.

• Potential Corporate sponsors of non-ESPGHAN sponsored events must be made aware of these principles beforehand. Failure to adhere to these principles will result in punitive action, including the possibility of prohibiting the corporate entity from sponsoring future events in conjunction with other ESPGHAN activities.

Honoraria and Reimbursement for Expenses.
• The event organizer/director and faculty members may receive a reasonable honorarium for their work and be reimbursed for travel and out-of-pocket expenses by the sponsor.

• There should be no payment to participants who attend the event.

• It is acceptable for the sponsoring company to provide subsidies for a modest social event or meal as part of the event.

• Participants should not receive gifts as an enticement to attend the event.

Introduction.
The primary responsibility of all physicians is the physical and mental well-being of their patients and their families. Physician members of ESPGHAN who choose to participate in research activities must be able to demonstrate that their activities are ethically defensible, socially responsible, and scientifically valid. ESPGHAN opposes the testing of medication or products that would further scientific knowledge but not improve the overall health or quality of life of the research subjects after completion of the study. ESPGHAN also opposes exploitation of people as research subjects in developing countries based on poverty, or by accepting a higher benefit to risk ratio than would be tolerated in Europe.

4.1. Industry Funding to ESPGHAN.
ESPGHAN recognizes that corporate industrial research and product development are important components in the overall advance of scientific knowledge to understand and treat gastrointestinal, liver and nutrition diseases in children. ESPGHAN also recognizes that non-profit funding does not fully fund non-corporate, academic research. Therefore, ESPGHAN is open to accepting unrestricted funding from corporate industrial sources to further academic research related to the above mentioned diseases in children.

4.1.1. Policy and Procedure.

• An independent committee of ESPGHAN members with no ties to the corporate donor will decide how to best distribute any funds collected. The President of ESPGHAN will be responsible for delegating this task to an existing committee within the organization or for appointing an ad hoc committee of ESPGHAN members specifically appointed for this purpose.

• If the distribution is based on a competitive basis, the designated independent committee of ESPGHAN members will choose recipients based on the scientific merits of their submitted work.

• The name of the research award may include the name of the corporate donor but may not make mention of any particular product or device associated with that donor.

4.2. Industry Funding to ESPGHAN Members.

ESPGHAN members may accept funds directly from industry to do research. All industry-sponsored research activities should be formally reviewed and approved by an appropriate Institutional Review Board whose goal is to ensure that the rights and welfare of human subjects are protected. The research should be carried out based on ethical principles, namely respect for persons, beneficence, non-maleficence, and justice. Such research should be conducted according to the standards and procedures which apply to individual jurisdictions.

4.2.1. Policy and Procedure.

• The design of a given study may be a collaboration between physician investigator and corporate sponsor; however, it must be based on sound scientific evidence and be socially responsible and ethically defensible.

• Patient enrollment and participation in industry-sponsored research studies shall commence only after obtaining full, open, informed, competent, and voluntary
consent from a patient or the parent/legal guardian, and an assent to participate in research by a minor when appropriate, unless the Institutional Review Board authorizes an exception to the requirement for consent. Research subjects must be informed before enrolling in the study if their physician will receive any fee, in excess of the normal practice fee, to enroll a patient in a study. The standards and procedures which apply to the jurisdiction where the research will be conducted must be observed. The principal investigator is responsible for the implementation of these standards and procedures.

• Any additional costs directly related to the research study should be paid by the industry sponsor, not by health care institutions or other insurance agencies regardless of whether these costs involve diagnostic procedures or direct patient services.

• Any ESPGHAN physician member with a significant financial interest in a corporate entity, which is also sponsoring the research project, is restricted from enrolling patients, managing a study, or obtaining informed consent for that research project. Violation of this rule represents a conflict of interest and will result in disciplinary action.

• Physician investigators engaging in clinical research on their own inventions, where no other researcher could do the study, must have Institutional Review Board approval and independent oversight to ensure patient safety, minimize undue patient risk, and maximize patient benefit from the study.

• Practicing physicians should not participate in studies unless they are assured by the industrial sponsors that the results will be made public within a specified, reasonable period.


ESPGHAN members have a responsibility to be open, honest, and fair in disclosing all associations, agreements, and contracts to avoid even the perception of falsehood, manipulation, bias, or dishonesty in matters of research, education, and patient care associated with this organization.

4.3.1. Policy and Procedure.

• All industry-related associations, agreements, contracts, and sponsorships related to any presented research must be disclosed at public meetings.

• When submitting manuscripts for publication in medical journals, physician members should disclose any relationship they share with companies providing funding or products for studies whether or not a given journal requires such disclosure.