International Headache Society Ethics Committee Report

Board of Trustees meeting
Wed, 4 September, 2019

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Topics

• Ethics Committee Aims
• A cautionary tale
• IHS policy for managing COI
• Industry sponsored programs at the IHC
• Industry sponsored research presentations at IHC
IHS Ethics Committee Aims (mission)

Identify, interpret, and manage current challenging ethical issues pertaining to headache medicine at three levels:

1: Headache Sufferers
- To promote the welfare of headache sufferers by publishing advice, guidance and recommendations on ethical issues relevant to research, practice and treatment of headache disorders

2: Headache Treatment and Research Organizations
- To draft statements which will bring the relevant ethical concerns in the field of headache medicine to the attention of governments, the medical and allied professions, the pharmaceutical and insurance industries, lay and charitable organizations and any other relevant parties
IHS Ethics Committee Aims (mission)

Identify, interpret, and manage current challenging ethical issues pertaining to headache medicine at three levels:

3. IHS Membership and Organization Activities

- To address ethical concerns of International Headache Society members regarding IHS activities
- To initiate reviews of IHS activities that raise ethical concerns that are referred to or identified by IHS Ethics Committee
A cautionary tale –

The end of the American Pain Society

- Multiple lawsuits allege that the APS leadership allowed themselves to be used by opioid manufacturers, as part of a false, industrywide marketing campaign, thereby helping to instigate the public health crisis that led to more than 300,000 opioid-related overdose deaths since 2000.

- The cost of defending against the suits and responding to multiple subpoenas, even in cases which the APS was not a defendant was so costly that budget could not be met.

- Declared bankruptcy 28 June, 2019
Conflict of Interest Policy

• COI is essentially unavoidable. It can be minimized and it can be managed to avoid unprofessional behavior (biased presentations, promotion of commercial products, withholding of information, dishonesty)

• Best approaches include prohibiting industry from controlling content of educational sessions and data presentations, and clear and specific disclosure of COI by each speaker and meeting planner.

• A responsible and productive alliance with pharmaceutical and other medical technology companies is both possible and sometimes desirable in pursuit of our organization’s goals. However there are a number of areas in which conflicts of interest, or the perception of such conflicts may arise. These areas generally involve the potential for bias in our policies, educational programs, and research. In order to minimize potential conflict of interest we endorse the following guidelines:
Conflict of Interest Policy

1. IHS shall maintain complete control over its policies. To this end, no representatives of pharmaceutical or medical device companies will participate in formulating or revising these policies.

2. IHS shall maintain complete control over the planning, content, and delivery of its educational programs. To this end, no representatives of pharmaceutical or medical device companies will be involved in planning or directing its public educational and scientific meetings.

3. IHS shall maintain complete control over planning, execution, and publication of IHS investigator-initiated research. IHS will decide when and where to submit results of these studies for publication.

4. IHS shall maintain complete control over the content of its website, newsletter, and any other publications. No IHS media will include any industry-sponsored promotional or marketing material or advertisements. Authors and creators of all IHS publications will disclose all ties with industry, including roles as consultants, investigators, sponsored speakers, shareholders, or employees, ideally specifying how disclosed ties might influence content. This information will be clearly stated in program syllabi.
Conflict of Interest Policy

5. IHS and members of its Board of Directors will strive to provide a balanced impartial view of data pertaining to commercial products. IHS will not endorse specific products.

6. IHS will accept grants for support of its programs, over which it has complete control, and which do not pose any significant conflict of interest.

7. IHS and members of its Board of Directors will not accept gifts from pharmaceutical or device companies, other than educational or clinically useful items of modest value, or modest meals at conferences.

8. Members of the IHS Board of Directors may receive reasonable compensation from pharmaceutical or other companies for services provided (e.g. bona fide consultation with pharmaceutical and medical technology companies, lecture engagements supported by industry sponsors, or participation as investigators in industry-sponsored research studies). These relationships will be made clear on the IHS public website.
Conflict of Interest Policy

9. Members of the IHS Board of Directors shall not use their position for private gain. They shall act impartially and not give preferential treatment to any private organization or individual.

10. Speakers at IHS educational conferences will disclose all ties with industry, including roles as consultants, investigators, sponsored speakers, shareholders, or employees, ideally specifying how disclosed ties might influence content of their presentations. This information will be clearly stated in program brochure, and updated by the speaker at the time of her/his presentation.

11. Promotional and marketing activities by pharmaceutical companies at IHS conferences will be clearly identified and delineated from educational and scientific presentations.

12. IHS will discourage the distribution of non-educational, non-clinically useful or excessive gifts to attendees at its conferences.

13. IHS shall maintain complete control over grants and scholarships it awards and will choose recipients in an unbiased fashion. To this end, no representatives of pharmaceutical or medical device companies will be involved at any level in awarding these grants.
Conflict of Interest Policy

Approved by the IHS Board of Trustees unanimously
Not yet on the IHS website for unclear reasons
Website does have a good spot for it in Policies:
Industry presentations at IHC

• 3 levels of presentations at IHCs:
  1) investigator-initiated research
  2) industry-sponsored research
  3) industry symposia (Industry satellites)
Industry presentations at IHC

Industry-sponsored research

A policy on platform presentations by industry: We recommend that industry sponsored research be presented in a separate session clearly labelled as such (e.g. “Industry Sponsored Research Session”) and we recommend that only academic scientists who are independent from industry be presenters. This separation and guideline should also be in place for poster presentations of industry sponsored research. We believe this approach is a clear way for meeting attendees to understand potential bias in presentations of data, and a logical way to handle COI of the academic presenters of industry sponsored research. (It avoids the need to analyse how closely academic researchers may or may not be tied to industry sponsors.)
Industry presentations at IHC

Industry programs (Satellite symposia)

• Some on the committee would discourage these sessions altogether, since if the content is deemed important, the meeting planners could simply design sessions at the scientific meeting to include this content. But if the Board considers these sessions essential, they should be very clearly delineated from scientific and education sessions.

• The committee recommends that IHS policy should be that speakers at satellite industry conferences cannot present at the scientific meeting on the same or similar topic (and conversely, that speakers at a scientific sessions cannot present at a satellite industry session on the same or similar topic. The Scientific Program Committee should be informed of the topic and speakers with sufficient time (ideally 6 months) before IHC in order to optimize planning of the scientific sessions and speakers (Especially to avoid the necessity of replacing a speaker)
Industry presentations at IHC

*Industry programs (Satellite symposia)*

- Alternatively –

- Speakers at satellites must disclose their leadership positions at IHS and that they will be expressing opinions not necessarily supported by the IHS.

- Speakers in an IHC scientific session must specifically disclose, in addition to the usual disclosures, if they presented an industry sponsored program at this meeting.

- Speakers in an IHC scientific session cannot have presented an industry sponsored program at this meeting on a related topic.
Other issues sent to the EC

• The number of presentations a member of faculty or board can make at an IHC: The Committee would encourage new and varied speakers at the IHC by limiting the number of presentations a speaker can make, but how this is done should be left up to the program committee with oversight by the Board of Trustees.

• Who should cover expenses (travel/accommodation) for IHC faculty members who are also speaking in an industry satellite – We suggest that IHS encourage speakers to receive travel expenses from the sponsoring companies if possible. Based on our recommendations above we would hope there is not as much overlap (i.e. speakers doing both activities) as in the past.
Some discussion of the above occurred in the BOT meeting London Jan 2019

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<tr>
<th>Question</th>
<th>Response</th>
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| Platform presentations by industry speakers – should we even have speakers who are industry employees? | Yes: 4  
No: 6  
Only in selected cases: 2  |
| Should these sessions be held at a separate time and place               | Yes: 8  
No: 4  |
| If the presenter is not an industry employee, but is presenting industry data, what is the best way to manage his/her conflict of interest | Open disclosure (slide/programme: 9)  
Leave to Ethics committee: 1  
Reference to origin of data: 1  
Avoid this situation: 1  |
| How much of this should just be left up to the discretion of the SPC?    | Leave to SPC: 1  
Official rules necessary: 5  |
| Should there be a limit on the number of presentations a member of faculty or board can make at an IHC? | Yes: 8 (ranging from 1 to 3 lectures)  
No: 4  |
| Should IHS Board members and education or media leaders of IHS speak at including industry symposia | Yes: 11  
No: 1  |
| Who should cover expenses (travel/accommodation) for IHC faculty members who are also speaking in an industry satellite | IHS: 2  
Industry (full): 8  
Industry (registration only): 1  
Unrealistic scenario (compliance): 1 |
Assumptions

• IHS as a professional organization, and its leadership wishes to maintain very high standards of professionalism, including proper management of COI (including the appearance of COI).

• Some degree of industry support, though bringing with it various COIs, is deemed essential for the health of the organization.

• Clear Society policies regarding relationships with industry will help members and leadership.

• It will be beneficial for the IHS to be transparent about its ties to industry and its policies for managing ethical issues that might arise.
References

• Steiner, T and members of the HIS Ethics Subcommittee. Ethical issues arising from commercial sponsorship and from relationships with pharmaceutical industry – Report and recommendations. Cephalalgia 2008, 28:1-25. (On IHS website now, though recommendations were not followed)

• Fineberg, HV. Conflict of Interest: Why is it important? JAMA 2017 317:1717-9 (...the influence of even small financial relationships is greatly underestimated...)


• Rothman, DJ, et al. Professional Medical Organizations and their relationships with industry – A proposal for controlling COI JAMA, 2009; 301:1367-72 (A very strict proposal to limit COI)