

### ***7.3.9 Commercial Use of Human Biological Materials***

Research using human tissues has resulted in numerous commercially available products for use in both research and treatment. The development of these products raises questions about who holds property rights in human biological materials, how to distribute profits derived from human tissues equitably, and what constitutes appropriately informed consent when patients donate biological materials to research that may ultimately result in one or more commercial products.

Physicians involved in research with human biological materials should:

- (a) Disclose potential commercial applications to the tissue donor before a profit is realized on products developed from biological materials.
- (b) Obtain informed consent to use biological materials in research from the tissue donor. Human biological materials and their products may not be used for commercial purposes without the consent of the tissue donor.
- (c) Share profits from the commercial use of human biological materials with the tissue donor in accordance with lawful contractual agreements.

Physicians must make diagnostic and treatment recommendations in keeping with standards of good medical practice. They must not allow the commercial potential of the patient's tissue to influence professional judgment.

***AMA Principles of Medical Ethics: II,V***

*Background report(s):*

CEJA Report 3-A-16 Modernized *Code of Medical Ethics*

CEJA Report E-A-90 Who should profit from the economic value of human tissue? An ethical analysis

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*AMA Principles of Medical Ethics: II,V*

## E. WHO SHOULD PROFIT FROM THE ECONOMIC VALUE OF HUMAN TISSUE? AN ETHICAL ANALYSIS

### HOUSE ACTION: ADOPTED

#### OVERVIEW

In 1980, the U. S. Supreme Court issued a landmark decision that spurred the development of the biotechnology industry by granting researchers the legal right to patent genetically engineered organisms with unique cellular characteristics. That same year, the U. S. Congress further contributed to the rapid growth of the biotechnology industry by amending patent regulations to permit the commercialization of products developed as a result of government-sponsored research. These two events were instrumental in transforming human cell-lines that previously had no economic value into potentially profitable commercial products.

A number of ethical questions are raised by the marketing of human biological materials. The Council on Ethical and Judicial Affairs of the AMA therefore has defined the following parameters to be observed when the commercial use of human tissue is contemplated by physicians:

- Informed consent must be obtained from patients for the use of organs or tissues in clinical research.
- Potential commercial applications must be disclosed to the patient before a profit is realized on products developed from biological materials.
- 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.
- Profits from the commercial use of human tissue and its products may be shared with patients, in accordance with lawful contractual agreements.
- 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.

#### BACKGROUND

Before the commercial use of human tissue was made possible under U. S. patent law, cellular products were freely exchanged among scientists conducting clinical research. As the economic value of such products became evident, the originators of genetically engineered cell-lines began to protect their commercial interests by making their products available only to those who agreed to use them exclusively for noncommercial research and to those who entered into licensing agreements that guaranteed the originator of the cell-line a percentage of any profits generated.

It has been estimated that, in the last ten years, half of all medical research institutions have applied for a patent on at least one biological product that originated from human tissue. In addition, nearly 350 commercial biotechnology firms in the United States are actively engaged in the commercial development of biotechnology products, approximately 25-30 percent of which have diagnostic or therapeutic applications. Most of these products are derived from human tissue. Overall, the total number of patent applications filed on such products tripled between 1980 and 1984, as compared to the previous five years. Universities, researchers and commercial firms that specialize in biotechnology all have benefited from the development of cell-lines derived from human tissue.

This rapid growth of the biotechnology industry has resulted in the commercial availability of numerous therapeutic products developed from human tissue, including, for example, alpha interferon (for hairy-cell leukemia), human insulin (for diabetes mellitus), human growth hormone (for growth retardation associated with pituitary function), hepatitis B vaccine (to confer immunity against the hepatitis B virus), monoclonal antibody OKT-3 (for acute renal transplant rejection), erythropoietin EPO (for chronic kidney failure), and tissue plasminogen activator (for vascular thrombosis), as well as 150 monoclonal antibodies for diagnostic testing purposes.

#### PROPERTY RIGHTS IN BIOLOGICAL MATERIALS

If products with commercial potential can be developed from cells with unusual traits, it is important to consider whether patients may assert a property right to these cells. Property rights may entitle patients to share in any profits derived from the commercialization of their tissue or its products.

Only limited, tangible property rights in the human body are recognized by U. S. common law. A right of custody, control and disposition of a human body may be exercised by a deceased individual's next of kin for the limited purpose of arranging for the cremation or burial of the body. A limited, tangible property right in the human body also is recognized by the Uniform Anatomical Gift Act which treats human organs as property for the purpose of facilitating their donation to others. This Act, however, does not provide for the commercial exchange of body parts; in fact, the sale of human organs was explicitly prohibited in 1984 by the National Organ Transplant Act. Property rights in the human body are linked even more remotely with the sale of tissues or fluids that are spontaneously regenerated by the body, such as blood and semen. Courts have tended to characterize the provision of these biological materials as a service, rather than the sale of tangible property.

Case law is just beginning to establish the legal parameters of property interests in the human body. The California Court of Appeals recently decided a case of first impression in which a patient asserted a property interest in cells that had been extracted from his body. The case of "Moore v. Regents of the University of California" involved a patient who consented to the surgical removal of his spleen as treatment for a rare form of leukemia. Upon examination of the extracted tissue, Moore's physicians discovered that the cells possessed unique and commercially exploitable characteristics. In tissue culture, the cells produced at least seven protein products of therapeutic and commercial value, including colony-stimulating factor, immune interferon (Type II), neutrophil migration-inhibition factor, T-cell growth factor, macrophage-activating factor, and fibroblast growth-stimulating factor. Without Moore's knowledge, his physicians developed and patented a cell-line utilizing the tissue from his spleen. The rights to the cell-line later were sold to a commercial corporation. The potential worth of the products derived from the cells has been estimated at \$3 billion.

#### ETHICAL CONSIDERATIONS

This case raises ethical questions involving informed consent, conflicts of interest and the equitable distribution of profits derived from human tissue and its products.

Typically, patients who consent to the use of their tissue for biomedical research do so with the expectation that the donated tissue will be used to further scientific knowledge and to enhance the health and well-being of other patients. The tissue is given by the patient as a gift on the assumption that it will be used in good faith for the medical benefit of others. Patients' perceptions of such donations might be very different if it is known that commercial profits are a potential objective of the research to be conducted. Patients, therefore, cannot provide fully informed consent to the use of their organs or tissues in clinical research unless potential commercial applications of the tissue and its products are disclosed.

Disclosure of potential commercial applications is further indicated because of the conflict of interest created by the physician's economic interest in the value of extracted tissue. Patients may fear,

for example, that their physician's economic interests will influence the type of care they receive or ultimately result in their exploitation. As suggested in Section 8.03 of "Current Opinions of the Council on Ethical and Judicial Affairs of the American Medical Association, 1989," conflicts of interest that arise in the course of the physician-patient relationship must be addressed by the following:

1. Economic interests that may influence the physician's treatment recommendations must be disclosed to the patient.
2. The physician may not exploit the patient in any way.
3. The physician's activities must be in strict conformance with the law.
4. The patient should be permitted to choose from among recommended alternatives to reject intervention altogether or to seek medical services elsewhere.
5. When a physician's commercial interests conflict so greatly with the interests of the patient as to be incompatible, the physician should make alternative arrangements for the care of the patient.

It therefore would be inappropriate for a physician to permit economic concerns to influence the diagnostic or therapeutic alternatives that are offered to a patient. It also would be inappropriate to subject a patient to medical risks based solely upon the physician's desire to retrieve economically valuable tissue. Invasive procedures should not be performed for the retrieval of cellular material that cannot be spontaneously regenerated by the patient because of its potential economic value, unless the intervention is otherwise indicated, in accordance with medically appropriate criteria.

With respect to the equitable distribution of profits derived from human tissue, patients must be permitted to decline commercial use of products developed from their cellular material, as an exercise of control over the terms and conditions of their participation in clinical research. Alternatively, patients may choose to share in the profits from commercial ventures that utilize their tissue or its products by entering into contractual agreements with physician researchers. For example, physicians may offer patients a small percentage of any profits that are realized on products derived from the patient's cells. However, it should be noted that most research on human tissue does not result in substantial commercial profits. It therefore should not be expected that patients in general will benefit financially from research involving their cells or cell products. In addition, it is unlikely that research will be jeopardized by patients who withhold informed consent for the commercial use of their cells, or by patients who demand unreasonable shares of any commercial profits that are generated.

#### IMPLICATIONS FOR ORGAN DONATION

Unlike tissue used in research, donated organs cannot legally be bought or sold in the United States. The recipient derives no economic benefit from the donation of an organ, nor does the donor benefit financially from the transplantation process. The distribution of commercial profits therefore is not at issue.

However, it has been suggested, as a means of increasing the supply of vital organs, that donors be compensated financially for providing organs for transplantation. The Council on Ethical and Judicial Affairs previously has determined that such compensation would not be appropriate. Section 2.15 of "Current Opinions of the Council on Ethical and Judicial Affairs of the American Medical Association, 1989" states:

**ORGAN DONATION.** The voluntary donation of organs in appropriate circumstances is to be encouraged. However, it is not ethical to participate in a procedure to enable a donor to receive payment, other than for the reimbursement of expenses necessarily incurred in connection with removal, for any of the donor's non-renewable organs.

Financial remuneration for the transplantation of vital human organs is distinguishable from the commercial sale of pathological or renewable tissue for use in biomedical research. Transplantable organs cannot be spontaneously regenerated by the donor, nor does the donor benefit therapeutically from removal of the organ. In contrast, the tissue specimens used in research can be placed in one of two categories: (1) either the tissue is a renewable bodily substance, or (2) removal of the tissue is based upon appropriate therapeutic indications.

It can be argued that these distinguishing features apply not only to organs that are offered for sale, but also to donated organs as well. However, the commercial sale of organs introduces an additional element of exploitation that is absent from organ donation. If the sale of vital organs were permitted, the most likely source of such organs would be individuals in extreme financial need. Others might be more reluctant to compromise their future health and well-being for the promise of immediate financial gain. The recipients of transplantable organs, on the other hand, would tend to be those individuals with the greatest financial resources with which to purchase available organs. The economic positions of the donor and the recipient, rather than medical considerations, therefore would become controlling factors in the distribution of transplantable organs. The Council previously has determined that such an approach is not acceptable. Section 2.03 of "Current Opinions" states, in relevant part, that:

Societal decisions regarding the allocation of limited health care resources should be based on fair, socially acceptable and humane criteria. Priority should be given to persons who are most likely to be treated successfully or derive long term benefit. Utility or relative worth to society must not determine whether an individual is accepted as a donor or recipient for transplantation, selected for human experimentation, or denied or given preference in receiving costly or scarce health care therapy or resources.

Appropriate medical criteria, rather than the relative financial positions of the organ donor and recipient, should govern transplantation decisions. The commercial sale of vital organs that cannot be spontaneously regenerated therefore would be inappropriate.

(References pertaining to Report E of the Council on Ethical and Judicial Affairs are available from the Office of the General Counsel.)

## F. AFFILIATE MEMBERS

### HOUSE ACTION: ADOPTED

The Council on Ethical and Judicial Affairs recommends the following individuals for Affiliate Membership in the American Medical Association:

#### U. S. Physicians in Foreign Countries

Carol Ann Narkevic, M. D.  
Kenya, East Africa

Dennis M. Sullivan, M. D.  
Cayes-Jacmel, Haiti

Chris George Palacas, M. D.  
Kampala, Uganda

#### Teachers of Medicine or of Sciences Allied to Medicine

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