

Guidance for the Heart Rhythm Society Pertaining to Interactions with Industry

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The mission of the Heart Rhythm Society (HRS) is to improve the care of patients by promoting research, education, resources for patients and their families, and optimal healthcare policies and standards. HRS sets professional standards for treatment of heart rhythm disorders and disseminates these standards to its members.

HRS works with clinicians, scientists, allied professionals, industry,¹ and government agencies to accomplish this mission. These stakeholders comprise a coalition of experts that furthers the field of heart rhythm disorders. Industry is an important member of this coalition, and HRS's relationship with industry is critical to the continued growth of the field. Advances in electrophysiology and pacing depend on a collaborative relationship between physicians and industry, who have worked together to develop lifesaving devices. HRS and its members continue to work collaboratively and effectively with industry. Yet the potential for conflict of interest in any industry collaboration exists. Thus, it is important to establish safeguards to avoid conflicts or misunderstandings.

ABBREVIATIONS ACCME = Accreditation Council for Continuing Medical Education; CME = continuing medical education; FDA = Food and Drug Administration; HRS = Heart Rhythm Society (Heart Rhythm 2011;8:e19–e23)

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On October 18, 2010, HRS convened the Relationships with Industry Task Force to consider whether it should continue to collaborate with industry, why collaboration may be important, and to set parameters around industry collaboration. The policies referred to in this document pertain to HRS as an organization and individuals in their roles as leaders of the organization, committee members, task force members, writing groups, or faculty in HRS-sponsored educational programs. It does not address the conduct of members outside their roles with HRS. This document represents the consensus conclusion of this Task Force and is endorsed by HRS Board of Trustees as official organization policy. It is divided into 11 sections: (1) Why Collaborate with Industry?; (2) Separation of Governance from Industry; (3) Perspectives on Industry Funding Accepted by HRS; (4) Disclosure of Relationships with Industry; (5) Research Grant Awards; (6) Continuing Medical Education (CME); (7) Non-CME Content; (8) Endorsement or Support of International Meetings; (9) Industry Relations and Health Policy; (10) Scientific and Clinical Documents; and (11) Publications.

The Task Force concluded that collaboration with industry on research and innovation is required to achieve HRS's mission. This decision rests on the principle that the problems faced by our patients cannot be solved if clinicians, scientists, and industry work in isolation. Nevertheless, because the potential for actual or perceived bias or conflict of interest does exist, it is necessary to establish strict ethical standards to protect the credibility of HRS and its members.

I. Why collaborate with industry?

Collaboration with industry on research is essential to HRS's mission, because health issues cannot be solved if clinicians, scientists, and industry work in isolation. Yet, without safeguards, collaboration with industry carries risk. Collaboration could bias physician and allied professional education, clinical and basic research, and health policy (including coding and reimbursement, proposed legislation, and advice to members when the Food and Drug Administration [FDA] issues a recall or safety advisory). However, these risks are outweighed by benefits of collaboration, which include:

- **Problem solving**, which is fundamental to engineering innovative technology, development of drugs, advances in research, and improved clinical care. In each of these fields it is difficult to make progress without an integrated, multi-disciplinary approach that leverages the expertise of all stakeholders.
- **Innovation**, which depends on the infrastructure provided by universities and industry. The exchange of ideas and scientific presentations at annual Scientific Sessions often spawns the concepts that shape priorities and lead to innovation.
- **The development of safe and effective technologies and drugs**, which is made possible by interaction among physicians, scientists, allied professionals, engineers, and the pharmaceutical and device industries. Important developments and preliminary investigations that are presented at annual Scientific Sessions may be adopted for clinical use and disseminated throughout the world to enhance patient care.
- **The development of guidelines and consensus documents**, which are influenced by well-designed, randomized trials that rely on the collaboration between industry and clinicians.
- **The development of standards for transparency in industry**, with which HRS has substantial influence. These standards bear directly on the use of industry's products and the care physicians and allied professionals provide.

II. Separation of Governance from Industry

HRS leaders have the responsibility to protect the organization's integrity. HRS leaders must avoid both actual and perceived conflicts that could harm HRS's image or undermine the credibility of its statements, guidelines, public testimony, or general reputation.

- **Disclosure: personal or family relationships:** All members of HRS's Board of Trustees, its committees, subcommittees, writing groups, and task forces must annually complete a written disclosure statement detailing their relevant commercial, professional, personal, and institutional relationships. These provisions also apply to the full-time HRS staff.
- **Disclosure: CME:** All participants who plan and disseminate CME materials must disclose all relevant financial relationships.

- **Industry participation in leadership:** Industry members (e.g., officers, employees, paid representatives) are prohibited from serving as trustees or officers in HRS, or serving on its committees. Industry members may serve on task forces if their expertise is germane.
- **Restrictions on President and President-Elect:** The Society's President and President-Elect are prohibited from receiving income from commercial entities that have the potential for conflict of interest during the year(s) in which they hold the position. They also are prohibited from equity shares, stock options, or any other indirect payment from industry.

III. Perspectives on industry funding accepted by HRS

HRS receives commercial, promotional, and educational funding from industry. The elimination of this funding could harm the scientific, educational, and public awareness activities of HRS. Eliminating industry funding would force HRS to raise membership dues and registration fees for annual scientific sessions and other programs, which would adversely affect attendance by physicians, scientists, and allied professionals.

HRS has established safeguards to prevent industry bias. They are:

1. HRS does not allow companies to place restrictions or provide guidance on CME expenditures.
2. All disclosure forms, including those of committee members, presenters, and members of the Board of Trustees, are publicly available on HRS's website.
3. HRS maintains control over CME educational programs at regional and national meetings.
4. HRS maintains control of its scientific and health policy objectives.

IV. Disclosure of relationships with industry

Personal income derived from industry relationships and from institutional, programmatic, and research support should be disclosed. Although personal income or equity in a company should be distinguished from institutional, programmatic, or research support, financial relationships with industry in each category have the potential to create bias.

Thus, HRS maintains an oversight committee that is responsible for (a) obtaining and randomly auditing disclosures; (b) providing and communicating a process for reporting potential violations; (c) evaluating complaints; (d) levying and enforcing sanctions; and (e) providing a mechanism for the appeal of decisions. Violations are reported to the Ethics Committee for review and sanctions if appropriate. Refusal to make adequate disclosure shall preclude an individual's participation in all HRS activities. Violations also may be reported to an individual's academic institution or organization. HRS shall maintain a process for disqualifying individuals who have a conflict that cannot be adequately dispelled with disclosure.

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