

# Industry working with physicians through professional medical associations

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The physician/surgeon's interactions with industry have come under scrutiny in recent years for several reasons. Although some think that the professional medical association or society may provide an avenue to allow such interactions with less risk, there are concerns and challenges for such organizations as it relates to ethical and professional norms of their members. This is one surgeon's review of some pertinent information regarding what the professional medical society provides to its members and what role industry plays in the society's ability to provide these benefits. There is an exploration of the risks involved and practical methods to control inherent conflicts of interest involved in this interaction. (J Vasc Surg 2011;54:41S-6S.)

In the public's impression, much of the focus of the physician's or surgeon's interaction with industry has focused on the violation of federal antifraud statutes by certain practitioners who were paid excessive "consultant fees" as potential kickbacks for using specific devices in their patients.<sup>1</sup> As a result, the issue of how industry works with the medical community has come under scrutiny. Medical associations and surgical societies provide a perceived avenue of "at arm's length" dealings with industry less likely to be viewed as an antitrust issue, but even these relationships are being scrutinized.<sup>2-7</sup> A review of what the professional medical society provides its members, the role industry has in the society's ability to provide membership benefits, the risks involved, and methods to control inherent conflicts of interest are the subject of this article.

## MEMBER BENEFITS PROVIDED BY THE PROFESSIONAL MEDICAL ASSOCIATION

Local, regional, national, and international professional medical societies provide many potential benefits but common to all is the desire to provide an educational experience for the members. As such, the societies shape clinical practice and affect patient care in a most direct manner. For the local and regional societies, this often means an annual meeting surrounded by an educational program. In some cases, the regional, national, and international societies may provide adjunctive educational experience outside of the annual meeting. Some of these courses involve education on emerging new technologies.<sup>8-10</sup> The choice of content, presenters, and moderators does influence a physician's decision regarding patient care. Generally, these experi-

ences are structured to provide continuing medical education (CME) credits required as part of a surgeon's local credentialing or more recently for Maintenance of Certification (MOC).

Most major professional medical societies have developed a professional journal to publish the latest research and clinical information pertinent to the society's and its members' needs. The content of these journals are generally peer-reviewed and certainly influence the care of our patients. The major journal can be augmented by other publications sponsored by the society, for example for the Society for Vascular Surgery there is *Vascular Specialist* and *SVS Pulse* with the major journal being the *Journal of Vascular Surgery*. The society may also offer on-line up-to-date information on clinical trials, research opportunities, and current medical news.<sup>8,10,11</sup> Others have published books or standardized courses that provide information on patient care and influence those members who utilize this information. Some examples are the Handbook of Venous Disorders: Third Edition, Vascular Education and Self-Assessment Program (VESAP), Advanced Trauma Life Support Course (ATLS) or Surgical Education, and Self-Assessment Program (SESAP).<sup>8,10,11</sup>

Practice guidelines have long been a function of medical associations. One prime example is the "Use of Anticoagulation" revised periodically and published in *CHEST*.<sup>12</sup> The Society for Vascular Surgery has recently entered this arena with a very structured evidence-based approach to the treatment of some select vascular disorders. In addition, the members can use patient educational articles on vascular diseases and treatments developed by the society.<sup>8</sup>

There are research grants and scholarships offered by medical societies to help the members to advance the basic science and clinical knowledge pertinent to the goals of the members. Certainly, the research proposals chosen will define the field for the future.

The Professional Medical Society provides some validation of the member's connection with the care of patients with a particular problem. For example, the Society for Vascular Surgery (SVS) notes that membership provides affiliation with the largest professional association in the world representing vascular surgeons and the prestige of

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using the SVS logo in one's practice. Members have the opportunity to serve on committees and councils that do impact the direction of the society. Participation in an on-line physician referral service and access to branding initiatives to develop one's practice, including free downloading of patient educational materials, press releases and interview guidelines for media promotion, screening materials, and guidelines to offer screenings are additional benefits.<sup>8</sup> Most of these services are available through the society's Web site which in itself is a membership benefit.

There are societies that provide clinical databases for the use of their members.<sup>11</sup>

There is also a legislative aspect to societal membership since many medical associations have a professional government affairs staff working on the members' behalf to impact federal legislative and regulatory processes directly related to the member's practice and patients.<sup>8,10</sup> The society often provides an advocacy support with a convenient on-line method to interface with federal government representatives.

Some larger national professional medical associations have even ventured into insurance and investment products as well as liaison with multiple organizations with some having an international interchange as well.<sup>8,10,11</sup>

For those of us who remember the humble beginnings of some of our societies, this laundry list of benefits is a far cry from the annual meeting for sharing of new knowledge and camaraderie envisioned by the founding fathers.

## INDUSTRY'S CONTRIBUTION TO PROFESSIONAL MEDICAL ASSOCIATIONS

Industry has become increasingly involved with the education of health care providers, including surgeons, through the support of medical professional associations/societies. Unlike academic medical centers that have several avenues to support their missions, professional societies generally gain support for their goals by membership dues and monies generated from the annual meeting and other educational programs. It is readily apparent that this support is inadequate to realize the many other activities expected of a modern professional society or even the educational mission of the society.<sup>7,13</sup> In the early to mid years of the last decade, industry funded 50% to 60% of all CME activities provided by nationally accredited CME providers and with the economic turnaround, this is likely a low estimate of support today.<sup>14,15</sup> In fact, in 2006, physician member organizations received 58.5% of their CME income from commercial support and advertising/exhibits.<sup>16</sup>

Industry has been willing to provide large sums of money to support patient-education materials, the most recent being a partnership between the American Academy of Family Physicians (AAFP) and Coca-Cola Corporation to support patient education materials on obesity prevention.<sup>6</sup>

Professional medical associations have endorsed industrial products to provide financial support for their many missions.<sup>17,18</sup> Whether the superiority of the products en-

dorsed was supported by evidence was generally not a point of elaboration.

The ability of our members to engage in research is enhanced by industry with which the medical societies partner to provide the research monies. Industry funds nearly 60% of all biomedical research performed in the United States with pharmaceuticals providing 30%, biotechnology firms another 20%, and medical device companies about 10%.<sup>19</sup> In 2004, this investment accounted for more than 50% of the clinical research being conducted in the United States.<sup>19</sup> This may become an even larger component of the research funding as the federal government decreases its commitment to basic and clinical research.<sup>20</sup>

It has not been unusual for industry to fund graduate medical education fellowships. In fact, in the summer of 2008 after an intensive investigation with prosecution of several orthopedic manufacturers by the Department of Justice, many orthopedic fellowships were in danger of cancellation due to lack of funding.<sup>1</sup> The American College of Cardiology has been involved with a joint industry venture to fund adult cardiology fellowships.<sup>4</sup> The American Academy of Dermatology Board of Directors apparently acquired partial funding from industry for several new dermatology positions with the goal of increasing the supply of dermatologists.<sup>21</sup>

Indirect support and potential influence by industry on the development of practice guidelines has occurred by virtue of the fact that panel members have benefited from research support and/or payment of activities on advisory boards or as consultants.<sup>22,23</sup> There has also been direct financial support for the development of guidelines by companies with a vested interest.<sup>22</sup>

Industry supports our medical journals through advertisements, purchase of articles and sometimes entire issues, and occasionally by supporting supplemental issues. The profits can be so impressive that a journal can be sent free to physicians, and the journal and its sponsor can reap huge profits.<sup>24</sup> This can be especially true for supplements funded by a single company and dealing with one drug as an example.<sup>24</sup>

Some of the available databases sponsored by medical societies are funded in part or completely by industrial support allowing free access for the members.<sup>25</sup>

During the early 2000s, some specialty physician medical associations had over 50% of their operating budget provided by commercial support and exhibit fees, and in a period of economic stress, this may have escalated in the last several years.<sup>14</sup> In 2008, 24% of the operating budget of the American Academy of Orthopedic Surgeons and 29.5% of the operating budget of the American Orthopedic Association came from orthopedic industry, which had not decreased from prior years.<sup>1</sup>

I believe it is safe to say that industry provides a significant contribution to medical associations which allows their members to be provided with services they have come to expect. Overall, I would venture that 30% to 50% of the operating budget of most professional medical societies,

both medical and surgical specialties, is garnished somehow from a relationship with industry. The societal goals and objectives requiring this amount of funding are all commendable and desirable, but the question arises whether there is some trade-off or compromise of goals when the funding is from a for-profit enterprise.

### THE RISKS OF PROFESSIONAL MEDICAL ASSOCIATION/INDUSTRIAL INTERACTIONS

The Professional Medical Society and Industry groups have different norms by which they must live. This difference is exemplified by what people view as professionalism and commercialism. Commercialism is seen as buyers and sellers acting in their own interest. Companies are in business and their duty is to their stockholders to make money. For pharmaceutical and medical device companies, this means selling products to our patients.<sup>4</sup> Since we are the gatekeepers, any access, influence, and gratitude to and from the physician/surgeon are considered a good investment. Industry has an interest in supporting medical associations to gain favor with the leadership and board members who decide the program, sit on guideline committees, and generally determine the direction of the society.<sup>4</sup> The people in companies often are very compassionate in providing our patients the best that they can, but the business aspects are still their prime duties. I believe Sieghart may have expressed it best when he noted that in a professional relationship, altruism is paramount and self-interest has no place, which is a striking difference from the rules of conduct applicable to every other market supplying goods and services.<sup>26</sup>

The professional medical society has an ethical obligation to its members, our patients, and society. The professional medical society is an extension of its members of which its leaders are a part, all of whom are subject to the professional norm. The professional norm involves recognizing certain obligations for the privileges society has granted each. Such obligations include the responsibility to gain and use medical knowledge with integrity, in the best interest of the patient and free a self-serving interest.<sup>27-29</sup> Some would contend that interest is not a sufficiently strong term, but rather it is our duty to best serve our patients.<sup>4,30</sup> It is the duty of the medical society to provide unbiased education and services for the members and by extension, the members' patients. By the education provided, the practice guidelines endorsed, and the ethical norms espoused by the medical society, the practice of medicine must be enhanced and optimized. The public agenda of the professional medical association advocates for the best interest of their members, for patients and for society in general.<sup>3</sup> The professional medical society represents expertise and authority for those in and out of the medical arena.<sup>2,3</sup> The professional medical society is the "public face" for the specialty and the profession. This public impression places much power in the medical society but also comes with an obligation to conform to the professional norm.

Since the professional medical society is held in such esteem by the public, any situation that potentially compromises clinical decision making, adversely affects health care delivery or undermines the reputation of the profession is detrimental.<sup>3,31</sup> Any real or perceived commercial bias can affect membership enrollment, credibility as a source of continuing medical education, jeopardize certification by the Accreditation Committee for Continuing Medical Education (ACCME), and diminish effectiveness as a "professional voice" to the public.<sup>2</sup> There is no question that the medical profession is held to a different standard and the medical society must recognize, and then realize, its missions within this framework. When the medical society steps over these bounds, either perceived or real, the trust placed in the profession comes into question. There are examples in which a professional medical association/industrial interaction has caused concern and were detrimental to the reputation of the medical professional association; so the risk is real.

There are some aspects of interacting with industry that might be more challenging for professional organizations than individuals since industry is so visible at societal functions. At the annual meeting, industry has banners, booths, and industrial-sponsored symposia. This visibility can be perceived as endorsement.<sup>2</sup> So the professional society, when considering conflict of interest, must consider a wide range of issues from sponsorship to how to address industrial symposia held in close proximity to the annual meeting.

The funding of continuing medical education by industry is extensive, and many stakeholders in the dissemination of unbiased information have voiced concerns.<sup>16,32</sup> A joint project between a professional medical society and industry to produce a patient educational product has generated significant controversy likely because of the funding amount and the specific industry involved.<sup>6</sup> Endorsement by a professional medical society, especially when a fee is paid, is often seen as selling one's integrity to the highest bidder.<sup>17,18</sup> Industrial-supported research tends to favor the industrial product in a statistical sense that stresses a need for vigilance when entering into such an arrangement.<sup>33</sup> Certainly, statements made by professional medical societies regarding the results of research, which may favor one industrial product, particularly when that society is benefited by its association with that industry and when the potential conflict of interest or interaction with industry had not been properly disclosed, can result in a harsh response from the public.<sup>4</sup> The integrity of the society has also been called into question when industry appeared to have significant influence over societal sponsored fellowships, guidelines, journals, and other efforts that were being supported by industry.<sup>4,21-23</sup> It appears that essentially all joint ventures between professional medical/surgical societies and industry have generated controversy when impropriety was perceived.

## METHODS TO CONTROL CONFLICT OF INTEREST

There are basically two ways to address conflict-of-interest issues. One strategy is to continue the activity but attempt to manage the risk or, alternatively, one can divest oneself of the risk by ceasing the activity. Certainly there has been a trend closer to a divestment rather than a management strategy by a diverse group, especially those addressing the ethic issues.<sup>2,4,5</sup> However, many find that a middle road is more practical for the survival of the medical society and the control of conflict of interest.<sup>2,3</sup> There is one area in which essentially all authors believe that a joint venture with physicians, surgeons, and their organizations with industry is desirable and required. The expertise of each is needed to bring a novel pharmaceutical or medical device to the patient.<sup>4,34,35</sup> But even this joint venture must be well-defined, properly valued with deliverable work, and must not step into the area of marketing or sales.

So what has the community of professional medical societies done to address conflict of interest? Some have formulated a conflict-of-interest statement for all members, including the leadership by default.<sup>36</sup> Some have published conflict-of-interest statements that include statements specifically addressing how a member should conduct him/herself when a leader within the society.<sup>37</sup> Others have conflict-of-interest policies for the leadership of the society.<sup>38</sup> The most advanced project to address conflict-of-interest policies for professional medical societies is through the Council of Medical Specialty Societies, which published a voluntary "Code of Interactions with For-Profit Health Sector" and has 13 medical societies formally adapting the code with commitment to full implementation.<sup>39,40</sup> The approach is much like the Advanced Medical Technology Association and Pharmaceutical Research and Manufacturers of America codes of interaction with health care providers formulated, however, for their device-related or pharmaceutical industrial members.<sup>41,42</sup> The full code of interaction is a 25-page document that had broad-based member input and is available at the Council of Medical Specialty Societies Web site.<sup>43</sup> There are 10 principles for "Interaction." Independence is the first principle, stating that all societal activities will be free of company influence and that all societal/industry interactions will be guided by a high-level group (eg, Ethics Committee, Conflict of Interest Committee). Possibly the most controversial component of the principle of independence is that no key society leader, defined as those in the presidential line of succession, chief executive officer and editor(s)-in-chief of the society journal(s), may have direct financial relationship with companies during his or her term of service. In addition, the society will have written agreements with companies for educational grants, corporate sponsorship, charitable contributions, business transactions, and support of research grants. Transparency is the second principle and involves making available to the members and public, the society conflict of interest policies/forms and disclosing company support. There will also be written disclosure

policies for key leaders, board members, committee members, and others directly serving the society. The financial and uncompensated relationships of key leaders and board members will be available to the members and the public. The third principle regards accepting charitable contributions that is appropriate if it aligns with the societal mission and is free of company influence. In addition, policies for consistent and appropriate recognition of donors are to be adopted. The fourth principle addresses accepting corporate sponsorship that is acceptable if it aligns with the society mission, involves reasonable efforts to seek multiple sponsors, and does not allow for company logos on "gifts." If used for support of data registries, corporate sponsors cannot participate in direct registry management. The fifth principle regards societal meetings and has four subcategories. GME grants must comply with ACCME standards for commercial support. The society must have full control over the entire program from topics to speaker selection allowing presentation of a balanced educational program addressing areas of knowledge gaps. The society itself will address any COI issues. All CME-accredited satellite symposia must comply with ACCME standards and must be clearly distinguished from societal CME activities. Non-CME programs must be clearly distinguished from societal programs. The society will adopt written policies governing exhibits and the conduct of the exhibitors during the meeting. Exhibit booths should be outside of attendees' obligate route to societal CME activities, and no key leader should participate in company promotional/marketing events. The sixth principle deals with awarding of research grants. Again, independence is critical in that companies cannot influence the selection of recipients, meet with the recipients, receive intellectual property rights or royalties resulting from the research, or influence the results or manuscripts resulting from the research. Societal research supported by corporate funding requires disclosure and independence of all aspects of the research. Clinical practice guidelines are the seventh topic and must be evidence-based, free of company influence and not directly supported by companies during development or publication. There are many safeguards needed in the generation of practice guidelines, including disclosure of relevant relationships prior to and updated during the development process. Any conflicts must be resolved by the society prior to panelist involvement. The majority of guideline development panel members must be free of conflict of interest relevant to the guideline and the panel chair must be free of conflict during, and for 1 year after, the guideline publication. The guideline recommendations must go through multiple levels of review both within and outside the society and, when published, any conflicts of interest should be disclosed with the publication. The entire process must be completely devoid of corporate influence at all levels. Societal journals must have editorial independence from the society and advertisers, all conflicts of interest must be disclosed for published works, and "ghost-written" manuscripts prepared by or on behalf of a corporation is prohibited. The society must adopt written policies setting stan-

dards for advertising. Standards of licensing is the final principle that stresses to the society the need for written standards to prevent misuse, unintended use, modifications, or implied endorsement by the society of company products or services. These principles use both the management of conflict of interest and, in some cases, divestment when seen as most needed to control conflict-of-interest issues. Little is directly stated about the value of deliverables, which is often the test of what task is being performed for what goal, but it would be imagined that the written policies should address some component of this issue.<sup>2,4</sup>

Maintaining independence in all societal activities, disclosure of all interactions especially by societal leadership, and accepting grants not earmarked by industry for a particular individual or industry-inspired project are fine principles of interaction. However, underlying all these principles to manage conflict-of-interest risk is the knowledge that “money speaks.”<sup>4</sup> The problem is that none of us see ourselves as affected by corporate influence, which simply is not true.<sup>3,3,4,4,5</sup> We, as individuals, and when functioning within a professional medical society must realize and react to the fears of our patients, the legal system, and the federal government.<sup>3,4</sup> We, as a professional medical society, must not become so tied to industrial support that the society cannot (or will not) function without that support.<sup>3,5,6</sup> Fearing the risk of sounding editorial, maybe there should be some thought to decreasing our dependence on industry by restricting overall support from industry to no more than 25% of the societal budget as some have suggested, and starting the weaning process.<sup>3</sup>

The rationale for principles regarding the professional medical association interaction with industry have been published and some are referenced for review.<sup>2-6,15,17,22-24,30,31,35</sup> It is very important for professional medical societies to address the issue of conflict of interest for the good of their members and the public interest. We need viable professional medical societies, who will be our voice to the world with the social trust required to make them effective advocates for our patients and medicine in general.

## CONCLUSION

The professional medical and surgical society interactions with industry have come under scrutiny, as have all physician/industry interactions. The interaction of the professional medical society with industry has become more entangled, as the societies have offered more and more member-expected benefits. Industry likely funds 30% to 50% or more of most professional medical associations' member benefits by supporting the annual meeting, CME courses, fellowships, research, patient educational brochures, and the list goes on. Industry is in business to improve the shareholders' profits. Physicians, and by extension our professional societies, are in the medical profession with prime interest in the optimal care of their patients unaffected by self-interest. Since the professional medical society is the public face of our profession and directs many of our professional decisions by virtue of education, publications, and practice guidelines in addition to other activi-

ties, the issue of conflict of interest becomes a real concern for members, patients, and other interested organizations. Since public trust and the society's integrity are so important to the society's advocacy for its members and our patients, any real or perceived event that could call into question the society's duty to the public good is unacceptable. As a result, methods to manage or divest conflict of interest with industry are being proposed and implemented. Maintaining robust professional medical associations free of industrial influence over the core missions of the society is the desire and goal of all these efforts.

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