

## OPINIONS OF COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS

The following opinions, 1-9, were presented by Michael S. Goldrich, MD, Chair:

### 1. GUIDELINES TO PREVENT MALEVOLENT USE OF BIOMEDICAL RESEARCH

#### HOUSE ACTION: FILED

At the 2004 Annual Meeting, the House of Delegates adopted the recommendations of Council on Ethical and Judicial Affairs Report 9-A-04, "Guidelines to Prevent Malevolent Use of Biomedical Research." The report emphasizes the importance of establishing an overall ethical framework for responsible biomedical research. This framework would ensure that biomedical research continues to generate medical innovations while preventing harms that may be incurred through its corruption, notably including its application to the development of biological weapons. The Council issues this Opinion, which is based on CEJA Report 9-A-04. It will appear in the next version of *PolicyFinder* and the next print edition of the *Code of Medical Ethics*.

#### E-2.078 Guidelines to Prevent Malevolent Use of Biomedical Research

Physicians who engage in biomedical research are bound by the ethical obligations of the medical profession and also are required to meet responsibilities of the scientific community. Beyond their commitment to the advancement of scientific knowledge and the betterment of public health, physician-researchers must strive to maintain public trust in the profession through their commitment to public welfare and safety, as demonstrated through individual responsibility, commitment to peer review, and transparency in the design, execution, and reporting of research.

Biomedical research may generate knowledge with potential for both beneficial and harmful application. Before participating in research, physician-researchers should assess foreseeable ramifications of their research in an effort to balance the promise of benefit from biomedical innovation against potential harms from corrupt application of the findings.

In exceptional cases, assessment of the balance of future harms and benefits of research may preclude participation in the research; for instance, when the goals of research are antithetical to the foundations of the medical profession, as with the development of biological or chemical weapons. Properly designed biomedical research to develop defenses against such weapons is ethical.

The potential harms associated with some research may warrant regulatory oversight. Physician-researchers have a responsibility not only to adhere to standards for research, but also to lend their expertise to the development of safeguards and oversight mechanisms, both nationally and internationally. Oversight mechanisms should balance the need to advance science with the risk of malevolent application.

After research has been conducted, consideration should be given to the risk of unrestricted dissemination of the results. Only under rare circumstances should findings be withheld, and then only to the extent required to reasonably protect against dangerous misuse.

These ethical principles should be part of the education and training of all physicians involved in biomedical research.

Issued December 2004 based on the report "Guidelines to Prevent Malevolent Use of Biomedical Research," adopted June 2004.

## 2. FINANCIAL INCENTIVES TO PATIENTS FOR REFERRALS

### HOUSE ACTION: FILED

At the 2004 Annual Meeting, the House of Delegates adopted the recommendations of Council on Ethical and Judicial Affairs Report 4-A-04, "Financial Incentives to Patients for Referrals." The report concludes that referral incentives may compromise the truthfulness of information patients share with others seeking the services of a physician. The Council issues this Opinion, which is based on CEJA Report 4-A-04. It will appear in the next version of *PolicyFinder* and the next print edition of the *Code of Medical Ethics*.

#### E-6.021 Financial Incentives to Patients for Referrals

Physicians should not offer financial incentives or other valuable considerations to patients in exchange for recruitment of other patients. Such incentives can distort the information that patients provide to potential patients, thus distorting the expectations of potential patients and compromising the trust that is the foundation of the patient-physician relationship.

Issued December 2004 based on the report "Financial Incentives to Patients for Referrals," adopted June 2004.

## 3. PHYSICIAN OBLIGATION IN DISASTER PREPAREDNESS AND RESPONSE

### HOUSE ACTION: FILED

At the 2004 Annual Meeting, the House of Delegates adopted the recommendations of Council on Ethical and Judicial Affairs Report 6-A-04, "Physician Obligation in Disaster Preparedness and Response." This report offers guidance to the medical profession on the ethical obligations that arise in the face of adversity. The Council issues this Opinion, which is based on CEJA Report 6-A-04. It will appear in the next version of *PolicyFinder* and the next print edition of the *Code of Medical Ethics*.

#### E-9.067 Physician Obligation in Disaster Preparedness and Response

National, regional, and local responses to epidemics, terrorist attacks, and other disasters require extensive involvement of physicians. Because of their commitment to care for the sick and injured, individual physicians have an obligation to provide urgent medical care during disasters. This ethical obligation holds even in the face of greater than usual risks to their own safety, health or life. The physician workforce, however, is not an unlimited resource; therefore, when participating in disaster responses, physicians should balance immediate benefits to individual patients with ability to care for patients in the future.

In preparing for epidemics, terrorist attacks, and other disasters, physicians as a profession must provide medical expertise and work with others to develop public health policies that are designed to improve the effectiveness and availability of medical care during such events. These policies must be based on sound science and respect for patients. Physicians also must advocate for and, when appropriate, participate in the conduct of ethically sound biomedical research to inform these policy decisions. Moreover, individual physicians should take appropriate advance measures to ensure their ability to provide medical services at the time of disasters, including the acquisition and maintenance of relevant knowledge.

Issued December 2004 based on the report "Physician Obligation in Disaster Preparedness and Response," adopted June 2004.

#### 4. MEDICAL TESTIMONY

##### HOUSE ACTION: FILED

At the 2004 Annual Meeting, the House of Delegates adopted the recommendations of Council on Ethical and Judicial Affairs Report 12-A-04, "Medical Testimony." The report offers guidance to physicians who testify in legal proceedings, building on prior AMA policy and the efforts of other medical societies that currently engage in professional self-regulation related to the conduct of physicians who provide expert testimony. The Council rescinds the current Opinion E-9.07, "Medical Testimony," and issues this Opinion, based on CEJA Report 12-A-04. It will appear in the next version of *PolicyFinder* and the next print edition of the *Code of Medical Ethics*.

##### E-9.07 Medical Testimony

In various legal and administrative proceedings, medical evidence is critical. As citizens and as professionals with specialized knowledge and experience, physicians have an obligation to assist in the administration of justice.

When a legal claim pertains to a patient the physician has treated, the physician must hold the patient's medical interests paramount, including the confidentiality of the patient's health information, unless the physician is authorized or legally compelled to disclose the information.

Physicians who serve as fact witnesses must deliver honest testimony. This requires that they engage in continuous self-examination to ensure that their testimony represents the facts of the case. When treating physicians are called upon to testify in matters that could adversely impact their patients' medical interests, they should decline to testify unless the patient consents or unless ordered to do so by legally constituted authority. If, as a result of legal proceedings, the patient and the physician are placed in adversarial positions it may be appropriate for a treating physician to transfer the care of the patient to another physician.

When physicians choose to provide expert testimony, they should have recent and substantive experience or knowledge in the area in which they testify, and be committed to evaluating cases objectively and to providing an independent opinion. Their testimony should reflect current scientific thought and standards of care that have gained acceptance among peers in the relevant field. If a medical witness knowingly provides testimony based on a theory not widely accepted in the profession, the witness should characterize the theory as such. Also, testimony pertinent to a standard of care must consider standards that prevailed at the time the event under review occurred.

All physicians must accurately represent their qualifications and must testify honestly. Physician testimony must not be influenced by financial compensation; for example, it is unethical for a physician to accept compensation that is contingent upon the outcome of litigation.

Organized medicine, including state and specialty societies, and medical licensing boards can help maintain high standards for medical witnesses by assessing claims of false or misleading testimony and issuing disciplinary sanctions as appropriate.

Issued December 2004 based on the report "Medical Testimony," adopted June 2004.

## 5. PHYSICIAN PARTICIPATION IN SOLICITING CONTRIBUTIONS FROM PATIENTS

### HOUSE ACTION: FILED

At the 2004 Annual Meeting, the AMA House of Delegates adopted the recommendations of Council on Ethical and Judicial Affairs Report 7-A-04, "Physician Participation in Soliciting Contributions from Patients." This report offers guidance for ensuring that solicitation of contributions from patients does not compromise the integrity of the patient-physician relationship. The Council issues this Opinion, which is based on CEJA Report 7-A-04. It will appear in the next version of *PolicyFinder* and the next print edition of the *Code of Medical Ethics*.

#### E-10.018 Physician Participation in Soliciting Contributions from Patients

Donations play an important role in supporting and improving a community's health care. Physicians are encouraged to participate in fundraising and other solicitation activities while protecting the integrity of the patient-physician relationship, including patient privacy and confidentiality, and ensuring that all donations are fully voluntary. In particular:

1. Appropriate means of soliciting contributions include making information available in a reception area and speaking at fundraising events. Physicians should avoid directly soliciting their own patients, especially at the time of a clinical encounter. They should reinforce the trust that is the foundation of the patient-physician relationship by being clear that patients' welfare is the primary priority and that patients need not contribute in order to continue receiving the same quality of care.
2. The greater the separation between the request and the clinical encounter, the more acceptable the solicitation is likely to be.
3. When physicians participate in solicitation efforts as members of the general community, they should seek to minimize perceptions of overlap with their professional roles.
4. Physicians in institutions that rely on fundraising personnel for donation requests should work to protect privacy and confidentiality of patient information. In particular, physicians should ensure that any patient information used for solicitation activities reveals only basic demographic data, not personal health information. When the medical service delivered or the diagnosis is identifiable by the nature of the physician's practice or the physician's specialty, permission from the patient should be obtained prior to divulging any information to third parties.
5. When patients initiate requests to contribute, physicians should refer them to appropriate sources of information or fundraising personnel.

Issued December 2004 based on the report "Physician Participation in Soliciting Contributions from Patients," adopted June 2004.

## 6. SURROGATE DECISION-MAKING, AMENDMENT

### HOUSE ACTION: FILED

The careful review of Opinion E-8.081, "Surrogate Decision-Making," that was undertaken in addressing Resolution 2 (A-03), "Selection of Health Care Decision-Making Surrogates," prompted the Council on Ethical and Judicial Affairs to suggest changes to the Opinion. In particular, CEJA believes that Opinion E-8.081 should acknowledge legal standards at the state level that may restrict surrogate decision-makers' authority. The Council also aims to clarify the scope of the Opinion through other minor changes. These amendments were presented as an appendix to CEJA Report 3-A-04, "Selection of Health Care Decision-Making Surrogates," which recommended that the CEJA Opinion be amended accordingly at the 2004 Interim Meeting of the House of Delegates. The amended Opinion will appear in the next version of *PolicyFinder* and the next print edition of the *Code of Medical Ethics*.

## E-8.081 Surrogate Decision-Making

Competent adults may formulate, in advance, preferences regarding a course of treatment in the event that injury or illness causes severe impairment or loss of decision-making capacity. These preferences generally should be honored ~~followed~~ by the health care team out of respect for patient autonomy. Patients may establish an advance directive by documenting their treatment preferences and goals in a living will or by designating a health care proxy (durable power of attorney for health care) to make health care decisions on their behalf.

In some instances, a patient with diminished or impaired decision-making capacity can participate in various aspects of health care decision-making. The attending physician should promote the autonomy of such individuals by involving them to a degree commensurate with their capabilities.

~~If an incompetent patient is to receive medical treatment lacks the capacity to make a health care decision, a reasonable effort should be made to identify a prior written expression of values such as a pertinent living will, or a health care proxy. the presence of an advance directive. When such a patient lacks a documented advance directive, or when reasonable efforts have failed to uncover such relevant documentation, physicians should consult defer to state law to identify a surrogate decision maker. Physicians should be aware that under special circumstances (for example, reproductive decisions for individuals who are incompetent), state laws may specify court intervention. In the absence of state law specifying either appropriate surrogate decision-makers or a process to identify them, the patient's family, domestic partner, or close friend should become the surrogate decision-maker. Family includes persons with whom the patient is closely associated such as close friends or unmarried living partners. In the case wWhen there is no family, domestic partner, or close friend, but there are persons who have some relevant knowledge of the patient, such persons should participate in the decision-making process. In all other instances, a physician may wish to consult utilize an ethics committee to aid in identifying a surrogate decision-maker or to facilitate sound decision-making.~~

When there is evidence of the patient's preferences and values, decisions concerning the patient's care should be made by substituted judgment. This entails considering the patient's advance directive (if any), the patient's views values about life and how it should be lived, how the patient has constructed his or her identity or life story, and the patient's attitudes towards sickness, suffering, and certain medical procedures.

~~In some instances, a patient with diminished or impaired decision making capacity can participate in various aspects of health care decision making. The attending physician should promote the autonomy of such individuals by involving them to a degree commensurate with their capabilities.~~

If there is no reasonable basis on which to interpret how a patient would have decided, the decision should be based on the best interests of the patient, or the outcome that would best promote the patient's well-being. Factors that should be considered when weighing the harms and benefits of various treatment options include the pain and suffering associated with treatment, the degree of and potential for benefit, and any impairments that may result from treatment. Any quality of life considerations should be measured as the worth to the individual whose course of treatment is in question, and not as a measure of social worth. One way to ensure that a decision using the best interest standard is not inappropriately influenced by the surrogate's own values is to determine the course of treatment that most reasonable persons would choose for themselves in similar circumstances.

Physicians should recognize the proxy or surrogate as an extension of the patient, entitled to the same respect as the competent patient. Physicians should provide advice, guidance, and support; explain that decisions should be based on substituted judgment when possible and otherwise on the best interest principle; and offer relevant medical information as well as medical opinions in a timely manner. In addition to the physician, other hospital staff or ethics committees are often helpful to providing support for the decision-makers.

In general, physicians should respect decisions ~~that are~~ made by the appropriately designated surrogate ~~and based on the standard basis of sound substituted judgment reasoning or the best interest standard.~~ In cases where there is a dispute among family members, physicians should work to resolve the conflict through mediation. Physicians or an ethics committee should try to uncover the reasons that underlie the disagreement and present information that will facilitate decision-making. When a physician believes that a decision is clearly not what the patient would have decided, ~~or could not be reasonably judged to be within the patient's best interests, or primarily serves the interest of a surrogate or a third party, the dispute should be referred to an ethics committee~~ should be consulted before requesting court intervention ~~resorting to the courts.~~

Physicians should encourage their patients to document their treatment preferences or to appoint a health care proxy with whom they can discuss their values regarding health care and treatment in advance. Because documented advance directives are often not available in emergency situations, physicians should emphasize to patients the importance of discussing treatment preferences with individuals who are likely to act as their surrogates. (I, III, VIII)

Issued December 2001 based on the report "Surrogate Decision-Making," adopted June 2001; updated December 2004.

## APPENDIX

The amended Opinion would read as follows:

### E-8.081 Surrogate Decision Making

Competent adults may formulate, in advance, preferences regarding a course of treatment in the event that injury or illness causes severe impairment or loss of decision-making capacity. These preferences generally should be honored by the health care team out of respect for patient autonomy. Patients may establish an advance directive by documenting their treatment preferences and goals in a living will or by designating a health care proxy (durable power of attorney for health care) to make health care decisions on their behalf.

In some instances, a patient with diminished or impaired decision-making capacity can participate in various aspects of health care decision-making. The attending physician should promote the autonomy of such individuals by involving them to a degree commensurate with their capabilities.

If a patient lacks the capacity to make a health care decision, a reasonable effort should be made to identify a prior written expression of values such as a pertinent living will, or a health care proxy. When reasonable efforts have failed to uncover relevant documentation, physicians should consult state law. Physicians should be aware that under special circumstances (for example, reproductive decisions for individuals who are incompetent), state laws may specify court intervention. In the absence of state law specifying either appropriate surrogate decision-makers or a process to identify them, the patient's family, domestic partner, or close friend should become the surrogate decision-maker. When there is no family, domestic partner, or close friend, persons who have some relevant knowledge of the patient should participate in the decision-making process. In all other instances, a physician may wish to consult an ethics committee to aid in identifying a surrogate decision-maker or to facilitate sound decision-making.

When there is evidence of the patient's preferences and values, decisions concerning the patient's care should be made by substituted judgment. This entails considering the patient's advance directive (if any), the patient's views about life and how it should be lived, how the patient has constructed his or her identity or life story, and the patient's attitudes towards sickness, suffering, and certain medical procedures.

If there is no reasonable basis on which to interpret how a patient would have decided, the decision should be based on the best interests of the patient, or the outcome that would best promote the patient's well-being. Factors that should be considered when weighing the harms and benefits of various treatment options include the pain and suffering associated with treatment, the degree of and potential for benefit, and any impairments that may result from treatment. Any quality of life considerations should be measured as the worth to the individual whose course of treatment is in question, and not as a measure of social worth. One way to ensure that a decision using the best interest standard is not inappropriately influenced by the surrogate's own values is to determine the course of treatment that most reasonable persons would choose for themselves in similar circumstances.

Physicians should recognize the proxy or surrogate as an extension of the patient, entitled to the same respect as the competent patient. Physicians should provide advice, guidance, and support; explain that decisions should be based on substituted judgment when possible and otherwise on the best interest principle; and offer relevant medical information as well as medical opinions in a timely manner. In addition to the physician, other hospital staff or ethics committees are often helpful to providing support for the decision-makers.

In general, physicians should respect decisions that are made by the appropriately designated surrogate and based on the standard of substituted judgment or best interest. In cases where there is a dispute among family members, physicians should work to resolve the conflict through mediation. Physicians or an ethics committee should try to uncover the reasons that underlie the disagreement and present information that will facilitate decision-making. When a physician believes that a decision is clearly not what the patient would have decided, could not be reasonably judged to be within the patient's best interests, or primarily serves the interest of a surrogate or a third party, an ethics committee should be consulted before requesting court intervention.

Physicians should encourage their patients to document their treatment preferences or to appoint a health care proxy with whom they can discuss their values regarding health care and treatment in advance. Because documented advance directives are often not available in emergency situations, physicians should emphasize to patients the importance of discussing treatment preferences with individuals who are likely to act as their surrogates. (I, III, VIII)

Issued December 2001 based on the report "Surrogate Decision-Making," adopted June 2001; updated December 2004.

## **7. ARTIFICIAL INSEMINATION BY KNOWN DONOR, AMENDMENT**

### **HOUSE ACTION: FILED**

Upon reviewing Opinions that address HIV/AIDS, and upon further consultation at the Open Forum held at the 2004 Annual Meeting of the House of Delegates, the Council on Ethical and Judicial Affairs has determined that in several instances the specific focus on HIV/AIDS is unjustified. Rather, the focus ought to be expanded to include other blood-borne pathogens. Furthermore, the Council has identified legal language in this particular Opinion that does not belong in such an ethics policy. For this reason, CEJA is amending Opinion E-2.04, "Artificial Insemination by Known Donor" as follows. The amended Opinion will appear in the next version of *PolicyFinder* and the next print edition of the *Code of Medical Ethics*.

#### **E-2.04 Artificial Insemination by Known Donor.**

Any individual or couple contemplating artificial insemination by husband, partner, or other known donor should be counseled about the full range of infectious and genetic diseases for which the donor or recipient can be screened, including communicable disease agents and diseases. ~~HIV infection.~~ Full medical history disclosure and appropriate diagnostic screening should be recommended to the donor and recipient but are not required.

Informed consent for artificial insemination should include disclosure of risks, benefits, and likely success rate of the method proposed and potential alternative methods. Individuals should receive information about screening, costs, and procedures for confidentiality, when applicable. The prospective parents or parent should be informed of the laws regarding the rights of children conceived by artificial insemination, as well as the laws regarding parental rights and obligations.—~~If the donor is married to the recipient, resultant children will have all the rights of a child conceived naturally.~~

~~If the donor and recipient are not married, an appropriate legal rule would treat the situation as if the donor were anonymous: the recipient would be considered the sole parent of the child except in cases where both donor and recipient agree to recognize a paternity right.~~

Sex selection of sperm for the purposes of avoiding a sex-linked inheritable disease is appropriate. However, physicians should not participate in sex selection for reasons of gender preference. Physicians should encourage a prospective parent or parents to consider the value of both sexes.

If semen is frozen and the donor dies before it is used, the frozen semen should not be used or donated for purposes other than those originally intended by the donor. If the donor left no instructions, it is reasonable to allow the remaining partner to use the semen for artificial insemination but not to donate it to someone else. However, the donor should be advised of such a policy at the time of donation and be given an opportunity to override it. (I, V) Issued June 1993; updated December 2004.

## 8. ARTIFICIAL INSEMINATION BY ANONYMOUS DONOR, *AMENDMENT*

### HOUSE ACTION: FILED

Upon reviewing its opinions that address HIV/AIDS, the Council on Ethical and Judicial Affairs has determined that in several instances the specific focus on HIV/AIDS is unjustified. Rather, the focus ought to be expanded to include other blood-borne pathogens. For this reason, CEJA is amending Opinion E-2.05, “Artificial Insemination by Anonymous Donor.” The amended Opinion will appear in the next version of *PolicyFinder* and the next print edition of the *Code of Medical Ethics*.

#### E-2.05 Artificial Insemination by Anonymous Donor.

Thorough medical histories must be taken of all candidates for anonymous semen donation. All potential donors must also be screened for infectious or inheritable diseases which could adversely affect the recipient or the resultant child. Frozen semen should be used for artificial insemination because it enables the donor to be tested for communicable disease agents and diseases ~~HIV infection~~ at the time of donation, and again after an interval before the original semen is used, thus increasing the likelihood that the semen is free of ~~HIV infection~~ blood-borne pathogens. Physicians should rely on the guidelines formulated by relevant professional organizations, such as the American Society of Reproductive Medicine, the Centers for Disease Control and Prevention, and the Food and Drug Administration, in determining ~~the interval between the initial and final HIV test,~~ which disorders to screen for, and which procedures to use in screening. Physicians should maintain a permanent record which includes both identifying and non-identifying health and genetic screening information. Other than exceptional situations where identifying information may be required, physicians should release only non-identifying health-related information in order to preserve the confidentiality of the semen donor.

Physicians should maintain permanent records of donors to fulfill the following obligations: (1) to exclude individuals from the donor pool who test positive for infectious or inheritable diseases, (2) to limit the number of pregnancies resulting from a single donor source so as to avoid future consanguineous marriages or reproduction, (3) to notify donors of screening results which indicate the presence of an infectious or inheritable disease, and (4) to notify donors if a child born through artificial insemination has a disorder which may have been transmitted by the donor.

Informed consent for artificial insemination should include disclosure of risks, benefits, likely success rate of the method proposed and potential alternative methods, and costs. Both recipients and donors should be informed of the reasons for screening and confidentiality. They should also know the extent of access to non-identifying and identifying information about the donor. Participants should be advised to consider the legal ramifications, if any, of artificial insemination by anonymous donor.

The consent of the husband is ethically appropriate if he is to become the legal father of the resultant child from artificial insemination by anonymous donor. Anonymous donors cannot assume the rights or responsibilities of parenthood for children born through therapeutic donor insemination, nor should they be required to assume them.

In the case of single women or women who are part of a homosexual couple, it is not unethical to provide artificial insemination as a reproductive option.

Sex selection of sperm for the purposes of avoiding a sex-linked inheritable disease is appropriate. However, physicians should not participate in sex selection of sperm for reasons of gender preference. Physicians should encourage a prospective parent or parents to consider the value of both sexes.

In general, it is inappropriate to offer compensation to donors to encourage donation over and above reimbursement for time and actual expenses. (I, V) Issued June 1993; updated December 2004.

## **9. CONFIDENTIALITY OF HIV STATUS ON AUTOPSY REPORTS, AMENDMENT**

### **HOUSE ACTION: FILED**

The Council on Ethical and Judicial Affairs proposes that Opinion E-5.057, "Confidentiality of HIV Status on Autopsy Reports" be rescinded. Indeed, Opinion E-5.051, "Confidentiality of Medical Information Postmortem," offers more extensive and comprehensive guidance on confidentiality protections after death, making Opinion E-5.057 unnecessary. Subsequent to the filing of this rescission, Opinion E-5.057 will be deleted from the next version of *PolicyFinder* and the next print edition of the *Code of Medical Ethics*.

## REPORTS OF COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS

The following reports, 1-5, were presented by Michael S. Goldrich, MD, Chair:

### 1. DIRECT-TO-CONSUMER DIAGNOSTIC IMAGING TESTS

#### HOUSE ACTION: REFERRED

Resolution 508 (I-01), “Inappropriate Medical Screening Tests” and Resolution 509 (A-02), “Commercialized Medical Screening” raised concerns regarding the emergence into the market place of “commercial medical screening,” wherein tests are advertised directly to consumers. Thus, patients without referral from a physician can pay to be tested for a broad range of conditions. Together, these resolutions called for a close examination of the use of such tests, their effectiveness, and their marketing.

At the 2003 Annual Meeting, the Council on Scientific Affairs (CSA) presented its report on scientific aspects of three specific diagnostic imaging tests (electron beam computed tomography (CT) for determining coronary artery calcification, spiral CT for lung cancer screening, and CT colonography for colon cancer screening). The CSA report was built upon the premise that preventive services should be supported by evidence that demonstrates improved health outcomes or quality of life, as well as cost-effectiveness (Policy H-425.997, AMA Policy Database). It briefly discussed issues of sensitivity, specificity, and predictive value regarding screening tests, and highlighted that to be considered effective, screening tests should be capable of detecting a high proportion of disease in preclinical phase, among other criteria. Overall, the report concluded that evidence was currently lacking to support these three specific tests without referral by a physician. Finally, in its recommendations, the CSA noted “That considering the summary information in this report, the Council on Ethical and Judicial Affairs [should] further consider the ethical ramifications of commercialized medical screening.”

The proliferation of direct-to-consumer diagnostic imaging tests, including full-body scans, raises not only scientific and policy questions regarding effectiveness and overall costs but also ethical questions regarding the limited clinical encounter that takes place between patient and physician. This report, therefore, focuses on the role of the physician involved in delivering direct-to-consumer diagnostic imaging tests and also considers issues related to their commercialization. This report does not address other diagnostic tests that may be available to patients without referrals, such as pregnancy tests, HIV tests, genetic screening, or other laboratory tests.

#### MEDICAL ENCOUNTERS TO PROVIDE PREVENTIVE SERVICES

All encounters between patients and physicians need not stem from symptoms of a possible medical illness or be related to therapeutic interventions. Indeed, there has been considerable emphasis on preventive care, as physicians can play an important role in assisting patients to maintain good health. However, there also has been substantial debate in recent years regarding various preventive services and their clinical validity, particularly in relation to expanding use of imaging technology. In the face of uncertainty, large-scale studies have been undertaken to better assess the benefits and harms of various interventions. When findings from such research have failed to support common practices, there has been much confusion among the public. As much as possible, medical practice should be based on evidence; similarly, preventive services should be rigorously evaluated before they are widely adopted.

#### *Screening Tests and Informed Consent*

Whenever offering tests, whether for diagnostic workup or for screening purposes, physicians generally must obtain informed consent. Moreover, the ethical and legal principles of a patient’s right to self-determination and physicians’ concurrent obligation to respect patients’ autonomy generally require that physicians and patients engage in a shared decision-making process. This entails physicians sharing with patients information that addresses the nature of the test, the reasons for it, and the benefits that may result (i.e., diagnostic information). In addition, any physical risks inherent in an imaging test, as well as other risks such as ambiguous results that necessitate further testing, and alternatives to the test (with their respective advantages and disadvantages) must be communicated. By presenting such information in addition to their own recommendations, physicians generally seek the patient’s understanding and authorization to proceed. This exchange of information is intended to help patients make choices that are aligned with their own values and preferences. When the goal of mutual understanding and agreement has been reached, the ethical requirements for informed consent have been fulfilled.

When tests are performed in asymptomatic patients, it is imperative that physicians explain their nature and possible results. Overall, physicians must be able to explain to patients that some tests are more or less accurate and that results may not be definitive but may merely reveal increased probabilities that a certain condition may develop. When presenting risks of testing, physicians must discuss the possibility of false negatives: if this is not mentioned, the patient may leave with a (false) sense of well-being and later ignore symptoms of ill health. The possibility of false positives--a frequent outcome of CT screening--may lead to additional tests, costs, and anxiety. Even true negative results must be explained carefully, since a patient may otherwise have the impression that unhealthy behavior can be continued--for example, continuing smoking because a lung scan was negative. On a more positive note, there may be some psychological benefit if a test accurately detects no disease. Yet, physicians must not capitalize on patients' fears and should not offer testing when, in their judgments, the risks outweigh the potential benefit (e.g., given the patient's age and medical history, the low probability of a positive finding is outweighed by the risks of the procedure). Overall, physicians must communicate in terms that patients can understand the unique aspects of diagnostic and screening tests including their specificity, sensitivity, and predictive value.

Although the benefits of positive findings may appear straightforward, detection of a condition may have no effect on morbidity or mortality. Therefore, before testing, physicians also should discuss the implications of positive findings, including the likelihood of successful treatment.

#### *Limitations of Direct-to-Consumer Diagnostic Imaging Services*

In the context of certain imaging tests, it has been argued that patients should be permitted to access and pay for such tests without a referral because the risk of physical harm caused by the test is minimal. This is a departure from the practice of tests being ordered within an existing patient-physician relationship, in which either the physician ordering the test or the one performing it is available to discuss the test and its results, and to offer treatment options or other follow-up advice as may be necessary. Such discussion and follow-up are necessary even through there may be few or no options for treatment.

A study of self-referred full body CT imaging found that follow-up often is lacking. A large proportion of centers offering such tests simply mail results to the patient; a smaller proportion of centers provided results during a consultation between a physician and the patient; and only one center mailed results to the patient's primary care physician after a consultation.

### OFFERING NEW TECHNOLOGIES

#### *Assessment of New Technologies*

The profession has certain responsibilities in the development of new medical knowledge, including helping to determine the safety, efficacy, and appropriateness of new treatments or products. Some have argued that new technologies should be tested in a controlled setting before broad clinical adoption. Moreover, "foregoing this step may jeopardize future research, place the patient at risk of unexpected health consequences due to invasive follow-up, and lead to unwarranted health care expenditures well beyond the out-of-pocket expense initially incurred."

The American College of Radiology, in a statement on CT screening examinations, has concluded that more research is necessary to evaluate whether lung scanning, coronary artery calcium scoring, and virtual colonoscopy are clinically valid or reduce the rate of mortality. The ACR has concluded that there is not sufficient evidence to justify recommending total body CT screening to patients with no symptoms or family history suggesting disease.

According to Opinion E-2.19, "Unnecessary Services," physicians should not provide medical services that they know are unnecessary. Medical services should always be based on scientific evidence, sound medical judgment, relevant professional guidelines, and due concern for economic prudence, as well as patient preferences.

#### *Considerations of Cost*

At a societal level, one of the most vexing concerns about new high-technology imaging tests is the question of costs. Although at this time direct-to-consumer tests are not reimbursed by health plans and therefore are available only to patients who are able to pay for them out-of-pocket, follow-up tests generally are covered by health plans. From this perspective, some commentators have criticized the practice of some hospitals to offer such screening programs as a means of generating income through the follow-up testing that is required to validate a positive test.

These commentators also have pointed out that many patients who are asymptomatic but desire high technology imaging tests, rather than self-referring and paying out-of-pocket, are seeking a referral with a false diagnosis by their physicians. The impact of pressure to “game the system” has been analyzed elsewhere, and the practice has been condemned by CEJA: Opinion E-9.132, “Health Care Fraud and Abuse,” states that “Physicians should make no intentional misrepresentations...to secure non-covered health benefits for their patients.”

### *Commercial Motivations*

The Council previously has noted that ownership interests in health care facilities can lead to conflicts of interest, whereby physicians’ clinical judgment may be unduly influenced by the prospect of financial gains from referrals. When a physician holds financial interests in a diagnostic imaging facility, every test carried out increases revenues, and every test not done represents a financial loss. In such circumstances, physicians should be guided by the warning not to provide, prescribe, or seek compensation for medical services that are unnecessary.

Commercial pressures are likely to be amplified when physicians who offer diagnostic imaging tests advertise their services directly to the public. Direct-to-consumer advertising can create false expectations and can compromise patient care rather than enhance it, especially when it does not appropriately convey to patients the risks involved in using a product or undergoing a treatment. Direct-to-consumer advertising regarding diagnostic imaging tests is likely to create the same kind of expectations unless it is truthful, easily comprehensible, and is not intended to mislead or deceive patients.

Physicians who offer direct-to-consumer diagnostic imaging services must be mindful that patients trust physicians’ medical expertise and rely on their advice to identify appropriate or necessary care. Patients’ desires and ability to pay are not sufficient by themselves to justify the provision of care when risks are present; balancing of benefits and harms is necessary. Physicians can preserve the professional ethos of medicine only by placing patients’ medical interests above their own financial interests.

### CONCLUSION

Many concerns regarding the medical validity of patient-requested diagnostic imaging tests have been raised by the Council on Scientific Affairs. Ideally, these services should be supported by evidence demonstrating improved health outcomes or quality of life, as well as cost-effectiveness. At this time, scientific data is insufficient to support broad access to these tests; more needs to be known about their predictive value, sensitivity, and specificity. While consumers may believe that these tests can bring psychological and emotional benefits, this also remains to be studied. Necessary data can only be gathered through carefully developed research protocols. Diagnostic imaging services that are performed without referral and outside of research protocols run counter to the medical profession’s intent to develop and use new technologies in a manner that is evidence-based and economically responsible.

### RECOMMENDATIONS

The Council on Ethical and Judicial Affairs recommends that the following be adopted and the remainder of this report be filed:

Diagnostic imaging services are being offered without prior referral by a personal physician. Many such services lack sufficient scientific data to validate their use and to support broad access to them. Accordingly, physicians and relevant specialty societies should advocate for the conduct of appropriate trials aimed at determining the predictive power of the tests, and their sensitivity and specificity for target abnormalities.

Physicians providing such imaging services are bound by the following ethical guidelines:

1. Performance of a diagnostic imaging test at the request of an individual is justifiable only if, in the judgment of the physician, the potential benefit of the service outweighs the physical and emotional risks.

2. Once a physician agrees to perform the test, a patient-physician relationship is established with all the obligations such a relationship entails. (See Opinion E-10.01, "Fundamental Elements of the Patient-Physician Relationship" and Opinion E-10.015, "The Patient-Physician Relationship.") In the absence of a referring physician who orders the test, the testing physician assumes responsibility for the patient's clinical evaluation, as well as pre-test and post-test counseling concerning the test and possible results.
3. In obtaining the patient's informed consent (see Opinion E-8.08, "Informed Consent"), the testing physician should discuss, in a manner the patient can understand, the following aspects of a test:
  - its nature, the reasons for performing it, and possible findings;
  - the risks and benefits that may flow from the test, including reassurance by a true negative finding;
  - alternatives to the test, including no test, and their respective advantages and disadvantages;
  - the inaccuracies inherent in testing and the possibility of inconclusive results or false positives and false negatives, which may require further assessment and additional costs.
4. After completion of the diagnostic imaging test, results should be discussed with the patient, either by the testing physician or by a qualified physician to whom the patient is referred. Post-test discussions should include appropriate advice regarding follow-up tests, medical treatment, or other intervention.
5. Physicians who hold financial interests in imaging facilities must not place those interests above the welfare of their patients, as stated in Opinions E-8.03, "Conflicts of Interest: Guidelines" and E-8.032, "Conflicts of Interest: Health Facility Ownership by a Physician." Moreover, physicians who advertise diagnostic imaging services should ensure that advertisements are truthful, easily comprehensible, and not misleading or deceptive.

(References pertaining to Report 1 of the Council on Ethical and Judicial Affairs are available from the Ethics Standards Group. The Council also gratefully acknowledges the American College of Radiology Committee on Ethics for its contributions to this report.)

## **2. DISCIPLINE OF IMPAIRED PHYSICIANS BY CEJA (RESOLUTION 2, I-03)**

### **HOUSE ACTION: RECOMMENDATION ADOPTED AND REMAINDER OF REPORT FILED**

This report responds to inquiries made to the Council on Ethical and Judicial Affairs, regarding its disciplinary policies and procedures affecting American Medical Association members and applicants with a history of impairment. Particularly, Resolution 2 (I-03), introduced by the Oklahoma Delegation, called upon CEJA to give substantial weight to an impaired physician's status with the applicable state medical association and participation in a state-sponsored physicians health program (PHP). The resolution also called upon CEJA to adopt certain procedures into its rules whereby a case would be held in abeyance if a recovering physician was in good standing with the state medical association and was participating in such a PHP. Absent other circumstances, a conclusion to the case would be provided that would not result in a sanction reportable to the National Practitioner Data Bank (NPDB).

Resolution 2 (I-03) was referred to the Board of Trustees and assigned to CEJA to respond directly. This report describes CEJA's rules and practices regarding the discipline of impaired physicians.

## BACKGROUND

### *AMA Bylaws*

The following sections of the AMA Bylaws are most relevant to this report:

- 1.111 Admission.** A person eligible for active constituent membership in the American Medical Association becomes a member of the AMA upon certification by the secretary of the constituent association to the Executive Vice President of the AMA, provided there is no disapproval by the Council on Ethical and Judicial Affairs. The Council may consider information pertaining to the character, ethics, professional status and professional activities of the applicant. The Council shall provide by rule for an appropriate hearing procedure to be provided to the applicant.
- 1.121 Admission.** Active direct members are admitted to membership upon application to the Executive Vice President of the American Medical Association, provided that there is no disapproval by the Council on Ethical and Judicial Affairs. The Council may consider information pertaining to the character, ethics, professional status and professional activities of the applicant. The Council shall provide by rule for an appropriate hearing procedure to be provided to the applicant.
- 1.20 Maintenance of Membership.** A member may hold only one type of membership in the American Medical Association at any one time. Membership may be retained only as long as the member complies with the provisions of the Constitution and Bylaws and Principles of Medical Ethics of the AMA.
- 1.61 Active Constituent Members.**
- 1.611** The Council on Ethical and Judicial Affairs, after due notice and hearing may censure, suspend or expel an active constituent member from the American Medical Association for an infraction of the Constitution or these Bylaws, for a violation of the Principles of Medical Ethics, or for unethical or illegal conduct.
- 1.62 All Other Members.**
- 1.621** The Council on Ethical and Judicial Affairs, after due notice and hearing, may censure, suspend or expel any active direct, affiliate, honorary or international member of the AMA for an infraction of the Constitution or these Bylaws, for a violation of the Principles of Medical Ethics, or for unethical or illegal conduct.
- 6.403 Original Jurisdiction.** The Council on Ethical and Judicial Affairs shall have original jurisdiction in:
- 6.4031** All questions involving membership as provided in 1.111, 1.121, 1.131, 1.151, 1.611 and 1.62 of these Bylaws.

### *The Health Care Quality Improvement Act*

The Health Care Quality Improvement Act, 42 USC §§11101, et seq., includes the following provisions, also relevant to this report:

42 USC §11133(a)(1)(C). Reporting of certain professional review actions taken by health care entities

Each health care entity which...is a professional society [and which] takes a professional review action which adversely affects the membership of a physician in the society, shall report to the Board of Medical Examiners [disciplinary information, which shall be forwarded to the National Practitioner Data Bank].

42 USC §11151. Definitions

(1) The term “adversely affecting” includes reducing, restricting, suspending, revoking, denying, or failing to renew...membership in a health care entity.

\* \* \* \* \*

(9) The term “professional review action” means an action or recommendation of a professional review body which is taken or made in the conduct of professional review activity, which is based on the competence or professional conduct of an individual physician (which conduct affects or could affect adversely the health or welfare of a patient or patients), and which affects (or may affect) adversely the...membership in a professional society, of the physician. Such term includes a formal decision of a professional review body not to take an action or make a recommendation described in the previous sentence and also includes professional review activities relating to a professional review action.

#### *Relevant AMA Policies*

Most persons suffering from alcoholism or other chemical dependencies, if treated under medical supervision and with continuous monitoring, can undertake normal professional responsibilities (H-30.974, AMA Policy Database). Accordingly, AMA policy encourages state medical societies to establish treatment programs for physicians suffering from alcoholism or substance abuse, and also encourages medical licensing boards to utilize the services of state medical society treatment programs to treat and monitor physicians in those programs (H-95.955 and H-275.964; see also AMA Model Impaired Physician Treatment Act).

More recently, the Council developed ethical guidance on physician health and wellness that emphasizes intervention and rehabilitation over sanctions (E-9.0305). Concurrently, the Council amended Opinion E-9.031, “Reporting Impaired, Incompetent, or Unethical Colleagues,” to clarify the instances when an impaired physician should be reported (See also E-8.121(2)(d), H-275.952, and H-275.998). Notwithstanding these Opinions, it remains unethical for a physician to practice medicine while under the influence of alcohol or other chemical agents that impair the ability to practice medicine (E-8.15).

Moreover, medical societies have a civic and professional obligation to report to the appropriate governmental body or state board of medical examiners credible evidence that may come to their attention involving the alleged criminal conduct of any physician relating to the practice of medicine (E-9.04).

#### CEJA DISCIPLINARY PROCEDURES REGARDING IMPAIRED PHYSICIANS

##### *CEJA Disciplinary Function*

As previously reported in the CEJA Report 5-A-03, “Professional Self-Regulation and the Judicial Function of the Council on Ethical and Judicial Affairs,” the Council generally considers disciplinary cases in which a physician previously has been found liable or has been sanctioned by a criminal court, a licensing board, a governmental agency such as the Federal Drug Enforcement Agency, or other investigative body.

Such information comes to the attention of the AMA through two principal channels. Specifically, a review by CEJA can be triggered by statements made in the membership application form,\* or by a report to the AMA of a disciplinary action taken by a state licensing board, a medical society, or hospital. In particular, state licensing authorities have communicated licensure information to the AMA for many years supporting the AMA’s overall credentialing activities for US physicians, irrespective of AMA membership.

Except in the rarest of circumstances, CEJA does not reexamine the sanction or penalty; rather, it confines its inquiry to evidence bearing on whether to impose sanctions against the existing member or to reject an application for membership.

---

\* Membership Qualifications Questions are as follows: 1. Have you been convicted of fraud or a felony within the last five years? 2. Has any action, in any jurisdiction, been taken regarding your license to practice medicine within the last five years or extending to within the last five years? This includes...[any] sanctions or conditions imposed upon a license. 3. Have you been the subject of any disciplinary action by any medical society or hospital staff within the last five years?

### *Scope of CEJA's Disciplinary Function*

The Council primarily imposes disciplinary sanctions on physicians who fall into one of the following categories established by a Board of Trustees Report on "AMA Initiative on Quality of Medical Care and Professional Self-Regulation - Review of Membership Rolls": (1) Conviction of fraud or a felony involving professional misconduct or moral turpitude; (2) Licensure revocation or forced surrender for reasons related to incompetence or unprofessional conduct; (3) Discharge from the armed forces or from government employ, based on incompetence or unprofessional conduct (BOT Report II, A-87). These infractions mandate systematic exclusion from the AMA, subject to proper notice to the physician and a right to a hearing.

Moreover, the BOT Report identified other intermediate sanctions such as probation, which are imposed for a wide range of misconducts that vary from one jurisdiction to another. Of particular importance for this CEJA report are sanctions against physicians for misconduct that was compounded by a finding of impairment that resulted in referral to a PHP. Examples include physicians who steal drugs from a hospital dispensary, perform surgical operations while inebriated, self-prescribe in violation of accepted medical or legal procedures, or traffic narcotics.

Importantly, a physician does not come to the Council's attention merely for being enrolled in a PHP. If a physician has enrolled in such a program prior to any disciplinary sanction by a licensing board, or if the licensing board simply has referred the physician to a PHP without imposing a reportable disciplinary sanction, the AMA does not receive any information related to the conduct of the physician.

When there is information that an ethical or legal violation occurred that merits CEJA's attention, the member or applicant is contacted to ascertain whether he or she wishes to present any additional information for CEJA's consideration. Based on all information that is presented to it, CEJA determines whether the physician's conduct may be excused or whether it warrants a plenary hearing. A plenary hearing affords the member or applicant the right to present further arguments or other information, including oral or written testimony by individuals familiar with the circumstances of the physician, such as an officer of a PHP. The Council never imposes a sanction without offering a hearing to the physician. If CEJA does take a disciplinary action, the decision is, to the extent required under the procedures of the Health Care Quality Improvement Act, reported to the National Practitioner Data Bank and to the respective state medical or national specialty societies.

### *Orders of Probation*

As explained in CEJA Report 5-A-03, the Council can place members on probation when they have committed intermediate offenses that do not warrant rejection of an application or revocation of membership. Generally, probation is imposed upon physicians who retain their medical licenses (possibly under an order of probation from their licensing board) and are able to demonstrate progress toward remediation or rehabilitation, which may include participation in a PHP. While on probation, AMA members are required to submit to the Council semi-annual written reports attesting to their conduct.

The AMA reports orders of probation, as well as their completion, to the National Practitioner Data Bank and to the applicable state licensing board. Physicians often perceive such reports to the NPDB as injurious or detrimental.

### *Monitoring Status*

Following recent dialogue with the Tennessee Medical Foundation, CEJA initiated a policy of "monitoring" certain physicians. Monitoring allows CEJA more flexibility when applicants or AMA members have committed less serious violations and they are well along the road to rehabilitation. In such instances, the physicians are required to submit semi-annual written reports on their participation in the PHP but the review does not adversely affect membership and is not reported to the NPDB or to a medical licensing board.

The Council employed monitoring for the first time in late 2003. The long-term utility and appropriateness of monitoring physicians remain to be determined. Much will depend upon the frequency of its use and administrative issues that might evolve.

## CONCLUSION

Resolution 2 (I-03) called upon CEJA to give substantial weight to an impaired physician's status with the applicable state medical association and participation in a state-sponsored physicians health program (PHP). The resolution also called upon CEJA to modify its rules such that, absent other circumstances, the case of a physician in good standing with the state medical association and participating in such a PHP would be held in abeyance and would not result in a sanction reportable to the National Practitioner Data Bank (NPDB).

The Council is mandated to review the membership status of any member or applicant who has been found to have violated the *Principles of Medical Ethics* or other ethical and legal obligations. Violations that result in licensing actions are often the cause for CEJA's review. A physician does not come to the Council's attention merely for being enrolled in a physician health program.

In recognition that some impaired physicians who come to CEJA's attention have committed less serious violations and may be well along the road to rehabilitation as demonstrated by their participation in a PHP, the Council already had implemented a "monitoring" status. This status does not affect membership, and is not reported to the NPDB. This specific practice and CEJA's overall procedures fulfill all of the requests made in Resolution 2 (I-03). The Council remains committed to supporting the recovery of physicians with substance abuse problems.

## RECOMMENDATION

The Council on Ethical and Judicial Affairs recommends the following and that the remainder of this report be filed:

That Resolution 2 (I-03) not be adopted.

### **3. PATIENT PRIVACY AND THIRD PARTIES TO THE CLINICAL ENCOUNTER**

#### **HOUSE ACTION: REFERRED**

Adoption of Resolution 8 (A-03), Patient Privacy and Sales Representatives, has established new policy that "oppose[s] the presence, inclusion or involvement of pharmaceutical sales representatives in clinical situations without the full knowledge and informed consent of patients" (Policy H-100.967, AMA Policy Database).<sup>\*</sup> The resolution also directed the AMA to promulgate appropriate guidelines to protect patient privacy and confidentiality and to prevent inappropriate intrusion into the doctor/patient relationship, in collaboration with the pharmaceutical industry.

In addition to the privacy and confidentiality concerns raised by the practice known as "shadowing," concerns may stem from arrangements termed "preceptorships," which entail a payment to physicians who agree to allow an industry representative to observe interactions with patients. In considering these practices, the Council on Ethical and Judicial Affairs has opted to examine more broadly instances in which other parties are privy to a patient-physician encounter.

#### **PATIENT-PHYSICIAN RELATIONSHIP AND PRIVACY**

The AMA's *Code of Medical Ethics* includes several opinions that make clear the importance of protecting patient privacy and the confidentiality of their health information. This key dimension of the therapeutic alliance is first noted in the *Principles of Medical Ethics*, which states that a physician "shall safeguard patient confidences and privacy within the constraints of the law."

---

<sup>\*</sup> Resolution 8 (A-03) was adopted in lieu of Resolution 15 (A-03), "Patient Shadowing," which directed "our American Medical Association [to] request that its members evaluate the ethical and confidentiality problems of pharmaceutical representatives shadowing physicians in order to follow their practice patterns;" and that "our AMA refer this issue of 'shadowing' to the AMA Council on Ethical and Judicial Affairs."

This Principle is elaborated in Opinion E-10.01, “Fundamental Elements of the Patient-Physician Relationship,” which states: “The patient has the right to confidentiality. The physician should not reveal confidential communications or information without the consent of the patient, unless provided for by law or by the need to protect the welfare of the individual or the public interest.” The notion of confidentiality is further elaborated in Opinion E-5.05, “Confidentiality,” which explains:

The information disclosed to a physician during the course of the relationship between physician and patient is confidential to the greatest possible degree. The patient should feel free to make a full disclosure of information to the physician in order that the physician may most effectively provide needed services. The patient should be able to make this disclosure with the knowledge that the physician will respect the confidential nature of the communication. The physician should not reveal confidential communications or information without the express consent of the patient, unless required to do so by law.

It can be reasonably assumed that health care professionals know, understand, and observe the tenets of confidentiality. The same cannot be said for individuals who are not health professionals, so any such individuals invited by a physician should not be permitted to observe a clinical encounter until the physician ensures that they understand and are committed to the same medical standards of confidentiality as are health professionals. The physician need not hold third parties invited by the patient to the same standard.

Recently, CEJA addressed the notion of privacy in Opinion E-5.059, “Privacy in the Context of Health Care:”

Physicians must seek to protect patient privacy in all of its forms, including physical, informational, decisional and associational. Such respect for patient privacy is a prerequisite to building the trust that is at the core of the patient-physician relationship.

....Physicians should be aware of and respect the special concerns of their patients regarding privacy. Patients should be informed of any significant infringement on their privacy of which they may otherwise be unaware.

With regard to patient’s health information, Opinion E-7.025, “Records of Physicians: Access by Non-Treating Medical Staff,” cautions that “Only physicians or other health care professionals who are involved in managing the patient...may access the patient’s confidential medical information. All others must obtain explicit consent to access the information.”

These policies recognize that, in the provision of health care, neither the claim to privacy nor the expectation of confidentiality can be absolute, but need to be balanced with other requirements. A similar balancing between the protection of patients’ legal right to the privacy of their personal health information and the use and transmission of this information has been enacted by the “Privacy Rule” of the Health Insurance Portability and Accountability Act (HIPAA).

### THIRD PARTIES AND THE THERAPEUTIC ENCOUNTER

The patient-physician encounter often is not exclusively private: multiple health care professionals participate in the provision of hospital-based care. Also, third parties who are not health professionals, such as interpreters and chaperones, may be present during medical encounters. Health professionals, including medical students, also may wish to observe a patient-physician encounter for educational purposes. The value of education, however, does not override the need for the patient to be aware of the individuals’ identity and role and to authorize participation (see Opinion E-8.087, “Medical Student Involvement in Patient Care”).

When a patient refuses inclusion of a third party such as a chaperone in the medical encounter, the physician must determine whether care can be provided safely and effectively without the third party. If the physician determines that a replacement for the third party is needed and the patient refuses inclusion of the new third party, the encounter may have to be canceled.

Other parties become involved in the patient-physician relationship when they accompany patients, such as parents of a minor or caregivers of an adult patient. The involvement of these third parties may be necessary when patients lack capacity to make health care decisions. At other times, patients may desire assistance or support during the medical encounter. This occasionally may raise concerns from the perspective of the physician, particularly when proper medical care necessitates private consultation with a patient. If possible, this should be explained in advance. In instances when a patient and a physician do not agree on the presence of such a third party, the patient should have an opportunity to seek care through means that accommodate the presence of another party.

Patient shadowing and preceptorships introduce into the patient-physician encounter third parties who are not health professionals and have goals other than patient care. Some are industry representatives who are engaged, directly or indirectly, in promoting products, and through their observation of patient-physician interactions, seek to understand and potentially influence the physician's decision-making process. It is important to distinguish personnel who facilitate or contribute to patient care from those wishing to observe patient-physician encounters for purposes other than the patient's benefit. For example, some industry representatives may become involved in the patient-physician encounter to train or assist physicians, as in the surgical implantation of medical devices. The third party's willingness to offer payment to access patient-physician encounters clearly indicates that these encounters advance the third parties' own goals, rather than the patient's. This undermines the patient-physician relationship; consequently, physicians should not accept payment from third parties to access clinical encounters.

Other third parties who are not health professionals, such as legislators, community leaders, or students, may occasionally be invited, with patients' consent, to observe patient-physician encounters, for the purpose of better understanding various aspects of medical practice and health care.

#### CONSENT TO THIRD PARTY INVOLVEMENT

Patient autonomy is expressed through the power to make choices. Although the right to self-determination relates most importantly to choosing among diagnostic and treatment options, it extends to other aspects of health care, such as controlling disclosure of health information. Therefore, whenever a third party is to be privy to a patient-physician encounter, the patient should be told the party's role, and generally should be afforded the opportunity to exclude from the encounter third parties who are not required for the provision of safe and efficient care.

It is important for physicians to recognize that some patients may want to exclude third parties, but feel uncomfortable refusing their presence. Physicians, therefore, must be alert to the possibility that the third party's presence negatively affects the interaction and compromises. On such occasions, the third party should be excluded. Also, it should be made clear to patients that they retain the right to refuse the third party's presence at any time during the encounter.

Finally, when patients lack decision-making capacity, physicians should discuss the inclusion of third parties in the medical encounter with the surrogate decision-makers. Observation by persons who are not health professionals of encounters between physicians and patients lacking decision-making capacity, however, represents a substantial invasion of privacy and generally should not be permitted.

#### CONCLUSION

Absolute privacy of the patient-physician encounter is often not possible, due to needed assistance by other professionals or patient caregivers. Nevertheless, physicians are ethically and legally bound to protect their patients' privacy, so the presence of non-clinical observers should be limited. Moreover, third parties should join a patient-physician encounter only after patients have been informed of the parties' roles and have given consent to their inclusion in the encounter. It is inappropriate for physicians to accept payment from third parties who are observers of patient-physician encounters.

## RECOMMENDATIONS

The Council on Ethical and Judicial Affairs recommends that the following be adopted and the remainder of this report be filed:

Physicians are ethically and legally responsible for safeguarding patient privacy. This responsibility requires that physicians inform patients of the involvement and roles of third parties, including members of the health care team (e.g., nurses, residents, students, and employees of outside companies who provide needed technical assistance), health professionals who are learning through observation, and observers who are not health professionals. Third parties who are not health professionals--other than those invited by the patient--must understand and be committed to the same medical standards of confidentiality as are health professionals.

Patients must agree to allow the presence of any third party during a medical encounter. When a patient refuses inclusion of a third party, the physician must determine whether care can then be provided safely and effectively. If it cannot, the physician may need to involve a replacement acceptable to both patient and physician, or to cancel the encounter. In some circumstances, such as concerns about abuse, it may be appropriate for physicians to exclude a third party who is accompanying the patient.

If a patient lacks decision-making capacity, the physician should obtain permission for the participation of third parties involved in the patient's care from a surrogate decision-maker. Third parties who are not health professionals may wish to observe encounters between physicians and patients who lack decision-making capacity; however, this represents a substantial invasion of privacy and should not be permitted, except under rare circumstances.

Some patients may feel uncomfortable refusing the presence of a third party. When a physician recognizes such a situation, it should be discussed with the patient until a mutually satisfactory resolution is reached. Physicians should avoid situations in which a third party's presence may negatively influence the medical interaction and compromise care.

Physicians should not accept payment from a third party to observe a medical encounter because accepting such payment may undermine the patient-physician relationship.

## 4. TRANSPLANTATION OF ORGANS FROM LIVING DONORS

### HOUSE ACTION: REFERRED

#### INTRODUCTION

Continuing scientific discoveries and innovation in the field of organ transplantation have increased the variety of organs that can be transplanted and the range of individuals who can donate or receive an organ. This explains a constantly increasing number of potential recipients waiting for organs, which has grown at a faster rate than organs have become available. This has resulted in a persistent shortage of organs for transplantation.

Many initiatives have endeavored to increase the number of organs available for transplantation. Some have focused on gaining a better understanding of what motivates individuals to consider organ donation. Others have focused on identifying new sources of organs, such as donation after cardiac death. From the first successful transplantation in the 1950s through the 1970s, kidneys came from living donors related to the recipients. Subsequently, cadaveric organs largely replaced organs from living donors, but efforts in the last decade to increase living donation are transforming the field. Since 2001, the majority of donated kidneys came from living rather than cadaveric donors. Moreover, living donors can donate not only kidneys, but also liver segments, lung lobes, and parts of other organs.

Living donors usually derive no physical benefit from a surgical procedure that presents the usual risks of surgery, including infection or death during or after surgery and temporary or permanent disability. They also face the risk of organ failure resulting in the need for transplantation. The probability and magnitude of risk varies with the

organ being donated. The risks to a kidney donor, for example, are fairly well understood, have a relatively low incidence, and are considered minimal beyond the regular risks of surgery; the risks to an individual who donates a liver, a procedure that is less common, are more significant.

Because living donors are initially healthy and voluntarily place themselves in harm's way, they require special protection. The purpose of this report is to examine living donation in the context of the goals of medicine and to develop guidelines for physicians who are involved in the transplantation of these organs.

#### LIVING DONATION AND THE GOALS OF THE MEDICAL PROFESSION

Principle VIII of the American Medical Association's *Principles of Medical Ethics* states, "A physician shall, while caring for a patient, regard responsibility to the patient as paramount." An initial question that arises is whether physician participation in the transplantation of organs from living donors is consistent with this Principle. The procedure presents risks, but no physical benefits to the living donor, so some argue that physician participation in the procedure is antithetical to the professional obligation to do no harm. At the very least, they maintain that living donors should be used only as a last resort for individuals who need a transplant, but have been unable to obtain one through the national waiting list. Yet, the medical profession has performed living donation because the lives of some patients with end organ failure depend on the organs in very short supply, and some individuals are willing to donate the organs needed to save or enhance the lives of these patients--usually the donors' relatives and friends.

This collaboration between the public and physicians is almost without parallel. The context, however, is not entirely unlike physicians' role in enrolling human subjects in phase 1 and 2 clinical trials, which usually do not offer direct benefits to participants. Under these circumstances, members of the profession have agreed to facilitate a process that entails risks but no physical benefit to willing participants for the benefit of others.

#### *Risks/Benefits Assessment*

Living donation provides an alternative for individuals awaiting transplantation and effectively increases the existing organ supply. In addition to likely reducing waiting time, organs from living donors provide other benefits to recipients: time to search for a well-matched organ, control over the operation's timing, and often a higher quality organ, thus improving the chance of short and long term survival of both the organ and the patient.

Several kinds of psychosocial benefits may accrue to the donor: rewarding feelings of altruism, empowerment, or increased self-esteem; a sense of closeness to the recipient, family, and/or the community; and satisfaction from having contributed to a valuable cause. Most of these benefits, however, are contingent on a positive outcome for the recipient. Bad outcomes for the recipient, including the possibility of death, may result in the donor feeling resentment, guilt, profound grief, or depression.

Benefits to donors often are related to the relationship between donor and recipient. Emotionally-connected donors may receive considerable psychological and emotional benefits because they have a bond with a relative, friend, or colleague who is suffering and in need. Benefits to altruistic donors--donors without a designated recipient--have not been measured, however. As such, it cannot be determined conclusively whether one type of living donor benefits from donation more than the other.

The risk-benefit balance of living organ donation cannot be calculated directly, but some relevant criteria can guide physicians through this process. At a minimum, a certain baseline should be met to justify the procedure. An offer of donation should not be accepted if the donation process presents a serious risk to the potential donor's life, health, or well-being or if the recipient is unlikely to fare well with a transplant, as this would place an unreasonable burden on the donor.

#### APPROPRIATE SAFEGUARDS FOR LIVING DONORS

Nationally, transplant centers have begun establishing policies for the protection of living donors, but the comprehensiveness and stringency of these policies vary among centers. It seems reasonable that health care professionals in this country be guided by the same baseline standards. The Council suggests such standards in this report.

Transplantation of organs from living donors should occur only when appropriate safeguards are pre-established. It is already a matter of AMA policy that donors and recipients should be assigned separate physicians to avoid actual or perceived conflicts of interest that could undermine the protection of individual patients' best interests. It also seems self-evident that a major responsibility of the health care team is to determine, on physical and psychosocial grounds, whether a potential living donor is an appropriate candidate.

### *Informed Consent*

#### Comprehensive Disclosure

Potential donors must understand relevant risks and benefits associated with the contemplated procedure. Physicians, in partnership with potential donors and assisted by appropriate members of the health care team, should evaluate how donation might affect a patient's overall mental or emotional well-being, personal relationships with the recipient, family and friends, and lifestyle and activities over time. Financial matters also should receive consideration, including health insurance coverage, employment status, and possible effect on dependents in case of a bad outcome for the donor.

In addition, complete disclosure requires that the potential donor receive information regarding the risks and benefits associated with the recipient's transplantation: possible loss of the transplanted organ, potential death of the recipient, and alternative treatment available to the recipient. This information may be relevant to the level of risk the potential donor is willing to accept.

#### Voluntary Decisions

The context in which the emotionally-connected potential donors must reach a decision is highly charged: the life of the intended recipient is in jeopardy. Real or imagined pressure to donate from the potential recipient and other members of the family may be difficult to resist. A candidate who has been identified as a good match for a family member, but who is reluctant to proceed, may be driven by feelings like guilt to agree to donate. The health care team cannot prevent these situations from arising, but can strive to ensure that donation goes forward only when it is truly voluntary and free from undue pressure.

Some transplant centers have found it helpful to assign independent advocates to donors. These advocates are separate from the transplant team, though they may be employees of the same institution. They can help gauge the potential donors' understanding of risks, identify the need for additional information potential donors might want, and assess motivations for volunteering.

The motivations and pressures underlying an altruistic donor's decision to donate are likely to be significantly different. These must be thoroughly assessed to establish the voluntary nature of the decision. These donors may be acting out of a profound sense of altruism, but also may be trying to compensate for negative feelings such as inadequacy and loneliness, or acting on the basis of underlying psychopathology. Evaluations to identify these psychological states must be completed, as some preclude donation.

Because living donation affects not only the donor but also the donor's family, potential candidates should be encouraged to involve family members in the decision-making process. Some centers require that potential candidates' immediate family be notified when donation is being considered.

Finally, as part of the consent process, potential donors explicitly should be informed that they may withdraw from donation at any time before undergoing the operation. Reasons for declining to donate or for withdrawing after agreeing to donate should be kept confidential unless the potential donor agrees to disclosure. Some transplant centers provide potential donors with a medical excuse to shield them from undue family pressures and from the need to justify the decision to decline or to withdraw. This approach risks compromising trust in the physicians and in the profession. Instead, the health care team should be available to help communicate honestly and sensitively a potential donor's decision to decline or withdraw from donation.

### Potential Donors without Full Decision-Making Capacity

Unemancipated minors and incompetent adults lack the capacity to decide whether or not to donate an organ. Whether surrogate decision makers can consent to living donation on their behalf is questionable. On one hand, total prohibition maximizes the protection of such individuals. On the other hand, organ donation might be ethically justifiable in rare situations. For example, if the donor has a strong emotional attachment to the recipient and if there is good reason to believe that the donor would suffer greater psychological harm from the death of the recipient than medical harm from the removal of an organ for transplantation, it may be appropriate to proceed. Under no circumstance should individuals without full decision-making capacity be allowed to serve as donors for strangers.

#### *Financial issues*

Some financial issues are ethically relevant to living organ donation. Living donors may suffer considerable financial losses if they bear the expenses of travel, lodging, lost wages, and the medical care associated with donation. In order to protect the donor from undue burden, reimbursement for these costs should be permitted.

Whether financial incentives for living donors should be allowed is a distinct matter that is the source of some controversy. In support of their position, advocates of such incentives cite saving lives by increasing rates of organ donation and respect for personal autonomy, while opponents cite fear of exploiting the poor and aversion to treating human body parts as commodities. As in the case of motivations for cadaveric organ donation (E-2.151, AMA Policy Database), pilot studies could establish the facts of donation rates, exploitation, and commodification. At present, however, such incentives are illegal and are considered to be unethical (E-2.15).

### ALLOCATION OF ORGANS FROM LIVING DONORS

No uniform guidance currently govern how transplant centers can allocate organs donated by altruistic donors. Some transplant centers systematically give preferred access to patients listed locally. However, according to some commentators, these organs constitute a unique national resource, and recipients should be selected by the same allocation criteria used for distribution of cadaveric organs, and detailed in the AMA's *Code of Medical Ethics*. This relieves individual physicians of the need to make allocation decisions, a function that may conflict with their primary role as patient advocates.

Other allocation schemes arise at institutions that permit paired exchanges (also known as organ swaps), which are intended to increase the overall supply of transplantable organs. One model is direct paired exchanges, in which blood type incompatible donor-recipient pairs Y and Z are recombined to make compatible pairs: donor-Y with recipient-Z and donor-Z with recipient-Y. Such organ exchanges have been carried out with more than two pairs. Another model is a list paired exchange whereby a patient waiting for a transplant receives priority status for a cadaveric organ in exchange for someone donating on his or her behalf into the general organ pool. Such exchanges may place people with certain blood types at a disadvantage, so further study is warranted. Ultimately, only variations that produce a net gain of organs in the organ pool, but do not unreasonably disadvantage others on the waiting list, are ethically acceptable.

### THE NEED TO GATHER INFORMATION SYSTEMATICALLY AND CENTRALLY

A registry of living donors is maintained by UNOS, which collects demographic information and outcome data on all such donors up to a year after donation. In order to better understand living organ donation and to refine relevant standards, guidelines, and best practices, a more complete database with longer follow-up is needed. This would allow extensive analysis of relevant risks and benefits associated with living organ donation, and provide a solid basis for developing evidence-based standards for living donation. Donor motivation and the adequacy of the informed consent process also deserve further study.

Lack of consistency and systematic information illustrates the need for more oversight of the field. As transplantation of organs from living donors becomes more common and as centers across the country gather more information in this domain, increased consistency in basic policies would be likely to result.

## RECOMMENDATIONS

The Council on Ethical and Judicial Affairs recommends that the following be adopted and the remainder of this report be filed:

Donation of transplantable solid organs by living individuals exposes them to surgical procedures that pose risks but offer no physical benefits. The medical profession has pursued living donation because the lives of some patients with end organ failure depend on the availability of transplantable organs and some individuals are willing to donate the needed organs. This practice is consistent with the goals of the profession--treating illness and alleviating suffering--only insofar as the balance of risks and benefits to both donor and recipient is positive.

1. Because donors are initially healthy and then are exposed to potential harm, they require special protection. They should be assigned physician advocates separate from the recipients' to avoid actual or perceived conflicts of interest that could detract from promoting individual patients' best interests. The physicians' ethical focus should be on the selection of suitable donors, whose decision is adequately informed and voluntary.
  - (a) A major responsibility of the health care team is to determine whether a potential living donor is an appropriate candidate.
    - (i) A complete medical evaluation must rule out any serious risk to the potential donor's life or health.
    - (ii) Psychosocial suitability of the potential donor must be determined to identify disqualifying factors, or to enhance donation by addressing needs of the donor. Psychosocial evaluation also helps lay the foundation for informed consent and explores the potential donor's motivation to donate, including the possibility of undue financial or emotional pressure or asymmetric power relationships.
  - (b) The informed consent process for potential donors should be carried out by health care professionals who are not directly associated with the care of the recipients; their focus should be limited to the welfare of the donor.
    - (i) The potential donor must have full capacity to make decisions and must make a fully voluntary decision whether or not to donate.
    - (ii) Unemancipated minors and legally incompetent adults ordinarily should not be accepted as living donors because of their inability to fully understand and decide voluntarily, but exceptionally may be considered for emotionally-connected recipients with the informed consent of their legal guardian. Under no circumstance should individuals without full decision-making capacity be allowed to serve as unrelated living donors to strangers.
    - (iii) Relevant risks and benefits to both donor and recipient should be fully disclosed to the potential donor.
    - (iv) Physicians should ascertain that the potential donor has an adequate level of understanding of the information disclosed to him or her.
    - (v) The potential donor should be explicitly provided with the opportunity to withdraw for any reason, to be kept confidential unless permission for disclosure is granted. The health care team should be available to help communicate both honestly and sensitively a potential donor's decision to withdraw.
2. Living donors should not receive payment for their solid organs, beyond reimbursement for travel, lodging, lost wages, and the medical care associated with donation.
3. The distribution of organs from living donors may take several different forms.
  - (a) Most organs from living donors are directed to designated recipients, usually close relatives, but directed donations by unrelated donors are equally laudable and ethically acceptable. Living donations to designated recipients usually come from recipients' close relatives. Directed donations by unrelated donors are equally and ethically acceptable.

- (b) Paired exchange of organs (also known as organ swaps)--e.g., ABO incompatible donor-recipient pair Y and incompatible pair Z are recombined to make compatible pairs, donor-Y with recipient-Z and donor-Z with recipient-Y--can take many different forms. Variations are ethically acceptable if they produce a net gain of organs in the organ pool but do not unreasonably disadvantage others on the waiting list. Solicitation of donors may disadvantage some recipients, and therefore requires further study to evaluate its potential impact on the fairness of allocation.
- (c) Organs donated by living donors who do not designate a recipient should be allocated by relying on the algorithms that govern the distribution of cadaveric organs.

(References pertaining to Report 4 of the Council on Ethical and Judicial Affairs are available from the Ethics Standards Group.)

### 5. AMENDMENT TO OPINION E-9.025, “COLLECTIVE ACTION AND PATIENT ADVOCACY”

#### HOUSE ACTION: RECOMMENDATIONS ADOPTED AND REMAINDER OF REPORT FILED

In light of recent physician actions advocating for change to medical liability laws, the Council reviewed its current Opinion on collective action and determined that it should provide guidance that addresses non-employment related matters as well as labor matters. The Council also proposes language to emphasize that physician participation should be voluntary and free from undue pressure from colleagues. Further guidance on the legal risks that may arise from certain forms of collective actions can be obtained from the AMA's General Counsel.

Generally, edits of a current Opinion that simply provide clarification and do not change the substance of guidelines are presented to the House of Delegates in the form of a CEJA Opinion, which is then filed. Because the proposed amendments to current Opinion E-9.025 introduce substantive changes, CEJA wishes to present the edited Opinion to the House of Delegates in the form of a Report, to foster discussion of these changes before it issues the amended Opinion.

#### RECOMMENDATIONS

The Council recommends that Opinion E-9.025, “Collective Action and Patient Advocacy,” be amended as follows and the remainder of this report be filed:

#### E-9.025 Collective Action and Patient Advocacy for Change in Law and Policy

Physicians may participate in individual acts, grass roots activities, or legally permissible collective action to advocate for change, as provided for in the AMA's *Principles of Medical Ethics*. Whenever engaging in advocacy efforts, physicians must ensure that the health of patients is not jeopardized and that patient care is not compromised.

~~Collective action should not be conducted in a manner that jeopardizes the health and interests of patients. Formal unionization of physicians, and including physicians-in-training, may tie physicians' interests obligations to the interests of workers who may not share physicians' primary and overriding commitment to patients and the public health. Physicians should not form workplace alliances with those who do not share these ethical priorities.~~

Strikes and other collective action may reduce access to care, eliminate or delay necessary care, and interfere with continuity of care. Each of these consequences raises ethical concerns is contrary to the physician's ethic. Physicians should refrain from the use of the strike as a bargaining tactic. In rare circumstances, individual or grassroots actions, such as brief limitations of personal availability, may be appropriate as a means of calling attention to needed changes in patient care. Physicians are cautioned that some actions may put them or their organizations at risk of violating antitrust laws. Consultation with legal counsel is advised.

~~There are some measures of collective action that may not impinge on essential patient care. Collective activities aimed at ultimately improving patient care may be warranted in some circumstances, even if they create inconvenience for the management.~~

~~Physicians and physicians-in-training should take full advantage of the tools of collective action through which to press for needed reforms: through the use of informational campaigns, non-disruptive public demonstrations, lobbying and publicity campaigns, and collective negotiation are among the options available which do not limit services to patients or other options that do not jeopardize the health of patients or compromise patient care.~~

~~Physicians' collective activities should be in conformance with the law. Physicians are free to decide whether participation in advocacy activities is in patients' best interests. Colleagues should not unduly influence or pressure them to participate nor should they punish them, overtly or covertly, for deciding whether or not to participate. (I, III, VI)~~

Issued December 1998 based on the report "Collective Action and Patient Advocacy," adopted June 1998. Updated December 2004 based on the report "Amendment to Opinion E-9.025, 'Collective Action and Patient Advocacy.'"

## APPENDIX

The amended Opinion would read as follows:

### E-9.025 Advocacy for Change in Law and Policy

Physicians may participate in individual acts, grass roots activities, or legally permissible collective action to advocate for change, as provided for in the AMA's *Principles of Medical Ethics*. Whenever engaging in advocacy efforts, physicians must ensure that the health of patients is not jeopardized and that patient care is not compromised.

Formal unionization of physicians, including physicians-in-training, may tie physicians' obligations to the interests of workers who may not share physicians' primary and overriding commitment to patients. Physicians should not form workplace alliances with those who do not share these ethical priorities.

Strikes and other collective action may reduce access to care, eliminate or delay necessary care, and interfere with continuity of care. Each of these consequences raises ethical concerns. Physicians should refrain from the use of the strike as a bargaining tactic. In rare circumstances, individual or grassroots actions, such as brief limitations of personal availability, may be appropriate as a means of calling attention to needed changes in patient care. Physicians are cautioned that some actions may put them or their organizations at risk of violating antitrust laws. Consultation with legal counsel is advised.

Physicians and physicians-in-training should press for needed reforms through the use of informational campaigns, non-disruptive public demonstrations, lobbying and publicity campaigns, and collective negotiation or other options that do not jeopardize the health of patients or compromise patient care.

Physicians are free to decide whether participation in advocacy activities is in patients' best interests. Colleagues should not unduly influence or pressure them to participate nor should they punish them, overtly or covertly, for deciding whether or not to participate. (I, III, VI)

Issued December 1998 based on the report "Collective Action and Patient Advocacy," adopted June 1998. Updated December 2004 based on the report "Amendment to Opinion E-9.025, 'Collective Action and Patient Advocacy.'"