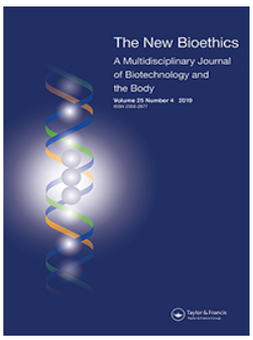

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Taylor & Francis Group

The New Bioethics

A Multidisciplinary Journal of Biotechnology and the Body

ISSN: 2050-2877 (Print) 2050-2885 (Online) Journal homepage: https://www.tandfonline.com/loi/ynbi20

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To cite this article: Luciana Riva, Giorgio Resta, Alberto Gambino & Carlo Petrini (2019) Donation of Human Biological Materials in the European Union: Commodifying Solidarity in the Era of the Biotechnological Revolution?, The New Bioethics, 25:4, 349-358, DOI: 10.1080/20502877.2019.1679965

To link to this article: https://doi.org/10.1080/20502877.2019.1679965

Published online: 08 Nov 2019.

THE NEW BIOETHICS, Vol. 25 No. 4, 2019, 349–358

Donation of Human Biological Materials in the European Union: Commodifying Solidarity in the Era of the Biotechnological Revolution?

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The use of human biological materials (HBMs) involves a number of issues from both an ethical and a legal point of view. In recent decades, the purposes for which this material has been used have increased. The development of therapeutic products has led to the configuration of a market in which products have acquired an economic value. As soon as the private sector crosses the threshold of access to the use of human cells and tissues, a conflict may arise between the altruistic principles motivating the act of donation and the profit-making objectives . When donated material emerges from the public management setting and becomes a source of profit, the instrument of informed consent may not adequately protect the dignity of the donors. In the era of medical biotechnology revolution, any use of the donated material must be justified and consistent with the values motivating the act of donation.

KEYWORDS human biological materials, advanced therapy medicinal products, tissue donation, cell donation, altruism, informed consent

 DOI 10.1080/20502877.2019.1679965

Introduction

Since the middle of the last century, the use of organs, tissues and cells in clinical practice has developed greatly, with important results in the treatment of numerous diseases. Cells and tissues are increasingly used not only for therapeutic purposes, but also in research; furthermore, unlike organs, they can be stored for long periods in tissue and cell banks. The management and use of human biological materials (HBMs) in biomedical research raises a series of legal and ethical issues that have been widely debated and that concern, in particular, intellectual property, the transfer of materials and data, the protection of privacy and participant information and consent. The earliest human tissue banks were non-profit storage facilities located primarily in hospitals (Pirnay *et al.* 2015). Over time, the situation has changed: the increased potential of technology and improved knowledge of biology have increased the potential of using tissues and cells. New private players have entered the field as intermediaries and stakeholders. Today, the dynamics at play in the establishment of HBMs exchange systems have become more complex and different types of tissue and cells can be donated or 'transferred' to public or private institutions. Industrial corporations demand access to them and, as some authors have suggested, evolution in this field could lead in the near future to a scenario in which European conventional cell and tissue banks could become mere suppliers for corporate Tissue Establishments (TEs) (Pirnay *et al.* 2012). If the situation becomes excessively unbalanced towards a profit-oriented approach, the ethical principle on which the donation system is traditionally based could be weakened. As soon as the banking activity is no longer the exclusive competence of public hospitals, a conflict could arise between the altruistic principles motivating the act of donation and the profit-oriented principles of the industry (Pirnay *et al.* 2015).

Biological samples can currently be collected and stored for therapeutic use or for research purposes and, on occasions, the boundary between the two can be blurred. This is the case of donated cord blood units that, if unsuitable for storage and transplantation, can be used, with the informed consent of the donor, for research or for the development of cord blood-derived products (Riva *et al.* 2018). There is consensus that, in cases such as these, the accuracy of the information provided to the donor is of fundamental importance and must include the possibility that the material donated for research purposes may result in one or more commercial products. In Italy, the informed consent form for cord blood donation, adopted in accordance with the Ministerial Decree of 2 November 2015, explicitly states that donated material no longer suitable for storage can be used for research purposes, but also specifies that it can be transferred only between facilities belonging to the national health system (i.e. the public system) (Petrini *et al.* 2011). Recent research using cord blood has often been conducted in order to develop therapeutic products, such as the platelet gel (Riva *et al.* 2018). Private companies may also request access to the material (in particular, waste material) in order to develop products that do not have a specifically therapeutic purpose, i.e. reagents for culture media. In Italy, as mentioned above, the possibility of transfer to the private sector is not contemplated in the donor consent form (which is an integral part of a Legislative Decree). This implies the lack of a sufficient legal basis for the access and use of these materials and

demonstrates that an in-depth reflection on how the industry can access these materials, while respecting the dignity of the donor, has yet to take place.

The current Italian situation regarding umbilical cord donation shows the exact point in which a possible conflict is generated, namely, when a private company requires the use of material that has been donated for solidarity purposes, for 'the common good', to obtain a commercial product. As some have argued, it must be considered that for industry, the purpose of a public health service may not be the key priority (Pirnay *et al.* 2012). We do not mean to suggest that the involvement of the industry in the processing of cells and tissues is inevitably negative, rather we wish to underline the need for a careful examination of how it takes place and for transparent processes and precise rules.

Ethical principles underlying the act of donation

In Europe, supplies of blood for therapeutic use are obtained mainly through a free, voluntary donation system based on the principles of altruism and solidarity. The European Charter of Fundamental Rights (art. 3.2) explicitly sanctions the prohibition on making the human body and its parts as such a source of financial gain. In addition to blood and organs, a wide range of HBMs can be donated for the direct treatment of patients or for research purposes, i.e. to help improve medical treatment in the future. When considering or promoting the donation of material from the human body, a number of values are invoked, including altruism, autonomy, dignity, justice, solidarity, and maximization of common well-being and welfare. Solidarity, in particular, expresses the idea that 'we are all in this together', emphasizing the sense of belonging to a community in which every individual can be in a state of vulnerability and require biological material donated by others (The Nuffield Council on Bioethics 2011, Human bodies: donation for medicine and research, p. 121). In 1970, Richard Titmuss used the expression 'gift relationship' (Titmuss 1970) to describe a blood collection system based on voluntary and altruistic donations from people who want to contribute to the welfare of others. In this sense, bodily materials became the means through which a social contract is established, linking citizens through a gift relationship (Trommelmans *et al.* 2011, p. 153). Although the modifications that have occurred in the materiality of tissue exchange from the 70 s to the present time are remarkable, the gift metaphor is still widely used with regard to the act performed by donors. As pointed out, the gift notion is also often used rhetorically in order to obtain material that circulates on a commercial basis (Tallacchini 2006). In the circumstance in which a company wants to produce a drug from cells or other material donated voluntarily and for free, thereby obtaining a profit that exceeds the processing costs, the study should be subject to an ethical evaluation by an independent organization. This evaluation must guarantee that the material donated within a framework of values of solidarity and altruism is used ethically and that there is a clear advantage for the community.

One example of an approach that aims to safeguard the ethical value of the donation is the Italian plasma collection and processing system. The plasma that is collected and processed industrially comes exclusively from voluntary, anonymous and unpaid donations, mostly from regular donors. The industry processes plasma

as a 'raw material' for the production of plasma-derived medicinal products (PDMP). Considering that blood and plasma should, under no circumstances, become a source of profit, by analogy with the principle of the non-commercialization of the human body and its parts, in Italy, the production of PDMPs is defined in a quantitative and qualitative production plan agreed between the Regions and the manufacturers, in compliance with the Ministerial Decree of April 12, 2012. Thus, the Regions remain the fully entitled owners of the plasma and of all pharmaceutical specialities derived therefrom.

Generating a profit beyond processing costs could lead to a situation in which the goal of the public interest in the entire process is no longer immediate. Perhaps in some cases we should not even refer to the donor's act as a 'gift' but rather as a 'transfer of cells or tissues', an expression that is more neutral with regard to the expression of values (Pirnay *et al.* 2010, Trommelmans *et al.* 2011). 'Cell transfer' is neutral with respect to the connotation of altruism, but closer to the idea that the cells are something valuable that can be transacted.

As early as 2007, in view of the new scenarios that were emerging, some authors began to consider the act of informed consent for the donation of HBMs differently, i.e. as a contractual relationship that serves to formalize and regulate tissue transfer (Waldby and Mitchell 2006). In this perspective, consent no longer merely means respecting the patient's autonomy, rather it becomes a contract in which the terms of an agreement are made explicit even without the provision of financial compensation. The transparent declaration of the mechanisms of attribution of economic value to products based on HBMs is due, on ethical grounds, to the donor and the community in which the donation takes place. All phases of the process leading to marketing should be made transparent, both at the time of the donation and subsequently, for example through public reports. It is clear that in Europe there is a certain degree of commercialization of material of human origin, with different characteristics in individual Member States (Mahalatchimy *et al.* 2011, Lenk and Beier 2012). Nevertheless, a more vigorous ethical debate is required, especially where grey areas exist.

Regulations

The European Union Tissue and Cells Directives (EUTCDs) were drafted to ensure harmonized and high standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells across the European Union (EU). The EUTCDs consist in three Directives: the parent Directive (2004/23/EC) and two technical directives (2006/17/EC and 2006/86/EC). It is important to note that, in addition to EU law, national laws also apply. Rules concerning informed consent, in particular, vary at the national level and have been harmonized with regard to the field of data protection alone. Ethics committee regulations also differ from country to country. In 2007, they were supplemented with a Regulation (EC 1394/2007) on ATMPs. This Regulation established a scenario in which, unlike organs, human tissues and cells are legally marketable goods in a global market. A thorough ethical review should accompany the development of these products to ensure that research results are first and foremost beneficial to the public. Similarly, there should be a joint reflection on how to define final

prices, costs and 'reasonable costs' (Pirnay *et al.* 2015). Specifically, Regulation (EC) no. 1394/2007 created a new legal framework for gene therapy, somatic cell therapy and tissue engineering products by placing them in the 'drugs' category. Regulation 1394/2007 is a *lex specialis*, which introduced additional provisions to those set forth in Directive 2001/83/EC on the Community code relating to medicinal products for human use. As reported by the EMA, it was designed to ensure the free movement of these medicines within the EU, to facilitate their access to the EU market and to foster the competitiveness of European pharmaceutical companies in the field.

ATMPs are derived or produced from human tissue and cells; the donation, procurement and testing of the starting material involved in manufacture are governed by EU Directive 2004/23/EC. This Directive requires Member States to 'endeavour to ensure' that all donations from both living and deceased donors are 'voluntary and unpaid'. It states that 'As a matter of principle, tissue and cell application programmes should be founded on the philosophy of voluntary and unpaid donation, anonymity of both donor and recipient, altruism of the donor and solidarity between donor and recipient (Art. 18)' and refers to other legislative provisions for all matters concerning 'tissues and cells intended to be used for industrially manufactured products (Art. 6)'. The ATPM Regulation also states that, as regards the donation of human cells or tissues, principles such as the altruism of the donor and solidarity between donor and recipient should be respected. The Regulation emphasizes that 'As a matter of principle, human cells or tissues contained in advanced therapy medicinal products should be procured from voluntary and unpaid donation' (Art. 15). Nonetheless, as has been highlighted, with reference to European legislation, the human body is, at the same time, unsellable (for individuals) and marketable (for industry) (Tallacchini 2006).

The principle of the prohibition of financial gain with respect to the human body

In 2018, The European Medicines Agency approved the first allogeneic stem cell therapy product, Alofisel, developed from stem cells removed from fat tissue of adult donors, for use in the EU. The marketing authorization holder is the company Takeda Pharma A/S. In cases such as these, it can be assumed that the donor acts for altruistic reasons, despite the fact that an intermediary will benefit economically from selling the product. Further debate on how and if this could conflict with the principle of non-commercialization of the body is necessary. In the era of biotechnological revolution, body parts have become 'qualified' as commodities through the process of 'artefactualisation' (Parry 2008). This has widened the gap in relations between donor and their body parts, now incorporated in an artefact that theoretically contains a non-marketable part (human body materials) and a marketable part (technological process and/or intellectual labour). Although the principle of the prohibition of financial gain with respect to the human body is widely recognized and accepted worldwide, some authors have pointed out that there is, however, space for an exception within which certain carefully characterized forms

of commodification might come to be tolerated (Trommelmans *et al.* 2011, Lenk and Beier 2012). Different types of these artefacts, especially HTEPs, are produced in an environment where processes are subject to intellectual property rights and commercial interests are at stake (Lenk and Beier 2012). This, by the way, is a matter that was profusely discussed as soon as the first proposals concerning the patenting of biotech inventions were made public in the 1990s (Galloux 1998, Resta 2011).

The question of the patentability and commerciality of the human body was addressed in several documents, in particular, in the Convention of Human Rights and Biomedicine and in the Directive on the legal protection of biotechnological inventions (98/44/EC) issued by the Council of Europe (COE) and by the European Parliament and Council of the European Union, respectively. The Oviedo Convention imposes a ban on making a profit from the human body or its parts (Art. 21), whereas Directive 98/44/EC establishes the non-marketability of the human body. With regard to article 21, the Explanatory Report to the Convention on Human Rights and Biomedicine (Strasbourg, May 1997) states that: '(it) does not prohibit the sale of a medical device incorporating human tissue which has been subjected to a manufacturing process as long as the tissue is not sold as such'. The biological material becomes marketable by virtue of a production process, as in the case of ATMPs that are developed for a specific market. In 2018, the COE published the 'Guide for the implementation of the principle of prohibition of financial gain with respect to the human body and its parts from living or deceased donors' with the aim of supporting the interpretation of Article 21. Article 31 of the Guide states that

> Article 21 of the Convention on Human Rights and Biomedicine does not prohibit the trade, within the existing legal framework, in medicinal products and medical devices incorporating human tissue which have been subjected to a manufacturing process, as long as the tissue which is used as the starting material is not sold as such.

This provision seems rather ambiguous, also in relation to article 3 of the European Charter of Fundamental Rights, because it does not specify what is meant by 'manufacturing process'. It may refer to the process of 'substantial manipulation' as defined in Regulation 1394/2007; however, the definition is not unequivocal and the EMA itself had to establish a procedure to deal with borderline classification uncertainties.

Discussion

With regard to the dignity of the donor, the statement by which the sale of a medical device that incorporates a human tissue is admissible, provided it is subjected to a manufacturing process, requires more thorough ethical consideration. The conceptual ambiguity between the ban on selling cells and the possibility of incorporating them into products that can be marketed, such as HTTPs, is considerable. As has been highlighted, on a European level there are forms of commercialization of cells and tissues derived from the body and a certain degree of uncertainty about when it is permitted to commercialize human tissue also affects jurisdiction on an individual national level (Lenk and Beier 2012). The Nuffield Council on Bioethics reported that, in the UK, various regulatory statutes explicitly forbid 'commercial

dealings' in some circumstances, but are silent or permissive in others. The Human Tissue Act explicitly prohibits 'commercial dealings in human material for transplantation'; furthermore, commercial dealings in organs, non-reproductive tissue and blood for any purposes other than transplantation (i.e. for research) are not covered by this ban (The Nuffield Council on Bioethics 2011, p. 66).

Besides, some might think they should be able to sell body parts in just the same way that they can, for example, sell their cars. Across the EU, reproductive cells can be donated – not sold – to private businesses (with reimbursement of costs or compensation) that use them to obtain a profit. Although it can be assumed that those clinics provide irreplaceable medical treatment for people in need, it does not seem totally wrong to say that they sell donated cells. In all Member States, the Assisted Reproductive Technology (ART) sector is almost completely dominated by private establishments (Parry 2008). The term 'donation' is also employed in the specific case of reproductive cell donors, although apparently not in technical-legal terminology. However, if we analyse the *animus donandi* (understood as the psychological element underlying the act of donation) and we wonder whether it can really be traced back to solidarity with the community to which the subject belongs, the answer is far from obvious.

With the development of biotechnology, the donation of HBMs can no longer be considered *tout-court* as a 'gift' for an institution that represents all the potential beneficiaries in need. In the emerging new scenarios, is the informed consent model still suitable for sealing the relationship between donors and cell and tissue producers or should alternative legal forms of agreement be implemented? The AMA Code of Medical Ethics states that physicians involved in research with HBMs should disclose potential commercial applications to the tissue donor before a profit is realized, obtain informed consent and share profits from the commercial use of HBMs with the tissue donor in accordance with lawful contractual agreements (Opinion 7.3.9). We do not wish to suggest that the sharing of profits is a beneficial or necessary path or support the recognition of a personal property interest in the HBM source. Nonetheless, we do wish to emphasize that informed consent might not be the most suitable procedure for protecting the rights of the person who donates cells and tissues for research purposes. From an ethical point of view, informed consent is a concept that has developed within medical ethics and medical practice and refers to the act by which an individual authorizes a medical intervention, in the form of treatment or participation in research, after having acquired and understood all the relevant information. Through consent, the donor must allow something to be done with his/her tissue and cells. However, where economic interests are at stake, the supervision of independent bodies such as ethics committees or data protection authorities serves to ensure that these interests are also managed through the application of well-defined rules and criteria.

The sale prices of the final products should be fair and transparent with respect to valuable interests such as solidarity, altruism and commitment to the common good. ATMPs, in particular, are very expensive and this raises concerns about the affordability of these therapies by national health services and patients. Efforts should be made to improve publicly available information on pricing and reimbursement policy, emphasizing the public utility value of such innovative therapies.

Conclusions

The principle of solidarity and altruistic donation could be undermined when commercial profit is a potential goal of the research to be conducted. Altruism is recognized as a motivating factor in donation and is valuable because it emphasizes solidarity: the idea that we are 'all in this together' and should try to find common solutions to common problems. If the distance between the good donated (HBMs) and its application in favour of the common good grows and encompasses important economic and private interests, it is necessary to clarify the framework of values within which the act of donation is grounded. Solidarity emphasizes the relationship of commonality amongst the members of a community and it can diminish when the biological material that has been donated for altruistic purposes becomes a source of great economic interests. This possibility should be clearly disclosed during the informed consent procedure, leaving the donor the choice of accepting or refusing. To avoid 'the commercialization of altruism', donor solidarity is only respected when the economic gain is transparent and ethically assessed. On a European level, a clear ethical position should be adopted that does not leave grey areas regarding the possibilities for HBMs commercialization. In this article, we argued that in order for the informed consent document to be valid in the public context of tissue and cell donation, it must be accompanied by independent supervision and clearer rules if important private interests are at stake. When the 'donation' is no longer a gift based on the value of solidarity to an institution representing all potential beneficiaries, but rather a transfer of material to specific stakeholders that have their own interests, altruistic donations are subject to market forces and logics. We do not believe that we should pursue an approach involving the distribution of the profits obtained from products based on HBMs between donor and recipients, since this could hinder research and would be excessively difficult to implement. Instead, we stress the need for clarification on the concepts of 'prohibition of financial gain with respect to the human body' and 'ethical use of altruistically donated HBMs' in respect of the autonomy and dignity of the donor. In the era of the biotechnological revolution, clear guidelines are needed on the ethical and legal characteristics that the documents governing the transfer of cells and tissues must have.

Disclosure statement

No potential conflict of interest was reported by the authors.

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