

Blood and blood-associated symbols: some ethical and legal considerations

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Introduction

Olivier Garraud and Jean-Jacque Lefrère's article "Blood and blood-associated symbols beyond medicine and transfusion: far more complex than first appears"¹ competently examines the profound symbolic value of blood. The authors skilfully delve into our historical, spiritual and human cultural heritage to reveal contrasting symbolisms such as death/life, health/sickness, alliance/rivalry, among others.

The abstract of the article refers to an incongruity that is important not only because of its symbolic significance but also because of its legal, social and above all ethical implications, namely the contrast between the gratuitous nature of blood donation and the trade in plasma-derived products. Surprisingly, the issue is not examined further in the text of the article, though it warrants closer investigation.

The relevant laws and regulations of several nations envisage both the gratuitous, voluntary and unremunerated donation of blood and the commercialisation of plasma-derived products. The present article offers some considerations on this (presumed?) contradiction, taking French legislation as an example. Before proceeding further I should like to clarify two points in order to avoid possible misunderstandings:

1. The contrast between the voluntary donation of blood and the commercialisation of plasma-derived products can effectively be construed as a contradiction. I am personally convinced that we should maintain and defend schemes based on the gratuitous, voluntary and unremunerated donation of blood²; I am also convinced that it is reasonable (or at least almost inevitable) that some plasma-derived products should enter the commercial network. The paragraphs that follow are an attempt to motivate my argument.
2. The choice of France as an example is not intended in any way as a criticism of French legislation: the situation in numerous other nations is similar. It is not possible in the space of an editorial to review the regulations of several countries and, needing perforce to choose one country as an example, I decided (perhaps rather boldly) to refer to the country that is home to the authors of the article.

The situation in France

The principle that the donation of blood should be unpaid, voluntary, anonymous and free of coercion was first propounded in Law 52-854 of 21st July 1952³, and confirmed and extended in subsequent acts, such as Laws 93-5 of 4th January 1993⁴ and 98-535 of 1st July 1998⁵.

Law 52-854 explicitly excludes financial gain, but Article 5 establishes payment for donations "*d'urgence*" (particularly arm-to-arm transfusions in hospitals), adding that "the prices for operations involving human blood, plasma and other blood-derived products are fixed by decree of the Minister for Public Health in such a way as to exclude all financial gain" (hence the current provisions of L. 673 of the Public Health Code).

Article L.1221-1 of the Public Health Code states that "blood transfusions shall be performed in the interest of the recipient and raise ethical principles regarding the voluntary nature and anonymity of donation and the absence of gain".

Article L 1221-3 of the Public Health Code defines the conditions of gratuity: "no payment may be allocated to the donor, without prejudice to the reimbursement of expenses incurred, as specified by decree". The Code also clarifies that:

- "In this respect all cash payments, gift tokens, discount vouchers and other articles granting entitlement to favours extended by third parties, as well as objects of value, services or the bestowal of any advantages, are specifically forbidden" (Article D.1221-1);
- "Payments made by an employer to a donor within the context of his or her professional activities may be maintained for the duration of the donation and shall not be construed as payments within the meaning of Article L. 1211-4 provided that the duration of the absence does not exceed the time required for the journey from the workplace to -and, where applicable, from- the (blood) collection centre, as well as the time required for medical tests, the collection procedures and any recovery and refreshment period considered necessary for medical reasons" (Article D. 1221-2);
- "Tokens of gratitude offered to the donor in accordance with current regulations and the offer of refreshments following the donation are also authorised" (Article D.1221-3);

- "Blood transfusion centres may reimburse blood donors for any transport expenses incurred in connection with the donation, excluding flat rate reimbursements" (Article D. 1221-4).

Thus the voluntary nature of donation and the ban on selling blood do not preclude a reimbursement to the donor for his or her time and inconvenience. This is in line with both the Additional Protocol to the Convention on Human Rights and Biomedicine on the transplantation of organs and tissues of human origin (Article 21)⁶ and the WHO Guiding Principles on human cell, tissue and organ transplantation (Commentary on Guiding Principle 5)⁷.

Similar regulations are in force in a number of European countries. At the international level, however, it is worth noting that there is a considerable difference between the donation of whole blood and the donation of plasma for apheresis: in some states the gratuitousness of whole blood donation is strictly laid down, while in others the donation of plasma for apheresis is much less rigidly imposed (in some countries compensation of €25 is paid to donors, as provided by the European Commission)⁸.

The French regulations make an important distinction between "*produits sanguins labiles*" (labile blood products) and "*produits sanguins stables*" (stable blood products); the former are treated as medication, the latter are not⁹.

Article 1221-9 of the Public Health Code envisages a procedure to set tariffs for the transfer of labile blood products; this was subsequently implemented in the decree of 9th March 2010¹⁰.

A historical note

It is interesting to remember that until the middle of the last century the donation of blood in France was paid for¹¹.

The vast numbers of soldiers wounded in the First World War generated a dramatic need for enormous quantities of blood. In France there was a sharp rise in the numbers of transfusions after 1914, when Trooper Calas gave his blood in a Biarritz hospital to save Corporal Legrain. Thereafter an extensive awareness campaign was set in motion and donors received payments of various kinds. At the time transfusions amounted almost to surgical operations and donors were subjected to considerable inconvenience (largely because they usually had to travel to the recipient's bedside for arm-to-arm transfusions). In 1917 Dr. R Monod proposed a payment of between 20 and 100 francs¹².

After the Second World War, however, the practice of paying for blood came increasingly under fire¹³. Payment clashed with the feelings of brotherhood and altruism that the war had fostered. A Dr. Ranque wrote: "While

voluntary blood donors may belong to different blood groups they are nonetheless bound in a single affective group, a group that is influenced by the same ideal of altruism (...). Donations are generally made with no ulterior motive, no expectation of reward. For some the decisive factor is the pleasure of being useful and -as the moralists say- this is the subtlest of pleasures. For others, and they are by no means a minority, their act of charity is born of a supernatural imperative!"¹¹.

By 1949 the costs of these payments had reached the unsustainable sum of 91,872,468 francs¹⁴.

The problem of payments was overcome partly by the establishment of the *Centre National de Transfusion Sanguine* (1949) and the *Statut Provisoire de l'Hémobiologie* (27th March-18th April 1952)¹⁵.

Suggestions on how to reconcile unpaid donations and use (including sale)

The above paragraphs have sought to show how a system founded on unpaid donations may both envisage the possibility of some kind of reward and allow marketable products to be derived from the blood so donated. Legally speaking, the system is solid.

Ethically speaking too, it can be accepted that while the donation of blood is gratuitous (in line with the principles affirmed in numerous declarations and documents), therapeutic products derived from it can be commercialised.

There is nonetheless a lingering sensation of inconsistency.

This incongruity is not irreconcilable and a few legal and ethical considerations can help to heal the apparent rift.

1. In legal terms -and returning to France as an example- for a number of reasons stemming mainly from the need to create a legal framework for the process of compensating victims of the 1992 scandal concerning infected blood, blood is considered "*une chose*" (an object)¹⁶. The gratuitousness of blood donation is rooted in the principle that the human body is not a disposable commodity, but when blood becomes an element to be used for therapeutic purposes (i.e. an "object") it can be incorporated into a commercial network by the blood transfusion centres, which sell blood to healthcare centres. In this way the principle of gratuitousness is assured by the absence of profit, but there is no impediment to the development of a network for the commercialisation of blood-derived products. French legislation has been crafted to draw a clear distinction between therapeutic products, which can be traded, and parts of the human body; in this way donors are not involved in any commercial transaction.

2. In ethical terms, many authors have recently investigated the meaning of solidarity in the biomedical setting. As Garraud and Lefrère point out, human culture and spirituality are pervaded by the notion of "solidarity".

It is easy to attribute the principles of gratuitousness and non-marketability of blood to this notion of "solidarity", but "solidarity" is nonetheless not incompatible with remuneration and commercialisation¹⁷. The Nuffield Council on Bioethics has addressed these issues in two reports ("Solidarity. Reflections on an emerging concept in bioethics"¹⁸ and "Human bodies: donation for medicine and research"¹⁹). The Council identifies "altruism" as the form of solidarity able to reconcile the gesture of unpaid donation with forms of remuneration to donors and the commercialisation of products derived from the human body.

Three additional concepts may also come to mind: "epikeia", "biovalue" and the "theory of planned behaviour".

- 2.1 One of the values linked with solidarity is equity, which in turn is founded on, among others, the notion of "epikeia", which can apply to situations of the kind under discussion. The centuries-old tradition handed down from Aristotle and St. Thomas Aquinas teaches that "epikeia" can help to resolve real or apparent contradictions between theoretical principles and practical regulations²⁰.
- 2.2 Another concept for reflection is that of "biovalue" or "bioequity". Anthropology has a long tradition of working with broad concepts of value. Waldby suggested the term "biovalue" to describe a "surplus value of vitality and instrumental knowledge"²¹. This concept is pursued by Hoppe, who suggests "a third way" in terms of property classes, that of "bioequity or property in biomaterial"²², and develops his proposal on the back of the well-known sentence in *Moore v. the University of California*²³, affirming that "Equity (...) recognizes concurrent entitlements, one enjoying stronger protection whilst the other one enjoys the, prima facie less complicated, texture of legal ownership. This means that a certain thing can be legally owned by one party, whilst the equitable entitlement rests with another"²⁴. The notions of "bioequity" and "biovalue" are thus based on a distinction between ownership and use²² and suggest a possible basis on which to distinguish between donated elements of the human body and therapeutic products such as those mentioned above.
- 2.3 Another aspect that deserves consideration arises from the Theory of Planned Behaviour (TPB). This introduces the notion of perceived behavioural control, or a person's perception that he or she

can behave in a certain way as desired. Seen in this light, intentional behaviour is based on a careful assessment of the costs and benefits of particular actions. TPB has received considerable support as a cognitive model predicting a wide variety of behaviours, including blood donation behaviour²⁵⁻²⁸. This model predicts the possibility that a gratuitous and disinterested donation and the commercialisation of the product of that donation can be compatible²⁹, the important thing is that the act should be altruistically motivated, as the Nuffield Council on Bioethics has pointed out in the documents cited earlier^{18,19}.

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