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Access to human tissues for research and product development

From EU regulation to alarming legal developments in Belgium

Jean-Paul Pirnay[1], Etienne Baudoux[2], Olivier Cornu[3], Alain Delforge[4], Christian Delloye[3], Johan Guns[5], Ernst Heinen[6], Etienne Van den Abbeel[7], Alain Vanderkelen[1], Caroline Van Geyt[8], Ivan van Riet[9], Gilbert Verbeken[1], Petra De Sutter[7], Michiel Verlinden[10], Isabelle Huys[10,11], Julian Cockbain[12], Christian Chabannon[13,14,15], Kris Dierickx[16], Paul Schotsmans[16], Daniel De Vos[1], Thomas Rose[17], Serge Jennes[17] & Sigrid Sterckx[18]

Human organs and tissues differ in regard to their clinical and research uses and the regulatory legislation controlling their use. Organs such as livers and hearts are usually taken from donors who are brain-dead; in addition, kidneys can also come from live volunteers. Organs decay rapidly and need to be transplanted quickly. Surgeons and coordination teams in transplantation centres control the procurement, while dedicated national and international organisations facilitate their allocation.

Human tissues such as bone, skin and heart valves are usually removed from cadavers in hospitals, morgues or even funeral homes and, unlike organs, can be stored—sometimes for years—in tissue banks. These tissues can be used in numerous recipients as and when they are needed. In the early days of human tissue banking, not-for-profit banks, mostly located in hospitals, dominated the field. The tissues they stored—heart valves and skin, for example—saved many lives.

> *"Human tissues for research are said to be worth more than diamonds, being valued at US $500/g."*

Since the 1980s, the demand for human tissues has increased dramatically. The first tissue in significant demand was human bone for use in allografts in orthopaedic surgery. In the 1990s, the emerging field of regenerative medicine, which generates human tissue-engineered products (hTEPs), began to require access to human tissues. Eventually, pharmaceutical companies began using human tissue instead of animals in the early stages of medical product testing. Human tissues for research are said to be worth more than diamonds, being valued at US$500/g.

Inevitably, commercial tissue banks were set up to capitalise on this demand, starting in the USA. Most US tissue bank companies obtain their material through Willed Body Donation programs, run by the bank itself or through offshoots. They are allowed to charge processors and distributors "reasonable fees" for the procurement of cadaver tissue—harvesting, transportation, refrigeration and so on—rather than charging money for the donated tissue itself, as it is illegal in most countries to buy and sell human organs or tissues that are donated for free. Next, tissue processors and distributors can also charge "reasonable fees" for their contributions: processing, packaging, distribution, marketing and so on. Unfortunately, the term "reasonable fee" has never been defined and

1 Human Cell and Tissue Banks, Laboratory for Molecular and Cellular Technology, Queen Astrid Military Hospital, Brussel, Belgium. E-mail: jean-ul.pirnay@mil.be
2 Laboratory of Cellular and Gene Therapy, University Hospital Liège, Liège, Belgium
3 Orthopaedic and Trauma Surgery Department, Cliniques Universitaires St-Luc, Université Catholique de Louvain, Brussel, Belgium
4 Service d'Hématologie Expérimentale-Laboratoire de Thérapie Cellulaire Clinique, Université Libre de Bruxelles-Institut Jules Bordet, Bruxelles, Belgium
5 Faculty of Medicine and Pharmacy, Vrije Universiteit Brussel, Brussel, Belgium
6 Faculty of Medicine, Institute of Human Histology, Immunology Centre, University of Liège, Liège, Belgium
7 Centre for Reproductive Medicine, Ghent University Hospital, Gent, Belgium
8 Tissue Bank, Ghent University Hospital, Gent, Belgium
9 Division of Clinical Hematology, UZ Brussel, Brussel, Belgium
10 Faculty of Pharmaceutical Sciences, KU Leuven, Leuven, Belgium
11 Centre for Intellectual Property Rights, KU Leuven, Leuven, Belgium
12 Consultant European Patent Attorney, Gent, Belgium
13 Centre de Thérapie Cellulaire, Département de Biologie du Cancer, Institut Paoli-Calmettes, Marseille Cedex, France
14 Aix-Marseille Université (AMU), Marseille, France
15 Inserm-Centre d'Investigations Cliniques en Biothérapie (CBT)-510, Marseille, France
16 Centre for Biomedical Ethics and Law, KU Leuven, Leuven, Belgium
17 Burn Wound Centre, Queen Astrid Military Hospital, Brussel, Belgium
18 Department of Philosophy and Moral Sciences, Bioethics Institute Ghent, Ghent University, Gent, Belgium
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HUMAN ORGANS, TISSUES AND CELLS IN REGENERATIVE MEDICINE

ORGANS

Warm and cold ischemic phases before transplantation need to be kept to a minimum.

Thymus

Lungs

Heart

Liver

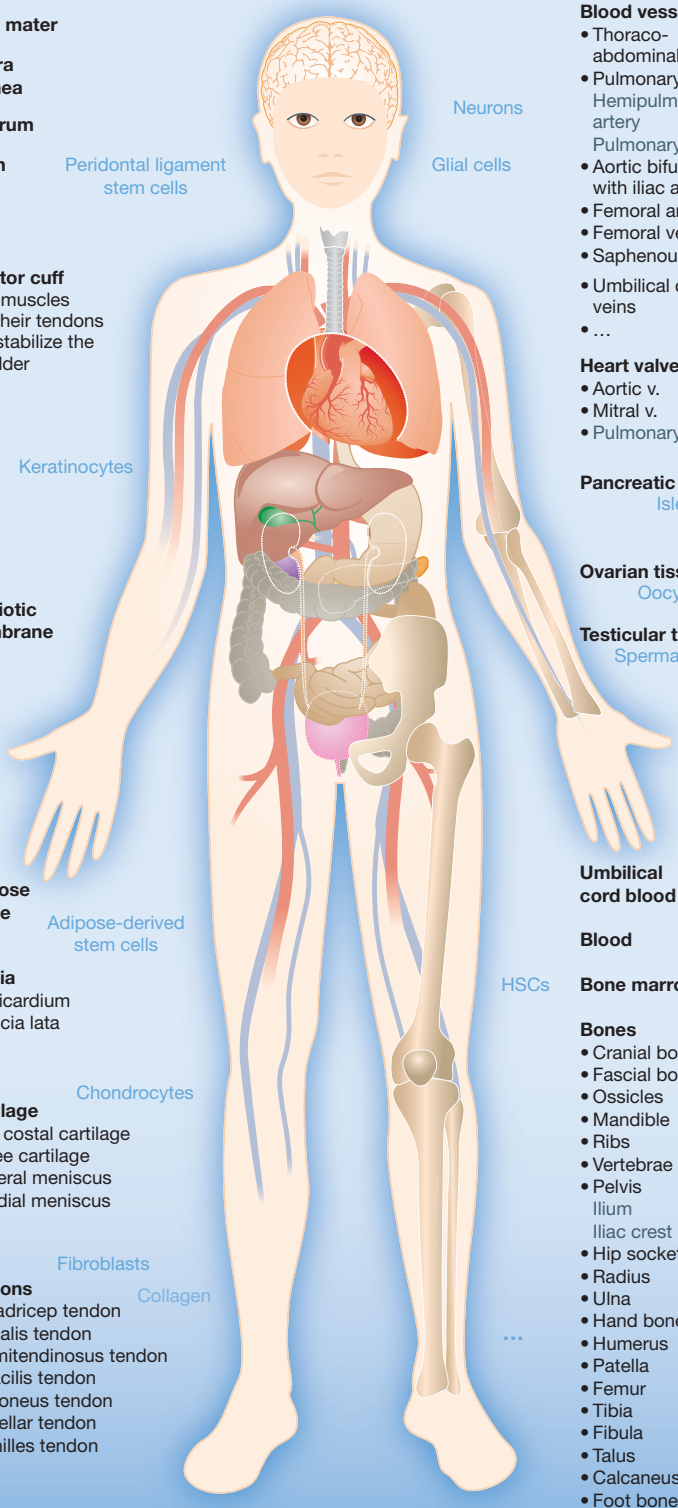
Pancreas

Kidneys

Intestine

HUMAN TISSUES & CELLS

Tissues and cells – normal and pathological – are banked for transplantation, research and other uses. Short to long term preservation/storage is possible.



Dura mater

Sclera
Cornea

Eardrum

Teeth
Peridontal ligament stem cells

Rotator cuff
Four muscles and their tendons that stabilize the shoulder

Skin
Keratinocytes

Amniotic membrane

Adipose tissue
Adipose-derived stem cells

Fascia
- Pericardium
- Fascia lata
- …

Chondrocytes

Cartilage
- Rib costal cartilage
- Knee cartilage
- Lateral meniscus
- Medial meniscus
- …

Fibroblasts

Tendons
Collagen
- Quadricep tendon
- Tibialis tendon
- Semitendinosus tendon
- Gracilis tendon
- Peroneus tendon
- Patellar tendon
- Achilles tendon
- …

Neurons

Glial cells

Blood vessels
- Thoraco-abdominal aorta
- Pulmonary artery
  Hemipulmonary artery
  Pulmonary patch
- Aortic bifurcation with iliac arteries
- Femoral artery
- Femoral veins
- Saphenous veins
- Umbilical cord veins
- …

Heart valves
- Aortic v.
- Mitral v.
- Pulmonary v.

Pancreatic tissue
Islet cells

Ovarian tissue
Oocytes

Testicular tissue
Spermatozoa

Umbilical cord blood

Blood

HSCs

Bone marrow

Bones
- Cranial bones
- Fascial bones
- Ossicles
- Mandible
- Ribs
- Vertebrae
- Pelvis
  Ilium
  Iliac crest
- Hip socket
- Radius
- Ulna
- Hand bones
- Humerus
- Patella
- Femur
- Tibia
- Fibula
- Talus
- Calcaneus
- Foot bones

…

MEDICAL APPLICATIONS

Normal tissue can be used as an allograft.

EXAMPLES

Cornea transplants
- Corneal transplantation
  Storage time for transplantation limited to 1–4 weeks.
- Corneal lenticules

Reconstruction due to cancer or trauma
- Breast reconstruction
- Facial reconstruction

Skin transplants
- Covering for severe burns
- Covering for diabetic foot ulcers

Heart valve replacement
Most common:
- Mitral valve replacement
- Aortic valve replacement
- Valve replacement in children with congenital heart disease

Vascular grafts/bypasses
- Limb-saving arterial surgery
- Femoral veins, saphenous veins and arterial grafts intended as A-V shunts

Amniotic membrane transplants
- Used in ophthalmic surgeries, e.g. as a permanent or overlaid graft in corneal surface reconstruction
- Stem cells are cultivated *in vitro* on amniotic membrane to treat limbal stem cell deficiency
- Used as skin substitute (e.g. in burn surgery)

Hematopoietic stem cells (HSCs)
- HSCs are usually derived from bone marrow, peripheral blood or umbilical cord blood. Autologous or allogeneic HSC transplantation is used to treat a wide spectrum of haematological, and increasingly, non-haematological disorders.

Cartilage, ligament or tendon allografts
- Anterior cruciate ligament repair
- Meniscal replacement
- Bladder slings

Bone allografts
- Spinal fusion
- Ridge augmentation in dental procedures
- Reconstruction of bone defects caused by cancer or trauma

Cosmetic surgeries & procedures without medical indication
- Lip augmentation
- Penis enlargement
- Wrinkle smoothing via collagen injection

this loophole is now being exploited to turn altruistic donations into profits. International tissue brokers and stock market listed tissue processors and distributors are emerging, with far-reaching consequences for the allocation of human tissues.

"... the term "reasonable fee" has never been defined and this loophole is now being exploited to turn altruistic donations into profits"

In contrast to the USA, Europe initially adopted a more restrictive attitude. Most of Europe's tissue banking activity remains at hospital tissue banks, while some specialised activities, such as tissue engineering, are outsourced to biotechnology companies. This situation has created tension between the altruistic principles of hospital tissue banks and industry's profit-oriented principles. Meanwhile, industry lobbying and the political desire to promote the growth of biotechnology markets and jobs have led to increasingly business-oriented legislation controlling human tissue handling in the EU. This shift has now gone so far that in some legislations, the risk arises that the interests of industry could take precedence over the interests of patients and research.

The legal framework for tissue donation, banking and usage in the EU is comprised of three EC Directives: the parent Directive 2004/23/EC, which provides the framework legislation, and two technical Directives, 2006/17/EC and 2006/86/EC, which give detailed requirements. In 2008, the Advanced Therapy Medicinal Product (ATMP) Regulation (EC) No 1394/2007, which covers hTEPs among other things, came into force. Because public health matters fall under the competence of the EU Member States, the Directorate General Enterprise of the European Commission invoked the "common safety concerns in public health" clause, which falls under the auspices of the EC, to create a regulatory environment that would facilitate a market for hTEPs. Pharmaceutical industry standards, such as good manufacturing practice (GMP) and marketing authorisation, were imposed upon the predominantly hospital-based human tissue transplantation field. In addition, the legal concept of "Tissue Establishment" was introduced, which expands on the conventional concept of a tissue bank. Companies with an accreditation as a Tissue Establishment would thereby obtain direct access to human tissues and cells. These regulations have established a crucial legal difference between organs and tissues: human tissues are legally tradable goods in a global market.

This commercialisation of human tissues raises several ethical and public health issues. Although acknowledging the legitimacy of these concerns, the EC invoked the principle of subsidiarity—whereby the EU only takes action in areas, which fall within its exclusive competence—to relegate ethical and public health issues to the Member States. The regulation of hTEPs prepared on a non-routine basis and used within the same EU Member State in a hospital under the exclusive responsibility of a medical practitioner (referred to as the "Hospital Exemption" rule) was also delegated to national-level actors. As a consequence, some member states have, through national legislation, shifted the focus of tissue banking from public-health-oriented public tissue banks to profit-oriented companies. We will explain here how this is taking place in Belgium under the radar of public attention.

Belgium is considered to have one of the best healthcare systems in Europe. It is sponsored by the state and provided by a mixture of state-owned and non-profit hospitals. The costs for patients are partially or fully covered by a health insurance fund and the government sets reimbursement prices. As mandated by the EU, Belgium has tried to address some ethical and public health issues in its implementation of the EC's Tissue and Cell Directives. The "Act regarding the procurement and use of human body material destined for human medical applications or for scientific research purposes" was adopted on 19 December 2008 and entered into force on 1 December 2009. It defines "human body material" as "any biological body material, including human tissues and cells, gametes, embryos and foetuses, as well as substances extracted there from, whatever the degree to which they have been processed". The law also introduced four types of "Tissue Establishments": Banks for Human Body Material, Intermediate Structures, Production Establishments and Biobanks. These "Tissue Establishments" need to be accredited and their activities and goals must be approved by an ethics committee.

According to the Act, human body material can only be procured by medical doctors in recognised hospitals and collected by a Bank for Human Body Material, which must be operated by a certified hospital. From then on, the "human body material manager"—a medical doctor affiliated to the bank—is responsible for the use of the material, including the allocation to a patient or Tissue Establishment. Banks for Human Body Material should be set up as not-for-profit establishments. An Intermediate Structure is only entitled to process, preserve, store and distribute human body material for further use in collaboration with a Bank for Human Body Material. Production Establishments can perform all operations, including production of ATMPs, provided such use is exclusively for autologous purposes. Commercial companies can obtain Intermediate Structure and/or Production Establishment licenses in Belgium. The import and export of human body material are restricted to Banks for Human Body Material and Production Establishments. The exact role of Biobanks still needs to be clarified, but basically they will collect, process, preserve, store and distribute human body material for scientific research only.

"While human tissue itself cannot have human dignity, human dignity is nevertheless concerned when human tissue is involved"

In summary, industry has gained access to autologous starting materials, but access to and the future use of allogeneic tissues and cells is controlled by not-for-profit hospital-operated Banks for Human Body Material. It is forbidden to store human body material for future autologous use, unless it can be used to treat a realistically impending pathology, or if the material is put at the disposal of the entire community. The prices for human tissue and cell "products" and for some processes are fixed by Ministerial Decree. These prices basically cover the costs of processing and leave no room for unreasonable profits, thereby inherently preserving the not-for-profit character of these activities.

The ATMP "Hospital Exemption" rule mentioned above, that is the regime pertaining to ATMPs prepared on a non-routine basis and used in a hospital within the same EU Member State under the exclusive responsibility of a medical practitioner, is not resolved yet and is the subject of fierce debate. More than 20 "products" produced by nine Belgian hospital Banks for Human Body Material are in fact ATMPs—we refer to them as "cloaked" ATMPs—whereas only a handful of ATMPs are produced by three Belgian companies. Only one of these commercial ATMPs, ChondroCelect®—autologous chondrocyte cultures for symptomatic cartilage lesions in the knee—is actually on the market. It is the only hTEP-ATMP that has obtained centralised European Marketing Authorisation since the implementation of the ATMP Regulation in 2008.

"Differences in consent to tissue donation, such as opting-in versus opting-out, create opportunities for exploitation by companies that lack ethical responsibility"

The hospital-based Banks for Human Body Material were notified by the Belgian Federal Agency for Medicines and Health Products that their products would fall under the definition of an ATMP and that the administration of these products to patients, as had previously occurred, would no longer be allowed after 30 December 2012. Since then, the status of these now "uncloaked" ATMPs has been contentious and their future remains uncertain. Some of the products, such as keratinocytes for severely burnt patients, have been applied to thousands of patients since the 1980s, and none of the numerous inspections over the years have ever revealed significant quality or safety issues. When looking at these developments, three questions come to mind: how can "products" that are produced and used in non-profit hospitals, and which originate from altruistic donations, become commercial medicinal products? Does it make sense to implement the Hospital Exemption rule if that rule *de facto* caters for the majority of products? And why are products that were developed 25 years ago suddenly called "advanced" or "innovative"?

Some of the measures introduced by Belgian legislators to prevent excesses quickly turned out to be futile. By way of example, a private umbilical cord blood bank—such banks have been criticised for nurturing false hopes among customers—found a way to bypass Belgian law and obtained a license to operate (http://www.journalismfund.eu/workinggrant/international-offensive-cord-blood-banking). At the same time, industry has started lobbying Belgian policymakers for better access to tissue material. The Commission on Social Affairs of the Belgian Senate set up a working group to evaluate the "opportunities and challenges associated with innovative therapies". The working group invited the three Belgian commercial Production Establishments involved in ATMP production, several professional trade associations and a few start-up companies to join its evaluation. However, the nine accredited hospital counterparts that are responsible for more than 20 formerly cloaked ATMPs, and the hospital Banks for Human Body Material, which provide the starting materials for cell and tissue-based therapies, were not invited.

According to their 2013 report, the working group identified three tissue bank-related issues that allegedly hamper the ability of companies to develop and commercialise innovative hTEP-ATMPs: an insufficient number of accredited public Banks for Human Body Material to ensure a sufficient supply of starting materials and the import and export of finished products; a lack of encouragement for Banks for Human Body Material to collaborate with companies that produce hTEPs; and the production of hTEPs must be performed in accordance with GMP standards, which the working group found to be inconsistent with the purpose of Banks for Human Body Material. However, according to an expert from the Belgian Ministry of Public Health, it has not been proved that Banks for Human Body Material are disinclined to provide human body material to the tissue engineering industry [1]. Indeed, had representatives of the Banks for Human Body Material been invited to the meetings of the working group, they would have argued against all three findings.

Regarding the first issue, the allegedly insufficient number of accredited public Banks for Human Body Material, we refer to the list of accredited Tissue Establishments published by the Belgian authorities (http://www.fagg-afmps.be/nl/binaries/Lijst%20MLM%20141016_tcm290-28032.pdf; http://www.fagg-afmps.be/fr/binaries/Liste%20MCH%20141016_tcm291-28032.pdf). According to this list (updated 16 October 2014), no less than 67 accreditations were issued (one accreditation for each tissue type), not including banks for human reproductive tissue. For a country of 11 million inhabitants, this is one of the highest concentrations of Banks for Human Body Material among all EU Member States.

Regarding the working group's second finding, the supposed lack of encouragement of the Banks for Human Body Material to collaborate with companies, the authors know of only three requests for collaboration between a company and a Bank for Human Body Material. One of them led to the development of the previously mentioned ATMP ChondroCelect®. Another request involves haematopoietic stem cells and the collaboration is still ongoing. A third public–private partnership involved keratinocytes and lasted for more than 10 years before both partners cancelled it a decade ago, owing to the introduction of business practices that were not compatible with the bank's mission statement: sales representatives had influenced physicians' choices, keratinocytes were offered to privately insured patients in less regulated or emerging markets, and a patent was applied for to cover the possible cosmetic use of human keratinocyte products. Successful collaborations between Intermediate Structures and Banks for Human Body Material are certainly possible and desirable, but in order to achieve this goal, Banks for Human Body Material should first of all be recognised as full partners and stakeholders.

"If Belgian citizens were to suspect that donated tissues become part and parcel of profit-maximizing activities, they might be more likely to exercise their right to opt-out"

What about the third claim that GMP standards are inconsistent with the purpose of Banks for Human Body Material? As a matter of fact, GMP standards might not be consistent with the tissue transplantation field as a whole, but since they were

imposed, hospital banks cannot ignore them. Even though not taken into account by EU policymakers [2], the main purpose of public hospital banks has always been to provide quality grafts for therapeutic use. Belgian Banks for Human Body Material have already invested heavily in clean room facilities and are getting ready to produce hTEPs in compliance with GMP requirements, even though there is no evidence that these investments will actually result in any significant improvement to the quality or safety of their grafts.

"There is a risk that the final destination of the donated human body material may partly be determined by differences in financial compensation"

The working group's report led to the submission, on 21 January 2014, of a bill to amend the Act of 2008 on the procurement and use of human body material [3]. This bill, if enacted, would allow Production Establishments to produce both autologous and allogeneic human tissue and cell products. It would give industry access to autologous and allogeneic human body material and would provide industry with full control over its use, without the need to collaborate with a Bank for Human Body Material. Belgian policymakers will now need to decide which entities will control the access to and use of donated tissue material. The problem, however, is that the current actors in the field have, to greater or lesser extent, conflicting interest. The interests of the general public, hospitals and industry are not always in line with each other.

Article 21 of the 1997 Council of Europe Convention of Human Rights and BioMedicine provides that it is not permissible for the human body or its parts *as such* to give rise to profits. This principle is based on the need to protect human dignity and to ensure that persons can be the authors of their own lives. With the advent of the biotechnological era, human dignity has been attributed an additional function—"human dignity as a constraint"—to prohibit practices because they compromise the intrinsic worth of persons and the integrity of the human species. These include human reproductive cloning, germ line intervention, creation of human chimeras, prenatal sex selection, and the commercialisation of the human body and its parts *as such* [4]. It does not, however, prevent specific commercial activities, such as the patenting of human body material in isolated, purified or slightly modified form.

Concerning post-mortem procurement of human body material for medical applications or for scientific research, the Act of 2008 extends the presumed consent regime that governs cadaveric organ transplantation in Belgium: first, from post-mortem removal of organs to post-mortem removal of any biological material that falls under the scope of this Act, and secondly, an extension from post-mortem removal for therapeutic purposes to post-mortem removal for research purposes. In other words, the Belgian law equates the absence of any registered objection to post-mortem removal of organs for transplantation with the absence of any objection to post-mortem removal of any body material for any purpose. No efforts have been made to inform the public of this new legal regime for the post-mortem procurement of body material. While human tissue itself cannot have human dignity, human dignity is nevertheless concerned when human tissue is involved. For some stakeholders, this implies that tissues originating from an altruistic donation should not be transformed into commercial products and should only be handled by non-profit-making tissue banks. In reality, private companies process or engineer donated human tissues and cells into more valuable medicinal products, which often requires extensive research and investments, which, it is argued, justifies the commercialisation of the resulting products. This is a dilemma, since hTEPs now consist of a non-commercialisable part (human body material) and a commercialisable part (technological processing). A possible solution would be to allow the commercialisation of human body material by companies that act in good faith—reflected in reasonable processing fees and approval from an ethics committee—and that produce beneficial therapeutic products.

Public health is not a key priority for private companies: their primary obligation is to maximise profits for their shareholders and investors. For human tissue products, this means that companies need to get access to starting materials and at low cost. Differences in consent to tissue donation, such as opting in versus opting out, create opportunities for exploitation by companies that lack ethical responsibility. Countries such as Belgium, which have an "opt-out" rule or presumed consent regime, are therefore interesting for brokers and corporate actors to get access to human tissue material for processing into highly profitable products. In this way, the values of solidarity and the common good that are supposed to underlie presumed consent are increasingly being eroded.

If everybody were charging "reasonable" fees, there would not be significant price variations for the same product. Instead, a wide variation in prices exists, ranging from hundreds to thousands of dollars for the same product. In sports medicine, tendon and bone allografts, for instance, fetch higher prices in areas with a flourishing sports culture than tendon and bone products for general orthopaedics. Average human cell and tissue product prices are almost five times higher in the USA than in Belgium [5]. The Belgian reimbursement price for ChondroCelect® is almost ten times higher than for the conventional non-ATMP analogues produced by two Belgian hospital Banks for Human Body Material. Due to the high costs of ChondroCelect®, reimbursement is now restricted to patients younger than 50 years.

In addition, some companies in the tissue engineering field cater to cosmetics rather than medical products. A striking example is the processing of human skin, the gold standard for the treatment of severe burns, into cosmetic products without medical indication, such as penis widening or lip enhancements, which fetch much higher prices than analogues for burn treatments. US burn centres were reportedly struggling to obtain skin because local tissue banks are committing all their donated skin to firms that market products for plastic and cosmetic surgery [6].

Such practices give rise to further questions. Tissue Establishments have a responsibility towards donors and donor families. In the USA, research has shown that donors wish that their donations result in products that meet medical needs or support research or medical education [6]. Donors and their families also expect their tissue to be treated with respect. However, human body material is increasingly viewed as a marketable commodity.

If Belgian citizens were to suspect that donated tissues become part and parcel of profit-maximising activities, they might be more likely to exercise their right to opt-out. This would put Belgium's successful opt-out donation system for organs, tissues and cells for transplantation in jeopardy because the current opt-out registers do not allow a person to differentiate between the use of their organs and that of any other body material. Even if people became aware of the Act of 2008, their only choice is between opting out of *all* types of donations, including for non-commercial organ transplantation, or opting out of *none*.

Hospital-based Tissue Establishments must be prepared to deliver human tissue with the required level of quality and safety, but also respect and protect the freedom of choice, the rights and health of the donors, and prioritise the collection and use of human body material according to therapeutic and scientific relevance. In hematopoietic progenitor cell (HPC) transplantation, international standards are being designed to protect donor safety, to prevent unnecessary pressure on the donor and to ensure an unbiased information process. These standards could be adapted to all types of healthy volunteer donations. A failure to regulate will increase the risk of unethical trade practices, which are usually associated with significant risks to donor and recipient safety and could negatively impact established not-for-profit therapeutic applications.

Finally, we suspect that the current Belgian regulatory framework will give rise to a competition between tissue banks and companies for access to limited and precious human cells and tissues. There is a risk that the final destination of the donated human body material may partly be determined by differences in financial compensation.

The Belgian healthcare system has traditionally been patient driven and based on the principles of human dignity, equity of access, quality and solidarity. These principles are not compatible with uncontrolled commercialisation of human tissues and cells. As explained above, the Belgian Act of 2008 has resulted in a twofold extension of the presumed consent from post-mortem removal of organs to post-mortem removal of any human body material and from post-mortem removal for transplantation to post-mortem removal for research purposes. In addition, a new bill, which is currently under consideration in the Belgian parliament to amend the Act of 2008, would hand over a significant measure of control of the tissue transplantation field to industry. Belgian citizens are unaware of this.

Ideally, the procurement and allocation of human tissues and cells should be controlled and facilitated by (inter)national non-profit organisations, comparable to organ donation and transplantation foundations such as Eurotransplant and Swiss Transplant. An excessive commercialisation of human body material could lead to a loss of trust in the transplantation field and could put at risk the successful "opting out" or "presumed consent" donation systems in some EU Member States. Policymakers seem enamoured by the methods and rhetoric of industry, leading them to neglect the interests of donors and their families and eroding the public values underlying the healthcare system.

Conflict of interest

The first 12 authors are members of the 'Human Cell, Tissue and Organ' working party of the Superior Health Council, a link between government policy and the scientific community in the field of public health in Belgium.

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