

GUIDELINES FOR SVS MANAGEMENT OF RELATIONSHIPS WITH INDUSTRY

There are two central tenets expressed in the Hippocratic Oath that are relevant to the relationship between the SVS and industry. The first is that the welfare of patients comes first and that the practice of medicine eschews external influences that might be harmful to patients or interrupt the “covenant of trust” between physician and patient. The second is that physicians should strive to maintain life-long learning and keep abreast of advances in medicine. While these apply to individual physician’s practice of medicine, they are also relevant to corporate deliberations of professional medical societies such as the SVS. Adherence and fidelity to these principles engender respect, trust and autonomy for the individual practitioner and for professional medical societies.

Through its many activities, the SVS makes distinctive contributions to the advancement of vascular care. The SVS’s educational venues (VAM, JVS, textbooks and CME courses) inform members of new and established diagnostic and treatment procedures. SVS Practice Guidelines and Reporting Standards establish evidence-based, optimal patient care. By engaging in outreach to medical students, residents, and fellows, the SVS ensures a future supply of completely trained vascular practitioners. The SVS also engages in public outreach through Vascular.org and other venues to promote vascular health and education. A public agenda is also manifest in health policy initiatives that advocate for the particular interests of SVS members, patients and for what we believe is best for society as a whole. The SVS Patient Safety Organization improves patient safety and the quality of health care delivery by providing web-based collection, aggregation, and analysis of clinical data submitted in registry format for all patients undergoing specific vascular treatments.(added)

The development of these and other SVS activities reflect a depth of expertise and maturation of authority that have significant influence inside and outside of medicine. Physicians from other specialties and the general public will increasingly rely upon SVS evidence-based information and recommendations in the treatment of vascular disease. Therefore, any compromise of scientific integrity or unqualified commitment to patient care must be anticipated and avoided.

The relationship between professional medical societies and industry has come under increasing scrutiny. The chief concern is that industry through its financial support of medical societies may influence educational and other society activities in a manner that would compromise clinical decision making. As a consequence, this might lead to adverse delivery of optimal health care and undermine the reputation of the profession. On the other hand, a healthy relationship between professional medical societies and industry can promote optimal and excellent health care. Collaboration can lead to research, innovation, new treatments, and expanded educational activities. As an example, industry support of CME meetings reduces costs to individual attendees and thereby makes CME more accessible. For rapidly evolving technologies and devices that involve high costs, industry support of CME may be essential. Training on newly-approved devices may be mandated by the FDA, and professional medical societies have an obligation to their membership to partner with industry in facilitating training.

Industry for the purposes of these guidelines and COI policy is defined as for-profit entities that develop, produce, market or distribute drugs, devices, and services or therapies (other than the delivery of patient healthcare) used to diagnose, treat, monitor, manage, and alleviate health conditions.

The SVS receives approximately 20 percent of its annual revenue from industry support. This comes from unrestricted grants for the VAM, income derived from the VAM exhibits, and unrestricted grants to support SVS research projects. Thus, there exists a significant financial relationship between the SVS and industry that is subject to external scrutiny. In order to clarify and promote a healthy and ethical relationship with industry, the SVS ad hoc Task Force on Industry Support developed the following guidelines. The principles underlying the guidelines include transparency, full disclosure of all individual and SVS financial relationships with industry, and the maintenance of appropriate barriers between industry transactions and programmatic decisions.

GUIDELINES FOR SVS RELATIONSHIPS WITH INDUSTRY

I. GENERAL PRINCIPLES

- A. SVS will develop all programs, products, services, and advocacy positions independent of industry influence.
- B. SVS will separate its fundraising efforts and business transactions from programmatic decisions.
- C. SVS will use written agreements with companies for grants, sponsorship, charitable donations and business transactions that will specify what the funds are for, the amount given, and the separate roles of the company and the Society.
- D. These guidelines will apply to SVS, the SVS Foundation and the SVS Patient Safety Organization.

II. TRANSPARENCY

- A. The SVS will disclose industry support for SVS activities to include company name, category of support (e.g., educational grant, research support, and charitable donations), and length of support and dollar amount. This will be updated annually. There will be no restriction in the amount of aggregate industry support (e.g., 10%, 25% etc. of the SVS operating budget). However, the percent of SVS budget supported by industry will be disclosed.
- B. The SVS will disclose upon request all financial and uncompensated industry relationships that officers, members of the Board of Directors, Council chairs, committee chairs and SVS staff have reported to SVS.
- C. The SVS will make its conflict of interest policies known to its members and the public and will make individual disclosures available upon request.

III. EDUCATIONAL GRANTS AND CONTINUING MEDICAL EDUCATION

- A. SVS will comply with ACCME Standards for Commercial Support for all SVS-sponsored CME activities.
- B. SVS will retain control over the use of educational grants and implement safeguards designed to ensure that educational programs are non-promotional and free from commercial influence and bias. Industry educational grants for the Vascular Annual Meeting, for example, are unrestricted grants for the entire meeting, not for individual sessions.

- C. Individuals with control over SVS CME content, including SVS staff, will comply with established SVS ACCME procedures to identify and resolve all conflicts of interest prior to the CME activity being delivered to learners. The SVS Conflict of Interest Committee (see below) will serve as the final arbitrator for any unresolved conflicts of interest.
- D. Committee members and others responsible for developing educational content for SVS will disclose all financial or uncompensated relationships with companies. This includes the following groups: VAM Program Committee, Postgraduate Education Committee, VESAP editors and CME course directors.
- E. The chairs and co-chairs of the VAM Program Committee and Postgraduate Education Committee may have no direct financial relationships with industry.
- F. The majority of the members of the VAM Program Committee and the Postgraduate Education Committee may have no direct financial relationships with industry.
 - i. The threshold for an individual to be considered conflict-free is zero income.
 - ii. Individuals with more than \$50,000 in income in aggregate from industry may not serve on either committee.
 - iii. A direct financial relationship is a compensated relationship held by an individual that should generate an IRS Form W-2, 1099 or equivalent income report.
 - iv. Chairs who wish to serve have six months to terminate any direct financial relationships after appointment.
 - v. Chairs and committee members may accept research support as long as grant money is paid to the institution (e.g., academic medical center) where the research is conducted, not to the individual. Research support, uncompensated services and other permitted relationships should nevertheless be disclosed to the Society.
- G. SVS will limit support opportunities to general topics that are not product-specific.
- H. SVS will make efforts to achieve a diversified portfolio of industry support for CME programs.
- I. Satellite Symposia at Vascular Annual Meeting.
 - i. Satellite Symposia are not part of the ACCME-accredited portion of the VAM, and SVS will take appropriate steps to make this known to VAM attendees.

- ii. SVS will direct companies to announce or publish in symposia material that their symposia are not part of the ACCME-accredited portion of the VAM.
- iii. Satellite Symposia will not conflict with scheduled VAM events.
- iv. SVS officers, Board of Director members, VAM Program Committee and Postgraduate Education Committee members may attend but may not participate in Satellite Symposia as speakers, moderators or other significant participants, as this gives the appearance that SVS is endorsing company product(s).

J. Company logos will not be placed on items such as lanyards, tote bags, highlighters, flash drives or other company branded items.

IV. EXHIBITS

- A. SVS will have written policies governing the nature of exhibits and the conduct of exhibitors. SVS policies will require exhibitors to comply with applicable laws, regulations and guidance. SVS policies may place limits on exhibits and exhibitor conduct to ensure that the tone of the exhibit hall is professional in nature.
- B. SVS will only permit exhibitor gifts to attendees that are educational and modest in value. Non-educational, branded items are prohibited.
- C. SVS will ensure that educational sessions for which SVS CME credits are granted (such as poster sessions) are physically separated from company exhibits.
- D. SVS officers, Board of Director members, Chairs of Councils and Committees, VAM Program Committee and Postgraduate Education Committee members, and JVS Editors (senior editors, associate editors and assistant editors) may not participate in any promotional/marketing events held in the exhibit hall as speakers, moderators or other significant participants.

V. SOCIETY PUBLICATIONS

- A. SVS print and electronic publications accepting advertisements (those published by third parties), will have policies to ensure editorial independence from their advertisers.
- B. SVS publications will require editors and reviewers to disclose financial and other relationships with industry.
- C. SVS publications will require authors and trial site directors to disclose financial and other relationships with industry.
- D. SVS will not accept advertising in any SVS publications (print or electronic media) with the exception of those published by contracted third parties (e.g. Elsevier).

E. Editors of SVS Publications (JVS, JVSULD, VESAP and Rutherford,) may have no direct financial relationships with industry during their terms of service.

i. The threshold for an individual to be considered conflict-free is zero income.

ii. A direct financial relationship is a compensated relationship held by an individual that should generate an IRS Form W-2, 1099 or equivalent income report.

iii. Editors should terminate any direct financial relationships within six months of their appointment.

iv. Editors may accept research support as long as grant money is paid to the institution (e.g., academic medical center) where the research is conducted, not to the individual. Research support, uncompensated services and other permitted relationships should nevertheless be disclosed to the Society.

VI. ENDORSEMENTS AND LICENSING

A. SVS will adopt written policies that set standards for licensing intended to prevent misuse, unintended use and modification of licensed material.

B. SVS will prohibit use of licensed materials and trademarks to imply Society endorsement of industry products and services.

C. SVS will not engage in company product endorsement.

VII. RESEARCH GRANTS (Applies to SVS and SVS Foundation)

A. SVS will not permit industry to select or influence the selection of recipients of grants awarded by the SVS. SVS will appoint independent committees to select recipients of grants supported by industry funds based on peer review of grant applications.

B. Companies will not be allowed to choose topics for research grants.

C. SVS will not name research grants for companies.

D. SVS will not require grant recipients to meet with companies that supported the SVS-awarded grant.

E. SVS will not permit companies who support SVS-awarded grants to receive intellectual property rights or royalties arising out of the grant funded research.

F. SVS will not permit companies who support SVS-awarded research grants to control or influence publications that arise from the grant-funded research.

G. SVS will not permit device companies to be involved in management of any registries, including decisions to sell or otherwise disclose or publish registry data.

VIII. EDUCATIONAL GRANTS FOR STUDENTS, RESIDENTS, AND FELLOWS

- A. Industry funds for scholarships or other funds to support medical students, residents and fellows to attend educational events may be permitted provided that selection of recipients is made by SVS or by the recipient's academic institution.
- B. Educational grants will not bear a company name or logo.
- C. SVS will not require grant recipients to meet with companies that supported the SVS-awarded grant.

IX. CLINICAL PRACTICE GUIDELINES AND PERFORMANCE/OUTCOMES MEASURES

- A. SVS will not permit industry support of the development of clinical practice guidelines, performance measures or outcomes measures.
- B. Members of any committees or writing groups related to guideline development, document oversight, performance measures or outcomes will disclose all financial or uncompensated relationships with industry. Relevant relationships must be disclosed prior to panel deliberations and are required to be updated throughout the guideline development process.
- C. The chairs and co-chairs of these writing groups and committees may have no direct financial relationships with industry and are to remain free of such conflicts of interest for at least one year after Guideline publication.
- D. The majority of the members of the writing group/committee may have no direct financial relationships with industry relevant to the subject matter of the Guideline. If a direct financial relationship with industry is disclosed for one procedural product and the company produces a product related to the subject matter, this still constitutes a conflict of interest.
 - i. The threshold for an individual to be considered conflict-free is zero income.
 - ii. Individuals with more than \$50,000 in income in aggregate from industry may not serve on a writing group/committee.
 - iii. A direct financial relationship is a compensated relationship held by an individual that should generate an IRS Form W-2, 1099 or equivalent income report.
 - iv. Chairs who wish to serve have six months to terminate any direct financial relationships after appointment.
 - v. Chairs and writing group members may accept research support as long as grant money is paid to the institution (e.g., academic medical center) where the research is conducted, not to the individual. Research support, uncompensated services and other permitted relationships should nevertheless be disclosed to the Society.

- E. Complete disclosure information from writing group members will be published with the guidelines or measures.
 - F. Writing group members and staff are not permitted to discuss guidelines or measures development with company employees or representatives, will not accept unpublished data from companies, and will not permit companies to review guidelines in draft form, except in cases of public or member comment on draft guidelines as part of the Society's guideline development process.
 - G. SVS will not permit direct industry support for the initial printing, publication or distribution of guidelines or measures. After initial development, printing, publication and distribution is complete, the Society can accept industry support for further distribution of the guideline, translation of the guideline, or repurposing of guideline content.
 - H. Writing group members should decline offers from positively or negatively affected companies to speak about the guideline on behalf of the company for at least one year after publication.
- X. CHARITIBLE DONATIONS FROM INDUSTRY (Applies to SVS and SVS Foundation)
- A. SVS will control the use of donations from industry consistent with the SVS mission and strategic plans.
 - B. SVS will decline donations where the donor expects to influence programs or advocacy positions.
 - C. Donations targeted for broad categories are acceptable, consistent with the SVS mission (e.g., research, education, patient information, international programs, etc.).
 - D. SVS will adhere to applicable tax rules and legal standards for acceptance of donations.
 - E. SVS will engage in appropriate recognition of donors. Donor recognition is a fundamental part of fundraising and should be conducted with appropriate limitations.
 - i. Donors may be recognized in print materials, in private or public ceremonies, and with banners and other visual displays.
 - ii. Donor recognition should be provided in a manner that does not imply donor influence over SVS programs or advocacy positions.
- XI. PROGRAM SPONSORSHIP BY INDUSTRY
- A. SVS may accept sponsorship for Society programs outside CME or research, but the sponsored programs must be consistent with the Society's strategic plan or mission.
 - B. SVS will make efforts to seek multiple sources for outside funding for sponsored programs.

- C. SVS will engage in appropriate recognition of program sponsors.
- D. Company logos on non-educational company-branded items (e.g., tote bags, lanyards, notebooks, highlighters, etc.) will not be permitted as is consistent with generally accepted standards for ethical interactions defined in the PhRMA and AdvaMed Codes.
- E. SVS will provide the required physician information to industry for compliance with the Physician Payment Sunshine Act when the nature of the corporate support so requires.
- F. SVS activities and programs seeking industry support will be made known to the Conflict of Interest Committee who will advise the SVS Executive Committee on the appropriateness of company support for such activities.
- G. SVS will not accept company support for the following activities: Society Board of Directors, council and committee meetings; Society management meetings and other meetings concerned with governance, planning and oversight of the Society; published materials related to the Society's membership recruitment, identity or governance.