

Opinion on problems arising because of the development of methods using human cells and their derivatives. Report.

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Opinion

The Committee reiterates its deep-rooted attachment to the principle that products of human origin are without price and therefore can neither be bought nor sold.

The Committee was consulted on ethical problems arising because of the financial repercussions of human cell cultures. Because of the importance of the subject, the scope of the following Opinion has been extended to deal also with biological derivatives of cells or their components (DNA molecule for instance).

Cells, which are a product of the human body, for that very reason cannot be traded by the person who originated them. However, that person may donate them, in the same way as blood is donated.

If that person is unwell, sampling cells for diagnosis or therapy must be considered as implicitly authorised by the person concerned if, and only to the degree required, sampling is necessary for that purpose. Nevertheless, patients should always be informed that their samples may be used for scientific research when that is so.

Later use of the sample, which must remain strictly anonymous, may fall into two categories :

a) the product is a substance (a molecule, or a segment of a DNA molecule, for instance) which has required sometimes considerable effort to develop or isolate (interferon, erythropoietin as in the case considered, monoclonal antibodies);

b) the product is a cell which is used as a laboratory reagent. It must however be cultured, sometimes cloned or even modified to achieve indefinite replication (immortalisation).

It can be argued that there is less development work in the latter case, but payment is acceptable for the work that is involved.

The commercial product which may be the outcome of development work must be considered separately. It becomes part of normal distribution circuits.

The result of these considerations is that the person from whose body the cells were sampled has no rights over the consequences of their processing and use, and that his heirs cannot have rights over these cells and their derivatives which he did not have himself.

However, if the cells are to be used for purposes other than diagnosis, therapy, or cognitive research, and are intended for a purely economic use, the Committee disapproves.

Issues arising in this context would merit further consideration, in particular as regards

action by the authorities. The Committee therefore intends to make a complementary examination of the subject at a later time.

Report

Cells from a human body cannot be considered as any different from any other part of the body. There is no reason therefore to exclude them from the principle of non-commercial use. As a result, humans cannot be authorised to sell their own cells .

The reasons for this ban are identical to those which prevent the trade of for instance, blood or an organ. They are based on the dignity of the human being, fear of abuse, exploitation of poverty. However, this is not so as regards the donation of cells which should not be prohibited any more than is the donation of blood.

For a healthy donor, there is no particular difficulty.

For an ailing individual, the question is more complex. The assumption at the outset is that sampling is necessary for therapeutic reasons.

Two initial problems must be dealt with :

a) Should donation be explicit ?

The patient accepts every aspect of therapy which his disease demands. He therefore also accepts sampling. It may be considered that donation of cells is implicit for the following reasons : when sampling is unambiguously necessary, and beneficial, as is frequently the case, it is part of the agreement to receive therapy formulated *ab initio* . A requirement of explicit consent for donation would be difficult to explain to certain individuals, and would be a pointless impediment to research.

b) Does donation imply a rejection of any financial consequence ?

On the part of the donor, the only possible answer is in the affirmative.

But the cells, after culture, are used to manufacture biological or medical substances and sold for that purpose. Is this not a contradiction of the ban on selling products of the human body ?

It should be recalled at this point that the donation to which the donor has consented explicitly or implicitly, concerned cells. Two possibilities arise :

1) *The subject here is no longer a product of the human body, but a derivative in the form of a manufactured substance.* Consequently, after the collection phase there is the processing phase (to produce interferon or erythropoietin in the occurrence submitted). In this case, the price is not for a portion of a human body, it is for work performed and the resulting substance;

2) *the second possibility is that the cell itself is sold, and not its separated derivative* . It can be used in laboratory tests. There is no convincing reason why the conditions should be more stringent and thereby possibly deprive science of an item for research.

Indeed, the concept of donation should suffice to prevent any abuse of donors, and furthermore it must be recognised that the technical work is what mostly justifies any financial consequence.

In the circumstances, the subject, has made a donation, and thereafter has no claim on the

work and products of others. Heirs - this being the specific question put to us - have no greater claim than the originator.

The problem of possible use of human cells for the manufacture of non medical products cannot be ignored.

If such a case, the donation would lose its philanthropic element and its justification. It would no longer be connected to diagnosis and therapy.

A purely commercial operation would become a possibility. If that were accepted, there would be an obligation to inform the individual concerned of the use which would be made of the sampled cells.

However, even if that condition is fulfilled, the Committee cannot accept as ethical that a product of the human body passes totally out of the domain of health to enter the economic sector.

The diagnostic or therapeutic end purpose makes the commercial nature of the process tolerable. If only the commercial aspect remains, justification for the use of products of the human body vanishes.