



ADVISORY OPINION OF THE CODE OF ETHICS

Subject: Disclosure of Professionally Related Commercial Relationships and Interests

Issues Raised: 1) How can an ophthalmologist assess the potential for conflict of interest?
2) When and how must an ophthalmologist disclose professionally related commercial relationships and interests to patients and other relevant parties?

Applicable Rules:

Rule 2. Informed Consent
Rule 11. Commercial Relationships
Rule 15. Conflict of Interest

Definitions (exclusively for the purposes of this Advisory Opinion)

“Commercial health care entity” - A proprietary health-related business having separate and distinct objectives with regard to profit, such as pharmaceutical, devices, and medical equipment industries and related entities or business partners.

“Threshold financial interest/ownership” - One hundredth of one percent (0.01%).

“Family member” - Spouse, domestic partner, parent, mother-in-law, father-in-law, child, spouse of child, grandchild, brother, sister, or spouse or child of a brother or sister.

“Ownership” - An interest held by an individual or an individual's family member.

“Commercial relationship” - A formal business relationship between a commercial health care entity and a physician.

“Conflict of interest” - A discrepancy between the ophthalmologist's professional responsibilities to serve the patient's best interests and his or her own personal interests or incentives.

“Commercial interest” - (See expanded definitions in “Financial Relationships That Require Disclosure” section below)

- 1) Fee arrangements with another physician or practitioner (other than any of the ophthalmologist's partners, co-employees, employees, or employer).
- 2) Interest in facilities, equipment, devices, procedures, and pharmaceutical agents.

Background

Although holding commercial interests in itself is not necessarily unethical, the ophthalmologist must respect the importance of the patient's interest above his or her own when these interests differ. Patients have a right to trust that a service or product is recommended to them because it is an appropriate balance of safety, efficacy, and cost based on sound professional judgment and unbiased by extraneous factors or inducements.

A conflict of interest is a discrepancy between the ophthalmologist's professional responsibilities and

his or her personal interests or incentives. When a practicing ophthalmologist has professionally related commercial interests, the potential exists for a conflict of interest in patient care. It is essential that conflicting commercial interests be disclosed to the patient and to colleagues who may be affected by them. However, not all commercial interests necessarily raise conflicts. Of equal importance in this discussion is the distinction between, and the physician's understanding of, those arrangements or relationships that raise conflicts of interest and those that do not. Examples of arrangements or relationships with commercial health care entities that may not raise conflicts include hospital-sponsored golf tournaments for the hospital's clinical staff or a modest industry-sponsored meal in a setting conducive to an educational endeavor.

A general guideline (embraced by the British Medical Association and the American College of Physicians) as to the appropriateness or inappropriateness of a commercial relationship or other such arrangement is for the ophthalmologist to assume the position of the patient and ask himself or herself the following: Would you be willing to have these arrangements or inducements generally known? This advisory opinion is based on this criterion of accountability, with the recommendation to err on the side of disclosure when in doubt.

Ophthalmologists should be careful to observe any additional disclosure requirements that may be mandated by state or federal law.

Financial Relationships That Require Disclosure

The following are examples of specific commercial relationships that require disclosure to patients and other relevant parties. These examples identify a disclosable professionally related commercial interest:

1. **Fee arrangements** with another physician or practitioner (other than any of the ophthalmologist's partners, co-employees, employees, or employer), specifically, if any portion of the global fee for the ophthalmological service is allocated, divided, or split with the other physician or practitioner through the direct or indirect payment or reimbursement practices of any third-party payor or payment agency, or if the global fee for the service of the other physician or practitioner is allocated, divided, or split with the ophthalmologist.
2. **Interest in facilities** (such as Ambulatory Surgery Centers [ASCs], optical dispensaries, and laser centers), equipment, devices, procedures, and pharmaceutical agents, **specifically** if an interest of one hundredth of one percent (0.01%) or more in one of the above is directly or indirectly owned by (a) the ophthalmologist, (b) a family member, (c) any other physician or practitioner with respect to whom the ophthalmologist has a commercial relationship described in paragraph (1) above, or (d) any entity of which any person described in clause (a), (b), or (c) above is either an owner, partner, shareholder (otherwise than as a shareholder in a mutual fund), or venturer with a one hundredth of one percent (0.01%) or more interest, or a consultant, officer, director, trustee, beneficiary, or employee. An exception may be made for facilities such as ASCs and laser centers if it would be apparent to a reasonable person that those facilities are an integral part of the ophthalmologist's practice facility and hence are likely to be owned in whole or in part by the ophthalmologist or the ophthalmologist's practice group. For the purposes of this document, stock options shall be considered to be the ownership of an interest in an entity even if they have not been exercised or they are not currently exercisable.
3. **Stock options as consultant compensation.** Stock options may be utilized by publicly traded or start-up companies as a form of compensation in clinical research and product development consulting relationships. Because stock options have potential value that is closely linked to the outcomes of research or success of product development, they create financial incentives that may bias the actions of an ophthalmologist conducting clinical trials and must be disclosed to patients and other relevant parties.
4. **Royalty payments for intellectual property.** The ophthalmologist who holds intellectual property rights to a technology (or has a family member who holds such rights) and receives royalty payments for licensure to a commercial health care entity may be biased to recommend products or procedures using this technology over competing technologies due to financial

return. For instance, a physician who holds patent on a medication and licenses this to a pharmaceutical company should disclose this financial relationship before prescribing this medication to a patient.

5. **Direct financial support** from commercial health care entities, whether by cash payments, debt forgiveness, or by other means.
6. **Legal entanglement.** This would apply, for example, to the ophthalmologist who is a party to current or prior litigation with a commercial health care entity. Such legal entanglement could bias the physician toward or away from an involved entity or its products, even if utilization of the products or services of that entity are in the patient's best interest.

Arrangements That May Require Disclosure

The following are examples of potentially problematic arrangements between commercial health care entities and ophthalmologists. The ophthalmologist should scrutinize such arrangements for the potential to bias patient care and then adequately disclose them to the patient and other relevant parties.

1. Holding a controllable, negotiable interest in an ophthalmic-related business (e.g., financial investment, stock holdings, options, or warrants) either directly or through a family member that creates a conflict between the financial interests of the ophthalmologist and the medical interests of the patient.
2. Compensated board membership or a paid-consultant relationship with an ophthalmic-related business.
3. Receiving commercial support for educational and scientific meetings and research where the sponsor controls or influences the content of the meeting or research.
4. Contractual relationships with commercial health care entities in which economic incentives or penalties may influence patient care.
5. Any express or implied obligation to promote a company's products.
6. Accepting noneducational gifts from commercial health care entities. It is important to realize that the acceptance of a gift establishes a relationship between the donor and the recipient with expectations of reciprocity and that these gifts may violate a professional policy on conflicts of interest.
7. Participating in noneducational or nonbusiness-related activities (e.g., social functions, meals, travel, and entertainment) where there is no genuine professional benefit to the physician and no apparent benefit to, or advancement of, patient care.

Disclosure Methodology

Disclosure to Patients

Disclosure of conflicts of interest to patients may be either oral or written. In the case of an oral communication, the disclosure of the ophthalmologist's commercial interests shall be made as part of a communication containing a recommendation for treatment or a referral, and it shall reasonably apprise the patient of the commercial interest in question if that commercial interest has a reasonable chance of biasing decisions about patient care. If the patient expresses concern about the apparent conflict of interest, the patient should be informed of alternative avenues of obtaining care from other physicians with whom the ophthalmologist has no disclosable professionally related commercial interests.

In lieu of an oral communication to a patient, the ophthalmologist may make the required disclosure in a written communication using one or more of the following forms, or by using a similar methodology:

- Posting a conspicuous sign in an area that is likely to be seen by patients and patients'

- guardians.
- Incorporating a conspicuous written notice in the ophthalmologist's existing office documents, such as prescription sheets, office information or policy booklets, referral forms, and any similar regularly distributed information handout.
- Providing a written disclosure document for a patient or a patient's guardian.

Disclosure for Educational and Academic Activities

The ophthalmologist who lectures to other ophthalmologists, trainees, physicians, health care professionals, allied staff, and the general public, whether by live lecture, webinar, or recorded video or audio has a responsibility to disclose conflicts of interest at the inception of the lecture, in a manner in which the listener can readily understand the nature of the conflict or conflicts. This requirement exists whether or not such disclosures are mandated by continuing education or other regulations applicable to the lecture. Similarly, written publications, whether in the peer-reviewed literature, trade publications, textbooks, or web-based materials should disclose any real or perceived conflicts of interest. Ophthalmologists performing editorial peer review also have an obligation to report any conflicts of interest regarding the work in question to the editorial staff requesting review.

Publicly Available Disclosure Data. In the United States, pharmaceutical and device manufacturers are obligated by law to report payments and certain equity positions to physicians (see <https://www.cms.gov/openpayments>). These data are publicly available. Some other countries have similar reporting mechanisms. It is the responsibility of the ophthalmologist to ensure the reported data are correct. It is also the responsibility of the ophthalmologist to ensure that reported disclosures are consistent with publicly reported data. The availability of these datasets does not relieve the ophthalmologist of the reporting requirements noted previously.

Timing of Disclosure

An ophthalmologist's professionally related commercial interests must be disclosed to patients and other relevant parties at the time he or she makes a recommendation for, a referral to, offers a description of, or generally discusses one or both of the following:

- The advantages and disadvantages of the patient seeing another physician with whom the ophthalmologist has professionally related commercial interests
- Facilities, equipment, devices, procedures, or pharmaceutical agents with which the ophthalmologist intends to treat the patient and with which he or she has professionally related commercial interests

Applicable Rules

“Rule 2. Informed Consent. Informed consent is the process of shared decision-making between the ophthalmologist and the patient and must precede the performance of medical or surgical procedures. During the informed consent process, pertinent medical and surgical facts, and recommendations consistent with standard of care in medical/surgical practice must be presented in understandable terms to the patient or patient surrogate. Such information should include the indications, benefits, objectives, risks and possible complications of the procedure, alternatives to the procedure, and the potential consequences of no treatment. The operating ophthalmologist must personally confirm comprehension of this information with the patient or patient surrogate.”

“Rule 11. Commercial Relationships. An ophthalmologist's clinical judgment and practice must not be affected by economic interest in, commitment to, or benefit from professionally related commercial enterprises.”

“Rule 15. Conflict of Interest. A conflict of interest exists when professional judgment concerning the well-being of the patient has a reasonable chance of being influenced by other interests of the provider. Disclosure of a conflict of interest is required in communications to patients, the public, and colleagues.”

Other References

American Academy of Ophthalmology. Advisory Opinions of the Code of Ethics, “Delegation of

Services,” “Employment and Referral Relationships Between Ophthalmologists and Other Health Care Providers,” and “Post-Operative Care.” Available at: <http://www.aao.org/clinical-education/redmond-ethics-center>.

American Academy of Ophthalmology. Policy Statement, “Gifts to Physicians from Industry,” Available at: <https://www.aao.org/ethics-detail/policy-statement--gifts-to-physicians-from-industr>.

American Medical Association, Council on Ethical and Judicial Affairs. Code of Medical Ethics Current Opinions with Annotations, 2006–2007 ed. Sections 8.031, “Conflicts of Interest: Biomedical Research”, 8.032, “Conflict of Interest: Health Facility Ownership by a Physician and Clarification”, 8.061, “Gifts to Physicians from Industry and Clarification”, 8.08, “Informed Consent”, 8.09, “Laboratory Services”, 8.06, “Prescribing and Dispensing Drugs and Devices,” consolidation of previous opinions 6.04, “Fee Splitting: Drug or Device Prescription Rebates”; 8.06, “Drugs and Devices: Prescribing”; and 8.07, “Gifts to Physicians: Offers of Indemnity”, 6.02, “Fee Splitting”, 6.03 “Fee Splitting: Referrals to Health Care Facilities”, 8.05, “Contractual Relationships”, and 8.132, “Referral of Patients - Disclosure of Limitations”. Available at: www.ama-assn.org.

Angell, M. Relationships with the Drug Industry: Keep at Arm’s Length. *BMJ* 2009; Feb3:338.

Bauchner H, Fontanarosa PB, Flanagin A. Conflicts of interests, authors, and journals: New challenges for a persistent problem. *JAMA* 2018;320(22):2315-8.

Blum, JA, et al. Requirements and Definitions in Conflict of Interest Policies of Medical Journals. *JAMA* 2009;302(20):2230–34.

Blumenthal, D. Doctors and Drug Companies. *N Engl J Med* 2004;351:1885–90.

Brennan TA, et al. Health industry practices that create conflicts of interest. *JAMA* 2006;295(4):429–33.

Campbell EG, et al. National Survey of Physician-Industry Relationships. *N Engl J Med* 2007; 356:1742–50.

Campbell, EG, et al. Physician Professionalism and Changes in Physician-Industry Relationships from 2004 to 2009. *Arch Intern Med* 2010;170(20):1820–26.

Chimonas, S, et al. Show us the Money: Lessons in Transparency from State Pharmaceutical Marketing Disclosure Laws. *Health Services Research* 2010; Feb45(1):98–114.

Chren, MM. Doctors, drug companies and gifts. *JAMA* 1989;262(24):3448–51.

DeAngelis, CD. Conflicts of interest and the public trust. *JAMA* 2000;284:2237–38.

DeAngelis, CD. The Influence of Money on Medical Science. *JAMA* 2006;296:996–98.

Department of Health and Human Services. Final Rule on Regulations Related to Individual Conflicts of Interest in Federally-funded Research. Federal Register Final Rule (Aug 2011). Available at: <http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf>.

Jost, TS. Oversight of marketing relationships between physicians and the drug and device industry: a comparative study. *Am J Law Med*. 2010;36(2–3):326–42.

Kuehn, BM. IOM: Increase Policing of Conflicts of Interest. *JAMA*. 2009;301(20):2083.

Norris SL, et al. Conflicts of Interest in Clinical Practice Guideline Development: A Systematic Review. *PLoS One*. 2011;6(10):e25153. doi: 10.1371/journal.pone.0025153.

PhRMA, “Code on Interactions with Healthcare Professionals.” Available at: <https://www.phrma.org/about/codes-and-guidelines>

Ross, JS, et al. Pharmaceutical Company Payments to Physicians: Early Experiences with Disclosure Laws in Vermont and Minnesota. <https://jamanetwork.com/journals/jama/fullarticle/206127>

Slentz DH, Nelson CC, Lichter PR. Characteristics of industry payments to ophthalmologists in the open payments database. *JAMA Ophthalmol* 2019; 137(9):1038-1044

Van Gelder RN, Siegfried CS. ROI, COI, and the ethical obligations of journals. *Ophthalmology* 2022; 129(6):602-604.

| | |
|--------------------------|-----------------------------------|
| Approved by: | Board of Directors, June 1990 |
| Revised and Approved by: | Board of Trustees, May 1994 |
| Reaffirmed by: | Board of Trustees, April 1998 |
| Revised and Approved by: | Board of Trustees, October 2002 |
| Revised and Approved by: | Board of Trustees, September 2005 |
| Revised and Approved by: | Board of Trustees, January 2009 |
| Revised and Approved by: | Board of Trustees, July 2010 |
| Revised and Approved by: | Board of Trustees, June 2018 |
| Revised and Approved by: | Board of Trustees, February 2023 |

©2023 American Academy of Ophthalmology®
P.O. Box 7424 / San Francisco, CA 94120 / 415.561.8500