Title of Paper

‘The Biopolitics of Blood: Ethics, Commerce and Regulation in the European Union’

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Paper presented at Workshop No. 16: ECPR Joint Sessions of Workshops
Granada, Spain: 14-19 April 2005

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In his seminal work on social policy in the context of the collection and supply of human blood, Richard Titmuss (1970) described the altruistic motivation of the voluntary, unpaid donor who makes an anonymous blood donation to a stranger recipient as a ‘gift relationship’. He argued that voluntary, unpaid blood donation encouraged altruism and provided a significant way in which social solidarity was expressed between human beings. The altruistic motivation that characterised the making of such a donation meant that the donation was much more likely to be safe for a recipient than one that was made by a donor who was paid to donate blood. By the end of the 1970s, Titmuss’s conception of the ‘gift relationship’ that linked altruism in blood donation to blood safety had become central to ethical discourse in national blood policy in European countries whose blood supplies were organised around achieving self-sufficiency through voluntary, unpaid blood donation (Hagen, 1982).¹ The continuing validity of such ethical discourse was brought into question, however, in the wake of HIV/AIDS blood contamination episodes in a number of such countries in the 1980s (Feldman and Bayer, 1999). The political fall-out from such episodes provided the impetus for action at European Union (‘EU’) level in the 1990s, resulting in the inclusion of a treaty competence to act on blood-related matters, and the establishment of an EU-wide regulatory framework for blood quality and safety (Farrell, 2005: 134).²

¹ In this paper, I employ the commonly-used term ‘voluntary, unpaid donor’. This form of blood donation is more formally referred to as ‘voluntary, non-remunerated blood donation’, which is defined as involving ‘persons who give, plasma or other blood components of their free will and receive no payment for it, either in the form of cash, or in kind, which could be considered a substitute for money. This includes time off work, other than reasonably needed for the donation and travel. Small tokens, refreshments and reimbursement of direct travel costs are compatible with voluntary, non-remunerated donation’ (see Beal and van Aken, 1992: 2).

² Article 152(4)(a) EC was included in the Treaty of Amsterdam and provides that measures can be adopted ‘setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member State from maintaining or introducing more protective measures.’
In this paper, I examine the continuing validity of ethical discourse in European blood policy and regulation that employs Titmuss’s conception of the ‘gift relationship’ to link altruism in blood donation to blood safety. In the first part of the paper, I trace the origins of such ethical discourse situating it within the wider academic literature on altruism, as well as altruism in the context of blood donation. I then consider how the development of the international commercial blood industry in the 1970s resulted in such ethical discourse assuming a prominent place in national blood policy in Europe. In the second part, I review the circumstances that led to the HIV/AIDS blood contamination episodes in the United Kingdom (‘UK’) and France. Although there were differing outcomes in each of the countries, I argue that over-reliance on such ethical discourse adversely impacted on the assessment and management of the risk posed by HIV/AIDS to the blood supply. Instead, a range of institutional, regulatory, scientific, as well as ethical factors, needed to be incorporated into such risk assessment in order to ensure blood safety. In the final part of the paper, I examine the influence of such ethical discourse on recent developments in EU blood policy and regulation. I argue that the failure of EU decision-makers to take on board the lessons learned from the national HIV blood contamination episodes is likely to cause problems with ensuring blood safety in the future, given the complex sourcing, production and supply issues involved in managing the demand for blood products throughout the Union.

The ‘Gift Relationship’: Altruism, Blood Donation and Safety

Altruism has been broadly defined as ‘a motivational state that has, as its ultimate goal, increasing another’s welfare’ (Batson, 1998:21). It has also been suggested that altruism can take several forms: reciprocal, kin-related, induced and pure (Badcock (1986:120-121). Pure altruism has been defined as intentional, voluntary behaviour on the part of one individual to benefit another without expectation of external reward (Piliavin and Charng, 1990: 30). Titmuss’s conception of the ‘gift relationship’ in the context of blood donation comes closest to this definition of pure altruism, involving as it does the voluntary, unpaid donor (who he called a ‘voluntary community donor’), who donates blood anonymously to a stranger recipient without expectation of external (financial) reward:
‘...[In providing] the free gift of blood to unnamed strangers there is no formal contract, no legal bond, no situation of power, domination, constraint or compulsion, no sense of shame of guilt, no gratitude imperative, no need for penitence, no money and no explicit guarantee of or wish for a reward or a return gift. They are acts of free will; of the exercise of choice; of conscience without shame’ (1970: 89).

Although Titmuss conceded that the motivation of such donors could not be characterised as ‘complete, disinterested, spontaneous altruism’, he nevertheless wished to distinguish his ideas on altruistic motivation in gift-giving (in the context of blood donation) from those of the noted French anthropologist, Marcel Mauss. In The Gift (1950), Mauss examined the role of gift-giving in a number of non-industrialised societies, and argued that it represented a form of reciprocal altruism that established a perpetual cycle of exchange, which in turn regulated social relationships. Titmuss (1970: 224-226) had adapted Mauss’s ideas, arguing that gift-giving in the context of blood donation had a potentially important role to play in regulating social relationships in industrialised societies. In Titmuss’s view, altruism in blood donation, as exemplified in the voluntary, unpaid donor, promoted important human values, represented a significant way in which social solidarity was expressed between human beings, and provided evidence of the social contract around which a particular society was organised (see also Singer, 1973: 320; Murray, 1987: 32-35).³

Titmuss’s views on the role of altruism in the context of blood donation were subsequently challenged by a number of academic authors. Arrow (1972: 355-60) argued that altruism in the context of blood donation did not contribute to the effective functioning of the market in blood. Instead, it should be seen as a residual phenomenon, only to be activated once self-interest had been exhausted (cf. Singer, 1973). Moore (1991: 206) suggested that altruism in the context of blood donation by voluntary, unpaid donors should not be viewed as pure. Many such donors in fact derived personal satisfaction and self-esteem from such an act, which was also accompanied by a cost-benefit assessment of the likelihood that family and friends would need blood at some point in the future. Healy (2000:1654-1655) was also

³ Mary Douglas (1990: viii) argued in the foreword to a later translation of The Gift that Mauss would have disagreed with Titmuss’s views on altruism in gift-giving (in the context of blood donation), as he believed that reciprocal, rather than pure altruism, more accurately described the role of ‘gifts’ in social relationships.
sceptical of the link between pure altruism and blood donation arguing that altruism was ‘embedded’ within blood transfusion services run by charitable organizations, such as the Red Cross, as a way of providing institutional ‘opportunities’ for individuals to make donations.

Titmuss (1970: 142-157) also argued that the altruistic motivation of the voluntary, unpaid donor made it much more likely that donated blood would be free from disease that could harm the recipient. To support such an argument, he compared the hepatitis infection rates of American and British blood recipients. He suggested that the high rate of infection among American recipients was due to the widespread use of paid donors in the United States, and that the low rate among British recipients was due to the use of voluntary, unpaid donors. Titmuss’s views in this regard were subsequently challenged by two American academics, Sapolsky and Finkelstein (1977:18, 24). They suggested that the high rate of hepatitis infection among American recipients of blood, where such blood had been sourced from paid donation, could be explained by socio-economic factors, such as the poverty rate in the geographical area from which such donors were drawn, rather than by whether donors were paid or not. They argued that high hepatitis infection rates would be resolved over time as a result of further advances in technology, and not simply through encouraging altruism in blood donation. Notwithstanding such academic views on the matter, Titmuss’s findings proved to be highly influential in the United States, leading the then Nixon administration to reform the regulation of the American blood supply. By the end of the 1970s, whole blood was sourced solely from voluntary, unpaid donors, although payment continued for plasma donations used as source material for (fractionated) blood products (Starr, 1998: 251-257).

Titmuss’s arguments concerning the ‘gift relationship’ had been based on empirical research that had been collected in the mid to late 1960s. What such arguments did not take into account, however, was how developments in blood fractionation technology would subsequently transform the supply and demand for blood products on an international basis. Such technology had enabled the production of (fractionated) blood products on an industrial scale for the first time and had resulted in the growth of the international commercial blood industry. In the 1970s, ‘commercial fractionators’, which was the colloquial name given to companies
involved in the industry, developed a lucrative international market in factor concentrates that had brought about a revolution in the treatment of haemophilia. In order to meet growing demand by haemophiliacs, however, commercial fractionators needed to collect hundreds of thousands of plasma donations, which were to be used as source material in the manufacture of such products (Starr, 1998: 220-224).

Commercial fractionators collected plasma donations through a technique known as plasmapheresis, which involved separating the donor’s plasma from other blood components and then returning such components to the donor’s body. Plasmapheresis enabled donors to donate much more frequently than those who donated whole blood, but the donation process took more time. Commercial fractionators were prepared to pay donors for their time and effort in undergoing plasmapheresis, and they argued that it provided the easiest way to ensure a ready source of supply (Hagen, 1982; 18, 114). In the absence of a ban on financial payment for plasma donation, commercial fractionators established plasma collection centres in the United States, as well as in the developing world, in order to collect sufficient source material for their products (Hagen, 1982: 134). By the mid 1970s, however, ‘blood bankers’, who were medico-scientific professionals working in national blood transfusion services, as well as international public health officials, were becoming increasingly concerned about the exploitative practices being engaged in by commercial fractionators in relation to poor and destitute donors in the developing world.

During this same period, scientific evidence also became available showing high rates of hepatitis infection in haemophiliacs who were using factor concentrates manufactured by commercial fractionators, and sourced from paid donors (Starr, 1998: 220). These products

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4 ‘Haemophilia’ is a genetic condition carried by females, but affecting male offspring, and results in a deficiency of either clotting factor VIII or IX. Haemophilia can be mild, moderate or severe. Depending on the level of severity, haemophiliacs require regular treatment with blood products rich in the relevant clotting factor to arrest spontaneous internal bleeding into joints and organs (Krever, 1997: 163-164).

5 ‘Factor concentrates’ are blood products that have been sourced from thousands of plasma donations. Plasma donations are pooled, and undergo a treatment process known as fractionation whereby clotting factor is separated from the plasma. The clotting factor comes in the form of a vial of white powder, to which water is added, before administration to arrest internal bleeding. Vials of factor concentrates can be stored in a refrigerator enabling haemophiliacs to treat most of their bleeds at home. The introduction of factor concentrates reduced the need for frequent hospital visits, which had characterised the treatment of haemophilia in the past, and drastically improved the quality of life of haemophiliacs (Krever, 1997:166).

6 The World Health Organization (WHO) publicly condemned such practices at its Assembly in 1975: see Resolution 28.72: Geneva, Switzerland.
became known as ‘commercial concentrates’ in order to distinguish them from factor concentrates that were manufactured by national blood transfusion services, and sourced from voluntary, unpaid donors.

The combination of such scientific evidence, as well as growing knowledge of exploitation of blood donors by commercial fractionators, ignited an enduring international ethical and scientific debate concerning the merits of voluntary, unpaid over paid blood donation. At a practical level, the main antagonists in the debate were European ‘blood bankers’ and commercial fractionators that were based in both the United States and Europe. On ethical grounds, blood bankers supported altruism in blood donation, as exemplified in the voluntary, unpaid donor, embodied in Titmuss’s ‘gift relationship’. They argued that blood defined the essence of what made us human, and should therefore not be treated as a commodity to be bought and sold in the marketplace. Paying donors for their blood encouraged donors to lie about their health status, but also created the potential for donor exploitation by commercial fractionators, particularly as plasmapheresis enabled donors to make plasma donations on a frequent basis. The environment created by paying for blood donations also meant that it was much more likely that a new transmissible disease would appear first in the paid donor population (Beal and van Aken, 1992: 3; Keown, 1999: 98-99).

Commercial fractionators argued that they were simply responding to consumer demand for blood products in the absence of national blood transfusion services in Europe being able to do so. In response to international pressure, commercial fractionators had also closed down their plasma collection operations in the developing world, and were now relying predominantly on American paid donors. As such, they suggested that the plasma they collected from their paid donors was now as safe as the blood collected from voluntary, unpaid donors. They also argued that paying donors was the only way in which an adequate supply of plasma could be assured, given the time it took to make a plasma donation by plasmapheresis, and the frequency with which donors could make a donation by this method (see Krever, 1997: 176-177; Starr, 1998: 233-247).

Blood bankers’ objections to what they viewed as exploitative practices engaged in by the commercial blood industry, and scientific data which showed high rates of
hepatitis infection in recipients who had used commercially-sourced blood products, confirmed their ethical commitment to voluntary, unpaid blood donation, as well as the link between this form of donation and blood safety. Given the pivotal position played by blood bankers in blood transfusion services, such a link became entrenched in blood policy at national, as well as European, level. The centrality of such discourse was maintained notwithstanding the fact that it was becoming increasingly clear that many national blood transfusion services were experiencing difficulties in meeting the ever-increasing demand for factor concentrates in the 1970s. Such difficulties had led to some national governments approving the importation of commercial concentrates to meet such demand (Hagen, 1982: 139-150). Such importations took place in spite of ethical objections by blood bankers, and notwithstanding the commitment in national blood policy to achieving self-sufficiency in blood and blood products sourced from voluntary, unpaid donation. For blood bankers, such disjunction between ethics on the one hand, and the reality of managing the demand for blood products on the other hand, led them to view such importations as a temporary measure pending the achievement of national self-sufficiency in factor concentrates.

By the start of the 1980s, Titmuss’s conception of the ‘gift relationship’ dominated ethical discourse in national blood policy in European countries whose blood supplies were organised around achieving self-sufficiency through voluntary, unpaid donation. In reality, this had become difficult, if not impossible, to achieve for some countries, and they had become increasingly reliant on commercially-sourced blood products to meet consumer demand. In reality, commercial fractionators now had a significant, if publicly unacknowledged, influence on the blood supply in Europe, and yet ethical discourse within national blood policy remained unchanged. The stage was set for the entry of a new blood-borne transmissible disease that would expose the consequences of this disjunction between the ethics and the reality of managing national blood

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7 From 1949 onwards, the Council of Europe was involved in developing policies and guidelines in the field of blood transfusion. An Expert Committee was convened with responsibility for advising the Council on policy, as well as issuing guidelines and recommendations, on blood-related matters. The Committee was predominantly composed of blood bankers involved in the running of national blood transfusion services in the Council’s Member States. The Council of Europe’s blood policy supports the collection of blood on a voluntary, unpaid basis, national self-sufficiency in blood and blood products, and the manufacture and supply of blood and blood products on a not-for-profit basis (Hagen, 1993: 15).
supplies, and would call into question the continuing validity of ethical discourse in national blood policy that linked altruism in blood donation to blood safety.

**The Impact of HIV Contamination of the Blood Supply**

The AIDS epidemic first emerged in the Western world in the United States with initial reports of gay men contracting the disease in 1981. By 1982, the first cases of AIDS had also been reported in both blood transfusion recipients, as well as in haemophiliacs who had used commercial concentrates. By the start of 1983, it was clear that AIDS was likely to be a blood-borne infectious disease that posed a significant risk to recipients of blood and blood products (Leveton et al, 1995: 60-70). The fact that the United States had become the epicentre for the AIDS epidemic presented a particular problem for European haemophiliacs who were using commercial concentrates, as such products were likely to be sourced from the same high-risk donor pools that were responsible for cases of AIDS among American haemophiliacs (Farrell, 2004: 64-65). In addition, cases of AIDS were already being reported in various European countries, making it likely that national blood supplies were at risk of being contaminated with the disease through their local donor populations (Feldman and Bayer, 1999). In the next section, I examine how ethical discourse in national blood policy, which linked altruism in blood donation to blood safety, influenced the assessment and management of the risk to haemophiliacs from HIV/AIDS in the UK and France.

**United Kingdom**

As had been eulogised by Titmuss back in 1970, the British blood transfusion service had long been committed to achieving self-sufficiency in blood and blood products through voluntary, unpaid donation. By the 1980s, however, British blood bankers’ ability to realise this in practice had become purely aspirational for a number of reasons. Firstly, British bankers were not in a position of control over the ordering of factor concentrates by haemophilia doctors to be used by their patients. Some doctors preferred commercial concentrates, some locally-sourced factor concentrates, and yet others used a mixture of both, depending on regional availability. Secondly, and more importantly, longstanding political and financial neglect had led to institutional dysfunction within the British blood transfusion service, which had been organised on a regional basis within the overall structure of the National Health Service (‘NHS’).
The ‘regionalisation’ of the service had resulted in a structural inability to effectively manage the collection and supply of blood on a national basis and this, in turn, had contributed to difficulties in achieving self-sufficiency in factor concentrates. The extent of such dysfunction was such that it had led one senior blood banker to describe the service as a ‘fragmented and disorganised shambles’ by the 1980s (Cash, 12/9/1987: 617).

One of the consequences of such dysfunction was that even if haemophilia doctors had wanted to prescribe locally-sourced factor concentrates for their patients, they were often unable to do so. In 1980, the Blood Products Laboratory, the major manufacturing facility for the production of factor concentrates in the UK, was declared unfit to continue with its operations following an inspection by the national regulator for medicines. This forced the then Conservative government to make an urgent injection of funds to upgrade the facility. As a result of such investment, the government promised self-sufficiency would be achieved by 1984, but the new facility was not actually opened until 1987 (Cash, 12/9/87: 618). Blood bankers viewed the importation of commercial concentrates to address the shortfall in supply as a temporary measure pending the achievement of self-sufficiency. From the mid 1970s onwards, however, importation of such products had increased steadily to the point that, by the early 1980s, commercial concentrates were accounting for at least 50% of blood products used by British haemophiliacs. Such importations took place with only minimal national regulatory control being exercised over the quality and safety of the source material used in such products. Although the national regulator for medicines was responsible for the licensing of such products, the source material came from the plasma donations of American paid donors. As such, it was essentially reliant on the American regulator, the Food and Drug Administration (‘FDA’), as well as commercial fractionators themselves, to manage the risk posed by HIV/AIDS to commercial concentrates that were, in turn, being used by British haemophiliacs (Farrell, 2004: 125).8

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8 A subsequent inquiry commissioned by the American government revealed that the FDA had suffered agency capture by commercial fractionators and had failed to adequately address the risk posed by HIV/AIDS to blood and blood products in the United States (Leveton et al, 1995: 10)
Once HIV testing became available, the UK was shown to have a low level of HIV infection among blood transfusion recipients who had received blood from local voluntary, unpaid donors, but a comparatively high rate of HIV infection among haemophiliacs who had used commercial concentrates (Cheingsong-Popov et al, 1/9/984; see also Tables 1 and 2 below). Although it was estimated that just over a third of the British haemophilia population had been infected with the virus, the actual rate of HIV infection among (severe) haemophiliacs who used commercial concentrates on a regular basis was in fact much higher at 75% (Rizza et al, 2001).

By the early 1980s, the ‘volunteer donor image’ promoted by the British blood transfusion service increasingly ‘fronted’ a system that was ‘heavily dependent on commercial sources’ (Berridge, 1996: 38). It was an image, however, that was clung to by blood bankers, and promoted by politicians and civil servants in national blood policy. The disjunction between ethical discourse and the day-to-day reality of managing a blood supply that was in fact heavily dependent on commercially-sourced blood products presented a problem in terms of managing the risk to haemophiliacs from HIV/AIDS. Giving centrality to such ethical discourse resulted in a form of ‘blindness’ on the part of those involved in blood policy-making whereby the importation of commercial concentrates was characterised as a temporary aberration from ethical norms and a transient risk to safety, one that would disappear once self-sufficiency in locally-sourced factor concentrates was achieved. As a result, the present danger to haemophiliacs from the continued use of commercial concentrates was ignored. In the case of the UK, an ethical commitment to altruism in blood donation was, on its own, not enough to ensure blood safety in this instance. Other factors needed to be taken into account, including the epidemiology of foreign donor populations, the national coordination of supply and demand for blood and blood products, the technical capacity to meet national demands for (fractionated) blood products, and the need for an independent, well-resourced national regulator to ensure blood quality and safety.
Table 1
HIV Infection of Haemophiliacs in Selected Western European Countries as at 1992

<table>
<thead>
<tr>
<th>Country</th>
<th>No. Tested</th>
<th>No. Positive</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Belgium</td>
<td>291</td>
<td>19</td>
<td>6.5</td>
</tr>
<tr>
<td>Denmark</td>
<td>310</td>
<td>89</td>
<td>28.7</td>
</tr>
<tr>
<td>Finland</td>
<td>238</td>
<td>2</td>
<td>0.8</td>
</tr>
<tr>
<td><strong>France</strong></td>
<td><strong>2684</strong></td>
<td><strong>1036</strong></td>
<td><strong>38.6</strong></td>
</tr>
<tr>
<td><strong>Germany F.R</strong></td>
<td><strong>3176</strong></td>
<td><strong>1177</strong></td>
<td><strong>37.1</strong></td>
</tr>
<tr>
<td>Greece</td>
<td>881</td>
<td>176</td>
<td>20.0</td>
</tr>
<tr>
<td>Italy</td>
<td>2957</td>
<td>768</td>
<td>26.0</td>
</tr>
<tr>
<td>Luxembourg</td>
<td>20</td>
<td>2</td>
<td>10.0</td>
</tr>
<tr>
<td>Netherlands</td>
<td>217</td>
<td>36</td>
<td>16.6</td>
</tr>
<tr>
<td>Spain</td>
<td>2799</td>
<td>1147</td>
<td>41.0</td>
</tr>
<tr>
<td>Sweden</td>
<td>389</td>
<td>98</td>
<td>25.2</td>
</tr>
<tr>
<td><strong>United Kingdom</strong></td>
<td><strong>3545</strong></td>
<td><strong>1206</strong></td>
<td><strong>34.0</strong></td>
</tr>
</tbody>
</table>


Table 2
AIDS Cases in Blood Transfusion Recipients in Selected Western European Countries as at 1992

<table>
<thead>
<tr>
<th>Country</th>
<th>Total Cases of AIDS</th>
<th>Cases of BT AIDS</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Belgium</td>
<td>1297</td>
<td>84</td>
<td>6.5</td>
</tr>
<tr>
<td>Denmark</td>
<td>1120</td>
<td>20</td>
<td>1.8</td>
</tr>
<tr>
<td>Finland</td>
<td>126</td>
<td>5</td>
<td>4.0</td>
</tr>
<tr>
<td><strong>France</strong></td>
<td><strong>22939</strong></td>
<td><strong>1201</strong></td>
<td><strong>5.2</strong></td>
</tr>
<tr>
<td><strong>Germany F.R</strong></td>
<td><strong>9205</strong></td>
<td><strong>178</strong></td>
<td><strong>1.9</strong></td>
</tr>
<tr>
<td>Greece</td>
<td>721</td>
<td>44</td>
<td>6.1</td>
</tr>
<tr>
<td>Italy</td>
<td>15780</td>
<td>217</td>
<td>1.4</td>
</tr>
<tr>
<td>Luxembourg</td>
<td>57</td>
<td>2</td>
<td>3.5</td>
</tr>
<tr>
<td>Netherlands</td>
<td>2478</td>
<td>35</td>
<td>1.4</td>
</tr>
<tr>
<td>Spain</td>
<td>17029</td>
<td>189</td>
<td>1.1</td>
</tr>
<tr>
<td>Sweden</td>
<td>772</td>
<td>39</td>
<td>5.1</td>
</tr>
<tr>
<td><strong>United Kingdom</strong></td>
<td><strong>6929</strong></td>
<td><strong>82</strong></td>
<td><strong>1.2</strong></td>
</tr>
</tbody>
</table>

France
Like their British counterparts, French blood bankers had also long been committed to achieving self-sufficiency in blood and blood products sourced from voluntary, unpaid donation. This form of donation also carried a particular socio-cultural resonance in France. The voluntary, unpaid donor, known as *le bénévolat*, was associated with the liberation of France in World War Two, with patriotic French following the advancing Allied armies and donating blood to injured soldiers to aid victory. By the end of the war, the voluntary donor was a national hero, a symbol of national freedom and solidarity (Steffen, 1999: 99). In the postwar period, voluntary donor associations had been formed at both local, and national level, and they played an influential role in organising and promoting blood donation in France (Hermitte, 1996: 96-109). The symbolism associated with the voluntary, unpaid donor only served to entrench ethical discourse in national blood policy, which linked altruism in blood donation to blood safety.

Although there had been a longstanding commitment on the part of French blood bankers for achieving self-sufficiency in blood products, this had proved to be problematic in the case of factor concentrates. At the time, the French blood transfusion service was organised on a regional basis, and this had led to institutional dysfunction in managing demand for such products on a national basis. Blood bankers who ran regional services were highly protective of their operations, and the funding arrangements in place for factor concentrates meant that they were often in competition with one another, creating difficulties in coordinating the collection of plasma so as to achieve national self-sufficiency in such products (Setbon, 1993: 78-83; Hermitte, 1996: 145-148). In the early 1980s, ongoing difficulties in achieving self-sufficiency had resulted in the importation of commercial concentrates for use by select groups of haemophiliacs. This was seen as a temporary measure by blood bankers until self-sufficiency was achieved. With the Socialist government coming to power in the early 1980s, there was a renewed political commitment to achieving national self-sufficiency. The government gave the Parisian blood transfusion service a mandate to achieve national self-sufficiency, providing substantial funds to upgrade its manufacturing facilities as well as overall national control over the importation of blood products (Casteret, 1992: 64).
During this time, Direction-Générale de la santé (‘DGS’), which was part of the larger Ministry of Health and Social Affairs, was the state department that had overall institutional responsibility for national blood policy and regulation. Despite having considerable regulatory powers in this regard, DGS suffered from a chronic lack of financial, personnel and administrative resources, and this severely hampered its ability to exercise such powers effectively (Steffen, 1999: 100). Combined with a state institutional culture that had traditionally deferred to medico-scientific professionals in the exercise of their expertise, DGS adopted a consensual, reactive approach to managing risks to the blood supply, essentially ‘rubber-stamping’ advice received from blood bankers who dominated its blood advisory committee (Casteret, 1992: 21; Geronimi et al, 1992: 116-117). Such an approach was highlighted in the formulation and implementation of AIDS donor screening guidelines. In 1983, DGS published such guidelines based on advice it had received from its blood advisory committee. Over the next two years, many blood bankers failed to implement such guidelines at regional level, fearful of alienating their existing donor base, and spurred on by their belief in the inherent safety of voluntary, unpaid blood donation. Although DGS subsequently became aware that such guidelines were not being implemented, it failed to impose any regulatory sanctions upon blood bankers to ensure adherence to such screening measures (Farrell, 2004: 72-80).

French blood bankers’ belief in the inherent safety of voluntary, unpaid donation, provided the main frame of reference for their assessment of the risk posed by HIV/AIDS to the national blood supply. When the first cases of AIDS were diagnosed in French haemophiliacs, investigations revealed that locally-sourced, as well as commercial concentrates, were implicated in such cases. Notwithstanding the outcome of such investigations, however, blood bankers chose to publicly assert that such cases were wholly attributable to the use of commercial concentrates by such haemophiliacs. They argued that once self-sufficiency was achieved, the safety of French haemophiliacs would be assured (Casteret, 1992: 71-72). Blood bankers also continued to collect blood on the streets of Paris and Marseilles, despite the high number of AIDS cases in such cities, and blood collections were also maintained in French prisons. Prison blood collections had long received political and institutional support in France because they were seen as enabling prisoners to engage in an act of social rehabilitation. Such collections also provided an easy and reliable way for
blood bankers to obtain blood on a regular basis, particularly at regional level. As a result, such collections continued notwithstanding the fact that many prison donors were likely to be at high-risk of carrying the AIDS virus due to the exponential growth of intravenous drug use in French prisons in the early 1980s (Geronimi et al, 1992: 55-68).

In early 1985, evidence became available to blood bankers showing a high prevalence of HIV positive donors in Paris. Michel Garetta, then head of the Parisian blood transfusion service, took the decision to continue to distribute locally-sourced factor concentrates held in his inventory although he knew that all such products were likely to be contaminated with HIV. He was also aware at the time of making such a decision that safer products were now available for haemophiliacs, which had undergone a heat treatment process to inactivate the virus. Having to discard such inventory, however, would have meant incurring substantial financial losses as well as having to admit that national self-sufficiency in factor concentrates had not been achieved. Unable to admit such failure to his political masters, Garetta continued to supply factor concentrates from his existing inventory to unsuspecting French haemophiliacs (Casteret, 1992: 149-150; 170-173).

Once HIV testing was introduced, it became clear that France had one of the most highly contaminated blood supplies in Europe with a high rate of infection among blood transfusion recipients, as well as haemophiliacs (see Tables 1 and 2 above). Subsequent investigations revealed that although blood donations by prison inmates represented only 0.37% of all blood donated in France, they had accounted for at least 25% of AIDS cases in blood transfusion recipients in 1985 alone (Geronimi et al, 1992: 55-68). Paris and Marseilles had the highest number of HIV positive donors, attributable in large part to the large number of mobile blood collections on the streets of such cities. The pooling of plasma from Parisian, as well as prison donors, in the manufacture of factor concentrates had been largely responsible for the high rate of HIV infection among French haemophiliacs, which in the case of (severe) haemophiliacs in Paris was over 75% (Casteret, 1992: 63).

The HIV blood contamination episode in France revealed that ethical discourse in national blood policy, which linked altruism in blood donation to blood safety, was
inadequate for assessing risks to the blood supply. There was a high HIV prevalence among certain sections of the local voluntary donor population, such as Parisian and prison donors, and this presented a particular problem for the safety of haemophiliacs using factor concentrates, where such products were sourced from thousands of plasma donations in Garetta’s manufacturing facility in Paris. The pooling of such donations as part of the manufacturing process for factor concentrates meant that even one HIV positive donation could infect a whole batch. Unlike in the UK, the different epidemiological profile of voluntary, unpaid donors in France meant that achieving self-sufficiency in factor concentrates did not necessarily equate with increased safety for haemophiliacs. The contamination episode also showed in stark terms how an ethical commitment to altruism in blood donation was an inadequate frame of reference for assessing risks to the blood supply. While such ethical commitment may have reflected important socio-cultural values in French society, additional factors needed to be taken into account in managing such risks in the interests of blood safety. Such factors included the need for national coordination in managing risks to the blood supply, knowledge of the epidemiological profile of the local donor population, an independent and well-resourced national regulator responsible for blood quality and safety, and a cost-benefit analysis of whether national self-sufficiency would enhance blood safety in response to particular risks to the blood supply.

In the 1990s, the HIV blood contamination episode in France developed into an enduring and divisive political scandal. Known as *l’affaire du sang contaminé*, the political fall-out from the scandal resulted in widespread reform to national blood and regulatory institutions, the jailing of prominent blood bankers such as Garetta, three separate legal investigations, and the political trial of three former Ministers who had responsibility for the blood supply in the 1980s (Farrell, 2004: 96-101). The intensity of public reaction to the circumstances that had led to the HIV blood contamination episode revealed citizens’ anger and disillusionment over the perceived failure of those in political leadership, together with their scientific advisers, to adequately manage such public health risks (Farrell, 2004: 108-109). What such reaction also revealed was the continuing symbolic importance of blood itself, as well as blood donation, representing as it did an affirmation of important social values relating to kinship, identity and community (Murray, 1998: 71; Nelkin, 1999: 275). The
important social values symbolised in blood donation had been ‘contaminated’ by the failure of those with political and institutional responsibility for the national blood supply to manage the risk of HIV/AIDS. In France, the HIV blood contamination scandal provided a timely reminder for those in political leadership that blood continued to carry deep cultural resonance, and that citizens’ commitment to altruism in blood donation remained strong. It also sounded a warning to government policymakers and regulators that they needed to pay particular attention to public sensitivities on these issues, while at the same time seeking to manage the complex sourcing, production and supply issues involved in the management of the blood supply.

**Developments in EU Blood Policy and Regulation**

HIV blood contamination scandals in Member States, such as France, provided the catalyst for action at EU level on blood-related issues in the 1990s. In the absence of a treaty competence to act on such issues, EU institutions issued a series of ‘soft law’ instruments affirming the EU’s commitment to achieving self-sufficiency in relation to the ‘Community blood supply’ through ‘voluntary, unpaid blood donation’ (Farrell, 2005: 136-137). A specific competence to act in relation to blood quality and safety was subsequently included in the Treaty of Amsterdam (see Article 152(4)(a) EC). Such competence has provided the legal basis on which the EU has established a transnational regulatory framework for blood quality and safety in the ‘Blood Directive’, which was required to be implemented by Member States by the 8th of February 2005.9 The EU’s commitment to Community self-sufficiency through voluntary, unpaid blood donation in its key policy and regulatory instruments is consistent with widespread support amongst European citizens for maintaining this method of blood collection.10 In reality, however, EU decision-makers face a dilemma in trying to meet public expectations in this regard in the face of the day-to-day reality of managing the demand for blood products throughout the Union. In the early 1990s, it was estimated that there was at least a 50% shortfall in the amount of plasma needed to meet such demand on an EU-wide basis (Lewis, 13/1/93).

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Data published by the Commission in 1994 also showed that there was a significant dependency on the part of some Member States on the importation of commercially-sourced blood products. The Commission’s data in this regard, however, did not paint an up-to-date or comprehensive picture of such dependency, as it had been based on information that had been collected between 1989 and 1991, and a number of Member States, such as Germany, had failed to provide accurate data on the matter. Since such time, the Commission has failed to publish any more data on the issue, and there appear to be no plans to do so in the foreseeable future. In the absence of up-to-date data, it is therefore difficult to estimate the extent of plasma shortfall, as well as ongoing dependency on the part of Member States on commercially-sourced blood products. What can be said with certainty, however, is that the shortfall continues to exist and it has led to the development of a bifurcated system for managing the Community blood supply. Within such system, whole blood is collected from voluntary, unpaid blood donors on a national basis, and a mixed public/private system operates in relation to plasma, which is collected from paid as well as unpaid donors, both within and outside the EU. Member States, such as Germany and Austria for example, operate for-profit fractionation programmes where donors are paid to donate their plasma, whereas other Member States, such as the Netherlands and the UK, operate not-for-profit fractionation programmes organised around voluntary, unpaid donors (Hagen, 1993: 63-83).

Although plasmapheresis programmes involving voluntary, unpaid blood donors exist in certain Member States, such as the Netherlands, in order to address the plasma shortfall in blood products, there has been no systematic EU-wide approach to publicising and increasing the number of such programmes. As a consequence, European citizens have a very low level of awareness of what plasmapheresis is, or how it could contribute towards addressing the current EU-wide shortfall in plasma needed for blood products. National collections of plasma to meet such shortfall have also been further complicated by the appearance of new transmissible diseases in the blood supply, such as variant Creuzfeldt Jakob Disease (‘vCJD’). In the case of the UK, for example, the appearance of this new disease led to the identification of a

12 See footnote 10 above.
potentially high-risk group of British blood donors. In order to minimise the risk of transmission of vCJD in the blood supply, the UK government took the decision to sanction the long-term importation of plasma from paid donors in the United States. Such plasma was to be used as source material by the Blood Products Laboratory in the manufacture of factor concentrates supplied to the NHS (Boseley, 14/5/98).

Although the optimal functioning of the single market is central to the EU’s aims and objectives, EU decision-makers are also confronted with monopolistic and/or protectionist policies on the part of some Member States in relation to the management of national blood supplies. The ethical commitment to the supply of blood and blood products that have been sourced from local voluntary, unpaid donors has been used by some Member States to partition and/or close-off national markets to commercial fractionators, as well as not-for-profit fractionators from other Member States (Leikola, 14/2/96). While EU decision-makers need to juggle increased political sensitivities at national level to issues surrounding blood quality and safety, such protectionist policies have proved difficult to justify particularly in the face of concerted opposition from commercial fractionators, which form a constituent part of the international pharmaceutical industry, which is highly influential at EU level (Farrell, 2005: 140).

In light of the complex range of factors that EU decision-makers are required to take into account in devising and implementing blood policy and regulation, to what extent could, or should, ethical discourse, which links altruism in blood donation to blood safety, continue to play a role in the assessment of risks to the Community blood supply? With political sensitivities at a high level due to HIV blood contamination scandals at national level, as well as ongoing public support for voluntary, unpaid donation, EU decision-makers appear to have taken the decision to publicly espouse an ethical commitment to a Community blood supply that is self-sufficient and sourced from voluntary unpaid blood donation, which is line with public expectations. A recent example of such commitment can be found in the Recital to the Blood Directive. In paragraph 23 of the Recital, reference is made to the importance of encouraging voluntary, unpaid blood donations ‘as a factor contributing to high safety standards for blood and blood components and therefore to the protection of human
health’, and in paragraph 32 to attaining Community self-sufficiency as being one of the objectives of the Directive.\(^{13}\)

The fact that achieving Community self-sufficiency through the sourcing of blood and blood products through voluntary, unpaid donation was not made a mandatory requirement within the substantive terms of the Blood Directive, however, is indicative of a reluctance on the part of Member States to be legally bound to realise this objective in practice. There is also little evidence that the EU is prepared to engage in a concrete programme of action by which self-sufficiency through voluntary, unpaid donation could be achieved throughout the Union. The absence of up-to-date, publicly available data on the current level of Member State dependency on commercially-sourced blood products, which could provide the empirical basis for such a programme, shows there is a lack of political will at EU level to go beyond simply espousing an aspirational commitment to Community self-sufficiency through voluntary, unpaid blood donation. Despite recent developments in blood policy and regulation, there is little evidence that the lessons learned from national HIV blood contamination episodes have been taken on board at EU level. The ethical commitment to altruism in blood donation looks set to remain central to EU blood policy, notwithstanding the day-to-day reality of a mixed public/private market in blood products throughout the Union. Such an approach has all the hallmarks of a political compromise, one that is likely to pose ongoing problems with the assessment and management of risks to the blood supply in the future.

**Conclusion**

This paper examined the continuing validity of ethical discourse in blood policy and regulation in the European context that employs Titmuss’s conception of the ‘gift relationship’ to link altruism in blood donation to blood safety. The continuing relevance of such discourse in structuring the assessment and management of risks to the blood supply was examined by reference to HIV/AIDS blood contamination episodes in the UK and France. The outcome of such episodes revealed that such ethical discourse was not an adequate frame of reference for assessing risks to the blood supply. Instead, there was a need to incorporate a range of institutional,

regulatory, scientific, as well as ethical factors into such assessment, in order to ensure blood safety. These included the need for institutional coordination of all relevant parties involved in managing risks to the blood supply, knowledge of the epidemiological profiles of local and foreign donor populations, independent and well-resourced regulatory control, and whether self-sufficiency was technically or economically feasible as an appropriate response to managing particular risks to the blood supply. In addition, the UK case study highlighted the problems that can arise in assessing such risks where disjunction exists between ethical discourse on the ‘gift relationship’ and the day-to-day reality of a blood supply that was in fact heavily dependent on commercially-sourced blood products to meet consumer demand.

Although HIV blood contamination scandals in Member States, such as France, provided the catalyst for action on blood quality and safety at EU level, it is not clear that the lessons from such episodes have been taken on board by EU decision-makers. Ethical discourse that links altruism in blood donation to blood safety continues to play a central role in EU blood policy, despite the fact that it remains purely aspirational in the light of the ongoing shortfall in the amount of plasma needed for blood products on an EU-wide basis. In reality, a mixed public/private system has emerged to address such shortfall, with plasma being collected from paid and unpaid donors, both within and outside the EU. Formulating strategic policy, and implementing regulation, on blood-related matters has also proved to be a complex undertaking at EU level. Ensuring the optimal functioning of the single market, which is central to the aims and objectives of the EU, clashes with attempts at national level to engage in protectionist policies in relation to the sourcing of blood products. Widespread support for voluntary, unpaid donation among European citizens and raised political sensitivities resulting from national HIV blood contamination scandals also mean that publicly acknowledging the reality of the day-to-day management of the EU blood supply does not currently appear to be a politically acceptable option.

There is still a place for ‘the gift relationship’ in the context of blood donation in the European context, much favoured by its citizens as affirming important social values. The outcome of HIV blood contamination episodes at national level showed, however, that altruism in blood donation is but one factor, among several, which may contribute to blood safety. In the light of such contamination episodes and given
recent developments in EU blood policy and regulation, there is an urgent need for a more realistic and open debate about how social values embodied in the ‘gift relationship’ should be honoured in the context of blood donation within the Union. At the same time, those in political leadership need to evaluate how such values are to be reconciled with managing the complex sourcing, production and supply issues involved in meeting the demand for blood products in the twenty-first century. The failure to do so may condemn those involved in blood policy and regulation at national, as well as EU level, to repeating the mistakes of the past, in seeking to manage the assessment of risks to the blood supply in the future.
References


