

# Mapping the role of official bioethics advice in the governance of biotechnologies in the EU: The European Group on Ethics' Opinion on commercial cord blood banking

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In the early 1990s, the EU's proposed bioeconomic agenda provoked ethical concerns among its citizenry. In response to the political impasse between economic and ethical imperatives, as well as the perceived lack of democratic legitimacy, the EU established an expert bioethics advisory body, known as the European Group on Ethics in Science and New Technologies (EGE). Situated at the boundary between law, bioethics and economic policy, the EGE plays an ambiguous role in the governance of biotechnologies in the EU. To elucidate the nature of its role and influence, this paper considers the EGE as an integral element of a broader web of governance spanning EU and Member State institutions. Using as a case study the emerging controversy surrounding commercial cord blood banking, we explore whether the EGE and its ethical opinions on this matter have contributed to the democratic legitimacy of the EU.

## 1. Introduction

The complex institutional and operational arrangements of the EU often provoke claims of a lack of democratic legitimacy (Weiler et al. 1995; Heretier 1999; Kohler-Koch and Rittberger 2007; Menon and Weatherill 2007; Bellamy 2010). From this perspective, the governance of biotechnologies in the EU is problematic. While biotechnologies are seen as 'key for the future competitive development of the Community' (European Commission 1991: 1), many are recognised by the European Commission, since at least the early 1990s,<sup>1</sup> as ethically contentious, generating a tension between some citizens and the European Commission's vision of their increased

commercialisation. In response, and seeking in part to rectify the (perceived) democratic deficit, the European Commission created an expert bioethics advisory body in 1991, now known as the European Group on Ethics in Science and New Technologies (EGE).

Situated at the boundary between law, bioethics, and economic policy, the EGE plays an ambiguous role in the EU governance of biotechnologies. Previous studies highlight the EGE's uncertain place in both the EU legal order, given that it has no firm basis in the constituent treaties or legislative structures (Busby et al. 2008) and 'involves a blurring of normative moral and legal orders'

(Plomer 2008: 840); and the EU political order, as a broker at the boundary between economic and cultural pressures on decision-making legitimacy (Salter and Jones 2002a,b; Jasanoff 2005). With the exception of our own previous work (Busby et al. 2008), these studies focus on the contribution of EGE opinions to determining the ethical constraints on human embryonic stem cell research for the Biotechnology Directive (where the EGE's influential role is documented, and which confers the EGE's mandate to evaluate 'all ethical aspects of biotechnology') or for the Framework Programmes. In this paper, using as a case study EGE Opinion No. 19 on the 'Ethical aspects of umbilical cord blood banking', we examine the nature of the EGE's influence in the governance response to the emerging controversy around commercial cord blood stem cell banking in Europe. Our focus on this Opinion, published in 2004, reflects its place in responding to widespread ethical concerns within the EU about the legitimacy of commercial cord blood banking and the development of the Tissues and Cells Directive (European Parliament and the Council of the European Union 2004), where the EGE had the potential to influence the ethical parameters for standards of quality and safety of human tissues and cells (which in this context include cord blood) for transplantation.

### 1.1 Aims and methods

The work of bioethics advisory bodies has grown as governments have recognised the new challenges posed by recent developments in the biotechnologies and the need to engage the ethical concerns (both actual and perceived) of publics. Much analysis of such bodies has focused on their role in advising national governments, particularly in the USA, where such bodies are well established. Kelly's (2003) analysis of the 'boundary work' of the US Human Embryo Research Panel finds that these bioethics groups perform ethical debate about issues that cannot be resolved through other political mechanisms. In the EU, the study by Hervey and Black (2005) on the governance of stem cell research highlighted the role of ethical norms and declarations. They concluded that such declarations can be considered to be an influential form of soft governance.

Turning to the EGE specifically, there has been criticism by legal scholars of its lack of a clear constitutional basis and its unclear relationship with the European Commission. Plomer et al. (2006) write of a blur between legal and moral reasoning that may afflict the EGE, and question its authority and credibility. We have previously concluded that the EGE's constitutional status is at best 'grey' given that it has no firm basis in the EU's constituent treaties, or the legislative structures developed to enhance the legitimacy, transparency, accountability and representativeness of EU legislative and executive decision-making (Busby et al. 2008). There are, though, more positive views: Jasanoff (2005: 218) observes

that the EGE's mandate is indicative of a distinctive governance framework characterised by the 'permeability of the boundary between law and ethics'.

Drawing on perspectives from law, political science and sociology, we investigate how the EGE operates within a broader network of institutions and relations that govern biotechnologies in the EU. We consider the EGE as an integral element in a 'web of governance'—an analytic term used to resolve our earlier difficulty in fully explaining, through a narrow legal approach, the role or influence of the EGE in law, specifically on the legislative process surrounding the Tissues and Cells Directive (Busby et al. 2008). We searched the relevant legislative databases but found no mention of Opinion No. 19. In looking at the EGE as part of a 'web of governance', rather than in more linear, top-down or dichotomous (law/ethics; law/politics) terms, we develop a multilayered understanding of the generation of, and role played by, official EU ethics advice, which takes account of the interactions between institutional actors at the EU and national levels.

The development of biotechnology policy has posed particular governance challenges as it involves specialist technical and ethical domains beyond the competences and understanding of EU policy-makers. The pace of biotechnological development, and the sensitive social and ethical issues it raises, has forced EU policy-makers to re-evaluate traditional concepts of regulation. Creating a web of governance around these issues is seen as a way to develop more informal yet continuous linkages with the required sources of expertise and knowledge. Alongside technical groups and networks of policy advisors, bioethics advisory groups, such as the EGE, play a significant part in advising on the direction, value, and legitimacy of developments in science and technology.

This paper stems from a small project that investigated the role played by the EGE in the governance response to ethical problems associated with commercial cord blood banking in the EU. Documentary analysis of the social scientific literature encompassing bioethics advisory groups, EGE publications, legislative proposals, Commission strategies, European Parliament proceedings and outputs of the National Ethics Committees was undertaken to trace the broader impact of (and influences on) the EGE.

Eight focused, semi-structured interviews were conducted with former and current members of the EGE instrumental in the development of Opinion No. 19 and with the former and current heads of the EGE Secretariat.<sup>2</sup> Access to the current EGE members was managed by the head of the Secretariat. The EGE deliberates in private, and requests to attend and observe its internal procedures were denied. Permission was granted to interview the chairperson, the two rapporteurs and the head of the Secretariat. Former members were interviewed at their convenience.

We begin by tracing the evolution of the EGE's mandates, membership and methods in this context. We then outline the governance problem of tissue banking in Europe, and analyse the EGE's response. The nature of the EGE's role and influence in a web of bioethical governance is then considered. We conclude by examining whether the EGE's activities and its opinions have helped to broaden the legitimacy base of EU decisions.

## 2. Evolution of the EGE: Its mandates, membership and methods

### 2.1 Mandates

The Group of Advisors on the Ethical Implications of Biotechnology (GAEIB) was established by the Commission in 1991 to provide 'neutral, independent, pluralist and multidisciplinary' advice to EU decision-makers on the ethical dimensions of biotechnologies (EGE 2009). The GAEIB's mandate echoed the rationale for its establishment to support the regulatory process, including the Biotechnology Directive (98/44/EC on the legal protection of biotechnological inventions) that was then being contested for ethical reasons by the European Parliament (EGE 1991). The GAEIB published two early Opinions that influenced the development of the Directive and the terms of its eventual adoption.<sup>3</sup> In recognition of its role as an ethical arbiter in the bio-political disputes surrounding the Directive, Article 7 confers 'official status' upon the EGE, the GAEIB's successor, by granting it a continuing mandate to evaluate 'all ethical aspects of biotechnology' (European Parliament and the Council of the European Union 1998).

A Commission Decision established the EGE in December 1997 (European Commission 1997). Under its first mandate (1998–2000), the expanding role of the EGE, as compared to the GAEIB, is evident from the description of its main objectives by Commission President Jacques Santer:

...to help break down barriers in fields which require a multi-disciplinary approach, not only scientific and legal but also philosophical, sociological and economic; to provide European decision-makers with clear and up-to-date basic information, enabling them to be properly informed in carrying out their duties; to promote dialogue that stimulates mutual tolerance so that all viewpoints can be expressed before the Community authorities decide on appropriate regulations. (EGE 1998)

In this description, the EGE is the servant of 'European decision-makers', not solely the Commission.<sup>4</sup> Requests for opinions could now also be made by the European Parliament and the Council of Ministers. Whereas the GAEIB's task was simply to keep EU citizens informed, the EGE has an expanded role of promoting dialogue and actively encouraging at least tolerance of new technologies.

The EGE's mandate for 2000–5 was also established by an informal Commission Communication (EGE 2007). Yet its political legitimacy was strengthened when the Commission elevated its Secretariat to membership of the Bureau of European Policy Advisers (BEPA), where it reports directly to the President of the Commission and acts under his authority (EGE 2007). BEPA provides the President, his College of Commissioners and the Directorates-General with strategic upstream policy advice on issues relevant to the President's policy agenda. The EGE also began formally to network with the National Ethics Councils Forum (comprising representatives of the National Ethics Committees of the Member States) to exchange information, experience and best practice on ethical issues related to science. Via its links with BEPA, this network has extended to civil society organisations including think tanks, academia, and faith communities.

During this period, the Tissues and Cells Directive (2004/23/EC) on 'Setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells' was enacted (European Parliament and the Council of the European Union 2004). In developing its proposals for this Directive, the Commission referred explicitly to the EGE's Opinion No. 11 on the 'Ethical aspects of human tissue banking', expressly stating that its 'proposal for a Directive reflects the recommendations put forth by the EGE', and whose opinion will be respected in the future whenever necessary (European Commission 2002b). The final text of the Directive, especially its preamble, explicitly features ethical principles related to voluntary and unpaid donation found in the EGE Opinion.

A Commission Decision of May 2005 marks the first formal legal document establishing a mandate (2005–10) for the EGE (European Commission 2005a). Under this third mandate, the EGE developed links, via its Secretariat, with the Commission's Inter Service Platform which provides coordination across all 19 Commission services.<sup>5</sup> The EGE Secretariat coordinates the Inter Service Group on Ethics and EU Policies to facilitate the exchange of information and coordinate actions on ethics both within and external to the European Commission. In 2009, BEPA initiated the International Dialogue on Bioethics, jointly chaired by the President of the EGE and the Chairperson of the National Ethics Councils Forum, to facilitate information sharing between 42 European and non-European National Ethics Committees.

### 2.2 Membership

The EGE has evolved incrementally in both size and scope from a modest *ad hoc* advisory body to include wider expertise and more established members. With six members at its inception, the GAEIB expanded to nine in 1994.

Its members came from the disciplines of law, science, medicine, philosophy and theology and served terms of just two years. From 1998, the EGE's 12 members, including experts in sociology and informatics, initially served terms of three years before increasing to four from 2000 (see Table 1 for a list of members who contributed to the development of Opinion No. 19, published in 2004). Membership expanded to 15 in 2005 and encompassed additional expertise in food safety and pharmacology.

Since the Commission Decision of May 2005, a list of EGE members is published in the *Official Journal* (European Commission 2005b). Until recently, the documentary record states that EGE members were appointed by the Commission. However, in its third mandate, this power was transferred solely to the Commission President. When the Commission was questioned about this change, it responded that, informally, this had always been the case and this document merely formalised the procedure (European Parliament 2006b). New members of the EGE are recruited through an open call on the EGE website. Additional applications from other channels are also taken into consideration (European Commission 2005c). What these 'other channels' are is not entirely clear.

Members must have a university degree in ethics, philosophy, theology, law or science and relevant, internationally recognised high-level experience

(European Parliament 2006a). They are expected to attend at least four meetings a year (European Commission 2005c). There is no legal obligation on members to make statements of their interests, or even to declare any conflict of interest in a particular Opinion.<sup>6</sup> They are appointed *ad personam*; that is, they are independent and represent their own views and conscience.<sup>7</sup> However, the President is concerned with balance of geographical origin, gender and areas of expertise (Interview (c) 20 June 2007; Interview 24 October 2007). This suggests a representative element in the rationale behind the selection of the EGE's membership: different geographical constituencies represented in the EGE might map to broader cultural or historical outlooks that differ with respect to ethics. But at present, the need to ensure such representation (or alternatively, an explanation of why this is not necessary) is not codified.

### 2.3 Methods

While the EGE is formally obliged to agree its work with the Commission President, it can initiate its own Opinions, and in general it creates its own rules of procedure (European Commission 2005c). Under its 2000–5 mandate, the EGE was not formally obliged to establish close links with the Commission departments involved in

**Table 1.** Membership of EGE during the development of Opinion No. 19

Name	Member State	Professional affiliation	Expertise
Prof. Göran Hermerén (President)	Sweden	Professor of Medical Ethics, Faculty of Medicine, Lund University	Philosophy, medical ethics
Prof. Linda Nielsen (Vice-President)	Denmark	Professor of Law, Rector of University of Copenhagen	Bio-law
Prof. Nicos C. Alivizatos	Greece	Professor, Department of Public Law, Faculty of Law, University of Athens	Public law
Prof. Inez De Beaufort	Netherlands	Professor of Health Care Ethics, Medical Faculty, Erasmus University, Rotterdam	Theology, health care ethics
Prof. Rafael Capurro	Germany	Professor of Information Management and Information Ethics, Fachhochschule Stuttgart, Hochschule der Medien, University of Applied Sciences	Philosophy, information ethics
Prof. Yvon Englert	Belgium	Head of Fertility Clinic, and Professor of Medical Ethics and Deontology, Free University of Brussels	Obstetrics and gynecology
Prof. Catherine Labrusse-Riou	France	Professor of Law, University of Paris, Panthéon-Sorbonne	Private law, family law
Dr Anne McLaren	UK	Research Associate at Wellcome CRC Institute, Cambridge	Genetics, reproductive biology, developmental biology
Prof. Pere Puigdomènech Rosell (Rapporteur)	Spain	Research Professor at Department for Molecular Genetics, and Director of Institut de Biologia Molecular de Barcelona, CSIC	Molecular genetics
Prof. Stefano Rodota	Italy	Professor of Civil Law, University of Rome, Chairman of Italian Data Protection Authority, Chairman of European Group of Data Protection Authorities	Civil law
Prof. Günter Virt (Rapporteur)	Austria	Professor of Theology, Institute of Catholic Moral Theology, University of Vienna	Theology
Prof. Peter Whittaker	Ireland	Professorial Fellow, Centre for Economic and Social Aspects of Genomics, Lancaster University, UK	Molecular genetics, biology

the topic under consideration or to organise public round-table debates to promote dialogue and improve transparency (although these activities have been compulsory since the 2005–10 mandate), nor was it under any formal obligation to consult either other institutional actors within the EU or its Member States, stakeholders, or wider European publics. The group has adopted a number of *ad hoc* practices, usually at the discretion of the chairperson, including consulting experts and stakeholders representing a range of scientific, legal and ethical opinions, initiating studies and setting up working groups to collate scientific and technical information. In practice, the EGE also takes note of opinions and recommendations of National Ethics Committees in the Member States.<sup>8</sup> These interactions have expanded with each subsequent mandate. The range of information gathered is distilled to identify the salient ethical principles with the aim of achieving group consensus (Interview 19 June 2007; Interview (a) 20 June 2007; Interview (c) 20 June 2007; Interview 24 October 2007). Where consensus is not reached, a dissident opinion is appended to the main opinion, and each is signed by their respective supporters.

The EGE publishes its Opinions electronically. However, its working sessions are private. Accordingly, the internal documents of the EGE cannot be accessed, even from within the Commission (Interview 24 October 2007). Nevertheless, the EGE has developed some general principles of transparency, keeping proceedings as open as it deems necessary, for instance, with round-table discussions, and the electronic publication of these (since late 2005), and other materials received by the EGE.

Since its inception in 1991, the GAEIB/EGE has published 25 Opinions covering the spectrum of bioethical issues. Eight of these address the collection and deployment of human tissues and cells.

#### 2.4 An integral component of a web of governance?

The Group's evolving mandates, membership and methods are indicative of the fact that the EGE has increasingly operated in a broader network of institutions and relations that construct, negotiate and govern biotechnologies in the EU. Establishing its own legitimacy was an acknowledged challenge. In its first general report (EGE 2001: 2), President Noëlle Lenoir enquired:

How was the new European body on ethics...to establish its legitimacy not only with the different European institutions but also in relation to the many interest groups concerned?

Under Lenoir's presidency, the EGE seemed keen to gain a more official status, recognising that mere attention does not in itself play a legitimating role:

...it is high time to put an end to the current, paradoxical situation. On the one hand, the EGE is increasingly well known outside the Commission. International general and specialised media regularly report on its work. Students write

dissertations and theses examining its work. When the Group pays its traditional six-monthly visit to the country holding the EU presidency it is received by the highest national authorities. Yet it does not have genuine recognition within the Commission. Its status remains uncertain. A Community decision should enable it to be given a more official and, at the same time, clearer status. (EGE 2001: 18)

Its Secretariat does not see any lack of clarity concerning the EGE's status as an independent advisory body (Interview (c) 20 June 2007), within a web of governance interactions with other bodies within the EU and its Member States. We now outline the challenge of tissue banking governance, before considering the EGE's influences over this challenge.

### 3. Tissue banking in Europe: An ethical controversy

The use of human tissues and cells for transplantation has expanded greatly in recent years, and cooperation is required between tissue banks in order to achieve the best 'match' of tissue type for some patients (Rubinstein 2006). This has led to the establishment of a number of registries (e.g. EuroCord and NetCord) that facilitate the international exchange of such tissues.

Public tissue banks in European countries have, since their inception in the post-World War II years, been associated with particular social values and relationships bound by 'ethical citizenship, altruism and communitarian values' (Waldby 2006: 57).<sup>9</sup> Since the late 1980s, the EU has sought to encode these widely held values in its formal recommendations on blood and tissue banking (see Hervey and McHale (2004: 343–7) and Farrell (2006)). For instance, 'the philosophy of voluntary and unpaid donation...altruism of the donor, and solidarity between donor and recipient' is restated in Directive 2004/23/EC (European Parliament and the Council of the European Union 2004: recital 18). The idea of a market in private tissue banking challenges this longstanding emphasis on the importance of common good or solidarity in this domain.

The first public and private umbilical cord blood banks began to emerge in the 1990s following the discovery that cord blood stem cells could be used in transplant medicine as a less immunologically sensitive and less invasive alternative to bone marrow cells. Since the first pioneering transplantation of cord blood cells in France in 1988 to treat Fanconi's anaemia in a child, cord blood has been successfully transplanted in thousands of children for blood disorders (Gluckman et al. 1989). Similar progress in adult transplantations has followed recent developments in the use of double units to increase the cell volume (NetCord 2007).

From the point of view of physicians working in the field, the arrival of large-scale international private cord

blood banks in Europe was cause for widespread concern. They considered that the likelihood of an individual needing a cord blood transplant was extremely low, and its future ‘potential’ to cure a range of disorders speculative (World Marrow Donor Association 2006). Because most private banks do not publicly register their holdings, these are not made available to patients who might need them.

A further problem is posed by private banks’ marketing activities, and the promissory dynamic that is inherent in their business model. Bearing in mind that autologous transplants and cell therapies—where the patient’s own cells are used—would be of value only if new applications were developed for cord blood stem cells, what is being marketed is less a product or service than a promise of possibility. This marketing may also stoke insidious fears, as some clinicians and Members of the European Parliament (MEPs) have claimed: parents are prompted to focus on the possibility of the severe illnesses that might, rarely, result in stem cell transplants being needed for a child, and on the possibility that matched cells would not be available for their child.

Paradoxically, given that much of the opposition to private banks is posited on a lack of public utility, there is also the problem of the inequitable divide that might arise if progress in stem cell therapies enables the effective use of cells predeposited by individuals. If barriers to the use of autologous stem cell therapies were to be overcome, parents who could afford to bank their child’s cord blood stem cells would have been able to purchase an advantage. This prospect of inequitable access to future stem cell therapies adds a further edge to the objections.

Within the Commission, the Directorate-General for Health and Consumer Protection is primarily responsible for overseeing EU policy on the use of human tissues and cells in medicine. Specifically, Directive 2004/23/EC and its two implementing Directives are the basis for its actions for work on tissues and cells. Contrary to what might be expected from the account of the governance context above, in which ethics and values pose key challenges, much of the Directorate-General for Health and Consumer Protection’s work concerns the ‘technical’ aspects of setting basic standards for tissues and cells, so that when they are exchanged across borders, minimum standards, for example of testing for infection and contamination, will apply. We consider below the role that the EGE’s Opinion on cord blood banking has played in the EU’s governance response to tissue banking.

#### **4. EGE and the governance response to tissue banking in the EU**

The arrival of the private US-based bank Cryo-Cell in Europe in 2000 provoked complaint from politicians and clinicians who had been sensitised by earlier controversies

to commercial involvement in the biotechnology field. During a European Parliamentary session in April 2001 Dutch MEP, Ria Oomen-Ruijten, questioned the legitimacy of Cryo-Cell’s ‘direct to parents’ advertising methods and the therapeutic claims used to market its services, suggesting it was a matter for the EGE to consider. She labelled it a ‘campaign [that] plays on the concern of prospective parents to prevent illness, and the fear of death’ (European Parliament 2001b). Her question echoed broader concerns about consumer protection and public health raised in the debates on the Biotechnology Directive. Although hesitant to intervene in these enterprises where they are allowed by Member States (European Parliament 2001a), the Commission eventually agreed that commercial cord blood banking raises serious ethical questions and, in August 2001, instructed the EGE to prepare an Opinion on the ethical aspects of this type of activity (European Parliament 2002).

##### **4.1 EGE Opinion on ‘Ethical aspects of umbilical cord blood banking’**

The EGE published Opinion No. 19 in March 2004. The topic is unusually specific, for the EGE, but concomitant to its broader work on human tissues and cells. Whilst the thrust of the Opinion is critical of commercial cord blood banking, it does not recommend prohibition. The background section includes a statement of key ethical principles and values—beginning with ‘the principle of human dignity, which asserts the principle of non-commercialisation of the human body’ (Section 1.2). It also acknowledges some conflicts between these values, namely that ‘the values of freedom and free enterprise can conflict with the principles of solidarity and justice, according to which access to justice should be on an equitable basis’. The Opinion itself focuses on the practical, policy and legal implications of commercial cord blood banking in Europe. The raising of expectations and stoking of fears by promissory advertising, and the possibility of inequitable access to future stem cell therapies are particular concerns, along with potential threats to consumer safety. Private cord blood banking is shown to be inequitable and inefficient from a public health perspective.

To inform their deliberations, the EGE commissioned a worldwide review of cord blood stem cell banking that mapped current practices, their organisation and economic impact (Gunning 2003) and invited representations from professional groups, clinicians, tissue bankers and Commission departments via a series of closed hearings.<sup>10</sup> These activities were conducted in the context of a wider simultaneous discussion in EU institutions about proposals for Directive 2004/23/EC on the ‘Banking of human tissues and cells and their applications’. The EGE distilled these representations in the light of EU policy and law, national statements and opinions on the issue,<sup>11</sup> and ethical traditions, and

reiterated the most salient concerns in its Opinion. The Opinion also appears to have given the EGE the opportunity to reiterate principles that feature in its earlier work, and to update the context of its declarations.<sup>12</sup> The Opinion was issued to the President and distributed to Commissioners, Director Generals, MPs, National Ethics Committees and other key stakeholders, and made publicly available on its website (Interview (c) 20 June 2007).

In the text of the Opinion, and in our interviews, wider political resonances and implications were prominent. The Opinion begins on a critical note:

The legitimacy of commercial cord blood banks for autologous use should be questioned as they sell a service, which has presently no real use regarding therapeutic options. Thus they promise more than they can deliver. The activities of such banks raise serious ethical criticisms.<sup>13</sup> (Section 2.1)

The threat to the normative principles underlying tissue banking is central to the EGE's ethical concerns:

Tissue banks were up till now relying on free donation for treatment to the benefit of other persons or for research, and by the fact that it implies an act of solidarity or generosity it contributes to the social cohesion, while the commercial cord blood banks are running for profit. This reflects a more general shift to a privately funded health care system from a health system based on solidarity and motivated by public health considerations, which has characterised Europe in the last decades. (Section 1.22)

Several of the interviewees referred to the European values they considered essential in consideration of this issue, as well as to the international implications of a free trade in commercial tissue banking. One EGE member outlined the issues in this way:

I think personally the chief concerns with commercial uses is that they can help to undermine some important European values by allowing rich people to buy what they need or what they think they need, which is not the same thing. Whereas those with less economic resources may not always be able to afford what they would in fact need. This is a problem in Europe, but also [to a] larger extent in the global perspective... So the value at stake here is solidarity... traditionally healthcare is and should be based on solidarity and the idea is that those who need help should get it and that should be provided for by the national healthcare services. (Interview (a) 20 June 2007)

The fundamental principle of solidarity and the related principle of social equity featured prominently among the values listed by the EGE. To facilitate fair and widespread access to cord blood transplantation, the use and support of public cord blood banks was encouraged, not only for the potential future benefit of the donor and their family (see Section 2.11), even in exceptional cases of individuals or families at risk of specific diseases (see Section 2.9), but also for that of an increasing multi-ethnic population to

cater for all tissue types, regardless of their ethnic origin (Section 2.10). To make this viable, the EGE suggested that increased support for both public cord blood banks and networks between banks and registries to coordinate donations is needed to ensure their long-term functioning (Section 2.12). Consumer protection weighed heavily in EGE discussions:

I think that we had two main concerns. One, that proper information is given to the persons [who] are going to use these banks... that the information given should be precise and explicit in the fact that nobody at this moment has ever used or very rarely used any of these cells—maybe in the future, but at this moment there is no precise information. Second, I think... the quality of the cells... was one of our main concerns. The public banks offer very strict control. (Interview (b) 20 June 2007)

The need to police print media and internet advertising by commercial cord blood banks, and the adequate control by public authorities of such advertising (2.5), formed the core of the EGE's ethical judgement:

While some members of the Group consider that this activity should be banned, the majority of the Group considers that the activities of these banks should be discouraged but that a strict ban would represent an undue restriction on the freedom of enterprise and the freedom of choice of individuals/couples. These banks should operate under strict conditions. (Section 2.2)

The paradox presented by preserving both the freedom of enterprise and the freedom of choice weighed heavily against such an opinion being recorded:

[First,] it's the freedom of activity that has to be preserved and second, we were aware that some individuals, even if the... correct information is given, ... want to have the cells of their children [stored] in a private bank. Some people have insisted on going abroad... against the laws of their own country. So we have to protect these people... why should we forbid... the wish of these people. So most of our members accepted that we are not able to recommend a complete ban. (Interview (b) 20 June 2007)

Freedom of choice was underlined by another member as:

an important value in Europe... which in this particular case means that you are or should be, in principle, free to use the money that you have earned... as long as you don't harm others or yourself by your actions... This is in principle okay as long as, and this is important, the basis is free and informed consent. That is, as long as they have not been misled by the marketing of the big companies... (Interview (a) 20 June 2007)

The EGE considered it impossible, for ethical and other reasons, to restrict the movements or choices of consumers or of commercial enterprises in this context, as in others.<sup>14</sup> Instead, strict regulation including licensing and supervision of the procedures of both public and private banks

(where legal) by the competent State Authority is recommended (Section 2.3). The EGE also welcomed the Tissues and Cells Directive that provides an overarching European legal framework that encompasses both public and commercial cord blood banks (Section 2.6). In concluding, the Opinion recommends that:

... a European debate on the increasing role of the market in the healthcare system and its advantages and disadvantages should allow European citizens to be aware of the present trends and their implications, in particular on the issues raised in the present opinion. (Section 2.13)

As with earlier pronouncements on tissue banking, in this Opinion, the EGE is mediating between values of commerce and enterprise; and of altruism and solidarity. The Opinion recognises, but fails to confront, the threat posed by commercial bodies. Instead, it resorts to the suggestion of better information and a public debate to diffuse concern. The emphasis on provision of information to

consumers as a solution to these policy problems was also evident in our interviews. (Interview (a) 20 June 2007; Interview (b) 20 June 2007)

#### 4.2 The EGE's role and influence in a web of bioethical governance

The web of relations that exists between the EGE and the Commission, and between other European, national, bioethics, professional and clinical policy networks (see Fig. 1), provides its members with relative stability and authority to act on social and ethical concerns. All the EGE members who contributed to Opinion No. 19 also held positions on either national, European or professional bioethics committees. Pere Puigdomènech Rosell was a member of the Scientific Steering Committee of the Directorate-General for Health and Consumer Protection at a time (2000–3) when both the Tissues and Cells Directive and Opinion No. 19 were being developed.

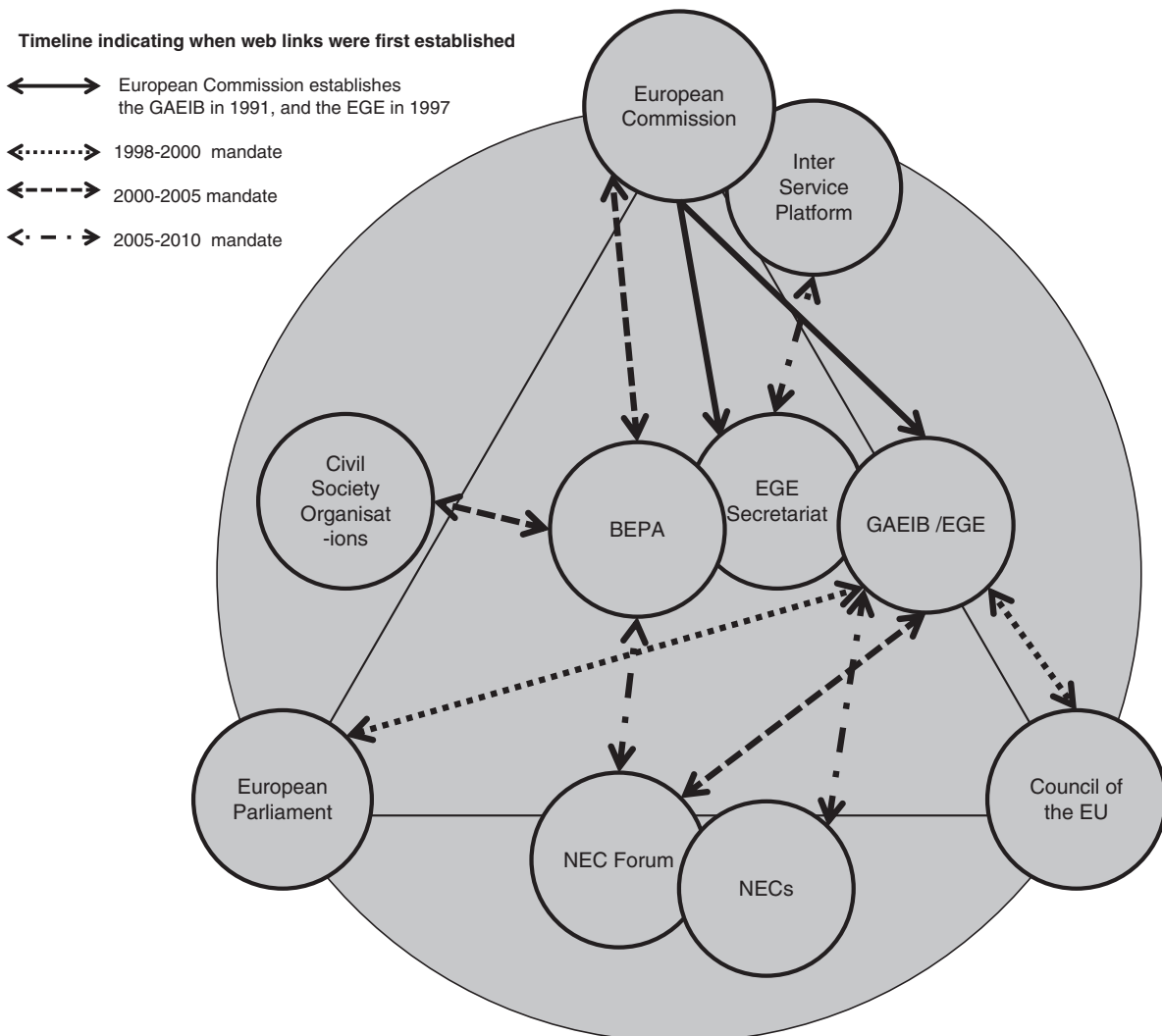


Figure 1. EGE's expanding links to a web of bioethical governance in EU.



These mutually beneficial relationships lend legitimacy to the authority of the Commission's politically and morally contested policies while, arguably, the EGE itself achieves substantive political cachet from its network of relations. One member considered the EGE's influence within the Commission to be substantial:

... the impact of the EGE is high because they are responding to a number of requests from the President which means that there is also from the Commission and from the President's side, the awareness that the EGE is an important item in the policy design. (Interview (c) 20 June 2007)

One curious exception is the lack of identifiable influence from Opinion No. 19 on EU legislative proposals, including the Tissues and Cells Directive. The proposal for the Directive referred explicitly to the earlier Opinion No. 11 by expressly stating that it 'reflects the recommendations put forth by the EGE', whose opinion will be sought and respected in future development of legislation (European Commission 2002b). The final text of the Directive, especially its preamble, explicitly features ethical principles found in the earlier Opinion, but does not specifically acknowledge a particular Opinion, only that the Opinions of the EGE have been taken into account (European Parliament and the Council of the European Union 2004). The timing and scope of Opinion No. 19, however, suggests the EGE's deliberations (between late 2001 and early 2004) overlap substantially with the development of the Directive. The tight focus of this Opinion—concerned exclusively with one form of tissue banking—may explain the absence of citations in legislative proposals, which are more likely to adopt a broader focus (Busby et al. 2008). Nor did we find specific evidence of Opinion No. 19 having been used in the interpretation of hard law. One EGE member speculated that the Opinion's lack of influence was probably due to its unusually prolonged consideration (over two-and-a-half years) and eventual publication just weeks prior to the Directive entering into force (Interview 8 August 2007).

Responsibility for the ethical stance of law and policy on cord blood banking remains to a considerable extent in the hands of Member States. Thus, some countries, notably France and Spain, have been able to take a stronger stance, prohibiting or constraining commercial cord blood banking. In Spain, regulations require that any cells privately stored must be registered and available to a patient who needs them: they may not be ring fenced for the exclusive use of the customer and their family (Santoro 2009). However, these national regulations do not prevent people taking advantage of commercial facilities available in other countries (European Hematology Association 2007). Both internationally, and in Europe, a number of facilities exist that provide for both public and private cord blood storage, sometimes known as 'hybrid cord banks'

(World Marrow Donor Association 2009). However, many EU Member States have allowed commercial cord banking to continue, albeit with the more rigorous quality controls that are now required by the Tissues and Cells regulatory framework.

Nonetheless, Opinion No. 19 appears to have had some influence internationally. Policies and guidelines issued by national networks of professionals, bioethicists and public sector tissue banks have cited it to question the legitimacy of commercial banking practices. For instance, Opinion No. 19 has informed several subsequent opinions by National Ethics Committees on umbilical cord blood banking, including those published by the Austrian Bioethics Commission (Günter Virt was invited to address the Health Ministry on the EGE's Opinion (Interview 19 June 2007) (Bundeskanzleramt Österreich 2008)) and the Swedish National Council on Medical Ethics (through the joint participation of Göran Hermerén in the Council and the EGE) (Swedish National Council on Medical Ethics 2005). In the UK, the Opinion has been cited by the Royal College of Obstetricians and Gynaecologists (Royal College of Obstetricians and Gynaecologists 2006), the Royal College of Midwives and by NHS Trusts. In this sense, it may also have provided an interpretative reference point for the conduct of individuals—for instance, clinicians, parents and commercial bodies. After the publication of the Opinion, some EGE members were contacted personally by interested parties from Spain, Uruguay and Argentina (Interview (b) 20 June 2007), by midwives concerned about the process of cord blood collection (Interview 24 October 2007), and by civil servants, the Red Cross and commercial bank shareholders (Interview 19 June 2007).

Some interviewees thought that the Opinion had been 'passively influential' (Interview 24 October 2007) on Member States who deal with such blood banks, and in terms of contributing to self-regulation by commercial banks (Interview (a) 20 June 2007), by drawing attention to the advertising claims of private banks where a recent shift emphasising that parents were paying for storage rather than a service was noted (Interview 8 August 2007; Interview 19 June 2007). One member judged that the Opinion 'certainly played a role' in the decision to establish a public rather than a private cord blood bank in his home country after he had debated the issue on television and in the national Medical Association and Council on Medical Ethics (Interview (a) 20 June 2007).

## 5. Conclusion: A legitimating role?

This paper set out to consider the contribution of the EGE, as an integral component of a web of governance, to the governance of tissue banking within the EU, and thus the extent to which the EGE might be said to contribute to

the democratic legitimacy of EU institutions. One document that has been particularly influential in framing discussions on legitimacy within the EU is the 2001 White Paper on European Governance (European Commission 2001). The White Paper proposed to address the democratic deficit by fostering greater openness, participation, accountability, effectiveness and coherence. Responding to a commitment made in the White Paper to publish guidelines on the collection and use of expert advice, a Commission Communication seeks to establish a sound knowledge base for better policies and a credible process of collecting and using expert advice (European Commission 2002a). The Communication establishes three core principles for better governance (which in the EU context double as norms of legitimacy)—quality, openness and effectiveness—that apply to all expert groups, whether *ad hoc* or permanent, who advise the Commission during the policy process. Quality is defined in terms of expert advice underpinned by excellence, independence and pluralism. Openness is defined as transparency and accountability of expert advice. Effectiveness is defined in terms of costs and proportionality of expert input into policy decisions; ergo, in terms of efficiency.

These principles of quality, openness and effectiveness set a practical framework for the EGE's activities: its mandates, membership, and working methods; its relationship with European decision-makers, stakeholders and publics. We now conclude whether or not the EGE's processes and advice (contained in its Opinions) can be considered to embody quality, openness and effectiveness, broadening the legitimacy base of EU decisions on ethically contentious technologies.

### 5.1 Quality, openness and effectiveness of expert ethical advice?

Since its inception as the GAEIB, the EGE has sought to provide 'neutral, independent, pluralist and multidisciplinary' advice to EU decision-makers on the ethical dimensions of biotechnologies. EGE members are distinguished by their internationally recognised expertise in their respective fields and their high-level experience on a range of national, European and professional bioethics advisory bodies. By increasing the range of knowledge-based expert opinions, it is assumed that genuinely authoritative—as well as legitimate—decisions are reached. Yet professional bioethics, such as that embodied by the EGE, has been criticised for drawing on a limited range of experience, as well as a narrow repertoire of arguments (Scully et al. 2006; Engelhardt 2011). The inclusion of lay bioethics through deliberation can illuminate areas of moral importance that professional ethics is likely to miss (Salter and Jones 2005). The bounding of value debates by professional ethicists reinforces a reductionist view of ignorant, incompetent publics.

The use of a consensus approach, whereby ethical reflection on a range of values is used to determine unanimous value judgements, is seen as a way for bioethics advisory bodies to contain and stabilise the tensions that exist at the boundary between science and politics (Kelly 2003). The fact that the EGE's ethical judgement is integrated across many divergent fields of expertise, each with their own traditions of transparency and accountability, can help to mask underlying philosophical issues and uncertainties, and exclude alternative risk framings, thus leaving the EGE vulnerable to charges of 'groupthink' (Leinhos 2005; Jasanoff 2009).

The EGE has created its own rules of procedure that render it relatively opaque even within the Commission, and to Parliament and the wider European citizenry, which exempts it from normal channels of political and public accountability. Adding new forms of expertise with each subsequent mandate may help to increase the credibility of the EGE, but has not fully addressed issues of accountability, where high standards of integrity (transparency and trust) must be upheld in the relations between the EGE and European decision-makers, stakeholders and publics. If EGE members claim to represent only 'themselves', to whom are they politically accountable? Who are their ethical 'constituents'?

In the case of Opinion No. 19, few concessions to openness were made. Developed before public round-table debates to promote dialogue and improve transparency became a statutory requirement for the EGE, it relied on closed hearings involving professional groups, clinicians, tissue bankers and Commission departments to broaden the value base. Only soliciting the opinions of experts, and not widely consulting the public for additional moral points of view falls short of satisfying the norms of legitimacy embodied by the Commission's principles for better governance. Concerned with balancing the tension between achieving transparency and efficiency, the EGE's recent adoption of public round tables (albeit limited to those disposed to travel to the venue) signals a growing concession to transparency balanced against long periods of closed discussion to facilitate the efficient exchange of views as well as allowing members to change their views over time (Interview 24 October 2007).

The fact that the EGE's members are appointed by the President may be an indication of the priority of its issues for the EU policy-making agenda: an indication of its political legitimacy. On the other hand, the fact that the European Parliament can also request opinions points to a broader role and responsibility for the EGE: one where public legitimacy is also required to satisfy the conditions of its mandate. Rather than be used as 'instruments for public awareness' (as described by a member of the EGE (Capurro 2005)) bioethics advisory bodies such as the EGE could, and perhaps should, function as deliberative spaces for public moral

discourse, legitimately serving goals related to both public and political interests. Plomer (2008: 858–9) suggests the EGE could:

... make a useful contribution to deliberative engagement with ethical questions in Europe if it were to operate as a deliberative chamber.

Bioethics advisory bodies that do not engage with broader lay values can be seen to not adequately represent the public interest and therefore lack a broader public legitimacy.

We conclude by reiterating that the EGE, as an integral component of a web of bioethical governance, has played a demonstrable role in influencing policies and positions relating to the commercialisation of cord blood banking in the EU and further afield. However, the extent to which the EGE's activities and its advice can be considered to embody principles of quality, openness and effectiveness, and thus broaden the legitimacy base of EU decisions, is only partial. The EGE's mandate 'to promote dialogue that stimulates mutual tolerance so that all viewpoints can be expressed', points to a broader role and responsibility. Yet the opacity of the EGE's working methods, as was the case for its Opinion on commercial cord blood banking, fails to satisfy the conditions of its mandate as well as those required for public legitimacy. Likewise, the EGE's elite membership and narrow repertoire of ethical arguments excludes and masks alternative views. On this basis, the EGE has largely failed to contribute to the democratic legitimacy and accessibility of EU decision-making processes on ethically contentious technologies. In this respect, charges of a democratic deficit persist.

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## Notes

1. See Communication on promoting the competitive environment (European Commission 1991: 1–2), where the Commission emphasised the need for ethical discussions on the development of biotechnology: 'it is imperative that problems of public acceptability, and ethical questions raised, be recognised and dealt with.

It is suggested that there should be advice available to the Commission in the area of ethics in biotechnology'.

2. Two other interviews with EGE members were planned but were unable to be scheduled. The first was due to the member's death, while the second failed to respond to our requests for an interview.
3. Opinion No. 3 on the 'Ethical questions arising from the Commission proposal for a Council Directive for legal protection of biotechnological inventions' and Opinion No. 8 on the 'Ethical aspects of patenting inventions involving elements of human origin'. The Directive also acknowledges that 'account has been taken of Opinion No. 8'. Later, Opinion Nos. 9 and 10 also address ethical issues relevant to the Biotechnology Directive and were published prior to the Directive's publication.
4. Although, this position is less clear in the legislative texts on which the EGE is based, in which the access of the other institutions to the EGE is mediated through the Commission.
5. These include public health, research, international affairs, biotechnology, legal services (Interview (c) 20 June 2007).
6. Although one of our interviewees stated that members are required to declare any conflict of interest (Interview (c) 20 June 2007).
7. This point was also emphasised in many of our interviews: (Interview 8 August 2007; Interview 18 October 2007; Interview 19 June 2007; Interview (a) 20 June 2007; Interview (b) 20 June 2007). One interviewee questioned the word 'representing' itself (Interview 19 November 2007).
8. For instance, the EGE participates in the Forum of National Ethics Councils, where all 27 Member States are represented. The work of the UK Nuffield Foundation was mentioned as particularly useful or influential (Interview (b) 20 June 2007; Interview (c) 20 June 2007).
9. This view is expressed in many European codes of ethics, including the Oviedo Convention, and is reflected in the political discussions about the uses of human tissues, notably of Directive 98/44/EC (European Parliament and the Council of the European Union 1998) and Directive 2004/23/EC (European Parliament and the Council of the European Union 2004).
10. Hearings of experts and Commission departments were held on 16 September 2003, 18 November 2003 and 16 December 2003 in Brussels and 20 October 2003 in Rome.
11. The preamble to Opinion No. 19 states, 'Having regard to the opinions expressed by national instances on that issue, namely the Opinion No. 74 of 12 December 2002 of the National Consultative Ethics Committee on umbilical cord blood banks for

autologous use or for research (France), the statement by the Belgian Medical Association addressed to gynaecologists and general practitioners, the opinion paper of October 2001 of the Scientific Advisory Committee of the Royal College of Obstetricians and Gynaecologists (UK), the opinion of 7th December 2001 of the Belgian Health Council on the revision of tissue banks' legislation and the American Academy of Paediatrics' recommendations of 14th July 1999' (EGE 2004).

12. Opinion No. 11 (1998) on the 'Ethical aspects of human tissue banking' and Opinion No. 15 (2000) on 'Ethical aspects of human stem cell research and use' addressed concerns such as the imperative to support public sector tissue banking, to constrain the activities of commercial organisations in this domain, and to continue to develop regulations to protect consumer safety, within a public health framework.
13. Cryo-Cell responded angrily to this point, perceiving it to be an attack on its commercial viability (Interview 24 October 2007).
14. While regulation of manufacture of blood and tissue products was under way at the EU level, systems for tissue donation and banking per se continued to be squarely in the competence of health systems in individual states—albeit that the need for coordination was becoming more evident (Farrell 2006). Private cord banks seemed to fall on the cusp of these various regulatory distinctions.

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