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Current Opinions of the Council on Ethical and Judicial Affairs

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Preamble:

The medical profession has long subscribed to a body of ethical statements developed primarily for the benefit of the patient. As a member of this profession, a physician must recognize responsibility to patients first and foremost, as well as to society, to other health professionals, and to self. The following Principles adopted by the American Medical Association are not laws, but standards of conduct which define the essentials of honorable behavior for the physician.

- I. A physician shall be dedicated to providing competent medical care, with compassion and respect for human dignity and rights.
- II. A physician shall uphold the standards of professionalism, be honest in all professional interactions, and strive to report physicians deficient in character or competence, or engaging in fraud or deception, to appropriate entities.
- III. A physician shall respect the law and also recognize a responsibility to seek changes in those requirements which are contrary to the best interests of the patient.
- IV. A physician shall respect the rights of patients, colleagues, and other health professionals, and shall safeguard patient confidences and privacy within the constraints of the law.
- V. A physician shall continue to study, apply, and advance scientific knowledge, maintain a commitment to medical education, make relevant information available to patients, colleagues, and the public, obtain consultation, and use the talents of other health professionals when indicated.
- VI. A physician shall, in the provision of appropriate patient care, except in emergencies, be free to choose whom to serve, with whom to associate, and the environment in which to provide medical care.
- VII. A physician shall recognize a responsibility to participate in activities contributing to the improvement of the community and the betterment of public health.
- VIII. A physician shall, while caring for a patient, regard responsibility to the patient as paramount.
- IX. A physician shall support access to medical care for all people.

Adopted June 1957; revised June 1980; revised June 2001

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2.07 Clinical Investigation.

The following guidelines are intended to aid physicians in fulfilling their ethical responsibilities when they engage in the clinical investigation of new drugs and procedures.

- 1) A physician may participate in clinical investigation only to the extent that those activities are a part of a systematic program competently designed, under accepted standards of scientific research, to produce data which are scientifically valid and significant.
- 2) In conducting clinical investigation, the investigator should demonstrate the same concern and caution for the welfare, safety, and comfort of the person involved as is required of a physician who is furnishing medical care to a patient independent of any clinical investigation.
- 3) Minors or mentally incompetent persons may be used as subjects in clinical investigation only if:
 - a) The nature of the investigation is such that mentally competent adults would not be suitable subjects.
 - b) Consent, in writing, is given by a legally authorized representative of the subject under circumstances in which informed and prudent adults would reasonably be expected to volunteer themselves or their children as subjects.
- 4) In clinical investigation primarily for treatment:
 - a) The physician must recognize that the patient-physician relationship exists and that professional judgment and skill must be exercised in the best interest of the patient.
 - b) Voluntary written consent must be obtained from the patient, or from the patient's legally authorized representative if the patient lacks the capacity to consent, following:
 - a) disclosure that the physician intends to use an investigational drug or experimental procedure,
 - b) a reasonable explanation of the nature of the drug or procedure to be used, risks to be expected, and possible therapeutic benefits,
 - c) an offer to answer any inquiries concerning the drug or procedure, and
 - d) a disclosure of alternative drugs or procedures that may be available. Physicians should be completely objective in discussing the details of the drug or procedure to be employed, the pain and discomfort that may be anticipated, known risks and possible hazards, the quality of life to be expected, and particularly the alternatives. Especially, physicians should not use persuasion to obtain consent which otherwise might not be forthcoming, nor should expectations be encouraged beyond those which the circumstances reasonably and realistically justify.
 - i) In exceptional circumstances, where the experimental treatment is the only potential treatment for the patient and full disclosure of information concerning the nature of the drug or experimental procedure or risks would pose such a serious psychological threat of detriment to the patient as to be medically

contraindicated, such information may be withheld from the patient. In these circumstances, such information should be disclosed to a responsible relative or friend of the patient where possible.

- ii) Ordinarily, consent should be in writing, except where the physician deems it necessary to rely upon consent in other than written form because of the physical or emotional state of the patient.
- 5) In clinical investigation primarily for the accumulation of scientific knowledge:
 - a) Adequate safeguards must be provided for the welfare, safety and comfort of the subject. It is fundamental social policy that the advancement of scientific knowledge must always be secondary to primary concern for the individual.
 - b) Consent, in writing, should be obtained from the subject, or from a legally authorized representative if the subject lacks the capacity to consent, following: (a) disclosure of the fact that an investigational drug or procedure is to be used, (b) a reasonable explanation of the nature of the procedure to be used and risks to be expected, and (c) an offer to answer any inquiries concerning the drug or procedure.
 - 6) No person may be used as a subject in clinical investigation against his or her will.
 - 7) The overuse of institutionalized persons in research is an unfair distribution of research risks. Participation is coercive and not voluntary if the participant is subjected to powerful incentives and persuasion.
 - 8) The ultimate responsibility for the ethical conduct of science resides within the institution (academic, industrial, public, or private) which conducts scientific research and with the individual scientist. Research institutions should assure that rigorous scientific standards are upheld by each of their faculty, staff, and students and should extend these standards to all reports, publications, and databases produced by the institution. All medical schools and biomedical research institutions should implement guidelines for a review process for dealing with allegations of fraud. These guidelines should ensure that
 - a) the process used to resolve of fraud does not damage science,
 - b) all parties are treated fairly and justly with a sensitivity to reputations and vulnerabilities,
 - c) the highest degree of confidentiality is maintained,
 - d) the integrity of the process is maintained by an avoidance of real or apparent conflicts of interest,
 - e) resolution of charges is expeditious,
 - f) accurate and detailed documentation is kept throughout the process, and
 - g) responsibilities to all involved individuals, the public, research sponsors, the scientific literature, and the scientific community is met after resolution of charges. Academic institutions must be capable of, and committed to, implementing effective procedures for examining allegations of scientific fraud. No system of external monitoring should replace the efforts of an institution to set its own standards which fulfill its responsibility for the proper conduct of science and the training of scientists.
 - 9) With the approval of the patient or the patient's lawful representative, physicians should cooperate with the press and media to ensure that medical news concerning the progress of clinical investigation or the patient's condition is available more promptly and more accurately than would be possible without their assistance. On the other hand, the Council does not approve of practices designed to create fanfare, sensationalism to attract media attention, and unwarranted expressions of optimism because of short term progress, even though longer range prognosis is known from the beginning to be precarious. With the approval of the patient or the patient's family, the Council, however, encourages the objective disclosure

to the press and media of pertinent information. If at all possible, the identity of the patient should remain confidential if the patient or the patient's family so desires. The situation should not be used for the commercial ends of participating physicians or the institutions involved.

(I, III, V) Issued prior to April 1977; Updated June 1994 and June 1998.

E-2.071 Subject Selection for Clinical Trials.

Ethical considerations in clinical research have traditionally focused on protecting research subjects. These protections may be especially important for those from socioeconomically disadvantaged populations who may be more vulnerable to coercive pressures. The benefits from altruism that result from participation in research, particularly for severely chronically ill persons, may justify equitable consideration of historically disadvantaged populations such as the poor. With these considerations in mind, the following guidelines are offered:

- 1) Although the burdens of research should not fall disproportionately on socioeconomically disadvantaged populations, neither should such populations be categorically excluded, or discouraged, from research protocols.
- 2) Inclusion and exclusion criteria for a clinical study should be based on sound scientific principles. Conversely, participants in a clinical trial should be drawn from the qualifying population in the general geographic area of the trial without regard to race, ethnicity, economic status, or gender.

If a subject's primary care physician determines that the subject received a clear medical benefit from the experimental intervention which is now moving towards marketing approval and chooses to seek authorization from the Food and Drug Administration (FDA) for continued use of the investigational therapy during the time period between the end of the protocol and the availability of the drug on the market, the investigator should work with the primary care physician, the product sponsor, and the FDA to allow continued availability of the product.

(I, V, VII) Issued June 1998 based on the report "Subject Selection for Clinical Trials," adopted December 1997 (IRB. 1998; 20(2-3): 12-15).

E-2.075 The Use of Placebo Controls in Clinical Trials.

Placebo controls are an important part of medicine's commitment to ensuring that the safety and efficacy of new drugs are sufficiently established. Used appropriately, placebo controls can safely provide valuable data and should continue to be considered in the design of clinical trials. The existence of an accepted therapy does not necessarily preclude the use of such controls; however, physician-investigators should adhere to the following guidelines to ensure that the interests of patients who participate in clinical trials are protected.

- 1) Investigators must be extremely thorough in obtaining informed consent from patients. To the extent that research is dependent upon the willingness of patients to accept a level of risk, their understanding of the potential harms involved must be a top priority of any clinical investigation. The possibility presented in some studies that patients often do not fully understand the research protocol and therefore truly can not give informed consent demonstrates a need to heighten the efforts of researchers to impress upon their subjects the nature of clinical research and the risks involved. Patients are capable of making decisions when presented with sufficient information and it is the responsibility of the institutional review board (IRB) and the individual investigators involved to ensure that each subject has been adequately informed and has given voluntary consent. Each patient must also be made aware that they can terminate their participation in a study at any time.
- 2) Informed consent cannot be invoked to justify an inappropriate trial design. IRBs as well as investigators have an obligation to evaluate each study protocol to determine whether a placebo control is necessary and whether an alternative study design with another type of

control would be sufficient for the purposes of research. Protocols that involve conditions causing death or irreversible damage cannot ethically employ a placebo control if alternative treatment would prevent or slow the illness progression. When studying illnesses characterized by severe or painful symptoms, investigators should thoroughly explore alternatives to the use of placebo controls. In general, the more severe the consequences and symptoms of the illness under study, the more difficult it will be to justify the use of a placebo control when alternative therapy exists. Consequently, there will almost certainly be conditions for which placebo controls cannot be justified. Similarly, the use of a placebo control will more easily be justified as the severity and number of negative side-effects of standard therapy increase.

- 3) Researchers and IRBs should continue to minimize the amount of time patients are given placebo. The rationale provided by investigators for the length of study will give IRBs the opportunity to ensure that patients are given placebo therapy for as short a time as possible to provide verifiable results. Additionally, the interim data analysis and monitoring currently in practice will allow researchers to terminate the study because of either positive or negative results, thus protecting patients from remaining on placebo unnecessarily.

(I, V) Issued June 1997 based on the report "Ethical Use of Placebo Controls in Clinical Trials," adopted June 1996.

E-2.076 Surgical "Placebo" Controls

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

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

- 1) Surgical "placebo" controls should be used only when no other trial design will yield the requisite data.
- 2) Particular attention must be paid to the informed consent process when enrolling subjects in trials that use surgical "placebo" controls. Careful explanation of the risks of the operations must be disclosed, along with a description of the differences between the trial arms emphasizing the essential procedure that will or will not be performed.

Additional safeguards around the informed consent process may be appropriate such as using a neutral third party to provide information and get consent, or using consent monitors to oversee the consent process.

- 3) The use of surgical "placebo" controls is not justified when testing the effectiveness of an innovative surgical technique that represents a minor modification of an existing surgical procedure.
- 4) When a new surgical procedure is developed with the prospect of treating a condition for which no known surgical therapy exists, using surgical "placebo" controls may be justified, but must be evaluated in light of whether the current standard of care includes a non-surgical treatment and the benefits, risks and side-effects of that treatment.
 - a) If foregoing standard treatment would result in significant injury and the standard treatment is efficacious and acceptable to the patient (in terms of side-effects, personal beliefs, etc.), then it must be offered as part of the study design.
 - b) When the standard treatment is not fully efficacious, or not acceptable to the patient, surgical "placebo" controls may be used and the standard treatment foregone, but additional safeguards must be put in place around the informed consent process.

Issued December 2000 based on the report "Surgical Placebo Controls," adopted June 2000.

E-2.077 Ethical Considerations in International Research

Physicians, either in their role as investigators or as decision-makers involved in the deliberations related to the funding or the review of research, hold an ethical obligation to ensure the protection of research participants. When the research is to be conducted in countries with differing cultural traditions, health care systems, and ethical standards, and in particular in countries with developing economies and with limited health care resources, U.S. physicians should respect the following guidelines:

- 1) First and foremost, physicians involved in clinical research that will be carried out internationally should be satisfied that a proposed research design has been developed according to a sound scientific design. Therefore, investigators must ascertain that there is genuine uncertainty within the clinical community about the comparative merits of the experimental treatment and the one to be offered as a control in the population among which the study is to be undertaken. In some instances, a three-pronged protocol, which offers the standard treatment in use in the U.S., a treatment that meets a level of care that is attainable and sustainable by the host country, and a placebo (see Opinion 2.075, "Surgical 'Placebo' Controls"), may be the best method to evaluate the safety and efficacy of a treatment in a given population. When U.S. investigators participate in international research they must obtain approval for such protocols from U.S. Institutional Review Boards (IRBs).
- 2) IRBs, which are responsible for ensuring the protection of research participants, must determine that risks have been minimized and that the protocol's ratio of risks to benefits is favorable to participants. In evaluating the risks and benefits that a protocol presents to a population, IRBs should obtain relevant input from representatives from the host country and from the research population. It is also appropriate for IRBs to consider the harm that is likely to result from forgoing the research.
- 3) Also, IRBs are required to protect the welfare of individual participants. This can best be achieved by assuring that a suitable informed consent process is in place. Therefore, IRBs should ensure that individual potential participants will be informed of the nature of the research endeavor and that their voluntary consent will be sought. IRBs should recognize that, in some instances, information will be meaningful only if it is communicated in ways that are consistent with local customs.
- 4) Overall, to ensure that the research does not exploit the population from which participants are recruited, IRBs should ensure that the research corresponds to a medical need in the region where it is undertaken. Furthermore, they should foster research with the potential for lasting benefits, especially when it is undertaken among populations that are severely deficient in health care resources. This can be achieved by facilitating the development of a health care infrastructure that will be of use during and beyond the conduct of the research. Additionally, physicians conducting studies must encourage research sponsors to continue to provide beneficial study interventions to all study participants at the conclusion of the study.

(I, IV, VII, VIII, IX) Issued December 2001 based on the report "Ethical Considerations in International Research," adopted June 2001.

E-2.079 Safeguards in the Use of DNA Databanks in Genomic Research

The following safeguards should be applied to the use of databases for the purpose of population-based genomic research:

- 1) Physicians who participate as investigators in genomic research should have adequate training in genomic research and related ethical issues so as to be able to discuss these issues with patients and/or potential research subjects.

- 2) If research is to be conducted within a defined subset of the general population, that is, an identifiable community, then investigators should consult with the community to design a study that will minimize harm not only for individual subjects, but also for the community. When substantial opposition to the research is expressed within the community, investigators should not conduct the study. When the community supports a proposal, investigators nevertheless should obtain individual consent in the usual manner. The same procedure should be followed whether the investigators intend to collect new samples and data or whether they wish to use previously archived data sets.
- 3) When obtaining the informed consent of individuals to participate in genomic research, standard informed consent requirements apply (see Opinion 2.07, "Clinical Investigation"). In addition:
 - a) Special emphasis should be placed on disclosing the specific standards of privacy contained in the study: whether the material will be coded (i.e.: encrypted so that only the investigator can trace materials back to specific individuals) or be completely de-identified (i.e.: stripped of identifiers).
 - b) If data are to be coded, subjects should be told whether they can expect to be contacted in the future to share in findings or to consider participating in additional research, which may relate to the current protocol or extend to other research purposes.
 - c) Individuals should always be free to refuse the use of their biological materials in research, without penalty.
 - d) Disclosure should include information about whether investigators or subjects stand to gain financially from research findings (see Opinion 2.08, "Commercial Use of Human Tissue"). Such disclosure should refer to the possible conflicts of interest of the investigators (see Opinion 8.0315, "Managing Conflicts of Interest in the Conduct of Clinical Trials").
 - e) Subjects should be informed of when, if ever, and how archived information and samples will be discarded.
- 4) To strengthen the protection of confidentiality, genomic research should not be conducted using information and samples that identify the individuals from whom they were obtained (i.e.: by name or social security number). Furthermore, to protect subsets of the population from such harms as stigmatization and discrimination, demographic information not required for the study's purposes should be coded.

(I, IV, V, VII) Issued June 2002 based on the report "The Use of DNA Databanks in Genomic Research: The Imperative of Informed Consent," adopted December 2001.

E-2.08 Commercial Use of Human Tissue.

The rapid growth of the biotechnology industry has resulted in the commercial availability of numerous therapeutic and other products developed from human tissue. Physicians contemplating the commercial use of tissue should abide by the following guidelines:

- 1) Informed consent must be obtained from patients for the use of organs or tissues in clinical research.
- 2) Potential commercial applications must be disclosed to the patient before a profit is realized on products developed from biological materials.
- 3) Human tissue and its products may not be used for commercial purposes without the informed consent of the patient who provided the original cellular material.
- 4) Profits from the commercial use of human tissue and its products may be shared with patients, in accordance with lawful contractual agreements.

- 5) The diagnostic and therapeutic alternatives offered to patients by their physicians should conform to standards of good medical practice and should not be influenced in any way by the commercial potential of the patient's tissue.

(II, V) Issued June 1994 based on the report "Who Should Profit from the Economic Value of Human Tissue? An Ethical Analysis," adopted June 1990.

- E-2.09 Costs.
- E-2.095 The Provision of Adequate Health Care.
- E-2.10 Fetal Research Guidelines.

E-2.10 Fetal Research Guidelines.

The following guidelines are offered as aids to physicians when they are engaged in fetal research:

- 1) Physicians may participate in fetal research when their activities are part of a competently designed program, under accepted standards of scientific research, to produce data which are scientifically valid and significant.
- 2) If appropriate, properly performed clinical studies on animals and nonpregnant humans should precede any particular fetal research project.
- 3) In fetal research projects, the investigator should demonstrate the same care and concern for the fetus as a physician providing fetal care or treatment in a non-research setting.
- 4) All valid federal or state legal requirements should be followed.
- 5) There should be no monetary payment to obtain any fetal material for fetal research projects.
- 6) Competent peer review committees, review boards, or advisory boards should be available, when appropriate, to protect against the possible abuses that could arise in such research.
- 7) Research on the so called dead fetus, macerated fetal material, fetal cells, fetal tissue, or fetal organs should be in accord with state laws on autopsy and state laws on organ transplantation or anatomical gifts.
- 8) In fetal research primarily for treatment of the fetus:
 - a) Voluntary and informed consent, in writing, should be given by the pregnant woman, acting in the best interest of the fetus.
 - b) Alternative treatment or methods of care, if any, should be carefully evaluated and fully explained. If simpler and safer treatment is available, it should be pursued.
- 9) In research primarily for treatment of the pregnant female:
 - a) Voluntary and informed consent, in writing, should be given by the patient.
 - b) Alternative treatment or methods of care should be carefully evaluated and fully explained to the patient. If simpler and safer treatment is available, it should be pursued.
 - c) If possible, the risk to the fetus should be the least possible, consistent with the pregnant female's need for treatment.
- 10) In fetal research involving a fetus in utero, primarily for the accumulation of scientific knowledge:
 - a) Voluntary and informed consent, in writing, should be given by the pregnant woman under circumstances in which a prudent and informed adult would reasonably be expected to give such consent.

- b) The risk to the fetus imposed by the research should be the least possible.
- c) The purpose of research is the production of data and knowledge which are scientifically significant and which cannot otherwise be obtained.
- d) In this area of research, it is especially important to emphasize that care and concern for the fetus should be demonstrated.

(I, III, V) Issued March 1980; Updated June 1994.

- E-2.105 Patenting Human Genes.
- E-2.11 Gene Therapy.
- E-2.12 Genetic Counseling.
- E-2.13 Genetic Engineering.

E-2.132 Genetic Testing by Employers.

As a result of the human genome project, physicians will be able to identify a greater number of genetic risks of disease. Among the potential uses of the tests that detect these risks will be screening of potential workers by employers. Employers may want to exclude workers with certain genetic risks from the workplace because these workers may become disabled prematurely, impose higher health care costs, or pose a risk to public safety. In addition, exposure to certain substances in the workplace may increase the likelihood that a disease will develop in the worker with a genetic risk for the disease.

- (1) It would generally be inappropriate to exclude workers with genetic risks of disease from the workplace because of their risk. Genetic tests alone do not have sufficient predictive value to be relied upon as a basis for excluding workers. Consequently, use of the tests would result in unfair discrimination against individuals who have positive test results. In addition, there are other ways for employers to serve their legitimate interests. Tests of a worker's actual capacity to meet the demands of the job can be used to ensure future employability and protect the public's safety. Routine monitoring of a worker's exposure can be used to protect workers who have a genetic susceptibility to injury from a substance in the workplace. In addition, employees should be advised of the risks of injury to which they are being exposed.
- (2) There may be a role for genetic testing in the exclusion from the workplace of workers who have a genetic susceptibility to injury. At a minimum, several conditions would have to be met:
 - (a) The disease develops so rapidly that serious and irreversible injury would occur before monitoring of either the worker's exposure to the toxic substance or the worker's health status could be effective in preventing the harm.
 - (b) The genetic testing is highly accurate, with sufficient sensitivity and specificity to minimize the risk of false negative and false positive test results.
 - (c) Empirical data demonstrate that the genetic abnormality results in an unusually elevated susceptibility to occupational injury.
 - (d) It would require undue cost to protect susceptible employees by lowering the level of the toxic substance in the workplace. The costs of lowering the level of the substance must be extraordinary relative to the employer's other costs of making the product for which the toxic substance is used. Since genetic testing with exclusion of susceptible employees is the alternative to cleaning up the workplace, the cost of lowering the level of the substance must also be extraordinary relative to the costs of using genetic testing.

- (e) Testing must not be performed without the informed consent of the employee or applicant for employment.

(IV) Issued June 1991 based on the report "Genetic Testing by Employers," adopted June 1991 (JAMA 1991; 266: 1827-1830).

- E-2.135 Insurance Companies and Genetic Information.
- E-2.136 Genetic Information and the Criminal Justice System.
- E-2.137 Ethical Issues in Carrier Screening of Genetic Disorders.
- E-2.138 Genetic Testing of Children.
- E-2.139 Multiplex Genetic Testing.
- E-2.14 In Vitro Fertilization.
- E-2.141 Frozen Pre-Embryos.
- E-2.145 Pre-Embryo Splitting.
- E-2.147 Human Cloning
- E-2.15 Financial Incentives for Organ Donation.
- E-2.155 Mandated Choice and Presumed Consent for Cadaveric Organ Donation.
- E-2.157 Organ Procurement Following Cardiac Death.
- E-2.16 Organ Transplantation Guidelines.
- E-2.161 Medical Applications of Fetal Tissue Transplantation.
- E-2.162 Anencephalic Neonates as Organ Donors.
- E-2.165 Fetal Umbilical Cord Blood.
- E-2.167 The Use of Minors as Organ and Tissue Donors.
- E-2.169 The Ethical Implications of Xenotransplantation.
- E-2.17 Quality of Life.
- E-2.18 Surrogate Mothers.
- E-2.19 Unnecessary Services.
- E-2.20 Withholding or Withdrawing Life-Sustaining Medical Treatment.
- E-2.21 Euthanasia.
- E-2.211 Physician-Assisted Suicide.
- E-2.215 Treatment Decisions for Seriously Ill Newborns.
- E-2.22 Do-Not-Resuscitate Orders.
- E-2.225 Optimal Use of Orders - Not - To - Intervene and Advance Directives.
- E-2.23 HIV Testing.
- E-2.24 Impaired Drivers and Their Physicians
- E-2.30 Information from Unethical Experiments.
- E-3.00 Opinions on Interprofessional Relations
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- E-6.00 Opinions on Fees and Charges
- E-7.00 Opinions on Physician Records
- E-8.00 Opinions on Practice Matters

E-8.03 Conflicts of Interest: Guidelines.

Under no circumstances may physicians place their own financial interests above the welfare of their patients. The primary objective of the medical profession is to render service to humanity; reward or financial gain is a subordinate consideration. For a physician unnecessarily to hospitalize a patient, prescribe a drug, or conduct diagnostic tests for the physician's financial benefit is unethical. If a conflict develops between the physician's financial interest and the physician's responsibilities to the patient, the conflict must be resolved to the patient's benefit.

(II) Issued July 1986; Updated June 1994.

E-8.031 Conflicts of Interest: Biomedical Research.

Avoidance of real or perceived conflicts of interest in clinical research is imperative if the medical community is to ensure objectivity and maintain individual and institutional integrity. All medical centers should develop specific guidelines for their clinical staff on conflicts of interest. These guidelines should include the following rules:

- 1) once a clinical investigator becomes involved in a research project for a company or knows that he or she might become involved, she or he, as an individual, cannot ethically buy or sell the company's stock until the involvement ends and the results of the research are published or otherwise disseminated to the public;
- 2) any remuneration received by the researcher from the company whose product is being studied must be commensurate with the efforts of the researcher on behalf of the company;
- 3) clinical investigators should disclose any material ties to companies whose products they are investigating including: financial ties, participation in educational activities supported by the companies, participation in other research projects funded by the companies, consulting arrangements, and any other ties. The disclosures should be made in writing to the medical center where the research is conducted, organizations that are funding the research, and journals that publish the results of the research. An explanatory statement that discloses conflicts of interest should accompany all published research. Other types of publications, such as a letters to the editor, should also include an explanatory statement that discloses any potential conflict of interest.

In addition, medical centers should form review committees to examine disclosures by clinical staff about financial associations with commercial corporations.

(II, IV) Issued March 1992 based on the report "Conflicts of Interest in Biomedical Research," adopted December 1989 (JAMA. 1990; 263: 2790-2793) ; Updated June 1999 based on the report "Conflicts of Interest: Biomedical Research," adopted December 1998.

E- 9.00 Opinions on Professional Rights and Responsibilities

E-10.00 Opinions on the Patient-Physician Relationship

E- Clarification of Opinion 8.032, "Conflicts of Interest: Health Facility Ownership by a Physician."

E- Clarification of Opinion 8.061, "Gifts to Physicians from Industry."

E- Clarification of Opinions 8.062, "Sale of Non-Health-Related Goods from Physicians' Offices, and 8.063, "Sale of Health-Related Goods from Physicians' Offices."