

Prohibitions against the transfer of human tissue and cells for profit¹

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Introduction

The human body is the single most venerated and protected subject matter in all civilized societies. It is protected from different angles by a huge body of law. One detail in this legal context, and one which so far has not attracted much attention, is the fact that some commercial transactions regarding human biological material are often prohibited. Societies especially shun the idea of selling body organs for transplantation. The legal position is usually based on the fear of poor people otherwise becoming providers of “spare parts” for wealthier people. Economically disadvantaged people could be compelled to sell organs and tissue for the profit involved. Material for transplantations is thus an example of objects that are not usually considered suitable for market transactions. Society is thought to be better served by a gift-based system of transplant material procurement and an egalitarian (non-financial) system of distribution of organs for donation.

However, in the past decade, as medical and scientific advances have proceeded at a rapid pace, several new uses have surfaced for human tissue. Human tissue and other forms of biological material can now in particular be used in research to develop new drugs and treatments. For example, routine blood samples are often used secondarily in research. Similarly, biopsy material or organs removed for therapeutic purposes may eventually be used in research. The surge in the biotech industry has therefore yielded a potential market for cells and by-products of cells. Research on this material can lead to valuable patents. Cell lines, developed from either healthy or cancerous human tissue, now serve as one of the most basic medical research tools. Where the research is directed towards the development of drugs and other useful biological substances, the commercial value of human tissue has become evident. The expanding range of possible uses may force some reconsiderations of the ethics of transactions in human material.

The purpose of this forthcoming article is to explore the legal situation regarding for-profit transfer of human biological material used in medical research. New developments in biotechnology have made it imperative to deal with this question. The key aspect is whether commercial transfer of human tissue for research purposes should be viewed with the same fear as the commercial transfer of biological material for transplantations is viewed at present. Is competitive bidding for research material of human origin allowed and perhaps even advantageous to society? It may be that research tolls deserve a different legal regime than transplantation material.

Clearly, the resolution of problems relating to commercial interests in non-integrated body parts will greatly affect the scientific and medical research community. For one thing,

transfer of human material for value consideration may speed up research. Preventing market-based solutions in this area of research could perhaps seriously impede essential research. But of course there are also important ethical considerations, especially for the patients or donors involved. Patients have an interest in having control over their bodies, and this interest may spill over into research on disintegrated parts of the same body. Opponents of for-profit transfer of human tissue often argue that the trade in human material is morally reprehensible and that such a schema would prey on the vulnerable, such as the poor and uneducated. A successful resolution of this dilemma must necessarily address all aspects of the debate, but in particular the effect on medical research and the ultimate cost to the public in economic and other terms.

The legal situation

Against the general backdrop presented above, the starting point for this legal study is Section 15 of the Swedish Transplantation Act (SFS 1995:831), which provides that someone who willfully and for profit, collects, donates, receives or acts as an intermediary in respect of, biological material from a living or a dead human or tissue from an aborted fetus, shall be fined or sentenced to imprisonment for up to two years. The same punishment shall be given to someone who wilfully uses such material knowing that the material previously has been collected, donated, received or handled by an intermediary, for profit. In the case of slight offences against the prohibition there should be no criminal liability. The provision is not applicable to transfer of blood, hair, mother's milk or teeth.²

Section 15 was introduced into Swedish law in 1995. Before that there was no specific prohibition against for-profit trade in human biological material. The legislative history of the provision explains that the aim of the provision is to prevent people in poor countries from giving up their organs for money. However, during the legislative process the provision was expanded to encompass much more than just trade in organs. It was formulated as a general provision that prevents all trade for profit in human tissue. It is not entirely clear from the preparatory works why the prohibition was expanded so greatly and what kinds of acts the expanded provision was designed to prevent. There are some examples, though, in the preparatory works. It is mentioned that procurement of human biological material for the manufacturing of cosmetics or for the purpose of a display at an exhibition is banned. Such procurements are not allowed, if they are for profit.

The preparatory works, however, have nothing to say concerning the procurement of human tissue for research purposes. Legislative history has traditionally been an important tool for legal interpretation in Sweden. One conclusion from this part of the study, therefore, is that not enough thought was directed to the way human biological material is used for commercial research at present. Nothing is said in the preparatory works about a situation where commercial enterprises procure human biological material for research or diagnostic purposes. It seems that this was never contemplated as an important use for human biological material. Thus at present there is some uncertainty in Sweden with regard to commercial actors handling biological material for research or diagnostic purposes.

The legal situation is further developed in the article, using traditional legal methods of interpretation. Firstly, the precise wording of the prohibition is analyzed in detail. It is concluded that the scope of the prohibition is very broadly formulated. It could, at least in theory, encompass many transactions that are actually carried out or at least contemplated at the moment in Sweden. Therefore if the language of the prohibition covers all transfers of human tissue for a profit purpose, it could seriously impede research by restricting access to research tools.

Secondly, an overview is presented of the present forms for commercial use of human biological material in research settings in Sweden. This part relies heavily on the study “The Industrial Use of Biobanks in Sweden: an overview” by Jens Laage-Hellman, which forms another part of this project. The case of Gemini Genomics AB, previously Eurona Medical, and also the case of UmanGenomics, are discussed in particular detail as examples of commercial research uses for human biological material.

A third section of the article addresses the international legal context of prohibitions against the transfer of human tissue and cells for value consideration. The discussion in this part centers around the convention adopted by the Council of Europe: “Convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine: Convention on human rights and biomedicine”. The Convention came into force on December 1, 1999, after five ratifications had been deposited. Countries ratifying the convention thereby pledge themselves to adopt their national law to the requirements of the Conventions and to provide legal safeguards for persons in accordance with the Convention.

Article 21 of the Convention is headed “Prohibition of financial gain” and provides the following:

The human body and its parts shall not, as such, give rise to financial gain.

An official commentary on the Convention, an Explanatory Memorandum, is available. It limits the scope of the prohibition against financial gain, with respect to discarded tissue. It provides: “The provision does not refer to such products as hair and nails, which are discarded tissues, and the sale of which is not an affront to human dignity.”³ Discarded material, e.g. hair and nails, may be transferred for financial gain provided that the sale is not an affront to human dignity.

Tentative conclusions

A preliminary conclusion drawn in this legal study about the Convention adopted by the European Council is that human biological material in Swedish biobanks could probably be considered discarded tissue. Therefore for-profit transactions in human biobank-material must not necessarily be prohibited. The Convention offers leeway for signatory States with respect to commercial transactions in discarded tissue. The aim of the cited international prohibition is primarily to prevent trade in organs for transplant, not to prevent the procurement by commercial actors of research tools, such as material stored in Swedish biobanks.

Finally, some additional tentative conclusions from the study can be mentioned here. The author of the article argues that a clear legislative response is required to eliminate the surrounding uncertainty in the law, which currently threatens to prevent private actors and private/public cooperation in the use of human tissue. The present uncertainty is clearly unsatisfactory. Hopefully the initiative to introduce a Swedish Biobanks Act will improve this situation. But the author also argues that the reasoning that led to the formulation of Section 15 of the Swedish Transplantations Act of 1995 and also the reasoning in the new proposal for a similarly worded prohibition in the Biobanks Act, are not wholly convincing. Material in biobanks is not stored there for transplantation purposes, but mainly for research and diagnosis. Commercial considerations and private actors play a prominent role in these fields, especially in medical research. The Swedish legislation is designed with transplantation cases in mind and is not really appropriate for research tools. Profit motives cannot be excluded

from medical research, nor probably from the procurement of medical research tools such as tissue samples. The important ethical considerations might need to be of a more specific kind. The author therefore concludes the study by arguing that the prohibitions against the transfer of human tissue and cells for valuable consideration should be limited to material that is used in therapeutic treatment of some person other than the person from whom the material was taken. Outside the therapeutic situation, uses for human biological tissue are so diverse and rapidly changing, that more specific legal rules than prohibitions against all forms of transfer for profit are necessary in order for ethical needs to be safeguarded without, at the same time, impeding research.

References

¹ This is an English summary of the article *Humanbiologiskt material och vinningssyfte*, which will be published in the Swedish legal journal *Juridisk tidskrift*, either in issue 4, 2000-2001, or in issue 1, 2001-2002

² Section 15 of the Swedish Transplantation Act (1995:831) reads: “Den som med uppsåt och i vinningssyfte tar, överlämnar, tar emot eller förmedlar biologiskt material från en levande eller avliden människa eller vävnad från ett aborterat foster döms till böter eller fängelse i högst två år. Till samma straff döms den som med uppsåt använder eller tar till vara sådant material för transplantation eller annat ändamål trots insikt om att materialet tagits, överlämnats, tagits emot eller förmedlats i vinningssyfte. I ringa fall skall inte dömas till ansvar.

“Första stycket gäller inte blod, hår, modersmjölk och tänder.”

³ Point 133 of the Explanatory Memorandum.