

Commercialization of Human Tissue Products

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The sale of human tissues is often prohibited either by the law of by ethical restraints. However, in recent times once a tissue becomes a "Tissue Product" it may escape such regulation. There have been several areas of increased or new commercial activity involving human tissue products including:

- Bone screws and Bone putty,
- Collagen products,
- Acellular Dermis (which though derived from human tissue no longer contain human cells),
- Preserved injectable fascia lata particles derived from screened cadavers (1),
- A Range of Blood products,
- Live culture products, including those derived from Human Stem Cells, embryonic or adult derived, for therapy or research that might in themselves become a saleable commodity eg: Mesenchymal Stem Cell products (2),
- Diagnostic products, and
- Non-medical uses of human tissue or human tissue products, such as in the manufacture of Human Collagen for cosmetic use.

There has been significant growth in large-scale purpose-built human research bio banks, often associated with pathology services. There are ethical issues involved because the living cultured tissue may contain potentially identifiable genomic material from the original specimen donor and intellectual property. Further discoveries from the use of cultured specimens may give rise to significant, even windfall, profits.

When tissue is made available by donation after death or because it was collected for diagnostic purposes for the patient, or during surgery, there is often no knowledge on the part of the donor or the family that downstream there may be significant commercial advantages to be gained from the use of products derived from the tissue, and there may be few effective legal or ethical controls over the use of the tissue. People usually donate tissue altruistically for the community benefit to be obtained for others by transplantation or through medical research.

One of the risks of commercialization is that it implicitly involves treating the tissue product as property, able to be disposed of by buying and selling for profit and not necessarily for purposes for which the tissue was given. In the future there may be an unwillingness to donate tissue if a *laissez faire* situation persists and some companies are drawing windfall profits from products manufactured from human tissue. This would be likely if a tissue culture had particularly properties that are valuable, such as containing cancer antibodies, for instance.

The development of ethical guidelines or statute law regarding commercial uses of human tissue products would assist with determining when commercial use may be ethically permissible and the restrictions that are needed to protect individuals and maintain community support for such activities.

If cultured human cells retain genomic information then there are also privacy concerns and issues to do with obtaining relevant

information about the donor or donor family's health or disease status and propensity for disease.

A notion that would seem to assist ethics committees in comprehending different attitudes toward human tissue and any products derived from it in any particular application is that of attenuation. That is, a tissue product may be considered to be 'attenuated' in a subjective sense when it has lost significance to the donor and donor family. This recognises that a person's attitude toward commercial uses of human tissue products may not be based upon any objective criteria such as when it has lost significant properties like genetic material. For instance someone may not object to their hair being sold by their hairdresser even though it may contain cells with their genetic material in it, but would object to someone selling acellular dermis derived from them after their death.

From an ethical point of view, where the genomic material has been lost, the privacy issues are different compared to intact genomic material which may permit identification. It stands to reason that if the genomic significance has been lost, then the uses of the tissue would seem not to be specific to the donor source or their family. There would therefore seem to be a loss of significance of the tissue for that donor and their family, and thus it may objectively be perceived to be attenuated. However we must recognise that such objective reasoning may not be acceptable to some members of the community.

A committee that I chaired for the Australian National Health and Medical Research Council proposed that the following considerations should also be used in determining if **Not-for-profit trade** or **For-profit commercialisation** exemptions should be allowed for tissue products that had not become attenuated, specifically,:

1. If a *community benefit* is likely to be derived from commercialisation that would offset the negatives of commercialization for the community and whether equity of access to those benefits is maintained;
2. If the use of the human tissue product has *genomic significance* to the individual donor or their family, whether the right to privacy and the researcher's obligations to provide information derived from the material and relevant to future health of the donor or their genetic relatives or other grouping will be met;
3. If members of the community would consider the commercial use of a particular product to be ethically unacceptable because it *commodifies the humanbody* and treats it as an object;

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4. If the *value* of the human tissue product derives from a property that is *unique to the individual donor or donor family* so that trade may therefore be seen as an exploitative and likely to undermine willingness to donate; and
5. If *perverse incentives* may arise from the commercial use of the product - that is, the manner in which the incentive for the donation, trade, exchange or commercialisation of human tissue leads to behaviour by or toward the parties involved, in ways they otherwise would not, or which may place them at risk of harm.
6. Obviously crucial to the regulation of this growing area of commercial use of human tissue products is whether we treat human tissue or products derived from it as *property* or whether there are *custody* obligations that must be transferred if the tissue or product is disposed of to another who exploits it commercially. There is a need to ensure that the donor's wishes and their interests continue to be protected. There is much at stake if the existing organ and tissue collection, storage and use practices, including the blood and tissue banks and transplantation, based as they are largely if not exclusively on altruism are undermined by uncontrolled commercialization.