

Virtual Mentor

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THE CODE SAYS

The AMA *Code of Medical Ethics*' Opinions on Using Drugs and Surgery for Purposes Other than Treatment

Opinion 8.06 - Prescribing and Dispensing Drugs and Devices

(1) Physicians should prescribe drugs, devices, and other treatments based solely upon medical considerations and patient need and reasonable expectations of the effectiveness of the drug, device or other treatment for the particular patient.

(2) Physicians may not accept any kind of payment or compensation from a drug company or device manufacturer for prescribing its products. Furthermore, physicians should not be influenced in the prescribing of drugs, devices, or appliances by a direct or indirect financial interest in a firm or other supplier, regardless of whether the firm is a manufacturer, distributor, wholesaler, or repackager of the products involved.

(3) Physicians may own or operate a pharmacy, but generally may not refer their patients to the pharmacy. Exceptionally, a physician may refer patients to his or her pharmacy in accord with guidelines established in Opinion 8.032 "Conflicts of Interest: Health Facility Ownership by a Physician." Physicians may dispense drugs within their office practices provided such dispensing primarily benefits the patient.

(4) In all instances, physicians should respect the patient's freedom of choice in selecting who will fill their prescriptions as they are in the choice of a physician and, therefore, have the right to have a prescription filled wherever they wish. (See Opinions 9.06 "Free Choice," and 8.03 "Conflicts of Interest: Guidelines.") Physicians should not urge patients to fill prescriptions from an establishment which has entered into a business or other preferential arrangement with the physician with respect to the filling of the physician's prescriptions.

(5) A third party's offer to indemnify a physician for lawsuits arising from the physician's prescription or use of the third party's drug, device, or other product, introduces inappropriate incentives into medical decision making. Such offers, regardless of their limitations, therefore constitute unacceptable gifts. This does not address contractual assignments of liability between employers or in research arrangements, nor does it address government indemnification plans.

(6) Patients have an ethically and legally recognized right to prompt access to the information contained in their individual medical records. Since a prescription is part of the patient's medical record, the patient is entitled to a copy of the physician's prescription for drugs or devices, including eyeglasses and contact lenses. Therefore,

physicians should not discourage patients from requesting a written copy of a prescription.

This opinion is a 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.”

Opinion 5.015 - Direct-to-Consumer Advertisements of Prescription Drugs

The medical profession needs to take an active role in ensuring that proper advertising guidelines are enforced and that the care patients receive is not compromised as a result of direct-to-consumer advertising. Since the Food and Drug Administration (FDA) has a critical role in determining future directions of direct-to-consumer advertising of prescription drugs, physicians should work to ensure that the FDA remains committed to advertising standards that protect patients’ health and safety. Moreover, physicians should encourage and engage in studies regarding the effect of direct-to-consumer advertising on patient health and medical care. Such studies should examine whether direct-to-consumer advertising improves the communication of health information; enhances the patient-physician relationship; and contains accurate and reasonable information on risks, precautions, adverse reactions, and costs.

Physicians must maintain professional standards of informed consent when prescribing. When a patient comes to a physician with a request for a drug he or she has seen advertised, the physician and the patient should engage in a dialogue that would assess and enhance the patient’s understanding of the treatment. Although physicians should not be biased against drugs that are advertised, physicians should resist commercially induced pressure to prescribe drugs that may not be indicated. Physicians should deny requests for inappropriate prescriptions and educate patients as to why certain advertised drugs may not be suitable treatment options, providing, when available, information on the cost effectiveness of different options.

Physicians must remain vigilant to assure that direct-to-consumer advertising does not promote false expectations. Physicians should be concerned about advertisements that do not enhance consumer education; do not convey a clear, accurate, and responsible health education message; do not refer patients to their physicians for more information; do not identify the target population at risk; and fail to discourage consumer self-diagnosis and self-treatment. Physicians may choose to report these concerns directly to the pharmaceutical company that sponsored the advertisement.

To assist the FDA in enforcing existing law and tracking the effects of direct-to-consumer advertising, physicians should, whenever reasonably possible, report to them advertisements that (1) do not provide a fair and balanced discussion of the use of the drug product for the disease, disorder, or condition; (2) do not clearly explain warnings, precautions, and potential adverse reactions associated with the drug product; (3) do not present summary information in language that can be understood

by the consumer; (4) do not comply with applicable FDA rules, regulations, policies, and guidelines as provided by the FDA; or (5) do not provide collateral materials to educate both physicians and consumers.

Based on the report “Direct-to-Consumer Advertisements of Prescription Drugs,” adopted December 1998.

Opinion 2.076 - Surgical “Placebo” Controls

The term surgical “placebo” controls refers to the control arm of a research study where subjects undergo surgical procedures that have the appearance of therapeutic interventions, but during which the essential therapeutic maneuver is omitted.

The appropriateness of a surgical “placebo” control should be evaluated on the basis of guidelines provided in Opinion 2.07 “Clinical Investigation,” as well as the following requirements:

- (1) Surgical “placebo” controls should be used only when no other trial design will yield the requisite data.
- (2) Particular attention must be paid to the informed consent process when enrolling subjects in trials that use surgical “placebo” controls. Careful explanation of the risks of the operations must be disclosed, along with a description of the differences between the trial arms emphasizing the essential procedure that will or will not be performed. Additional safeguards around the informed consent process may be appropriate such as using a neutral third party to provide information and get consent, or using consent monitors to oversee the consent process.
- (3) The use of surgical “placebo” controls may be justified when an existing, accepted surgical procedure is being tested for efficacy. It is not justified when testing the effectiveness of an innovative surgical technique that represents only a minor modification of an existing, accepted surgical procedure.
- (4) When a new surgical procedure is developed with the prospect of treating a condition for which no known surgical therapy exists, using surgical “placebo” controls may be justified, but must be evaluated in light of whether the current standard of care includes a non-surgical treatment and the benefits, risks, and side effects of that treatment.
 - (a) If foregoing standard treatment would result in significant injury and the standard treatment is efficacious and acceptable to the patient (in terms of side effects, personal beliefs, etc), then it must be offered as part of the study design.
 - (b) When the standard treatment is not fully efficacious, or not acceptable to the patient, surgical “placebo” controls may be used and the standard treatment foregone, but additional safeguards must be put in place around the informed consent process.

Based on the report “[Surgical Placebo Controls](#),” adopted June 2000; updated June 2003.

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