

# **‘Relais actors’ and co-decision first reading agreements in the European Parliament: the case of the advanced therapies regulation**

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**ABSTRACT** The processing of the advanced therapies regulation is of particular interest to scholars of the European Union’s (EU) legislative process and students of the European Parliament (EP) because it provides a case study which throws light upon assumptions commonly made about the role of the EP’s ‘relais actors’, the promotion of consensus-building within and between parliamentary committees, and the development of intraorganizational rules in response to early agreements in the co-decision procedure. An examination of the EP’s processing of the advanced therapies dossier provides an ‘unusual’ but vivid illustration of how the identification of committee rapporteurs as the most important parliamentary ‘relais actors’ fails to capture the increasingly important roles performed by shadow rapporteurs. Significantly, the ‘unusual’ occurrences associated with the processing of the advanced therapies regulation came at a crucial juncture in the reconsideration of the EP’s intraorganizational rules in relation to early agreements and the subsequent adoption of new Rules of Procedure in 2009.

**KEY WORDS** European Parliament; co-decision, first reading agreements; relais actors; rapporteurs.

## **INTRODUCTION**

On 30 December 2008 Regulation (EC) No 1394/2007 of the European Parliament (EP) and of the Council on advanced therapy medicinal products came into effect. This regulation had been signed by the Presidents of the European Parliament and the Council on 13 November 2007 and published as a *lex specialis* in the Official Journal on 10 December 2007. What started life as a Commission proposal, and finished life as the Regulation was a complex and technical measure designed to provide precise legal definitions of advanced therapy medicinal products, regulate industrially prepared or manufactured advanced therapy products and harmonize rules to ensure the free movement of such products within the European Union (EU). Certainly the Commission conceived of the measure as a matter of science, technology, regulation and the operation of the internal market. As such, the proposal appeared to be an ideal

candidate for an 'early agreement' in the co-decision procedure between the EP and Council – particularly as the Commission had identified early agreements as 'desirable for the more technical and non-conflictual' dossiers (Rasmussen 2007: 5). The expectation of an early agreement was enhanced further by the fact that in the 2004–9 Parliament first reading agreements had become 'in effect the norm in lawmaking within the European Union' (HL 125 2009: 37) with 72 per cent of co-decision procedures concluded at this stage (PE 427.162 2009: 8). That the advanced therapies dossier was concluded at first reading was, in this sense at least, of little surprise.

What was more of a surprise, however, was that the dossier was still concluded at first reading despite generating significant political conflict and, especially, intense controversy over ethics (interlinked with issues of national sovereignty) during its passage through the European Parliament. While the advanced therapies case raises important questions about the dimensionality of policy conflict within the EP – and particularly on occasion the importance of a 'libertarian–traditional' dimension involving ethical and moral conflicts alongside left–right and pro–anti integration axes – the specific focus of this article is upon what the processing of the dossier reveals about the role of the European Parliament's 'relais actors', the procedures promoting consensus-building within and between committees, and the development of intraorganizational rules in response to early agreements in co-decision.

## **INTERORGANIZATIONAL AND INTRAORGANIZATIONAL PROCESSES**

The European Parliament, even before the implementation of the Lisbon Treaty, had established itself indisputably as a co-legislature with the Council of Ministers. After the introduction of the co-decision procedure under the Maastricht Treaty in 1993 and after its extension under the Amsterdam Treaty in 1997, co-decision became what the European Parliament itself described as the 'normal legislative procedure' or 'the standard procedure'. In successive increments, co-decision came to cover 44 policy areas, encompassing over 50 per cent of Commission proposals tabled under the first pillar, and was simplified procedurally to expedite the processing of legislative dossiers (under the second version known as co-decision<sup>2</sup>). In this sense, the Lisbon Treaty simply marked the culmination of this trend, with 95 per cent of EU primary legislation covered by the procedure and with co-decision formally designated as the 'ordinary legislative procedure' (for an overview of the development of the procedure see Judge and Earnshaw [2008: 188–93, 230–6]).

While the legislative powers of the EP have thus been enhanced and refined procedurally through exogenous, formal treaty revisions, a parallel process of development and innovation has also been apparent in the adoption of endogenous, informal rules and modes of behaviour within the EP. Indeed, throughout its history the EP has demonstrated a capacity to maximize its legislative influence beyond formal treaty-prescribed powers through the

creative use of its own Rules of Procedure and Informal decision-making processes (Farrell and Héritier 2007; Héritier 2007; Hix 2002; Judge and Earnshaw 2008). More specifically Farrell and Héritier (2004) have examined the interconnection between interorganizational and intraorganizational arenas of decision-making, and have sought to theorize how changes to the macro-organizational relationship between collective actors affects internal processes of decision-making and the bargaining strength of individual actors within each collective actor. In examining the changes to the co-decision procedure, and especially the innovation of the 'early agreement' provision in the Amsterdam Treaty, they hypothesize that:

an exogenous constitutional change (the early agreement provision) from formal and sequential to informal and simultaneous interaction will first affect intraorganizational politics by changing the balance of power within each organization. Depending on the specifics of the constitutional change the influence of some individual actors (specifically, relais actors who engage with other organizational actors in the legislative process) over legislative outcomes will increase, whereas the influence of others will decrease. This will give rise to a subsequent effort by the organization (or, more precisely, the individual actors within the organization that have lost control over decision-making outcomes) to reestablish the status quo ante through the adoption of appropriate intraorganizational rules. (Farrell and Héritier 2004: 1190–1, emphasis in original)

The constituent elements of this proposition require some preliminary explanation: 'early agreements', 'relais actors' and 'appropriate intraorganizational rules'.

### **Early agreements**

Initially co-decision was conceived as a procedure in which the Commission, Council and EP interacted with each other in sequential stages or 'readings' culminating, where necessary, in a formal conciliation process. However, when confronted by the practical difficulties of operationalizing the procedure, informal structures – most notably in the form of 'trialogues' – were introduced to facilitate and expedite negotiations between the three institutions. In turn, these informal structures and modes of behaviour became institutionalized in the Amsterdam Treaty in a provision which allowed for the adoption of legislation at the first reading stage. This provision enabled legislation to be adopted at first reading if agreement was reached between Council and EP upon amendments to the Commission proposal; whereupon the Council indicated its willingness to accept this outcome should the amendments be confirmed in plenary. In effect representatives from the three institutions enter into informal triologue negotiations in anticipation of reaching an informal compromise. On the basis of compromises agreed with Council in these negotiations, the EP incorporates the Council's position in its own amendments to be voted on at first reading (requiring a simple majority vote in plenary – and hence a lower threshold than the

absolute majority required for parliamentary amendments to be adopted at second reading). This then enables the Council, acting by qualified majority voting (QMV), to conclude the procedure by accepting the Commission proposal as amended by the EP, and voted upon in plenary, to be transposed into a legal act.

In effect, therefore, first reading agreement constitutes a 'fast track' legislative procedure. Clearly such a 'fast track' procedure holds considerable attractions for the main legislative institutions and serves to institutionalize informal interorganizational negotiations. Clearly, also, given the decisive shift towards conclusion of co-decision dossiers at first reading stage, the lack of transparency and potential threats to democratic legitimacy have been identified as unattractive aspects of first reading agreements (e.g., Héritier 2007: 99–100; PE 406.309/CPG/GT 2008: 25–6). While the attention of the EP, and of academics, has largely been preoccupied with these wider interorganizational and 'macro' political concerns, the importance of understanding the 'micro' intraorganizational issues associated with this shift has also intensified. In particular, a fundamental question remains for investigation: 'How will an organization respond when an exogenous change increases the power of some relais actors over legislation vis-a-vis the organization as a whole?' (Farrell and Héritier 2004: 1190).

### **Relais actors**

Farrell and Héritier (2004: 1187), drawing upon Crozier and Friedberg's (1977) earlier work, identify relais actors as those 'who represent their own organization in discussions, [and who] form the link or "relais" to the other organization and owing to this link function are particularly powerful. They control the flow of information from their own organization to the other and vice versa'. In so far as they act as 'gatekeepers' or 'information brokers' relais actors are endowed with 'power in the intraorganizational bargaining of outcomes' (Farrell and Héritier 2004: 1188). Committee rapporteurs are identified by Farrell and Héritier (2004: 1200–1) 'as the most important relais actors' within the EP. They have 'quite extraordinary latitude to set the agenda of negotiations' and 'are particularly powerful when they are closely linked to large political groups and power brokers within the larger political groups in Parliament'; and their influence is seen to have increased in early agreement negotiations as the 'real discussion surrounding amendments have shifted from the committees into informal dialogues'. However, the obverse side of increased power for rapporteurs, according to Farrell and Héritier (2004: 1202), has been a diminution in the power of ordinary committee members generally, and of committee chairmen specifically, to the extent that '[o]ften they are effectively presented with a fait accompli by the rapporteurs and coordinators for the larger groups'.

### **Appropriate intraorganizational rules**

Before examining Farrell and Héritier's specific contention – that the development of intraorganizational rules pertaining to first reading agreements have

reflected a desire to curb the scope for independent action by relais actors (or to use principal–agent terminology to reduce ‘agency loss’) – it is worth noting that such intraorganizational rule changes have also been prompted by other factors. The first is, as Farrell and Héritier themselves acknowledge, that rapporteurs do not act in isolation – that shadow rapporteurs and group co-ordinators also make a contribution in co-decision negotiations. Shadow rapporteurs are appointed, certainly by the major political groups, for most major reports. They act as a powerful focal point of group activity on dossiers, leading discussions on the group’s behalf and mobilizing and co-ordinating group activity in the tabling of amendments in committee. Increasingly shadow rapporteurs have also become involved in informal negotiations with the other institutions at first reading (see HL 125 2009: Q28, Q81); and in many cases in their interactions with the rapporteur ‘practically constitute informal subcommittees’ (Corbett et al. 2007: 141). Yet, although the respective position of shadow rapporteur and group co-ordinator ‘has become more and more significant in recent years’ (Corbett et al. 2007: 141; see European Parliament 2009: Rule 192(3)), their contributions have ‘often and regrettably’ been overlooked by academics (Settembri and Neuhold 2009: 141).

The second factor prompting intraorganizational rule changes, as Farrell and Héritier predicted, is that the very recognition of the enhanced role of rapporteurs at first reading precipitates an organizational response. But, unlike Farrell and Héritier, the response may be conceived not simply as a zero sum attempt to recoup the ‘losses’ of individual actors (most notably committee chairs) but as an effort to generate collective mechanisms to regulate the independent action of rapporteurs. ‘Regulation’ has two dimensions: one positive in the sense of consensus-building, of securing wider support for deals reached in informal negotiations; and the second negative in the sense of monitoring, and where necessary constraining, the activities of relais actors during the course of these informal negotiations.

One form of consensus-building entails the activities of rapporteurs and the expectation that they will ‘shepherd’ amendments through the legislative process while ‘seeking to reach consensus within the committees’ (Farrell and Héritier 2004: 1196). In this respect their relationship with shadow rapporteurs and group co-ordinators is of some significance in building and sustaining the necessary consensus to secure a successful legislative outcome. Another positive dimension of consensus building in the EP has been the gradual development of a procedure – initially framed beyond the formal Rules of Procedure and known as the Hughes procedure (Corbett et al. 2007: 136) but with elements subsequently incorporated formally into the procedure known as ‘enhanced co-operation’ (European Parliament 2004a: Rule 47) and since 2007 designated as ‘procedure with associated committees’ (OJC 102E 24 April 2008: 89) – whereby a legislative dossier that falls roughly equally within the competence of more than one committee requires those committees to co-operate. The form of co-operation varies (European Parliament 2009: Rule 50), but one significant aspect of the procedure specifies that the committee responsible accepts,

without a vote, amendments where agreement has been reached among committee chairs that they ‘concern matters which fall within the exclusive competence of the associated committee’ (Rule 50). Whereas this procedure was little used in the 1999–2004 Parliament, with only 27 reports adopted in this manner, in the 2004–9 Parliament some 56 reports based on the enhanced co-operation procedure were adopted in the first three years up to September 2007. This led Settembri and Neuhold (2009: 144) to identify this procedure as ‘one key factor on the path to reaching consensus’ among committees on important proposals of ‘high complexity’.

## **EARLY AGREEMENTS: PROPOSITIONS**

The purpose of this article is to respond to Farrell and Héritier’s (2004: 1208) call that ‘closer attention’ should be paid to intraorganizational responses to interorganizational changes. Attention will be focused, therefore, upon two basic propositions: first, the definition of relais actors and the assumptions that rapporteurs are the pivotal relais actors in negotiations at first reading Farrell and Héritier (2004: 1200); and second, that proposals for significant revision of intraorganizational institutional rules will emerge but that their adoption is problematic given ‘the internal strife among “winners’ and “losers”’ (Farrell and Héritier 2004: 1208).

*Proposition 1: Rapporteurs are the pivotal relais actors in early agreements.*

Given the rapid rise in the number of early agreements, it would be expected that the position of the rapporteur as ‘the most important figure within the EP’ in the co-decision process (Rasmussen 2007: 3) would have been strengthened further since Farrell and Héritier’s article was published in 2004.

*Proposition 2: Appropriate intraorganizational rules: the regulation of the strategic modes of behaviour of the EP’s relais actors in their interorganizational transactions has assumed increased importance as early agreements become the norm in co-decision procedure.*

Farrell and Héritier’s basic contention is that: ‘In general it is fair to say that early agreements have resulted in substantial tensions between individual actors within Parliament who have lost influence over law making and relais actors who have gained influence’ (2004: 1206). Following this logic, they note that ‘losers’ – most particularly committee chairmen and the EP’s vice-presidents – have sought to limit the discretion of rapporteurs, while rapporteurs in turn have resisted changes which they believe would make it more difficult to reach consensus in dialogues. Hence, the move to early agreements ‘triggered a lot of conflict within Parliament’. The simple proposition to be examined here is that as ‘early agreements’ in the co-decision procedure have become routine so the stakes in the intraorganizational conflicts become higher and, consequently, the regulation of the strategic modes of behaviour of relais actors in their interorganizational transactions attains a high priority in the EP.

## CHOICE OF CASE STUDY

The case of the advanced therapies legislative dossier provides an opportunity to examine the intrainstitutional interactions of key relais actors and committees at the first reading stage of co-decision. In this sense it sheds light on the often neglected but increasingly important, and 'normal', interactions among strategic parliamentary actors at first reading (for the value of descriptive case studies see Johnson et al. [2008: 150]). In another sense, however, the advanced therapies case provides an example of how the operation of 'normal' processes of consensus-building – through the enhanced co-operation procedure and the interactions of rapporteur and shadow rapporteurs – may culminate in a unique event (so far, at least) where the preferences of the rapporteur and an agreed report are overridden by other parliamentary relais actors – shadow rapporteurs – and the development of a 'counter report'. In this sense the case falls into the 'unusual' (Gerring 2007: 101) or 'extreme' category of case studies (Flyvbjerg 2006: 229–30; Yin 2003: 40–3) of case studies. The case study is of value, therefore, in revealing how processes, which are designed to facilitate consensus-building, may result, in exceptional circumstances, in intrainstitutional conflict and contested legislative outcomes.

The advanced therapies case is also of importance, moreover, in its elliptical connection with broader processes of procedural reform in the EP. Significantly, the 'unusual' occurrences associated with the processing of the advanced therapies regulation came at a crucial juncture in the reconsideration of the EP's intraorganizational rules in relation to early agreements. The direct involvement of the Chair of the EP's Working Group on Reform, Dagmar Roth-Behrendt, as PSE (Party of European Socialists) shadow rapporteur in the advanced therapies case provided critical insights into how intraorganizational interactions impact upon policy outcomes.

## CASE STUDY: NARRATIVE

On 16 November 2005 the Commission presented its proposal for a Regulation of Parliament and Council on advanced therapy medicinal products (Commission of the European Communities 2005). The gestation period of the Commission's proposal had been protracted and involved extensive public consultation. The proposal addressed some of the issues attendant upon the rapid development of gene and cell therapy and tissue engineering in the interconnected scientific fields of biology, biotechnology and medicine. The Commission justified the proposal as an attempt to 'improve patients' safe access to advanced therapies' (Commission of the European Communities 2005: 3). Clearly the Commission conceived of the proposed regulation primarily as a measure that was: regulatory (by introducing a single, integrated framework of regulation); classificatory (in the sense of defining advanced therapy medicinal products); technical (in establishing detailed technical market authorization requirements and guidelines necessary to demonstrate 'quality, safety and efficacy' of the products); advisory (through the

creation of a Committee for Advanced Therapies); and harmonizing (by ensuring direct and harmonized access to the EU market).

### **The EP's processing of the proposal**

In December 2005 the Commission's proposal was forwarded to Parliament's Committee on Environment, Public Health and Food Safety (hereafter Environment Committee). The Industry (ITRE), Internal Market (IMCO) (which declined to produce an opinion), and, subsequently, the Legal Affairs Committees were also deemed responsible for producing opinions. In May 2006 the Legal Affairs Committee won the right to enhanced co-operation with the Environment Committee (under the then Rule 47 of the EP's Rules of Procedure). Miroslav Mikolášik (European People's Party and European Democrats (EPP-ED), Slovakia) was appointed as the Environment Committee's rapporteur, and Dagmar Roth-Berendt (PSE, Germany), Frédérique Ries (Alliance of Liberals and Democrats for Europe (ALDE), Belgium) and Adamos Adamou (European United Left-Nordic Green Left (GUE-NGL), Cyprus) were appointed as shadow rapporteurs for the major political groups. In turn, Pia Locatelli (PSE, Italy) was appointed as draftsperson for ITRE, and Hiltrud Breyer (Greens, Germany) as draftsperson for the Legal Affairs Committee.

Before deliberation in the EP's committees much of the lobbying associated with the proposal had focused on the relatively technical concerns of industry about the Commission's proposed wording of the legislation. Yet, in March 2006, David Earnshaw, in advising the Environment Committee, forewarned that: 'A major concern that Parliament will need to address is the approach taken by the Commission in responding to the lack of consensus in Europe about research involving embryonic stem cells and xenogeneic products' (PE 373.573 2006: 1). This 'lack of consensus' was highlighted further at a public hearing on advanced therapies organized by the EP's EPP-ED group on 11 May 2006 (EPP-ED 2006). The hearing was co-chaired by Miroslav Mikolášik, as rapporteur, and Peter Liese (EPP-ED, Germany), who was the chair of the EPP-ED's bioethics working group.

What the EPP-ED hearing signalled was the existence of two separate arguments in relation to the Commission's proposal, and that the proponents of each side were largely talking past each other. On the one side was a discussion about the detail of the proposal as a way of enabling and supporting industry in the development of new advanced therapies and establishing a licensing system for such products; and on the other was an argument about the ethics of embryonic stem cell research and the application of this and similar technologies in medicine (see respectively Niese [2006] and Klepaka [2006]).

Committee discussions had started by the time of the EPP-ED hearing, with the ITRE and the Legal Affairs Committees adopting their respective opinions in June and July 2006. The opinion of the Legal Affairs Committee was of particular significance as the Committee had, under the EP's Rule 47,



secured 'enhanced co-operation' with the Environment Committee. This rule was to prove to be of vital importance in the processing of the proposal.

The opinion of the Legal Affairs Committee resonated with one side of the argument noted above. The draftsman Hiltrud Breyer, a long-standing critic of biotechnology, in the justification of the opinion, made clear that:

The principle of the non-commercialization of the human body has to be respected. . . . The production of human-animal hybrids or chimeras constitutes a breach of the principle of the integrity of the person and of the principle of inviolability of human dignity. (PE 374.450 2006: 3–4).

In the event, all but 4 of the 60 proposed amendments submitted to the Committee were tabled by either Hiltrud Breyer or Peter Liese. Of the four amendments not tabled by Breyer and Liese, only two were adopted by the Committee and submitted subsequently to the Environment Committee; and, in total, some 49 amendments were adopted and forwarded to the Environment Committee. Most of these reflected the views, therefore, of critics – or at least sceptics – of biotechnology. A strong Green/EPP-ED alliance focused on bioethics had thus emerged on the processing of this proposal. Significantly, in the final vote on the opinion all EPP-ED members (or substitutes) turned out to vote in the Legal Affairs Committee, but only half of the Socialists and Liberals voted.

Not surprisingly, given Breyer's statement noted above, a number of 'ethical' provisions were included in the amendments adopted by the Legal Affairs Committee (PE 374.450 2006: Amendments 5, 20, 12, 39). However, on the other side of the argument, and as a result of Liese's amendments, industry concerns were met on a number of (arguably) minor issues (PE 374.450 2006: Amendments 27, 29, 30, 33–36, 47–49).

Most amendments tabled in the ITRE, the other opinion-giving committee, were identical to those tabled in the Legal Affairs Committee (PE 371.930 2006). Indeed, Slovak and Czech EPP-ED members Ja'n Hudacky' and Jan Br̄ezina respectively tabled exactly the same amendments that had been tabled in the Legal Affairs Committee by draftsman Breyer. It was no coincidence, therefore, that the outcome of the vote in ITRE was broadly similar to that in the Legal Affairs Committee. Equally, not surprisingly in the circumstances, the draftsman, Italian Socialist Pia Locatelli, (who was opposed to the 'ethical amendments') asked for her name not to be associated with the opinion forwarded by ITRE to the Environment Committee. As a result, the chair of ITRE, Giles Chichester (EPP-ED, UK), took over the opinion in his name.

In September 2006, the Environment Committee scheduled consideration of tabled amendments for the day before the Committee was due to vote. Forty-eight amendments were tabled by the rapporteur in his draft report and a further 72 amendments were tabled by other members. Again, there were clear signs of collusion by the opponents of biomedicine across the committees. The amendments tabled by the rapporteur, Mikolášik, included those tabled already in the opinion giving committees by his EPP-ED colleague, Liese, and by the Green MEP, Breyer.

Most of the amendments tabled, including the 'ethical amendments', were adopted in the Environment Committee's vote on 14 September primarily through the support of a majority of members of the EPP-ED, Greens and a few ALDE committee members (for details see PE 378.649 [2006: 8–9]). In particular, members of these groups who shared the position of Mikolášik, Liese and Breyer on ethical issues turned out to vote in committee. Other members, even up to the vote in committee, still tended to regard this proposal as largely technical and focused on the rather intricate details of pharmaceutical licensing. The success of the 'ethical amendments' during the vote, however, galvanized opposition to the position of Mikolášik, Liese and Breyer.

The position of the PSE members of the Committee was clearly to reject the 'ethical amendments'. The PSE's shadow rapporteur, Dagmar Roth-Behrendt, also sought to clarify the basis on which member states could continue to apply national legislation which restricted the use of certain human or animal cells, or the sale, supply or use of medicines based on embryonic stem cells. Roth-Behrendt's amendment had been developed following advice from Parliament's Legal Service; and sought to reconcile the conundrum of how national ethical rules regarding embryonic stem cells could continue to apply alongside harmonizing legislation, based on Article 95 EC, which envisaged their use as the basis for medicinal products licensed by the European Commission. Ultimately, however, this amendment was rejected 'amid a moment of pronounced confusion' (Agence Europe 27 September 2006). By the time the vote was taken on the Commission's proposal as amended, it had become clear that many individual amendments, which were unacceptable to a majority of the Environment Committee's members, had in fact been adopted. Moreover, further confusion was to reign when, after the vote on the amendments in the Environment Committee, the Committee decided to reject in its entirety (by a vote of 33 to 24 with one abstention) the Commission's proposal as amended.

Such confusion reflected the fact that supporters of Mikolášik's stance, primarily Greens and EPP-ED, had organized in advance of the Committee's meeting and so managed to mobilize majorities on votes on amendments tabled in the early rounds of voting. Once these initial successes began to be registered, however, other members of the Committee came to recognize, belatedly, the threat posed by the early amendments. Indeed, there was a dawning recognition throughout the voting session of 14 September 2006 that, what had been perceived initially by many MEPs to be a technical and esoteric regulation, in fact cloaked highly contentious and highly divisive ethical issues. For notable numbers of PSE and ALDE members the technical complexity of the regulation obscured the significance of its ethical dimensions until these dimensions were highlighted by the success of Mikolášik in securing the early amendments. At that late stage a majority was constructed, effectively by corraling opponents to the 'ethical amendments' – many of whom had been absent at the start of the voting session – to overturn the amendments by voting against the report as amended. The PSE and ALDE Members on the Committee voted to reject, while the EPP-ED and Greens voted in

favour of the amended proposal. This was a remarkable and almost unprecedented event in any committee of the European Parliament.

The decision to reject reflected the fundamental fissures within the Environment Committee over this issue and provides an exception to the general proposition advanced by Settembri and Neuhold that 'committees are real consensus-builders' (2009: 131), and that they 'generally work very consensually, regardless of the issues at stake and procedure applied' (2009: 147). Clearly, in the case of advanced therapies, this general proposition did not hold.

A revised version of the Mikolášik draft report returned to the Environment Committee in January 2007. This time the rapporteur sought to 'find the broadest possible consensus' (PE 380.740 2007: 41) through formally dropping (while informally continuing to advocate) the controversial 'ethical amendments' that had led to the rejection of his earlier draft report. He remained convinced that the approach chosen by the Legal Affairs Committee was the correct one. Thus, while proffering compromise and consensus to placate those committee colleagues who had so dramatically rejected his first efforts as rapporteur, he continued stubbornly to pursue the position effectively rejected some months earlier in September 2006.

The revised draft report was adopted at the end of January 2007, by 55 votes to 6 with 3 abstentions. Significantly, two amendments submitted by the Legal Affairs Committee were incorporated into the report on the basis of the then Rule 47 (see above) without a vote. The purpose of the amendments was to exclude from the Regulation 'products using materials which are controversial and for which differing Member States legislative provisions are intended to remain'; in other words, those which 'contain or are derived from human embryonic and foetal cells, primordial germ cells and cells derived from those cells' (PE 374.450 2006: 10). The outgoing Chair of the Environment Committee, Karl-Heinz Florenz (EPP-ED, Germany), judged these two amendments to fall within the competences of the Legal Affairs Committee rather than the Environment Committee. They were subsequently incorporated into the Environment Committee's report for direct submission to plenary. Predictably, given their genesis and content, these amendments became the focus of heated disagreement thereafter. Indeed, the temperature could immediately be gauged from the Commission's initial reported response that these amendments were 'unacceptable', 'radical', and 'dangerous for public health' (Agence Europe 22 February 2007).

### **Beyond committee: informal dialogues**

The German Presidency, anxious to broker an agreement at first reading, convened an initial dialogue on 28 February 2007, which included the rapporteur, shadow rapporteurs, Commission officials and the Council. It was clear from the outset that the Council and Commission would not accept the two 'ethical amendments'. Nonetheless, by early March, Walter Schwerdtfeger of the German Ministry of Health believed that 'agreement is not far off' (European

Voice 8 March 2007). This belief was founded upon the apparent willingness of Mikolášik to focus upon the technical aspects of the dossier and to compromise on the assessment of advanced therapies at EU level but with decisions as to their use in national territories left to member states. Yet this belief also proved to be unfounded as, by the end of March, negotiations had all but collapsed. Indeed, the prospects of agreement looked remote when rapporteur Mikolášik decided to abandon negotiations, during the final stage of a triologue held on 30 March, because Council negotiators refused to discuss the two 'ethical amendments' which had been voted by the Legal Affairs Committee and then included in the Environment Committee's report without a vote. Mikolášik was reported to have brought negotiations to an end 'with the official support of German Green, Hiltrud Breyer, and that of German Christian Democrat, Peter Liese (who was not directly taking part in the negotiations)' (Agence Europe 3 April 2007). In an EPP-ED press release of 30 March, Mikolášik noted that a first reading agreement was unattainable and, therefore, there would have to be second reading. He proceeded to note that:

I'm very much disappointed and regret the delay we have to face now. But I can't accept the non-respect of the competence of one of the major parliamentary committees. And I can't accept the criticisms about the delay from those who rejected my draft report in September of last year. (EPP-ED 2007)

These criticisms had come from both inside and outside of the EP. Inside, Dagmar Roth-Behrendt (PSE 2007) berated the rapporteur's 'irresponsible behaviour' which had 'given preference to his personal position' and had 'delayed the adoption of this important piece of legislation for at least another 12 months'. Outside, Eurordis, an umbrella organization representing patients with rare diseases, amplified the criticism of Mikolášik for 'eliminat[ing] the possibility of a first reading adoption of the long awaited regulation' and for having done so on the basis of his 'personal religious beliefs' (Agence Europe 6 April 2007).

### **Counter report**

Despite Mikolášik's termination of negotiations, the shadow rapporteurs – primarily those of the PSE (Dagmar Roth-Berendt), ALDE (Frédérique Ries) and GUE-NGL (Adamos Adamou) – worked around this impasse by continuing to negotiate with Council without Parliament's rapporteur. In doing so, it was clear at this stage that the EP could not be conceived as a 'unitary' or 'consensual' actor. Indeed, by the time of Parliament's April 2007 plenary session, a package of 75 amendments to the Commission's proposal had been agreed with Council. These were tabled as a 'counter report' to plenary in the names of the PSE, ALDE and GUE-NGL groups. Support for this new package was sought by the shadow rapporteurs in a letter to MEPs which called on them to approve the agreed package with Council and proposed the rejection of the Legal Affairs Committee's 'ethical amendments'. Importantly, the signature

of Françoise Grossetête (EPP-ED, France), who was one of Mikolášik's party colleagues and a Vice-Chair of the EPP-ED, was also appended to this letter. Numerous patients associations – including Eurordis and other groups representing patients with cancer, Acquired Immune Deficiency Syndrome (AIDS), diabetes and genetic diseases – also campaigned, with the encouragement of the Commission, for adoption of the 'counter report'.

The 'counter report' was discussed in plenary on 23 April 2007. In a frequently acrimonious debate the two sides took the opportunity to clarify their positions. Mikolášik dismissed the compromise reached by the shadow rapporteurs as 'individual action . . . undertaken without the knowledge of the rapporteur' (EP Debates 23 April 2007). He called upon plenary to support the report of the responsible committee – the Environment Committee – and pointed out that many of the amendments incorporated in the 'counter report' 'do not have the support of the committee responsible, the other two committees nor of the rapporteur'. He also drew attention to the 'clear provisions in the Rules of Procedure on enhanced cooperation between parliamentary committees' which had resulted in the inclusion of the 'ethical amendments' in the first place, and pointedly recorded his belief that 'apparently, enhanced cooperation is respected only when it suits certain colleagues' (EP Debates 23 April 2007).

Roth-Behrendt responded by recording the nature of the deal she and her fellow shadow rapporteurs had struck with Council. She noted that of the 75 amendments contained in the 'counter report', 32 were identical to those adopted by the Environment Committee, 18 were linguistic changes, 10 were compromises agreed with Council (which she pointed out that Mikolášik had supported in dialogue before breaking off negotiations), and 15 covered other linguistic or legal concerns. Moreover, she observed that the Commission and Council 'really supported us in reaching a result' and added that in her view 'they have come as close to Parliament's positions as they could – going further than I have seen before and further than I expected them to go' (EP Debates 23 April 2007). ALDE shadow rapporteur Frédérique Ries was equally clear, pointing in particular to the support that the 'counter report' had from some EPP-ED members: 'Something that has not yet been said is that this package also has the support of a number of MEPs from the Group of the European People's Party (Christian Democrats) and European Democrats and, contrary to what was explained by the rapporteur, it is accepted by the Commission and by the Council'. Such explicit support was evident in plenary debate with 5 of the 10 EPP-ED speakers recording their concern about the ethical amendments (though Peter Liese did note in his contribution that, in an internal EPP-ED vote the 'overwhelming majority' supported the 'ethical amendments').

Confirmation of Council's support came in plenary from Klaus Theo Schröder who, on behalf of the German Council Presidency, noted that the 'ethically motivated amendments' could not be agreed by Council and that 'it is the package produced by the shadow rapporteurs of the named groups on which agreement is possible at Council level' (EP Debates 23 April 2007). In

the subsequent plenary vote MEPs voted by 403 to 246 with 11 abstentions in favour of the PES–ALDE–GUE–NGL compromise.

The first reading agreement with Parliament was confirmed in May 2007 at the Employment, Social Policy, Health and Consumer Affairs Council. On 30 October 2007 Council formally adopted the Regulation, after lawyer–linguist finalization. It was signed by Parliament and Council Presidents on 13 November 2007 and published in the Official Journal on 10 December 2007 (OJ L 324, 10 December 2007: 121).

## DISCUSSION

### *Proposition 1: Rapporteurs are the pivotal actors in first reading negotiations*

The starting proposition of Farrell and Héritier (2004: 1200) was that rapporteurs, in their strategic position as relais actors in informal negotiations at first reading, are endowed with ‘quite extraordinary latitude’ in negotiations with the Council. However, the processing of the advanced therapies dossier reveals the perimeter boundaries of such latitude. In this case, the rapporteur proved not to be the only, or the most decisive, parliamentary relais actor. Effectively the rapporteur’s preferences were circumvented by a group of shadow rapporteurs. In Mikolášik’s own words this case:

marked a decisive separation from Parliamentary practice, whereby the shadow rapporteurs . . . bypassed the rapporteur and proposed new text to the vote, thus undermining the role of the European Parliament in the co-decision process. . . . This circumvention of customary practice [is] contrary to the spirit of democratic debate and the rule of law. (Mikolášik 2007: 324)

There was perhaps a certain irony that a rapporteur – who was believed by his shadow rapporteurs to have given ‘preference to his own personal position against a European Parliament unanimous decision’ and in so doing had damaged ‘the image of the European Parliament and the effective functioning of European institutions’ (PSE 2007) – should invoke the persistent normative concerns about transparency and the undermining of the EP’s collective contribution to the processing of co-decision dossiers.

### *Proposition 2: The development of appropriate intraorganizational rules*

In 2001 the EP’s Vice-Presidents proposed that early reading negotiations should be based on an appropriate mandate and that ‘the starting point’ for negotiations should be ‘active Council participation in Committee meeting’ (European Parliament 2001: 5). This was seen by Farrell and Héritier as an attempt by ‘losers’ in the EP to introduce intraorganizational rules to regulate the latitude of rapporteurs, as ‘winners’, in their informal negotiations with other institutional

actors. A more forceful attempt to regulate relais activity came in November 2004 when the EP's Conference of Presidents approved Guidelines For First and Second Reading Agreements (European Parliament 2004b).

Although non-binding, the 2004 guidelines sought to limit the scope for independent action on the part of rapporteurs and to establish 'a yardstick against which the behaviour of negotiators, above all, their ability to keep the confidence of their colleagues, both inside and outside the committee, can be judged' (Rasmussen and Shackleton 2005: 20). When the EP's Working Party on Parliamentary Reform, established in February 2007 with Dagmar Roth-Behrendt as its chair, attempted to use this yardstick it encountered difficulty in determining 'to what extent these guidelines have been applied since their adoption' (PE 406.309/CPG/GT 2008: 26). Moreover, Roth-Behrendt's direct experience of the intrainstitutional tensions encountered during the EP's processing of the advanced therapies dossier would have done little to dissuade her from the view that the guidelines needed to be revised 'with a view to strengthening their content' and to 'enhancing their status and improving their visibility' (PE 406.309/CPG/GT 2008: 27–8).

Of particular significance for present purposes was the recommendation of the Working Party to move the emphasis of the 2004 guidelines away from rapporteurs simply informing other parliamentary actors (shadow rapporteurs, group co-ordinators and committee chairs) of their activities, to a position where these other actors would be involved directly and formally in first reading negotiations. In this respect the Working Party made specific reference to a 'negotiating team' and that a decision to enter into first reading negotiations should also include specification of 'the composition of the negotiating team (rapporteur, committee chair, shadow rapporteurs)' (PE 406.309/CPG/GT 2008: 27). The importance of shadow rapporteurs and group co-ordinators in the negotiating process was underlined in the recommendation that 'the role, rights and duties of shadow rapporteurs and co-ordinators [should be clarified] in the Rules of Procedure' (PE 406.309/CPG/GT 2008: 28). This recommendation found reflection in Rule 192 in the EP's new Rules of Procedure, adopted in May 2009 and which entered force at the beginning of the EP's seventh mandate in July 2009.

In addition, a new Code of Conduct for Negotiating in the Context of Co-Decision Procedures was also included in the new Rules of Procedure (European Parliament 2009: Annex XX). While the term 'negotiating team' was retained in the Code of Conduct, it was notable that specific reference to shadow rapporteurs and committee chairs as part of the team was dropped in favour of a 'general principle' that 'political balance shall be respected and all political groups shall be represented at least at staff level in these negotiations'. Nonetheless, at a minimum, shadow rapporteurs (and committee chairs and co-ordinators) were expected, if time prevented full committee involvement, to receive reports from the negotiating team and to take decisions on agreements reached in dialogues.

Indeed, new Rule 70 required EP negotiators, in seeking agreements with the other institutions under the co-decision procedure, 'to have regard to the Code

of Conduct'. The new rule sought further to regulate the activities of the EP's relais actors by ensuring that before they entered into negotiations 'the committee responsible should, in principle, take a decision by a majority of its members and adopt a mandate, orientations or priorities'. Moreover, 'if the negotiations lead to a compromise with Council following the adoption of the report by the committee, the committee shall in any case be reconsulted before the vote in plenary' (European Parliament 2009: Rule 70).

In this way Rules 70 and 192, and the Code of Conduct, served to delineate the EP's most important relais actors in early agreement negotiations (and to do so more broadly than Farrell and Héritier's [2004: 1200] initial definition), as well as seeking 'to minimize the risk that specific actors within the organization will take opportunistic advantage' of informal first reading negotiations (as predicted by Farrell and Héritier [2004: 1190]).

## CONCLUSION

In heeding Farrell and Héritier's call – that greater attention should be paid to the intraorganizational consequences of the move to early agreements in the co-decision procedure – this article has identified, through examination of the case of the advanced therapies dossier, how the definition of 'relais actors' in the EP needs to be extended beyond committee rapporteurs themselves. The importance of shadow rapporteurs in the negotiating process, and in the final legislative outcome, was starkly revealed in the processing of the advanced therapies dossier. Indeed, more generally in the EP itself, it has become increasingly common for the contribution of shadow rapporteurs to be acknowledged in early agreement negotiations (see, for example Toine Manders, EP Debates 10 March 2009; Salvatore Tatarella, EP Debates 2 April 2009; Neena Gill, EP Debates 22 April 2009). Indeed, the rule changes enacted in July 2009 formally recognized the position of 'negotiating teams', rather than simply the rapporteur, in seeking agreements under the co-decision procedure (European Parliament 2009: Rule 70 and the Code of Conduct). More explicitly, Rule 192(3) states that committees 'may in particular decide to involve the shadow rapporteurs in seeking agreement with the Council in co-decision procedures'.

The advanced therapies case study also exposed the limits of consensus in committees. Rule 47 (European Parliament 2009: Rule 50) was clearly designed to enhance consensus-building among EP committees. In the case of the advanced therapies dossier, however, this rule led to the inclusion of two amendments in the Environment Committee's report which, far from securing consensus, exposed deep fissures within and between the EP's negotiators. Not only did these amendments limit the possibility of intraorganizational agreement, they also limited the possibility of interinstitutional agreement; as both Commission and Council respectively deemed them to be 'unacceptable' and 'a definite obstacle to agreement'.

The manifest divisions and disjunctions within the EP in its processing of the advanced therapies dossier occurred at the very time, February 2007, that a



Working Party on Parliamentary Reform had been established by the EP's Conference of Presidents. Undoubtedly the experience of the Working Party's chair, Dagmar Roth-Behrendt, as PSE shadow rapporteur for the advanced therapies dossier, at the very least, provided her with some critical insights when examining the 'work in committees and negotiations on codecision files'. The outcomes of this examination, found in the Working Party's recommendations for Rule changes and in the EP's adoption of new Rules and a Code of Conduct in 2009, provides support, therefore, for Farrell and Héritier's contention that 'losers' within the EP have sought to control the discretion exercised by rapporteurs (as initial organizational 'winners') in early agreement negotiations.

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