

Society for Excellence in Eyecare

Recommendations to Members: Relationships with Industry

I. Summary

Relations between physicians and industry are being closely examined and even targeted by enforcement authorities. Recent government enforcement developments are causing many physicians to reevaluate their relationships with pharmaceutical and device manufacturers. Important developments include the recent TAP Pharmaceuticals investigation and settlement, as well as the HHS Office of Inspector General's FY 2002 Work Plan. In particular, the OIG work plan indicates that the OIG plans to focus on the relationships between physicians and pharmaceutical companies. The OIG is concerned about drug companies providing anything of value to physicians and other health care providers as an inducement to order their products. The OIG intends to focus on what it estimates to be \$12 billion annually spent by the drug companies on "physician detailing." In the view of the OIG, such conduct creates both inherent conflicts of interest as well as kickback violations.

The members of the Society for Excellence in Eyecare are leaders in their field, performing state of the art ophthalmic procedures. Because of the size of their practices as well as their reputation in their profession, Society members are highly desirable customers from the perspective of industry, and high profile targets for both competitors and aggressive enforcement authorities. SEE believes that it is therefore prudent and advisable for its members to give serious thought and consideration to their own interactions with industry. Even if a given activity is not clearly illegal or unethical, the appearance of impropriety or a conflict of interest can result in unnecessary and expensive inquiries. Moreover, even the appearance of a conflict of interest can diminish patients' perception of, and confidence in, their eye care professionals¹ and therefore should be avoided. Many SEE members, acting in an abundance of caution, have asked for recommendations on how to appropriately interact with industry and avoid accusations of impropriety.

SEE remains mindful, however, of the many socially beneficial purposes of the interactions between eye care professionals and industry that benefit patients and patient care. As the patient's quality eye care advocate, SEE has developed guidance for its members in order to enable them better to avoid accusations of impropriety, while still enhance or supplement patient care through beneficial and appropriate interactions with industry. The recommendations that follow are not legal advice and do not state the legal standards or requirements. Rather, these recommendations are intended to help SEE members understand how to avoid scrutiny by steering clear of certain situations.

¹ For the purposes of these Recommendations, "eye care professionals" means ophthalmologists and optometrists.

II. General Guidance

Physicians must be sensitive to assure appropriate interactions between themselves and the promotional and sales efforts associated with the pharmaceutical and medical device manufacturing industries. In order to avoid allegations of illegality or impropriety, SEE recommends that its members follow these basic principles with industry:

- SEE members should use their judgment as ethical eye care professionals and err on the side of caution; if something feels uncomfortable, they should trust that instinct.
- Compensation, in cash or in kind, provided by industry should only be in return for actual work or time provided by the eye care professional and must be commensurate with the value of the work or time provided.
- The receipt of any compensation, in cash or in kind, or other promotional benefits should never be linked with any promise of future prescribing activity, future purchases or other types of support for products.
- Lavish gifts or entertainment, should not be accepted.
- Eye care professionals should use caution when charging patients for items or goods that the professional receives at a discount, and should avoid charging patients for goods or items received for free.

III. Recommended Questions SEE Members Should Ask Themselves When Interacting With Industry

SEE recommends that whenever an eye care professional is approached by an industry representative, the eye care professional should ask himself or herself the following initial questions. If the answer to any of these questions is “yes,” then the activity likely could be characterized as a conflict, inappropriate, or even as a legal or regulatory risk. In such instances, SEE recommends that its members exercise extreme caution.

- Are you being offered a gift of more than token value by the company?
- Did the presentation or “pitch” address the fact that you have historically been a high prescriber of that company’s products? That is, has it been made obvious to you that the reason you have been selected as the recipient of a “perk” is the fact that you have been a high prescriber of the company’s products?
- Is the company proposing to provide some type of financial benefit to you, if you agree to switch from a competing product to that company’s product?
- Do you feel an obligation to respond (for example, by prescribing the company’s products) when offered a financial benefit from a company? That is, is the offer likely to affect your prescribing habits?

- Are you being asked to participate in a “research grant” program in which you are given payments for minimal or nonexistent record keeping tasks?
- Are you being offered unrestricted research or education grant funds?
- Are you being offered compensation to participate in a study which has no apparent benefit to the company or the patient community?
- Are you being offered grants for studies of drugs or devices when the studies are of questionable scientific value and require little or no actual scientific pursuit?

IV. Specific Operational Suggestions

In addition to the recommendations articulated above, SEE refers its members to the American Medical Association’s guidance on interactions with industry for additional information. The following operational recommendations are based, in part, on the AMA guidelines, and are provided to SEE members as practical considerations.

Receipt of Gifts and Entertainment

General Recommendations

Gifts received by an eye care professional in a position to make or influence purchasing decisions from industry should be related primarily to the eye care professional’s work and/or produce a benefit to patients. Gifts should be items of no more than modest value. The AMA does not specify or recommend a particular dollar amount limit.

Eye care professionals should use their judgment concerning an estimated value for a gift or entertainment in the “open market.” Regardless, even gifts of no more than modest value should not be accepted frequently nor be received by large numbers of individuals in the same practice or organization.

Examples

Examples of appropriate gifts from industry that are not likely to cause a conflict of interest include:

- Pens, notepads, coffee mugs, and office snacks.
- Modest lunches or dinners.
- Diagnostic equipment,² or medical or scientific textbooks, of no more than modest value.

² The AMA offers stethoscopes as examples of appropriate modest diagnostic equipment.

Not Recommended

SEE members should use extreme caution when being offered the following from industry:

- Cash or cash equivalents. These should never be accepted in the absence of actual services. This includes such items as gift certificates, coupons exchangeable for a gift of the recipient's choice, airline frequent flyer points, or vouchers covering the cost of uncompensated care.
- "Points" based rewards or gifts.

Faculty or Consultant Arrangements/Focus Groups

Individuals who are *bona fide* meeting faculty, company consultants, researchers, or individuals who participate in industry focus groups may receive reasonable compensation for services rendered. In addition, SEE advises its members to provide these services in accordance with an appropriate written contract.

- Compensation for personal services may include reasonable travel costs and either an honorarium or payment for the faculty member's time. Payment for time should reflect fair-market value.
- Eye care professionals serving as faculty or company consultants should provide only legitimate, commercially reasonable services with real value, and he or she should perform the described services personally.
- Eye care professionals should decline token consulting or advisory arrangements. If a SEE member believes that the benefits received exceed the value of the contribution made, the member should consider a reevaluation of the relationship.

Attendance at Continuing Medical Education and Similar Activities

Underwritten Costs of Continuing Education Activities

Pharmaceutical or other companies frequently will underwrite the costs of continuing education activities such as grand rounds, continuing educational conferences, or medical specialty association meetings. SEE recommends that its members consider the following principles regarding attendance at such events or activities:

- Eye care professionals attending the activity or event should not accept educational grants or other funds or benefits merely for attending the activity or event, or to cover the cost of attending the activity or event.
- Educational grants may be used to reduce or eliminate the registration fee for a conference or continuing medical education course for all attendees, but not on an individual or per-case basis. Eye care professionals should not accept checks or vouchers to offset the registration fee at a particular conference or at a conference of the recipient's choosing.

Educational Dinners

Pharmaceutical or other companies may sponsor special educational dinners or other similar programs. The meal or other social activity should not be extravagant. Even for programs that do not carry continuing medical education credit, the educational component of the program should be of legitimate educational value. Otherwise, the program should be considered to be a gift or pure entertainment.

Faculty or Organizer

Eye care professionals who present or organize CME or similar events should at all times retain responsibility and control over the content or choice of faculty of the conference, meeting, or lecture.

Medical Students or Residents

Medical students, residents, or fellows may receive sponsorship funds to attend the educational, scientific, or policy-making meetings of national, regional and specialty professional associations. Payments, however, may not be made directly to any individual and the institution or professional association must select the attendee(s).

Promotional Events

Eye care professionals should not accept cash or cash equivalents to attend promotional events such as product launches or presentations about new label indications. SEE recommends that in such situations eye care professionals accept only a modest gift and/or a modest meal.

Attendance at Social Events

Attendance by eye care professionals at industry sponsored social events such as an evening meal, a sporting event or a theatrical performance is acceptable so long as the cost of the event is not extravagant. Eye care professionals should not accept reimbursement for travel expenses or overnight lodging connected with such attendance. Moreover, eye care professionals should be wary of the potential impropriety of the aggregation of several such events. Therefore, to avoid even the appearance of impropriety, SEE recommends that its members accept such invitations from particular companies infrequently.

Samples and Free Drug Product

Patients should never be billed or charged, directly or indirectly, for the provision or use of products labeled as “Samples - Not for Resale or Distribution.”

SEE recommends that to avoid impropriety, physicians should not accept samples of products for their own personal use or use by their families. The AMA guidelines permit the receipt and use of samples for personal or family use, so long as such practices do not interfere with patient access to samples. SEE, however, urges its members to use caution and avoid even the appearance of a conflict in this regard.

As for free or discounted products that are not samples, eye care professionals should not, directly or indirectly, bill patients or receive any remuneration for the provision or use of products that the eye care professional or his or her practice receives for free (and not part of a contractual based volume discount). In many circumstances, however, volume discounts are appropriate. In other segments of the health care industry, however, such as those items reimbursed under the Medicare fee schedule, it may be illegal to bill patients or receive any remuneration.

SEE advises all of its members to be wary of companies that attempt to sell their products by marketing the *profitability* potential to the physician of their products.

Promotional Items for Patients

Ophthalmic surgeons often receive from industry various products or items that directly benefit patients, such as “postoperative packs.” SEE members should be aware of potential issues which may arise.

- Physicians should never accept such packages or similar items *in return* for ordering items or services such as prescription drugs. Such conduct risks violating federal and/or state anti-kickback statutes, as well as ethical standards. The sale of such items to patients creates further kickback and ethical problems.
- Such items may be provided to the physician or surgery center packaged with a purchased item, such as an intraocular lens. Although there is no clear guidance in the law, such arrangements may be acceptable. The provision of the item(s) may be acceptable so long as the appropriate amounts are disclosed to the government as may be requested.

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The receipt of gifts, entertainment or other promotional benefits should never be linked with any promise of future prescribing activity, future purchases or other types of support for products.

This guidance is intended to establish general advice and recommendations for SEE members regarding their interactions with pharmaceutical and medical companies, and should not be considered to articulate the legal standards. Further, the recommendations

are neither definitive nor binding. Questions about specific activities or arrangements should be directed to a competent attorney.

Resources

For additional guidance, SEE refers its members to

- AMA Code of Medical Ethics, Addendum II: Council on Ethical and Judicial Affairs Clarification of Gifts to Physicians from Industry (E-8.061) <http://www.ama-assn.org/ama/pub/category/4263.html>
- The Federal Anti-Kickback Statute at 42 U.S.C. § 1320a-7b(b), and the corresponding safe harbor regulations at 42 C.F.R. § 1001.952.