Guidance for the Heart Rhythm Society Pertaining to Interactions with Industry

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Bruce D. Lindsay, MD, FHRS* Samuel J. Asirvatham, MD, FHRS,† Anne B. Curtis, MD, FHRS,‡ Melanie T. Gura, MSN, FHRS,§ David L. Hayes, MD, FHRS,† Jose Jalife, MD, FHRS,¶ George J. Klein, MD, FHRS,** Bradley P. Knight, MD, FHRS,†† Rachel Lampert, MD, FHRS,‡‡ Andrea Natale, MD, FHRS,§§ Douglas L. Packer, MD, FHRS,† Richard L. Page, MD, FHRS,¶¶ Melvin M. Scheinman, MD, FHRS,*** Amit J. Shanker, MD, FHRS,††† Paul J. Wang, MD, FHRS,‡‡‡ Jonathan P. Weiss, MD,§§§ Bruce L. Wilkoff, MD, FHRS,* Chris D. Busky, CAE¶¶¶

*From *Cleveland Clinic, Department of Cardiovascular Medicine, Cleveland, Ohio, †Mayo Clinic, Cardiology Department, Rochester, Minnesota, ‡University at Buffalo, Department of Medicine, Buffalo, New York, §NE Ohio Cardiovascular Specialists, Hudson, Ohio, ¶University of Michigan, Center for Arrhythmia Research, Saline, Michigan, **University Hospital, Cardiology Division, Ontario, Canada, ††Northwestern University, Feinberg School of Medicine, Chicago, Illinois, ‡‡Yale University School of Medicine, Cardiology Department, Branford, Connecticut, §§St. David's Medical Center, Austin, Texas, ¶¶University of Wisconsin School of Medicine and Public, Madison, Wisconsin, ***University of California–San Francisco, Cardiac EP, San Francisco, California, †††Bassett Healthcare, Center for Advanced Arrhythmia Medicine, Cooperstown, New York, ‡‡‡Stanford University School of Medicine, Cardiovascular Medicine Division, Stanford, California, §§§Utah Heart Clinic, Intermountain Heart Rhythm Services, Salt Lake City, Utah, ¶¶¶Heart Rhythm Society, Washington, DC.*

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)

Correspondence and reprint requests: Sonja Olson, Heart Rhythm Society, 1400K Street, NW, suite 500, Washington DC 20005. E-mail: solson@hrsonline.org.

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.

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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 disclosure 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.

Bias is difficult to quantify. Nevertheless, greater transparency is required. Previously, the value of financial relationships with industry has been categorized as: none; modest ($1–$10,000); or significant (more than $10,000). One of the limitations of this disclosure classification system is that one cannot determine whether the financial relationship is only slightly above $10,000 or substantially higher. Thus, the following categories are now being adopted in order to provide greater transparency: $0; $1–$10,000; $10,001–$25,000; $25,001–$50,000; $50,001–$100,000; and greater than $100,000.

V. Research grant awards

Collaboration among industry, the academic community, and HRS is essential to the discovery and development of new medications and technologies to improve the prevention, diagnosis, and treatment of heart rhythm disturbances and sudden cardiac death. HRS welcomes industry support of biomedical research. It seeks to ensure the design, conduct, and reporting of this research are unbiased and industry's contributions to research advance science and human health.

- *Grant awards*. Through its peer review committees, HRS is the sole administrator of its research funding programs. Industry sponsors may not initiate or designate research projects to be reviewed by an HRS committee through its peer review procedures.
- *Publication*. HRS expects and encourages dissemination of the results of research funded by its research funding programs through annual progress reports, articles published in scientific journals, and presentations at scientific meetings.
- *Restrictions.* Industry sponsors may not scrutinize, manage, direct, or control any research projects funded through HRS. Industry is not entitled to any intellectual property rights or rights to patents or patentable interests resulting from research funded through HRS.
- *Transparency*. HRS is committed to transparency in its relationships with industry and its support of research. All industry sponsored research support is disclosed through HRS's website.

VI. Continuing medical education (CME)

In 2009, HRS convened the CME and Industry Relations Task Force to review guidelines, processes, and policies to ensure the integrity of CME offered at the Annual Scientific Sessions or other programs supported by HRS. The objectives of the task force were to enhance operations, strengthen transparency, and address real or apparent conflicts of interest. On September 2, 2009, the task force recommended the following policies in a report to the Board of Trustees:

- *Separation of CME activities from industry exhibits.* HRS should separate CME activities from advertising and industry related exhibits.
- *Regulation of industry educational materials.* HRS should adhere to Accreditation Council for Continuing Medical Education (ACCME) guidelines, which limit distribution of promotional materials by industry to a conference's exhibit hall.[2]
- *Assessments prior to solicitation of funds.* HRS's Education Committee should vet all CME educational proposals prior to the solicitation of industry funds.
- *Separation of Education and Program Committees from industry.* HRS staff should work directly with the Program and Education Committees to identify content and faculty without input from industry.
- *Multiple supporters.* HRS seeks multiple supporters for its educational programs in order to avoid the perception that programs are tied to a specific company.
- *Regulation of Satellite Symposia.* HRS should require that official Satellite Symposia abide by ACCME guidelines and its Standards for Commercial Support.
- *Educating faculty who present CME.* All HRS officers, trustees, program committee members, and session moderators are encouraged to complete the National Faculty Education Initiative, which is designed to educate faculty about the differences between CME and promotional activities.
- *Everyone involved in the planning and dissemination of CME must disclose all relevant financial relationships.*
- *Elimination of bias during presentations.* Session chairs are responsible to identify bias and advise the audience that alternative opinions or methods should be considered. Disclosure should be required for all participants.

VII. Non-CME content

HRS publishes clinical and scientific information in many formats, including print and electronic media. Non-CME materials disseminate information, raise awareness, enhance knowledge, educate patients, and promote self-assessment. The cost of providing such products and services is substantial. In some instances it may serve HRS to request content from industry to ensure that materials can be developed rapidly and made available at reduced cost to HRS and the intended audience.

In order to safeguard the integrity of non-CME materials, HRS must ensure that they are free of bias in content or selection, and that materials have general applicability to the topic.

- *General applicability:* Materials should not focus only on one technology, manufacturer, or product type.
- *Origin of content:* Materials may be created by HRS or another qualified organization. Materials developed by industry must align with the mission and strategic goals of HRS, must be requested by HRS, and must follow the same review process.
- *Review process:* Materials must be approved by HRS Education Committee prior to dissemination to ensure that the content is balanced and not biased.

- *Financial support:* HRS may request financial support from industry for a list of approved materials. HRS will not accept funding for materials that have been developed or selected independently by industry.
- *Guidelines for industry-hosted non-CME clinical programs for Fellows in Training:* All Fellows in Training programs should adhere to Satellite Symposia guidelines.
- *Guidelines for use of non-advertising industry funds:* HRS accepts non-advertising independent funding from industry to support specific HRS activities if these do not include CME.

VIII. Endorsement or support of international meetings

Because innovation is international, HRS promotes and encourages participation in international meetings that share standards. In doing so, HRS takes into account legal and cultural variables that exist internationally. In order to obtain HRS support or endorsement, international meetings must meet the following standards:

1. *Program independence:* Financial support for the meeting should be directed to the meeting's organizers. It may not be contingent on the use of specific sessions and speakers.
2. *Travel support:* Meeting organizers should arrange travel without direct linkage to industry. If an industry sponsor directly supports speakers' travel expenses, this should be disclosed in order to ensure transparency.
3. *Disclosure:* Relationships and conflicts of interest must be disclosed in compliance with the laws and guidelines of the host country.
4. *Endorsement of documents:* Endorsement of documents or other written materials related to a meeting must adhere to the policies established for all HRS-endorsed documents.

IX. Industry relations and health policy

HRS advocates on issues of public policy. In some instances, collaboration with other professional organizations, the public sector, or industry may be required to achieve this. HRS must always maintain independence from real or perceived industry bias.

- *Development of performance measures.* Industry should not participate in HRS's development of performance measures. Industry has the opportunity to comment on the validity and feasibility of performance measures during a 30-day public comment period.
- *Legislative initiatives.* HRS may visit congressional representatives or their staff to represent the concerns of its members. These activities must be conducted with absolute independence from industry. HRS and industry representatives will not jointly advocate or educate policymakers.
- *Guidelines.* Evidence-based guidelines advocating the use of particular device- or pharmacologic-based therapies for management of arrhythmia disorders must be developed solely by HRS and other professional societies.
- *Reimbursement.* When appropriate, HRS collaborates with other medical specialty societies to present CPT Editorial Panel (CPT) and AMA/Specialty Society Relative Value Scale Update Committee (RUC) proposals. As a policy, HRS does not share reimbursement-related documents (e.g., proposals or Medicare reimbursement codes and descriptions) with industry prior to their public release.
- *Healthcare quality improvement initiatives.* Healthcare reform emphasizes data about the quality and costs of care. Registries are important to meet the demands for data. HRS may develop registries or participate with other professional organizations to achieve this end. Industry may be solicited to support registry operations through sponsorship of participant enrollment, marketing, and product development. However, registry data must not be proprietary or exclusive to any participating sponsor. While industry may request registry data analysis and research, HRS reserves the right to not share data from the registry.
- *Safety advisories and recalls.* HRS has worked with industry and the FDA to develop guidance for safety advisories and recalls. Depending on the severity of the problem, HRS may convene a panel of experts to review recommendations issued in accordance with FDA mandates and advise electrophysiologists on how to respond.
- *Increasing public awareness of arrhythmia-related disorders and therapies.* HRS may work with industry to develop promotional materials and activities for public awareness of arrhythmia disorders. HRS should not endorse specific products or manufacturers. If HRS agrees to endorse these activities, all materials must be submitted to HRS for review and approval by the Education or Executive Committee prior to their dissemination.
- *Access to medications.* HRS may be required to advocate on behalf of physicians and their patients when third-party payer coverage of medications lags behind FDA clearance.

X. Scientific and clinical documents

The production of documents guiding care is a highly valuable HRS service. The value of any document stems from the quality of its information and the credibility of its authors. HRS recognizes that many members who contribute to the production of scientific or clinical documents have financial relationships with industry, and has policies that are consistent with recent recommendations by the Institute of Medicine to safeguard the objectivity of writing groups.[3]

- *Financial policies:* HRS's scientific guidelines are developed without direct financial support from industry. Disclosure of financial relationships with industry is required at the initiation of the process, with an update prior to publication. Authors with financial relationships with industry may participate in discussions after disclosing

these relationships, but they may not vote on a matter related to that issue.

- *Selection of authors:* The nomination process should be designed to assemble a group comprising recognized experts, a balance of authors with divergent opinions, and "arms-length" experts as appropriate. No authors should own stocks or stock options or profit financially from the recommendations of the document. All authors are entitled to participate in discussions and writing. This policy takes into consideration that relationships with industry do not necessarily bias opinions or recommendations and that experts in the field should not be restricted from full participation in writing committee provided they recuse themselves when a potential conflict of interest arises. The priority on selection of authors should be their expertise, judgment, and writing ability. The chairs of the writing group are nominated by the Scientific and Clinical Documents Committee and/or Executive Committee. At least one of the chairs should be free of any relationships to industry that would apply to the document.
- *Topics and basis for recommendations:* The Scientific and Clinical Documents Committee considers potential topics for development of guidelines, and then prioritizes which documents should be developed.
- *Review process and approval for publication:* HRS documents are subjected to blinded reviews. The authors are required to respond to concerns raised by reviewers and revise the document as suggested, as with any other peer-reviewed document. The Scientific and Clinical Documents Committee determines whether the authors have responded in good faith and decides whether to submit the document to the Board of Trustees to approve it for publication.

XI. Publications

The Publications Committee and senior staff provide strategic direction, policy oversight, and business decision support for official print and electronic HRS publications, including the Society's journal, Heart*Rhythm.* The Editor in Chief of the journal has full editorial responsibility. The Editor in Chief is appointed by the Executive Committee and is subject to the same ethics guidelines as the President and President-Elect of HRS, which preclude receiving income from commercial entities that may pose a potential conflict of interest.

Conclusion

The Task Force on Industry Relations considered whether and how HRS should work with industry in selected areas and the impact of collaboration on its mission to improve the care of patients by promoting research, education, and optimal healthcare policies and standards. The Task Force concluded collaboration in certain areas among scientists, healthcare providers, and industry is critical to achieve this goal. This decision rests on the principle that the problems faced by our patients cannot be solved if clinicians, scientists, and industry work in isolation. The Task Force reviewed HRS policies to avoid industry bias or conflict of interest, and made specific recommendations pertaining to governance, education, health policy, disclosure, and authorship of scientific documents in order to avoid the risk that collaboration with industry would be detrimental to HRS's mission. The Task Force concluded that HRS has sufficient measures in place to prevent undue influence from industry or introduction of industry bias into HRS-sponsored educational programs, research, scientific documents, and policy initiatives. These recommendations have undergone peer review and approval by HRS's Scientific and Clinical Documents Committee and the Board of Trustees.

References

1. In this document, "industry" refers to for-profit entities that develop, produce, market or distribute drugs, devices, services or therapies used to diagnose, treat, monitor, manage, and alleviate health conditions. This definition is consistent with the Council of Medical Specialty Societies' Code for Interactions with Companies (April 2010), which is can be found at www.cmss.org/uploadedFiles/Site/CMSS_Policies/CMSS%20Code%20for%20Interactions%20with%20Companies%204-19-10.pdf.
2. Accreditation Council for Continuing Medical Education. ACCME Standards for Commercial Support. http://www.accme.org/dir_docs/doc_upload/68b2902a-fb73-44d1-8725-80a1504e520c_uploaddocument.pdf.
3. Lo B, Field MJ, editors. Conflict of Interest in Medical Research, Education, and Practice. Washington, DC: National Academies Press, 2009.

Appendix 1 Author Relationships with Industry and Other Entities

Author	Consultant Fees/Honoraria	Speaker's Bureau	Research Grant	Fellowship Support	Board Member/Stock Options/Partner	Other
Bruce D. Lindsay, MD	Medtronic[b] Boston Scientific[b] CardioInsight[b] Biosense Webster[b]	None	None	Medtronic[d] Boston Scientific[d] St. Jude Medical[d] Biosense Webster[d]	None	
Samuel J. Asirvatham, MD	Abiomed[b] Boston Scientific[b] Medtronic[b] Sanofi-aventis[b] Spectranetics[b] Stereotaxis[b]	None	None	None	None	
Anne B. Curtis, MD	Biosense Webster[b] Medtronic[b] Sanofi-aventis[b] St. Jude Medical[b]	Medtronic[b] Sanofi-aventis[c]	Medtronic[b] St. Jude Medical[b]	Medtronic[d]	None	
Melanie T. Gura, MSN	Boston Scientific[b] Medtronic[b] St. Jude Medical[b]	None	None	None	None	
David L. Hayes, MD	Biotronik[b] Boston Scientific[c] Medtronic[c] Sorin Medical[b] St. Jude Medical[b]	None	None	None	None	Royalty income from Wiley Blackwell Publishing[b]
Jose Jalife, MD	None	None	None	None	None	
George J. Klein, MD	Bard[b] Boston Scientific[b] Medtronic[d] Sanofi-aventis[b] St. Jude Medical[b]	None	None	None	None	
Bradley P. Knight, MD	Bard[b] Biosense Webster[b] Biotronik[b] Boston Scientific[b] Catheter Robotics[b] Medtronic[b] Sanofi-aventis[c] St. Jude Medical[b]	None	None	None	None	
Rachel Lampert, MD	Boston Scientific[b] Medtronic[b]	None	Boston Scientific[e] Medtronic[e]	None	None	
Andrea Natale, MD	Biosense Webster[c] Boston Scientific[b] Medtronic[b] Biotronik[b] Life Watch[b]	None	None	None	None	
Douglas L. Packer, MD	None	None	NIH[f] Medtronic CryoCath LP[f] Siemens AG[f] Thermedical (EP Limited)[f] Endosense[e] EpiEP[d] EP Rewards[d] Population Health Research Institute-Manilton Health Sciences General Hosp.[d] St. Jude Medical[f] Minnesota Partnership for Biotechnology and Medical Genomics/University of Minnesota[f] Biosense Webster, Inc.[f] and Boston Scientific[f]	None	None	Consulting (Speaker/Advisory Board): Biosense Webster, Inc. (Speaker/Adv. Bd.) ($0) , Cardialysis (Adv. Bd.) ($0), Endosense (Adv. Bd.) ($0), CyberHeart (Adv. Bd.) ($0), Medtronic CryoCath LP (Speaker/Adv. Bd.) ($0), Sanofi-aventis (Speaker/Adv. Bd.) ($0), Siemens AG (Adv. Bd.) ($0), St. Jude Medical (Speaker/Adv. Bd.) ($0), GE Healthcare (Adv. Bd.) ($0), Philips Healthcare (Speaker) ($0), CardioFocus (Adv. Bd.) ($0), InnerPulse (Adv. Bd.) ($0), Coherex (Adv. Bd.) ($0), OrthoMcNeill (Adv. Bd.) ($0), NACCME (Speaker) ($0), Skyline Ventures (Adv. Bd.) ($0), Toray Industries (Adv. Bd.) ($0), Imricor (Adv. Bd.) ($0). Dr. Packer received no personal compensation for these consulting activities Royalty income from Blackwell Publishing[b] and St. Jude Medical[e]

Appendix 1 Continued

Author	Consultant Fees/Honoraria	Speaker's Bureau	Research Grant	Fellowship Support	Board Member/Stock Options/Partner	Other
Richard L. Page, MD	None	None	None	None	None	Sanofi-aventis[a]: work on manuscripts related to ATHENA, a trial for which I served on the steering committee. No financial relationship for 2 years. Event committee co-chair for a grant, through Harvard that receives funding from industry but I receive no money from that trial (other than expenses through Harvard for meetings). The trial is supported by GlaxoSmithKline, SigmaTau, and Pronova BioPharma. I receive honoraria from a sub-study of that trial that is NIH funded, paid via Harvard[b].
Melvin M. Scheinman, MD	Bard[b] Biotronik[b] Boston Scientific[b] Medtronic[b] Sanofi-aventis[b] St. Jude Medical[b]	None	None	None	None	
Amit J. Shanker, MD	None	None	None	None	None	
Paul J. Wang, MD	Boston Scientific[b] LifeWatch[b] St. Jude Medical[b]	None	Medtronic CryoCath LP[b]	Biosense Webster[d] Boston Scientific[d] Medtronic[d] St. Jude Medical[e]	Stock Options: ACT Medical[b] Hansen Medical[c] Toper[b] VytronUS[b]	
Jonathan P. Weiss, MD	Biosense Webster[b] Johnson & Johnson[b] St. Jude Medical[b] Stereotaxis[b]	St. Jude Medical[b]	None	None	None	
Bruce L. Wilkoff, MD	None	None	None	None	None	Medtronic**[a] St. Jude Medical**[a] Spectranetics**[a]
Chris Busky, CAE	None	None	None	None	None	

a= $0
[b]= ≤$10,000
[c]= >$10,000 to ≤$25,000
[d]= >$25,000 to ≤$50,000
[e]= >$50,000 to ≤$100,000
[f]= >$100,000
**Advisory Board Position