HUMAN ORGAN TRANSPLANTATION


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I. Guiding Principles on Human Organ Transplantation

In May 1987, the Fortieth World Health Assembly adopted resolution WHA40.13 (Development of guiding principles for human organ transplants), reading as follows:

"The Fortieth World Health Assembly,
Recognizing the scientific progress achieved in human organ transplants in many Member States;
Concerned at the trade for profit in human organs among living human beings;
Affirming that such trade is inconsistent with the most basic human values and contravenes the Universal Declaration of Human Rights and the spirit of the WHO Constitution;
Commending the measures taken by some Member States to regulate human organ transplants and their decision to develop a unified legal instrument to regulate these operations;

REQUESTS the Director-General:

(1) to study, in collaboration with other organizations concerned, the possibility of developing appropriate guiding principles for human organ transplants;
(2) to report to the Health Assembly on the action taken in this regard."

In response to that resolution, the Director-General prepared a set of "Draft Guiding Principles on Human Organ Transplantation". These were submitted to the eighty-seventh session of the WHO Executive Board in January 1991. On 24 January 1991, the Board adopted resolution EB87.R22 (Human organ transplantation) in which it recommended that the Health Assembly endorse the Guiding Principles (after modification to take into account the Board’s suggestions). On 13 May 1991, the Health Assembly adopted resolution WHA44.25, reading as follows:

"The Forty-fourth World Health Assembly,
Having considered the report of the Director-General on human organ transplantation;
1. THANKS the Director-General for his report;
2. ENDORSES the Guiding Principles on Human Organ Transplantation contained therein;
3. RECOMMENDS that Member States take account of the Guiding Principles in the formulation of their own policies on human organ transplantation and that by appropriate means they disseminate the idea of multi-organ donation for human transplantation from deceased persons;
4. REQUESTS the Director-General:

(1) to review the Guiding Principles from time to time in the light of national experience in their implementation and of developments in the field of human organ transplantation;

— 5 —
(2) to disseminate the Guiding Principles as widely as possible to all interested parties."

The full text of the Director-General’s report on this subject is reproduced below (the format is identical to that contained in the Director-General’s Report on Human Organ Transplantation, presented to the Health Assembly as document A44/11).

INTRODUCTION

1. In resolution WHA40.13 (Development of guiding principles for human organ transplants), adopted in May 1987, the Forty-ninth World Health Assembly requested the Director-General to “study, in collaboration with other organizations concerned, the possibility of developing appropriate guiding principles for human organ transplants”.¹ The process of responding to this request was initiated in June 1989, following the adoption by the Forty-second World Health Assembly, in May 1989, of resolution WHA42.5 (Preventing the purchase and sale of human organs).

2. In order to take due account of the diversity in systems of health care and law, and of their social, cultural, religious and medical circumstances, the Director-General initiated a process of consultation involving a broad range of organizations and individual experts.² The principal initiatives were the establishment of an informal working group at WHO headquarters (with representatives from all relevant WHO programmes, as well as the Secretary-General of CIOMS) and the convening of an Informal Consultation on Organ Transplantation in Geneva (2-4 May 1990).³ This was attended by international experts in organ transplantation, medical ethics, health policy and law, and by representatives of intergovernmental and nongovernmental organizations.

3. This Consultation expressed the view that it was “indeed feasible to develop the Guiding Principles that had been called for in resolution WHA40.13” and reviewed an initial draft of a set of Guiding Principles. On the basis of the outcome of the Consultation, as set forth in the report of the Consultation, the initial draft was amended and widely distributed for comment to all participants and to other experts on medical, legal, ethical, cultural, religious and health policy aspects of organ transplantation. It was also sent for comment to all the WHO regional

¹ It should be noted that, in the course of the Thirty-ninth World Health Assembly, held in May 1986, a number of countries submitted a draft resolution on human organ transplants, dealing with, inter alia, ethical issues. It was agreed that, before the Health Assembly dealt with the matter, it should be considered by the Executive Board at its seventy-ninth session. A debate on the subject did in fact ensue at the latter session, which was held from 12 to 23 January 1987 (document EB79/1987/REC/2, pp. 178-182). The Director-General submitted a report entitled “Human organ transplantation” to the Board on that occasion (document EB79/1987/REC/1, Part I, Annex 16).

² The Director-General acknowledges with appreciation the particular contributions to the preparation of this document of Professor Bernard Dickens (Toronto), Professor Henri Kreis (Paris), Professor Peter Morris (Oxford) and Mr Russell Scott (Sydney).

³ The report of this Consultation is available (in English only) as document WHO/HLE/90.1.
offices. A Second Informal Consultation on Organ Transplantation, with smaller membership, was convened in Geneva on 3 and 4 October 1990,\(^1\) in order to review the second draft of the Guiding Principles, in the light of the comments and suggestions received, and to prepare a third draft from which this final draft is derived.

**Guiding Principles**

**on Human Organ Transplantation**

**Preamble**

1. As the Director-General's report to the seventy-ninth session of the Executive Board pointed out, human organ transplantation began with a series of experimental studies at the beginning of this century. That report drew attention to some of the major clinical and scientific advances in the field since Alexis Carrel was awarded the Nobel Prize in 1912 for his pioneering work. Surgical transplantation of human organs from deceased, as well as living, donors to sick and dying patients began after the Second World War. Over the past 30 years, organ transplantation has become a worldwide practice and has saved many thousands of lives. It has also improved the quality of life of countless other persons. Continuous improvements in medical technology, particularly in relation to tissue "rejection", have brought about expansion of the practice and an increase in the demand for organs. A feature of organ transplantation since its commencement has been the shortage of available organs. Supply has never satisfied demand, and this has led to the continuous development in many countries of procedures and systems to increase supply. Rational argument can be made to the effect that shortage has led to the rise of commercial traffic in human organs, particularly from living donors who are unrelated to recipients. There is clear evidence of such traffic in recent years, and fears have arisen of the possibility of related traffic in human beings. Health Assembly resolutions WHA40.13 and WHA42.5 are an expression of international concern over these developments.

2. These Guiding Principles are intended to provide an orderly, ethical, and acceptable framework for regulating the acquisition and transplantation of human organs for therapeutic purposes. The term "human organ" is understood to include organs and tissues but does not relate to human reproduction, and accordingly does not extend to reproductive tissues, namely ova, sperm, ovaries, testicles or embryos, nor is it intended to deal with blood or blood constituents for transfusion purposes. The Guiding Principles prohibit giving and receiving money, as well as any other commercial dealing in this field, but do not affect payment of expenditures incurred in organ recovery, preservation and supply. Of par-

\(^1\) The report of this Consultation is available (in English only) as document WHO/HLE/90.2.
ticular concern to WHO is the protection of minors and other vulnerable persons from coercion and improper inducement to donate organs.

* * *

Organs and tissues (referred to in this text as “organs”) may be removed from the bodies of deceased and living persons for the purpose of transplantation only in accordance with the following Guiding Principles.

GUIDING PRINCIPLE 1

Organs may be removed from the bodies of deceased persons for the purpose of transplantation if:

(a) any consents required by law are obtained; and
(b) there is no reason to believe that the deceased person objected to such removal, in the absence of any formal consent given during the person’s lifetime.

GUIDING PRINCIPLE 2

Physicians determining that the death of a potential donor has occurred should not be directly involved in organ removal from the donor and subsequent transplantation procedures, or be responsible for the care of potential recipients of such organs.

GUIDING PRINCIPLE 3

Organs for transplantation should be removed preferably from the bodies of deceased persons. However, adult living persons may donate organs, but in general such donors should be genetically related to the recipients. Exceptions may be made in the case of transplantation of bone marrow and other acceptable regenerative tissues.

An organ may be removed from the body of an adult living donor for the purpose of transplantation if the donor gives free consent. The donor should be free of any undue influence and pressure and sufficiently informed to be able to understand and weigh the risks, benefits and consequences of consent.

GUIDING PRINCIPLE 4

No organ should be removed from the body of a living minor for the purpose of transplantation. Exceptions may be made under national law in the case of regenerative tissues.

GUIDING PRINCIPLE 5

The human body and its parts cannot be the subject of commercial transactions. Accordingly, giving or receiving payment (including any other compensation or reward) for organs should be prohibited.
GUIDING PRINCIPLE 6

Advertising the need for or availability of organs, with a view to offering or seeking payment, should be prohibited.

GUIDING PRINCIPLE 7

It should be prohibited for physicians and other health professionals to engage in organ transplantation procedures if they have reason to believe that the organs concerned have been the subject of commercial transactions.

GUIDING PRINCIPLE 8

It should be prohibited for any person or facility involved in organ transplantation procedures to receive any payment that exceeds a justifiable fee for the services rendered.

GUIDING PRINCIPLE 9

In the light of the principles of distributive justice and equity, donated organs should be made available to patients on the basis of medical need and not on the basis of financial or other considerations.

* * *

COMMENTARIES ON GUIDING PRINCIPLES

COMMENTARY ON THE INTRODUCTORY STATEMENT:

The purpose of this introductory proposition is to establish a comprehensive and exclusive system for the removal of organs from deceased and living donors for transplantation. As cadaver donation is best dealt with by national legislation, each jurisdiction will determine the definition of “deceased person” and criteria of death, as well as the means of implementing the Guiding Principles.

COMMENTARY ON GUIDING PRINCIPLE 1:

There are two systems dealing with the obtaining of organs from deceased persons. These are the “opting in”/“contracting in” (“explicit consent”) system of post mortem organ removal, in which deceased persons express approval when the deceased person prior to death that they approve such removal, or an appropriate family member expresses approval when the deceased person left no statement or other evidence to the contrary, and the “opting out”/“contracting out” (“presumed consent”) system. This presumes that organs may be removed for transplantation from the bodies of deceased persons unless those persons when alive stated their objections, or perhaps
others who were close to them stated at an appropriate time that the
persons objected to their deceased bodies being so treated. In the
case of both the opting in and opting out systems, any statements
or other adequate indications of opposition by persons to posthumous organ removal from their bodies will prevent such removal.

When a deceased person leaves no evidence of opposition to
removal, the opting in system normally requires consent of an ap-
propriate family member for organ removal. In the opting out sys-
tem, no consent is required, but family members may take initiatives
to state the opposition of the deceased person or of themselves.

**Commentary on Guiding Principle 2:**

This provision is designed to reduce the possibility of a conflict
of interest that would arise if the physician or physicians determin-
ing the death of a potential donor were also involved in organ
removal or implantation.

**Commentary on Guiding Principle 3:**

The first paragraph of this Principle is intended to emphasize
the importance of developing cadaveric donation programmes in
countries where this is culturally acceptable, and to discourage dona-
tions from living, genetically unrelated donors, except for transplanta-
tion of bone marrow and of other acceptable regenerative tissues.

The second paragraph seeks to protect potential donors from
undue pressure and undue inducements from others. It emphasizes
the necessity for complete and objective information to be given to
the donor. It also takes into account issues relating to persons
(other than minors) who are legally incompetent to fulfil the require-
ments for "free consent" or the other conditions specified in this
paragraph.

**Commentary on Guiding Principle 4:**

This Principle provides for absolute prohibition of the removal
of organs for transplantation from legal minors. However, an ex-
ception concerning regenerative tissues may be allowed by national
legislation. In such cases, the protection of minors could be as-
sured by requiring, among other conditions, the minor's compre-
hending consent and the consent of the parent(s) or the legal
guardian. The parent(s) or the legal guardian may have a conflict
of interest, for example if they are responsible for the welfare of an
intended recipient of the donated tissues. In such a case, prior per-
mission of an independent body, such as a court or other appropri-
ate authority of comparable independence or status, should be
required. However, an objection by the minor should take effect
and prevail over any other consent.
COMMENTARY ON GUIDING PRINCIPLE 5:

This Principle is designed to prohibit traffic in human organs for payment. The method of prohibition, including sanctions, will be determined independently by each jurisdiction. The Principle does not prohibit payment of reasonable expenses incurred in donation, recovery, preservation and supply of organs for transplantation.

COMMENTARY ON GUIDING PRINCIPLE 6:

The intention of this Principle is to prohibit advertisements that have a commercial (profit-making) purpose. Promotion and encouragement of altruistic donation of human organs and tissues by means of advertisement or public appeal are not affected by this Principle.

COMMENTARY ON GUIDING PRINCIPLE 7:

This provision addresses medical professional and other involvement in removal, intermediate management and implantation of organs with knowledge, actual or constructive, that commercial transactions have occurred.

COMMENTARY ON GUIDING PRINCIPLE 8:

This provision reinforces Guiding Principle 7 by restricting entrepreneurial practice in organ recovery and implantation. A medical or other health practitioner uncertain whether a fee proposed to be charged is justifiable may seek the opinion of an appropriate licensing or disciplinary authority before the fee is proposed or levied.

COMMENTARY ON GUIDING PRINCIPLE 9:

This provision is self-explanatory.

II. Use of human organs and tissues for therapeutic purposes: a review of international and national legislation, codes and other measures to combat commercialism

On 15 May 1989, the Forty-second World Health Assembly adopted resolution WHA42.5 (Preventing the purchase and sale of human organs), reading as follows:

"The Forty-second World Health Assembly,

Concerned by the commercial trafficking in the organs of healthy donors, which exploits human distress and puts at increased risk the health of the donors;
HUMAN ORGAN TRANSPLANTATION

Aware that commercial arrangements for organ transplants are nevertheless being undertaken and that to date there has been little success in preventing trafficking in human organs;

Anxious to prevent the exploitation of human distress, particularly in children and other vulnerable groups, and to further the recognition of the ethical principles which condemn the buying and selling of organs for purposes of transplantation;

1. CALLS UPON Member States to take appropriate measures to prevent the purchase and sale of human organs for transplantation;

2. RECOMMENDS that Member States introduce legislation to prohibit trafficking in organs where this cannot effectively be prevented by other measures;

3. URGES Member States, in close cooperation with professional health organizations and supervising health authorities, to discourage all practices which facilitate commercial trafficking in organs;

4. REQUESTS Member States to report as soon as possible to WHO on action taken with respect to this resolution;

5. REQUESTS the Director-General to report to the Forty-fourth World Health Assembly the measures taken by the governments of Member States in furtherance of this resolution."

The following is the text of the Director-General’s report on this subject (contained in Part 2 of the above-mentioned document A44/11):*

INTRODUCTION

1. On 15 May 1989 the Forty-second World Health Assembly adopted resolution WHA42.5 (Preventing the purchase and sale of human organs). Operative paragraph 5 of this resolution requests the Director-General to report to the Forty-fourth World Health Assembly on the steps taken by the governments of Member States under this resolution. This report has been prepared on the basis of information received from Member States in response to a circular letter from the Director-General. In addition, a systematic search has been undertaken for all relevant material, and in particular legislative texts published in the WHO quarterly journal, the International Digest of Health Legislation. Acknowledged experts in developed and developing countries alike have been consulted in the preparation of the report. As far as possible, only primary sources have been cited, as well as statements and declarations issued by international and, in some cases, national governmental and nongovernmental organizations. The transmission of any additional material addressing the particular issues, of which Member States may be aware, would be welcome. It should be mentioned that no attempt has been made to review the abundant literature concerning allegations of reported commerce in human organs and tissues for transplantation purposes. Certain aspects of this matter are under review by the United

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* No substantive changes have been made to this part of the Report. However, for purposes of convenience, the system for the numbering of references has been modified. The term "IDHL" is used throughout for International Digest of Health Legislation. — ED.
Nations Sub-Commission on Prevention of Discrimination and Protection of Minorities, as well as by a number of nongovernmental organizations.

INTERNATIONAL DEVELOPMENTS

2. It appears that the first international effort to deal with this issue dates back to 1970, when the Committee on Morals and Ethics of the Transplantation Society adopted a Statement that includes a rubric (Prohibition of reimbursement for organ donation), affirming that “The sale of organs by donors living or dead is indefensible under any circumstances”.¹ In September 1985 the Council of the Transplantation Society proposed a series of “guidelines for the distribution and the use of organs from cadaver sources and from living unrelated donors”.² Paragraph 6 of the guidelines for cadaver organ distribution prescribes that “Transplant surgeons/physicians should not advertise regionally, nationally, or internationally”. Paragraph 2 of the guidelines for the donation of kidneys by unrelated living donors states that “It must be established by the patient and transplant team alike that the motives of the donor are altruistic and in the best interest of the recipient and not self serving or for profit. In the best interests of all concerned, the motivation and medical suitability of the donor should be evaluated by physicians independently of the potential recipient, the recipient’s physicians, and the transplant team. An independent donor advocate should be assigned to the unrelated donor to ensure that informed consent is made without pressure, to enhance personal attention given to the donor throughout the entire donation period, to ensure official expressions of gratitude, and to aid with subsequent problems or difficulties. In all instances, and especially in the exceptional case where the emotionally related donor is not a spouse or second-degree relative, the donor advocate would ensure and document that the donation was one of true altruism and not self serving or for profit”. Paragraph 3 states that “Active solicitation of living unrelated donors for profit is unacceptable”. Paragraph 6 states that “It should be clearly understood that no payment to the donor by the recipient, the recipient’s relatives or any other supporting organisation, can be allowed. However, reimbursement for loss of work earnings and any other expenses related to the donation is acceptable”. The Council also adopted the following Special Resolution:

“No transplant surgeon/team shall be involved directly or indirectly in the buying or selling of organs/tissues or in any transplant activity aimed at commercial gain to himself/herself or an associated hospital or institute. Violation of these guidelines by any member of The Transplantation Society may be cause for expulsion from the Society.”

3. On 11 May 1978 the Committee of Ministers of the Council of Europe adopted resolution R (78) 29 on “harmonisation of legislations of
member states relating to removal, grafting and transplantation of human substances”. Article 9 of the resolution reads as follows:

“No substance may be offered for profit. However, loss of earnings and any expenses caused by the removal or preceding examination may be refunded. The donor, or potential donor, must be compensated, independently of any possible medical responsibility, for any damage sustained as a result of a removal procedure or preceding examination, under a social security or other insurance scheme.”

4. On 1 July 1986, in the course of its General Assembly held in Budapest, the European Dialysis and Transplant Association-European Renal Association approved a Statement on “Safeguards for Live Kidney Donors”, which includes the following paragraphs:

“(1) The practice of organ transplantation involving coercion or payment to a donor to induce him to donate an organ or organs is unacceptable within ethical medicine.”

“(4) All responsible clinicians should make every effort to ensure that they do not become involved in transplantation from paid or coerced donors.

(5) The deliberate use of paid or coerced donors is incompatible with membership of the EDTA-European Renal Association.”

5. On 16 and 17 November 1987 a Conference of European Health Ministers was convened, under the auspices of the Council of Europe, in Paris, at the invitation of the then French Minister of Health and Family Affairs. The Final Text agreed on by the Ministers includes the following two paragraphs in Part II (The non-commercialisation of human organs):

“... A human organ must not be offered for profit by any organ exchange organisation, organ banking centre or by any other organisation or individual whatsoever. However, this does not prevent the compensation of living donors for loss of earnings and any expenses caused by the removal or preceding examination.

... Neither organisations nor individuals should advertise outside their national territory either for donation or transplantation.”

6. In October 1985 the Thirty-seventh World Medical Assembly, convened by the World Medical Association (WMA) in Brussels, issued a Statement on Live Organ Trade. Noting that “in the recent past a trade of considerable financial gain has developed with live kidneys from underdeveloped countries for transplantation in Europe and the United States of America”, the WMA condemned the “purchase and sale of human organs for transplantation”, and called on the “governments of all countries to take effective steps to prevent the commercial use of human organs.” At the Thirty-ninth World Medical Assembly, held in Madrid in October 1987, the WMA adopted a Declaration on Human
Organ Transplantation. Paragraph 8 of this Declaration condemns the “purchase and sale of human organs for transplantation”.6

7. A “Unified Arab Draft Law on Human Organ Transplants” was adopted at the twelfth session of the Council of Arab Ministers of Health, held in Khartoum from 14 to 16 March 1987. Article 7 of this text lays down that: “The sale, purchase or remunerated donation of organs is prohibited, and no specialist may perform a transplant operation if he knows the organ to have been acquired by such means.”7

8. A Congress on Ethics, Justice and Commerce in Transplantation: A Global Issue was held in Ottawa from 20 to 24 August 1989. A number of resolutions were agreed to on the final day. Resolution 2 (Commercialism and transplantation) confirms that “The buying and selling of human organs and tissue for transplantation is unacceptable”, and resolution 4 (Alleged criminal actions to obtain organs) reads as follows: “Criminal activity to obtain organs for transplantation is abhorrent. No evidence was presented to substantiate allegations of illegal and criminal acts to obtain organs but such allegations impose a duty to continue investigation by appropriate authorities.”

9. In the course of the XIV International Congress on Penal Law, held in Vienna from 1 to 7 October 1989 under the auspices of the International Association of Penal Law, a resolution was adopted on “Criminal law and modern bio-medical techniques”. This includes a Section 3 entitled “Organ transplants and artificial organs”, in which the following paragraph 3.10 appears:

“3.10 Commercialization of human organs and tissues should be prevented, if necessary by penal sanctions. In particular, national and international measures should be adopted to prevent the utilization of organs and tissues obtained through the exploitation of the economic needs of the donors or their relatives.”

AFRICAN REGION

10. Under the terms of Section 161 of Law No. 85-05 of 16 February 1985 on health protection and promotion of Algeria, the “removal and transplantation of human organs and tissues may not be subject to any financial transactions”.8

11. Section 28 of the Human Tissue Act, No. 65 of 1983, of South Africa lays down stringent provisions concerning “any payment in respect of the import, acquisition or supply of any tissue or gamete for or to another person for any of the purposes referred to”.9

12. In Zimbabwe, Section 17 of the Anatomical Donations and Post-Mortem Examinations Act, 1976, lays down that “no person, other than an authorized institution, may receive any fee, profit or remuneration for providing any other person for scientific purposes or therapeutic purposes with any tissue, other than blood or a blood product, removed
from the body of any deceased or living person, and any payment which has been received for such provision of tissue shall be refundable to the person who made it”. This provision is not, however, intended to “prevent any medical practitioner or dental practitioner from receiving remuneration for any professional services rendered by him to any person”.

REGION OF THE AMERICAS

13. In Argentina, Section 27 of Law No. 21,541 of 21 March 1977 on the removal and transplantation of organs and anatomical materials prohibits trade in human organs and tissues. Regulations for the implementation of this Law (as amended by Law No. 23,464) were promulgated by Decree No. 3011/77 of 3 October 1977, itself amended by Decree No. 397/89 of 28 March 1989. Annex 1 to the 1989 Decree includes a “code of ethics for banks of organs and/or anatomical materials”. One of the provisions in this code states that “organs and/or anatomical materials from a bank may not be bought or sold”.

14. In Bolivia, Section 90 of the Health Code promulgated in 1978 prohibits trade in organs, tissues and body fluids in general (however, the Health Authority is empowered to authorize their “interchange” for charitable purposes).

15. The Constitution promulgated in Brazil on 5 October 1988 prohibits (in Section 199) any kind of commercial transactions in human organs, tissues and substances (intended for transplantation, research, or therapeutic purposes), as well as any blood and blood derivatives.

16. In Canada, there is no relevant legislation at the national level. At present, the legislation of the various Canadian Provinces is based on the Uniform Human Tissue Gift Act, proposed in 1971 by the Uniform Law Conference of Canada. This model act has now been superseded by the Uniform Human Tissue Donation Act, which was approved by the Uniform Law Conference on 14 August 1989. It includes the following Section 15 (Commerce prohibited):

“15. (1) No person shall buy, sell or otherwise deal in, directly or indirectly, any tissue, body or body part for the purpose of a transplant or for a therapeutic purpose, medical education or scientific research.

(2) Any dealing in any tissue, body or body part that was lawful before this Act came into force shall continue to be lawful, provided this Act is complied with.

(3) A person who contravenes this section is guilty of an offence and liable on summary conviction to a fine of not more than $100,000 or to imprisonment for not more than 1 year, or to both.”

17. The relevant provisions in Nova Scotia are contained in the Human Tissue Gift Act, 1973; this includes a Section 11 laying down that “No
person shall buy, sell or otherwise deal in, directly or indirectly, for a valuable consideration, any tissue for a transplant, or any body or part or parts thereof other than blood or a blood constituent, for therapeutic purposes, medical education or scientific research, and any such dealing is invalid as being contrary to public policy." There is a corresponding provision in (for example) the Human Tissue Gift Act of Alberta and of Ontario and the Human Tissue Act of New Brunswick. 14

18. In Chile, there are relevant provisions in Book Nine of Decree-Law No. 725 of 11 December 1967 amending Decree-Law No. 226 of 15 May 1931 approving the Health Code, as amended by Law No. 18.173 of 25 November 1982. Section 145 of the Health Code excludes payment for organs, tissues and body parts from living donors for transplantation purposes. Under Section 152, any contract or agreement providing for the promise or supply for payment of any organ or body part for such purposes is null and void. Furthermore, Section 3(f) of Regulations issued on 3 June 1983 for the implementation of Book Nine of the Health Code requires a living donor to make a sworn declaration that he has received no compensation, valuable consideration, or other material benefit from the recipient or from third parties.

19. In Colombia, Section 7 of Law No. 73 of 20 December 1988, amending Law No. 9 of 1979 and laying down detailed provisions concerning the donation and transplantation of organs and anatomical parts for transplantation and other therapeutic purposes, prohibits the donation or supply of the anatomical parts referred to in the Law for gain; the use of such parts may not be compensated in cash or in kind in any way. 15 Further provisions were laid down in Decree No. 1172 of 6 June 1989, 16 Section 17 of which reiterates the prohibition of any form of remuneration or compensation for organs or anatomical parts intended for transplantation or for other therapeutic, teaching, or research purposes. Section 18 deals with the export of organs or anatomical parts, in the following terms:

"The export of organs or anatomical parts shall be prohibited. However, the Ministry of Health may, in the event of a serious public health catastrophe or for reasons of human solidarity, subject to due regard for national requirements and provided that the channels used are blood banks, authorize exports from time to time, if this is an appropriate means of inter-state assistance; nevertheless, this shall apply only in the case of anatomical parts obtained from cadavers, and exports may be effected solely for therapeutic purposes, provided always that no profit-making motive is involved."

20. In Costa Rica, Law No. 5560 of 20 August 1974 on human transplants prohibits any remuneration or compensation for organs and anatomical materials removed for therapeutic or research purposes. 17

21. In Cuba, Law No. 41 of 13 July 1983 on public health lays down that "The donation of organs, blood, and other tissues constitutes a highly humanitarian act". 18 Section 80 of the Regulations for the im-
plementation of the Law on public health, promulgated by Decree No. 139 of 4 February 1988, amplifies this provision, by specifying that "the donation of organs, blood, and tissues shall constitute a free and expressly voluntary act of the donor or of his representative, performed for humanitarian reasons."

22. In the Dominican Republic, Section 1 of Law No. 60-88 of 25 May 1988 on corneal donation lays down that "donations of eyes to become effective after death shall be made freely, without the anticipation of any remuneration".

23. In Ecuador, there are provisions in Law No. 64 of 26 May 1987 reforming the Health Code which clearly make it illegal to receive valuable consideration for cession of a cadaver or cadaver parts.

24. In Guatemala, Section 10 of the Regulations on dealings in organs and tissues from human beings or from cadavers, promulgated by Government Order No. 740-86 of 26 September 1986, provides that the donation of organs and tissues for transplantation purposes must always be free of charge.

25. In Honduras, Section 5 of the Law on the transplantation and removal of human organs and tissues, promulgated by Decree No. 131 of 23 November 1982, lays down that no payment, in cash or in kind, may be made in respect of human organs and tissues. Any payment or other compensation received by a living donor or by the relatives of a deceased donor is recoverable, without prejudice to the penal sanctions incurred.

26. In Mexico, the General Law on health of 26 December 1983, as amended by a Decree of 25 April 1987, includes a Section 333 laying down that human organs and tissues may not be imported into or leave the national territory without the prior permission of the Secretariat for Health. Section 21 of Regulations issued on 18 February 1985 for the implementation of this Law lays down that no payment may be made for the donation of organs and tissues for therapeutic purposes. Section 22 prohibits trade in organs or tissues that are detached or sectioned in the course of a surgical operation, an accident, or an unlawful act.

27. Law No. 10 of 11 July 1983 regulating the transplantation of organs and anatomical parts of Panama includes the following Section 4:

"The transfer of human organs or anatomical parts shall, in principle, involve no remuneration. Should the donor so request, he shall be entitled to payment of hospital medical expenses, laboratory charges, and similar expenses incurred by him, as well as compensation for loss of earnings during his absence from work by reason of examinations and other necessary procedures. Similarly, the recipient or recipients of an organ or anatomical parts shall be entitled to free medical care on the national territory provided by the medical establishments in which the donation takes place, in order to ensure follow-up to the donation."
28. In the *United States of America*, Title III (Prohibition of Organ Purchases) of the National Organ Transplant Act (approved by the President on 19 October 1984 as Public Law 98-507) has been summarized (unofficially) as follows:

"Under subsection (a) of Section 301, it is unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce. Penal provisions are laid down in subsection (b). Subsection (c) lays down that, for the purposes of subsection (a), the term 'human organ' means the human (including fetal) kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin, and any other human organ (or any subpart thereof, including that derived from a fetus) specified by the Secretary of Health and Human Services by regulation. The term 'valuable consideration' does not include the 'reasonable payments associated with the removal, transportation, implantation, processing, preservation, quality control, and storage of a human organ or the expenses of travel, housing, and lost wages incurred by the donor of a human organ in connection with the donation of the organ'.”  

29. At the State level, a Uniform Anatomical Gift Act was approved in 1968 by the National Conference of Commissioners on Uniform State Laws. Adopted (with variations) in all 50 States and the District of Columbia, it did not contain any explicit prohibition on commercial transactions. Such a ban does appear in the Uniform Anatomical Gift Act (1987), in the following Section 10 (Sale or purchase of parts prohibited):

"(a) A person may not knowingly, for valuable consideration, purchase or sell a part for transplantation or therapy, if removal of the part is intended to occur after the death of the decedent.

(b) Valuable consideration does not include reasonable payment for the removal, processing, disposal, preservation, quality control, storage, transportation, or implantation of a part.

(c) [Penal provisions].”

At the time of preparation of the present report, Arkansas, California, Connecticut, Hawaii, Idaho, Michigan, Montana, Nevada, North Dakota and Rhode Island had adopted statutory provisions based on this Section.

30. It should be mentioned that the Council on Ethical and Judicial Affairs of the American Medical Association has issued an Opinion on organ donation, stating that: “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.”
31. In Venezuela, the Law of 19 July 1972 on transplantation of human organs and anatomical materials includes a Section 5, which prohibits any remuneration or compensation for organs and anatomical materials removed for therapeutic purposes. Under Section 6, persons who act as intermediaries, for profit-making purposes, in the procurement of organs or anatomical materials for therapeutic purposes are liable to between four and eight years’ imprisonment.27

SOUTH-EAST ASIA REGION

32. As far as India is concerned, WHO has been informed that the Government of the State of Maharashtra appointed a special committee to examine commercial transactions in human organs, and related matters. That committee has now submitted a report, in the form of a draft bill, which would prohibit commercial trafficking of any nature in human organs for transplantation purposes. It had been expected that this bill would be enacted into law before the end of 1990.28 As of September 1991, the bill had not yet been enacted. WHO has been informed that a comprehensive bill on the subject of organ transplantation will be introduced in the Indian Parliament during the winter session of 1991.

33. In Indonesia, Government Regulation No. 18 of 16 June 1981 on clinical and anatomical autopsies and transplantation of human organs and tissues includes a Section 16 prescribing that neither the donor nor the donor’s family has any right to material compensation in respect of organs and/or tissues removed for transplantation purposes.

34. In Sri Lanka, the Transplantation of Human Tissues Act, No. 48 of 1987, includes a Section 17 entitled “Any sale, dealing in or disposal of a body, or any part or tissue thereof, prohibited”.29

EUROPEAN REGION

35. In Austria, under the terms of Section 62a of the Hospitals Law of 18 December 1956, as amended by the Federal Law of 1 June 1982, organ transplants may be performed only in non-profit-making hospitals. Organs or parts of organs of deceased persons may not be the subject of transactions carried out with a view to profit.30

36. In Belgium, Section 4 of the Law of 13 June 1986 on the removal and transplantation of organs lays down that “Organs and tissues may not be provided for profit, irrespective of the parties involved”, while “the Crown is empowered to make rules concerning the compensation of living donors at public expense or by the social security agency designated by it”. Such compensation is to cover both the costs and loss of income directly resulting from the provision of an organ.31

37. In Denmark, it is an offence under Section 20(3) of Law No. 402 of 13 June 1990 on the determination of death, autopsies, transplantation,
etc. to offer or receive any form of compensation in respect of the removal or transfer of tissues or any other biological materials for therapeutic purposes (as referred to in Sections 13 and 14 of the Law). It is likewise an offence to collaborate in such procedures, although aware of transactions of this nature.

38. In Finland, Section 11 of Law No. 355 of 26 April 1985 on the removal of human organs and tissues for medical purposes lays down that “no payment may be promised or given to the donor or his/her assignee for the removal and use of an organ or tissue or for the donation of a body as stipulated in the Law”.

39. In France, Section 3 of Law No. 76-1181 of 22 December 1976 on the removal of organs lays down that, “without prejudice to the reimbursement of any costs that organ removal procedures may entail, the removal of organs (for transplantation and other therapeutic purposes) may not give rise to any remuneration”. The preliminary draft Law on the life sciences and human rights (known as the “Brabant” draft) confirms the principle of non-remunerated donations. Specifically, the new Article L. 666-7 proposed for insertion in the Public Health Code affirms that “organ donation and the removal of products of the human body may not give rise to any financial compensation that benefits the donor, other than reimbursement of expenses incurred...”.

40. The inacceptability of commerce in human organs for transplantation purposes was reaffirmed by the National Consultative Ethical Committee for the Life and Health Sciences in its Opinion [Avis] of 13 December 1990 on “the non-commercialization of the human body”.

41. In Germany, except as stated below, there is currently no legislation on organ transplantation. However, the Cartel of German Transplantation Centres has formulated a Transplantation Code, binding on all physicians performing transplantations. One of the effects of this Code is that “any trade in organs or any commercialization of the transplantation... sector is, in principle, excluded”.

42. In what was formerly the German Democratic Republic, the Ordinance of 4 July 1975 on the performance of organ transplantations laid down, in Section 3, that “No material or financial benefits may be demanded, offered, or granted in return for organ donation”. Information made available informally to WHO indicates that this Ordinance remains in force, on an interim basis, in the five new Länder created as a result of the unification process.

43. In Greece, Law No. 1383 of 2 August 1983 on the removal and transplantation of human tissues and organs, lays down (in Section 2) that tissues and organs may be removed from a living donor for purposes of transplantation, and organs may be removed from a cadaver, only on a non-remunerated basis; any financial exchange between the donor, the recipient, their families, and any other person is prohibited (however, the costs of the removal procedure and of storage and transportation of the tissue or organ are not covered by this provision).
44. In Hungary, Section 2(1) of Ordinance No. 18 of 4 November 1972 of the Minister of Health for the implementation of the provisions of Law No. II of 1972 on health relating to the removal and transplantation of organs and tissues lays down that "The information provided by the physician to the donor must... specify that donation of the organ may be made only in the absence of payment and neither the donor, nor the patient or his relative, nor any other person may ask for or receive any form of remuneration".38

45. WHO has been informed that in Ireland the Medical Council would take a very serious view of any physician attempting to transplant purchased organs. There is no legislation on the subject.

46. In the case of Israel, there is no legislation on the subject but information provided to WHO indicates that the existing arrangements between the health and religious authorities preclude any commercial transactions in human organs for transplantation purposes.39

47. In Italy, the relevant provisions are contained in Sections 19 and 20 of Law No. 644 of 2 December 1975 regulating the removal of parts of cadavers for purposes of therapeutic transplantation and prescribing rules governing the removal of the pituitary gland from cadavers with a view to producing extracts for therapeutic purposes. Under Section 19, a penalty of imprisonment and a fine are imposed on any person who "receives money or other benefit or who accepts a promise thereof for agreeing to the removal, after his death, of parts of his body or of another person's body for the purposes covered by this Law". Section 20 imposes imprisonment and a fine on any person who "acquires for financial gain a part of a cadaver to be used for the purposes covered by this Law, or who has any kind of dealings therein". If the person is practising a health profession, he is, in addition, prohibited from practising his profession for between two and five years.40

48. In the case of Liechtenstein (a non-Member State), WHO has received the following communication from a senior official in the Government responsible for social and health affairs: "There is no legislation in Liechtenstein dealing with the transplantation of human tissue or organs of living persons or of embryos or dealing with the trade of human tissue or organs, since Liechtenstein does not dispose of the necessary technological facilities and staff capacities to perform any of the above-mentioned operations."41 Provisions dealing with cadaveric organ donation are contained in Section 14 of the Principality's Health Law of 18 December 1985.

49. The Law of 25 November 1982 regulating the removal of substances of human origin of Luxembourg includes a Section (16) establishing the principle of non-remuneration in respect of donations of human substances. This Section does however provide for the reimbursement of loss of revenue and other expenses that may be occasioned by organ removals.42

50. There is no legislation in Malta. However, guidance has been is-
sued by the Medical Council to the health authorities, in the following terms: "It is the unanimous view of the Council that, provided it is beyond doubt that the ‘donor’ will truly make a donation of the organ to be transplanted, it would not be unethical... to provide the facilities... or for a medical practitioner to carry out the necessary operation. In case the donor is a relative or a close friend of the patient the difficulty of ensuring that the offer is indeed a donation may be less than in the case of a complete stranger; and in the latter case, therefore, one is to require more clear evidence of the donation."

51. There is currently no legislation on organ transplantation in the Netherlands. However, a draft Law on organ donation (in the version dated 17 May 1990) includes a Section 2 which prescribes that "Consent for the removal of an organ with a view to receiving payment that exceeds the costs, including loss of earnings, directly linked with the removal of the organ, shall be null and void".

52. In Romania, the Law of 6 July 1978 on the safeguarding of the health of the population includes a provision (in Section 131) laying down that "The removal and transplantation of human tissues and organs may not be the subject of any financial transaction".45

53. Section 2 of Law No. 30 of 27 October 1979 of Spain on the removal and transplantation of organs prohibits any compensation for the donation of organs. It is however specified that "resources shall be made available to ensure that the execution of such procedures does not cause any hardship to the living donor or the family of the deceased person". The donor may not receive any financial compensation whatever, nor may the recipient be required to make any payment for the transplanted organ.44 These provisions are reiterated in Crown Decree No. 426 of 22 February 1980. Section 5 of this Decree states that the living donor ‘shall be guaranteed the care necessary for his recovery as well as coverage of any costs incurred as a result of the donation and operation’.45 Reference should also be made to Section 428 of the Penal Code (as amended by a Law dated 25 June 1983), which includes provisions making it a serious offence to obtain consent "against payment or reward" for, inter alia, organ transplantation.

54. In Switzerland, there is no federal legislation dealing with organ transplantation. It is however noteworthy that the Swiss Academy of Medical Sciences has issued "Medical ethical guidelines for transplantations" (dated 17 November 1981).46 These lay down that "human tissue for grafting must be provided free of charge, but the donor may be reimbursed for any expenses and for loss of earnings". These guidelines are stated by the Academy to be based on the "rules" formulated by the Council of Europe in its resolution R (78) 29 of 11 May 1978 (see paragraph 3). The Central Committee for Medical Ethics of the Academy is currently updating its guidelines in order to prevent, in more specific terms, the commercialization of organ transplantation.

55. Only one Canton (Ticino) appears to have enacted legislation prohibiting all commercial transactions in organ transplantation (the relevant
provisions are contained in Section 15(6) of the Health Law of 18 April 1989.\textsuperscript{47}

56. Certain of the Cantons (Fribourg, Glarus, Obwald, Solothurn, Thurgau, Valais and Zug) have specifically endorsed the guidelines of the Swiss Academy of Medical Sciences. It appears that in the Canton of Jura the Academy’s guidelines are observed, although not specifically mentioned in any legal instrument.

57. In Turkey, Section 15 of Law No. 2238 of 29 May 1979 on the removal, storage, transfer and grafting of organs and tissues prescribes that any person engaging in commercial transactions in human organs or tissues, or as the intermediary in such transactions, is liable to between two and four years’ imprisonment and a fine of between 50,000 and 100,000 Turkish lira, unless he is liable to a more severe penalty under the terms of another law.\textsuperscript{48}

58. In the United Kingdom of Great Britain and Northern Ireland, the Human Organ Transplants Act 1989 prohibits commercial dealings in human organs. Likewise prohibited are advertisements inviting persons to supply for payment such organs as are specified in the Act, or offering to supply such organs for payment.\textsuperscript{49}

59. A Law was promulgated in Yugoslavia on 15 July 1982 on the conditions governing the exchange and transport of parts of the human body for transplantation for therapeutic purposes. Section 4 of this Law prohibits any form of compensation for the donation of parts of the human body from living or deceased persons. The term “compensation” is defined to mean the “offer of services or the giving of any kind of reward”.\textsuperscript{50}

EASTERN MEDITERRANEAN REGION

60. In Cyprus, Section 4 of Law No. 97 of 1987 on the removal and transplantation of biological materials of human origin lays down that all donations or offers of biological materials for diagnostic, therapeutic, or research purposes must be gratuitous; commercial agreements or transactions are strictly prohibited.\textsuperscript{51}

61. In Egypt, there is no legislation as such but WHO has been informed that, as far as kidney transplants are concerned, the donor must be a relative or acquaintance of the patient. A patient of Egyptian nationality must be a relative of a donor of the same nationality. In the case of patients treated free of charge at State expense, the State covers treatment expenses, but does not provide any payment to the Egyptian donor.

62. In Iraq, Section 3 of Decree No. 698 of 27 August 1986 prohibits the sale or purchase of organs in any form. Physicians aware that organs have been the subject of sale or purchase are to refrain from proceeding with a transplant.\textsuperscript{52}

\textsuperscript{a} See Addendum, p. 28. — ED.
63. In Kuwait, Decree-Law No. 55 of 20 December 1987 on organ transplantation includes the following Section 7:

"7. Organs may not be sold or purchased in any fashion nor may any material reward be obtained in relation to them. Medical specialists may not carry out organ removal if they are aware that such a situation exists.

If an organ has been removed in accordance with the law, there shall be no right to its return." 53

64. In Lebanon, Section 1 of Decree No. 109 of 16 September 1983 on the removal of human tissues and organs for therapeutic and scientific purposes prohibits any form of compensation for the donation of tissues and organs. 54

65. In Saudi Arabia, there is no legislation at present, although WHO has been informed that it is absolutely prohibited to buy or sell human organs. Consideration is being given to approval of the "Unified Arab Draft Law on Human Organ Transplants" (see paragraph 7) as a guide for application in Saudi Arabia. 55

66. In the Syrian Arab Republic, Legislative Decree No. 204 of 15 October 1963, dealing with the establishment of eye banks, includes a provision (in Section 3) indicating that eye banks may supply eyes, on a free-of-charge basis, to ophthalmologists working in university, government, or private hospitals. Furthermore, Law No. 31 of 23 August 1972 on the removal and transplantation of organs from the human body includes a provision in Section 2 laying down that "no organ or part of an organ may be donated for financial gain or remuneration in kind" (however, the donor has the right to be treated in State hospitals at the State's expense). It is further laid down in Section 7 that "The removal and transplantation of organs and tissues, as well as hospitalization and treatment, shall be provided free of charge to citizens of the Syrian Arab Republic". 56

WESTERN PACIFIC REGION

67. In Australia, 57 all the States and Territories have introduced uniform legislation to regulate human tissue transplantation (the powers conferred upon the Federal Legislature under the Constitution are insufficient to justify federal legislation on transplantation). It should be recalled that Australia is a federation of six States and two Territories with a written Constitution conferring specific powers upon the Federal Legislature. In 1976-1977 the Australian Law Reform Commission (a federal body) produced a report entitled Human Tissue Transplants, which included model legislation. This model legislation provides an orderly regulatory system for obtaining and transplanting all human tissues, including organs, regenerative and non-regenerative tissue and blood (but excluding, in the case of living donors, semen, ova, and fetal tissues). The model legislation has, since 1977, been accepted and enact-
ed, with minor variations, by every State and Territory. Accordingly, Australia has in force uniform legislation on human tissue transplantation. Commercial transactions in human tissues are prohibited under criminal penalties. Some States have also expressly prohibited advertisements relating to the sale of tissues. A power of exemption has been retained by the governments for appropriate cases, e.g. where tissues have been properly obtained and then subjected to processing to enable use for therapeutic purposes.

68. In the Philippines, a Senate bill (1110) known as “The Human Organ and Tissue Procurement and Transplant Act of 1989”, which addresses the issue of the sale of human organs, has been introduced by Senate Teofisto Guingona.  

69. The Human Organ Transplant Act 1987 of Singapore includes a Part IV, entitled “Prohibition of trading in organs and blood”. Section 14 lays down that “a contract for arrangement under which a person agrees, for valuable consideration, whether given or to be given to himself or to another person, to the sale or supply of any organ or blood from his body or from the body of another person, whether before or after his death or the death of the other person, as the case may be, shall be void” and a person who enters into such a contract is guilty of an offence. Provision is however made for the acceptability of contracts or arrangements that provide solely for the reimbursement of “any expenses necessarily incurred by a person in relation to the removal of any organ or blood in accordance with the provisions of any other written law”. Similarly, the prohibition referred to does not apply to or in relation to any scheme introduced or approved by the Government granting medical benefits or privileges to any organ or blood donor, any member of the donor’s family, or any person nominated by the donor. Also prohibited is the issue of any advertisement relating to the buying or selling of organs or blood; any person who contravenes this prohibition is also guilty of an offence (Section 15).

REFERENCES

5. Issued by the World Medical Association as document 17.M (not reported in IDHL).

35. Communication from Professor W. Schoeppe and Dr A. Fürsch, dated 11 May 1990.
41. Communication from Dr Peter Wolff, dated 11 April 1990.
ADDENDA

In Malawi, it is an offence under Section 16 of the Anatomy Act, 1990, to supply, for gain or profit, tissue removed from the body of a deceased or living person for therapeutic or other purposes.\(^a\)

In Tunisia, Section 6 of Law No. 91-22 of 25 March 1991 on the removal and transplantation of human organs lays down that it is prohibited to carry out the organ removals referred to in the Law “against any financial compensation, or any other form of transaction, without prejudice to the reimbursement of the expenses to which such procedures may give rise”.\(^b\)

The information given for Yugoslavia in para. 59 (p. 24) has now been superseded. The Law of 15 July 1982 was repealed by the Law on the conditions governing the removal and transplantation of parts of the human body, promulgated by Decree No. 1266 of 18 October 1990 (to be covered in Vol. 43, No. 1, of the *IDHL*). Sec. 12 of this Law prohibits any financial or material compensation for the donation of body parts for transplantation purposes. The term “compensation” includes the offer of services and the granting of favours in any form.

\(^a\) A summary of this Act will appear in Vol. 42, No. 4, of the *IDHL*. — Ed.