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Inter-Institutional Dynamics in the Cross-border Provision of Healthcare Services

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Abstract

Welfare regulation in the European Union (EU) continues to crawl forward despite salient conflicts of interests. This paper addresses the fundamental puzzle of how regulatory competences may expand into the core of the welfare state and how conflicts are, eventually, managed in such processes. It analyses the EU cross-border provision of healthcare services. It is argued that the interplay between the Commission and the Court constitutes a powerful dynamic in generating new regulatory activities and in finding ways to set conflicts aside. The Commission draws on formulations offered by the Court in finding ways to manage conflict, for example by requiring 'proportionate' national policies which establish that national obstacles to free movement principles are 'objectively necessary'. The paper concludes that law and evidence-based policy-making serve as powerful resources for the Commission in managing conflict.

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Introduction

Welfare regulation in the European Union (EU) may lack a formal political mandate, but paradoxically continues to crawl forward. It moves forward as a result of free movement principles, developed through the non-political powers of European Court of Justice (ECJ) and the Commission. Inbuilt joint decision traps make it increasingly difficult to reverse the integration undertaken (Scharpf 2006, 2007). This paper analyses how EU healthcare integration is moving beyond the legal realm in which it has so far been advanced into a proposed administrative space of regulation. It thus examines how judicial interpretations feed into regulatory action, and how the Commission reasons regulatory actions and aims to tackle conflicts through the voice of law and evidence-based politics. The Commission-Court tandem is under examination, as well as the policy-shaping role of judicial integration, monitored by the Commission (Schmidt 2000; Schmidt 2004).

Article 49 of the Treaty envisages that there should be freedom to consume services throughout the single market. However, directives to develop the application of this Article in the area of social welfare have been blocked. This paper shows how social regulation in the EU has nonetheless expanded, both in substantive reach and effective impact on national welfare systems. Healthcare is a striking example of how social regulation has progressed beyond the classic 'regulatory function' into the 'redistribution function' as defined by Majone (1994; 1996). The development of an EU regulatory state in healthcare comes up against intense conflicts of interests. While competition between service providers across national boundaries can be justified as increasing allocative efficiency in the internal market for services, competition also has redistributive consequences. Traditionally healthcare has been allocated within the national territory to those residing there. If patients can travel abroad and then seek reimbursement for the cost of health services consumed elsewhere, domestic practices governing the allocation of these services may be challenged. Of particular political salience is the way that the institutionalisation of cross-border service provision can make it possible for mobile patients to queue-jump and access treatment more quickly, as well as possibly obtaining treatments that are not available domestically.

The second section of this paper shows how the European Court of Justice (ECJ) has played a particularly active role in this area. In its interpretations on free movement of healthcare services which will be analysed below, the Court has directly raised redistributive questions. What is a reasonable time for a patient to wait for a treatment when it more efficiently can be provided in the next-door member state? And on which grounds can a member state's health insurance system deny a patient access to a treatment available in another EU

member state? It is shown that the Court's responses to these questions call for a regulatory framework, proposing as they do that decisions about prior authorisation for patients seeking treatment abroad should be based on 'objective, nondiscriminatory criteria'. Such review of national measures is conducted against the principle of proportionality, which implies that national authorities are obliged to prove that policies are 'suitable' and 'necessary' if they constitute obstacles to the free movement of services. Furthermore, the regulatory framework proposes that available treatments should be determined by 'international medical science', and that waiting lists may be jumped when there is 'undue delay', and so on. All these formulations suppose that an international community of experts would be able to reach agreement on how these terms should be applied. The Court can be seen as formulating the issues presented in the cases before it in ways which are susceptible to solution through regulatory techniques, particularly through the references to expertise and the call for formalisation and transparency.

The third section shows how the Commission has taken up these formulations in its proposal for a Directive on the cross-border provision of healthcare. The Commission refers to the legal reasoning of the Court and finds back-up in the authoritative 'voice of law' when framing a policy problem to be undertaken at Community level. It thus translates the policy problem identified into a 'regulatory need'. Legal reasoning, which points out the relevant issue at stake and the relevant rules to be discussed and applied, frames the issues raised in individual cases in more general regulatory manner, identifying regulatory activities which need to be undertaken at Community level. Such line of case law constitutes a strong platform upon which the Commission can argue the need to clarify and codify through legislation. The individual conflicts and issues are taken beyond the Court's domain and into the administrative domain of the Commission. In this way, Court rulings move from ex-post interpretation into ex-ante validation of new regulatory activities. The link between judicial decision-making and the regulatory proposals is strong. For example, the Commission proposes to introduce an administrative review of proportionality which clearly resembles the Court's principle. Prior authorisation is only justifiable if national authorities can provide evidence that such policy is 'suitable' and 'necessary'.

The obvious question – to which there is as yet no answer – is whether the Commission's proposal will come to constitute an example of conflict management through regulation. In other words, will the member states put aside their objections, strongly expressed in the course of negotiations over the Services Directive, to the encroachment of Community regulation on this area of social welfare? The EU has already entered the area of healthcare regulation through several routes, including free movement of health professionals and

patients, the purchase of pharmaceuticals in other member states, coordination of social security and more recently the open method of coordination (Greer 2006; Hervey 2008; Hervey & McHale 2004; Kostera 2008; Lamping 2005; Mossialos et. al. 2002; Permanand & Mossialos 2005; Palm et al. 2000; Martinsen & Vrangbæk 2008). For the reasons outlined above, the cross-border provision of services through patient mobility has redistributive consequences that are politically salient, suggesting that regulation is more likely to be blocked. The argument of this paper is that, whatever the fate of this particular proposal, the Court's framing of the issues has created a significant impetus in this area of social regulation.

Regulating Healthcare in the European Union

Until 1998, Regulation 1408/71[i] was the main regulatory source for cross-border treatment in the EU. By means of the 1408/71 coordination scheme, patient mobility in the European Union was primarily based on precisely established balances between some access to the healthcare supplies of other member states through the regulatory system of 1408, but firmly controlled nationally through the governing principle of 'prior authorisation'. 'Prior authorisation' had for long constituted the effective means of national control. The principle lies down that if a patient requests to receive a publicly financed healthcare treatment in another member state, it has to be authorised beforehand by the competent healthcare institution. From 1998 onwards ECJ judgements seriously came to upset the established status quo between Community law and national legislation.

How judicial interpretations led the way

In a series of judgements, the European Court of Justice questioned the justification of 'prior authorisation' and gradually established that the principles of the internal market – and especially Article 49 of the Treaty - also applied to healthcare provision. The line of case law that the ECJ has produced since 1998 is a remarkable example of the Court's ability to progress European integration into the core of the welfare state – and thus redistributive politics. In this way, judicial interpretations of the scope and purpose of the Treaty prepare the terrain for further regulatory action. We then find that Court decisions – and not political aims or visions – indirectly set the agenda for new regulatory competences of the Community. Court decisions constitute authoritative reasoning which is reflected in the Commission's argumentative logic and formulation of proposals. In this way, the voice of law becomes 'the force of the better argument', through which the regulatory need and the proposed solution are developed. The 'principle of proportionality' constitutes

a central point of reasoning in the process furthering Community healthcare competence, whereby prior authorisation is evaluated against what is proportional. This has proved to be a powerful principle, since it gives grounds for the judiciary to determine whether the prior authorisation is 'suitable' and 'necessary'. The same logic of 'putting to test' whether a public policy measure is suitable and necessary is subsequently taken up by the evidence-based policy of the Commission, as will be demonstrated below.

The judicial foundation of the regulatory need unfolds in detailed manner through a decade of step-wise interpretations. In the introductory judgements of *Decker* and *Kohll*, the Court laid down that healthcare was a service within the meaning of the Treaty and therefore in principle subject to the freedom to provide services across borders.[ii] The requirement of prior authorisation was found to be a barrier to exercising this freedom, which, nevertheless, could be justified under certain circumstances. The first as well as the subsequent Court decisions in this way put forward a delicate balance of, on the one hand, cross-border freedom to provide services, and, on the other hand, grounds upon which to justify deviations from the application of this principle to healthcare. As an accepted departure from the general rule of free movement, the judgements acknowledge the risk of seriously undermining the financial balance of the social security system, the need to maintain a balanced medical and hospital service open to all and the need to plan nationally the capacities of the healthcare system.[iii] In this way, the Court entered the domain of conflict between the market freedoms of the European Union and the redistributive competences of the member states.

The immediate impact of the 1998 judgements was modest in that they considered only a limited scope of goods and services outside the hospital sector, namely a pair of spectacles and dental treatment. Furthermore the initial cases concerned the reimbursement-based Luxembourg healthcare system. Although at first severely upset, politicians found themselves reassured that the impact was limited to rather specific goods and services and to particular healthcare systems as the Luxembourg one.[iv]

Nevertheless in subsequent rulings, the ECJ extended its interpretation across the full range of EU healthcare systems. The *Geraets-Smits* and *Peerbooms* judgement of 2001[v] repeated - this time with regard to the Dutch 'benefit in kind' health insurance system - that prior authorisation constitutes a barrier to the free movement of services. Such a barrier may, however, be justified provided that 1) the decision on whether or not to grant treatment abroad is based on 'international medical science' and 2) an equivalent course of treatment can be provided in the competent member state without 'undue delay' taking into consideration the medical condition of the patient, broadly

defined. In the case of *Peerbooms*, the Court considered the right of Mr. Peerbooms to access a treatment which was not provided as part of the national healthcare package, but considered experimental by the Dutch system. The Court ruled that the decision on what is a 'normal' or a standard treatment has to be based on international medical science and not on national considerations alone. In this way, the Court envisages that citizens may *access other treatments* than those allocated in the national package. In addition, the *Smits* and *Peerbooms* cases present another regulatory question: what is a reasonable waiting time for healthcare treatment? The Court lay down that the patient shall not suffer '*undue delay*'; otherwise s/he is entitled to seek treatment across borders. Waiting lists as allocative mechanism in national healthcare systems are thereby restricted by Community law.

In the *Smits* and *Peerbooms* cases and the subsequent ones, the Court assessed prior authorisation against the principle of proportionality.[vi] One could argue that in the concrete case, as well as in the cases below, prior authorisation fails the test of proportionality. The national measure to control healthcare consumption is not precluded as a matter of principle – there may be reasons for it – but its justifiability and objective necessity does not stand the test conducted by the Court.

In the cases of *Smits* and *Peerbooms*, the Court further restricted national authorities' discretion in granting prior authorisation by emphasising that it can only be a justified barrier to the principle of free provision of services if it is based on '*objective, non-discriminatory criteria known in advance*' so that national authorities *cannot control* the procedure *arbitrarily*. Requests for authorisation must furthermore be dealt with within a reasonable time, and refusals to grant authorisation *must be open to appeal* (para. 90, C-157/99). In this way, the Court established that decisions on authorisation must be reasoned, reviewable and issued according to an acceptable administrative practice. They must be reviewed against the proportionate doctrine. By its emphasis on objectivity, explicit and assessable criteria and non-discrimination, the Court furthermore presented its reasoning through regulatory formulations, later to be taken up by the Commission.

A further significant step on the construction of EU healthcare regulation took place two years later with the case of *Müller-Fauré & Van Riet*[vii]. In this case, the Court issued yet another expansive interpretation by introducing a distinction between hospital and non-hospital care. In the case of *hospital care*, the Court restated its view that the requirement for prior authorisation is justified on condition that it is exercised proportionately and that the national authority has no scope for acting in an arbitrary manner. The matter was, however, quite different for *non-hospital care*. The Court ruled that national

authorisation constitutes a barrier to the freedom to provide services for non-hospital care, and that persuasive justification for maintaining such a barrier had not been brought before the Court. Again the concrete cases failed the proportionality test.

The Court proceeded further in the case of *Watts*[viii] where it ruled against the UK. The *Watts* case considered for the first time, the implications of the logic of the internal market for member states that generally combine the provision and financing of healthcare, such as the UK, Ireland, the Scandinavian countries and the Southern Member States, i.e. National Health Services organised as benefits in kind. In relation to the earlier line of case law, member states with National Health Service systems had argued that such organisation in general shielded them from openness to the cross-border provision of services. Mrs. Watts had, however, paid for the treatment in the first place, which made it possible for the Court to consider the case in the light of the parameters of the Treaty's article 49.

The *Watts* case meant that the rights of the European citizen, here acting as a patient, were brought into sharper focus. The matter concerned *waiting lists* as allocative means, and their justifiability. In this case, the Court entered further into the question of what constitutes 'undue delay', and set out a *reviewable criterion* for determining whether a period of waiting is *acceptable* in the context of EC law. The waiting time must not:

> exceed the period which is acceptable on the basis of an *objective medical assessment* of the clinical needs of the person concerned in the light of all of the factors characterising his medical condition at the time when the request for authorisation is made or renewed, as the case may be
>
> (paragraph 79 of the judgement, emphasis added).

Furthermore, the decision as to whether the patient faces undue delay in accessing services must be based on:

> an *objective medical assessment* of the patient's medical condition, the history and *probable course of his illness*, the *degree of pain* he is in and/or *the nature of his disability* at the time when the request for authorisation was made or renewed
>
> (paragraph 119 of the judgement, emphasis added).

Having enhanced the rights of the European patient by setting limits to the time period and the grounds on which the exercise of supranational rights can be put on hold, the Court went on to specify the institutional structures that member states must provide to protect those rights. The Court repeated the

conclusions from *Geraets-Smits* and *Peerbooms* as well as *Müller-Fauré* and *van Riet*, and stated that the prior authorisation procedures in member states cannot be discretionary, but must be based on objective, non-discriminatory criteria and allow for decisions on authorisation to be challenged in judicial or quasi-judicial proceedings (paragraphs. 115-116). Only when national administrations live up to these procedural requirements may their measures be found proportionate. Furthermore,

> To that end, refusals to grant authorisation, or the advice on which such refusals may be based, must refer to the *specific provisions* on which they are *based* and *be properly reasoned* in accordance with them. Likewise, courts or tribunals hearing actions against such refusals must be able, if they consider it necessary for the purpose of carrying out the review which it is incumbent on them to make, to seek the advice of *wholly objective and impartial independent experts*
>
> (paragraph 117 of the judgement, emphasis added).

From *Decker/Kohll* via *Smits/Peerbooms* to *Müller-Fauré* and *Watts*, it is clear that legal decisions have been pivotal to the integration of healthcare. Within a time span of less than a decade, national health policies have been taken far further into the internal market than politicians ever intended, or could have predicted. That EC law applies regardless of the organising characteristics of national healthcare systems when the conditions of the Treaty's article 49 are met.

Furthermore, the line of cases on patient mobility is rich in regulatory language, despite its redistributive impact. The Court judgments formulate regulatory questions and propose answers about what constitutes a reasonable waiting time and what treatments should be available. By introducing the doctrine of proportionality to national policies, it becomes the authoritative institution to review and set the overall standards for how national measures fulfil such procedural criteria.- For a national barrier to free movement such as authorisation to be maintained, it must stand the proportionality test and provide evidence that it is justifiable (de Búrca 1993; Tridimas 1999). Judicial politics contains the same logic of reasoning as later captured in the regulatory politics of the Commission. The justifiability of national obstacles must be proven, be necessary and suitable.

Instead of focusing on the need to balance national healthcare supplies, the Court underlines that rules and regulation must be objective, non-discriminatory, and decisions must be based on objective assessments, formulated by experts who are both impartial and independent. In its detailed manner, the Court dissects the allocative mechanisms of the healthcare area,

offers new venues to bypass the restrictions of national supplies and build up new redistributive cross-border routes.

Political responses and the first regulatory proposal

When the European Court of Justice issued its *Decker* and *Kohll* rulings, politicians reacted forcefully. The German Government, for example, initially spoke out very strongly against the judgements. The former German Minister of Health, Seehofer, was quick to argue that the rulings would undermine the German health system. He further held that the Court decisions were against the preferences of the member states and that the politicians should overturn the rulings through a Treaty amendment (Langer 1999, p. 54; Børsen, 7. May 1998; Politiken 9 June 1998). The former Minister found the *Decker/Kohll* case law revolutionary and argued that if Germany adopted its premises, it would be a long-term threat to the sustainability of the German health system (Spiegel 17/98, Fokus from 4 May 1998; Schaaf 1999, p. 274; Eichenhofer 1999; Interview, Deutsche Verbindungsstelle, 18 September 2001).

This initial outburst is in sharp contrast to the subsequent political response as nothing further happened. No treaty amendment. No formal legislative reactions. Meanwhile judicial integration proceeded.

In 2004, the Commission made its first attempt to regulate. It proposed to integrate the healthcare area in the proposal for a Directive on Services in the Internal Market.[ix] As a precise reproduction of the Court's decisions, Article 23 of the new Directive proposed 1) an *internal market for non-hospital care,* where the patient has a right to seek treatment in another member state without prior authorisation and subsequently have the costs reimbursed by the competent national institution, and 2) a right to *hospitalisation* in another member state, provided that the member state of affiliation offers the same treatment, and that *authorisation* has been granted beforehand. The health ministers, however, refused to have their policy area regulated as part of a general Directive on services, placed under the responsibility of DG Internal Market. Article 23 and thus the healthcare area was subsequently taken out of the Services Directive.[x]

Conflicting interests in healthcare regulation

It seemed clear that European healthcare could not be regulated purely on the basis of internal market norms. However, the Commission argued that the judicial decisions called for political codification and more administrative transparency. In September 2006, DG Health (SANCO) embarked on a consultation procedure on health services.[xi] The Communication called for

stakeholders to state their opinions on a set of questions related to the cross-border provision of health services. This open hearing procedure produced no less than 280 responses from stakeholders, ranging from member states, regional governments, healthcare organisations, healthcare providers, insurers, the industry and even individual citizens. The many stakeholders' contributions expressed a high level of split preferences (Martinsen 2007). The conflicts expressed in the many and varying contributions were, among others;

- Some member states addressed the redistributive means of *waiting lists* and argued that by intervening in the criteria for the use of waiting lists, waiting lists were challenged as means of planning capacity. Contained in the argument is that prior authorisation and waiting lists constitute fundamental rationing devices. These both concern the control of in- and outflow of patients.

- Another concern regarding national allocative mechanisms was that patient mobility challenges the scope of the *national healthcare packages* and the quality thereof. If some member states for political, medical, economic and/or normative reasons have decided not to provide specific treatment, mobile patients may access such treatment in other member states. Member states may experience growing demand to refund such treatment provided in other member states. Examples of conflicts are cost-intensive cancer treatments offered publicly in some member states but considered experimental in others, abortion, which is legal in some member states but prohibited in others, eye operations, spa-treatments publicly provided in some member states but not in others etc. Although it is explicitly stated in Court decisions, as well as in the subsequent Commission's proposal that the scope of cross-border treatment only covers what the patient is entitled to in his/her own member states, this concern has been continuously formulated, presumably due to the doubt that the *Peerbooms* ruling introduced, regarding access to what was considered experimental treatment in the Dutch healthcare system (see above).

- Another line of conflict was the one emerging between new and old member states. In the debate on the challenges and impacts of patient mobility, it has been argued that the new member states may benefit from the development as they might attract patients from other member states by offering price competitive treatment. The new member states, on the other hand, fear that they might have a considerable inflow of

foreign patients which challenge their ability to provide efficient and high quality healthcare for their own population.
- An explicitly distributive concern was raised that free movement will favour those who can afford it. The European rules provide that member states are only obliged to reimburse what the same treatment would have cost at home. Additional costs as well as cost of travel etc. must be paid by the patient him/herself. This favours those with private resources as well as patients from the majority of old member states where treatments are generally more expensive.

The counter-position to the opinions above which was expressed in some contributions was that patient mobility improves allocative efficiency, and that enhanced European competition could lead to cost reduction and contribute to financial reform. By integrating foreign supply, treatment can be offered at lower costs through an internal health market.

Conflicts also concerned the intra-institutional 'division of labour'. Internally in the Commission, it was not straightforward which DG should be in charge of formulating the healthcare mobility proposal (Interview, European Commission, 2007). Having had to leave patient mobility out of the Services Directive, it was, however, clear that internal market considerations should not be the primary ones in the directive proposal. On the basis of previous experiences, DG SANCO had a sufficiently persuasive platform to take charge of the formulation of the proposal, which it was required to formulate in cooperation with DG Employment, Social Affairs and Equal Opportunities and DG Internal Market. With SANCO in charge, it was communicated that the regulation primarily concerned supranational healthcare.

DG SANCO announced that the proposal would be presented on the 19 December 2007. However, surprisingly, on that same day the Commission decided to withdraw the proposal (EU observer 19 December 2007). Whereas it remains unclear what exactly triggered off the withdrawal, it is clear that many different actors and organisations worked behind the scene in the run-up to the presentation of the proposal. What is also clear is that split preferences hindered the Commission.

First of all, the college of Commissioners appear to have disagreed strongly internally on the directive and its principles. Various cabinets intervened against the proposal just before it was presented. Some expressed concerns on the impact on national health systems (EU observer, 7 February 2008). Others were concerned about how the proposal would be received by the public, suggesting that it could cause protests similar to the ones on the Services

Directive, which would be damaging during the process of ratification of the Lisbon Treaty.

Secondly, European social NGOs accused the proposal of not being sufficiently ambitious in the creation of a European system of healthcare regulation. The proposal would not effectively promote patient mobility and would not de facto ensure equal treatment, since patients themselves would have to reimburse the cost of travel and other expenses:

> Why does the EU directive not take account of other issues which are in the general interest of everyone living in the EU, such as equal access to affordable high quality health services for all, including particularly vulnerable groups […] That would show that the Commission understands the concept of collective solidarity, not only individual consumers' rights
>
> (Fintan Farrel 19 December 2007)[xii]

Thirdly, and likely to have been the key factor, members of the Party of European Socialists (PES) group in the European Parliament urged the Commission to withdraw the proposal, arguing that it would have considerable negative consequences for national healthcare systems. The main theme was the role of 'prior authorisation' as a national means of control to foreign supplies of publicly financed treatments (Dagens Medicin, 1 February 2008). A central argument from members of the PES group was that the proposal did not simply codify the legal interpretations by the ECJ, but furthered the integration process beyond the judicial developments (Politiken, 19 January 2008);

> The Commission moves one step further than the decisions from the European Court of Justice. It is highly problematic that prior authorisation is no longer required regarding the right to hospital treatment in another member state. That *deprives* the member states of *the instrument of economic and capacity planning* and runs the risk of *financially draining* the national healthcare systems, because the patients in this way can take money along outside their own member state
>
> (Christel Schaldemose 1 February 2008.)[xiii]

PES members also strongly emphasised to the Commission that the timing was badly chosen while the Lisbon Treaty remained to be ratified in several member states (Politiken, 10 January 2008). The president of PES and member of the European Parliament, Poul Nyrup Rasmussen, wrote to all socialist commissioners, expressing PES's concern, just before the Commission was to present its proposal (Politiken, 11 January 2008). A recurring concern of PES

members was national sovereignty. That the national autonomy of the welfare state was severely challenged runs through the various arguments. Several times it was emphasised that whereas integration up to the point brought by the ECJ needed clarification, further steps were unacceptable.

The final proposal – attempt to manage conflicts

The December 2007 attempt to achieve inter-institutional consensus on a proposal for healthcare regulation failed, despite the careful preparations by the Commission. However, the then health commissioner Markos Kyprianou continued to argue for the need to regulate in the field of cross border healthcare, given the decisions of the ECJ. According to Kyprianou, the Commission had no other option but to regulate, being prompted by the ECJ rulings. Shielding behind a pro-active Court, the commissioner argued on the grounds of necessity; 'I don't think [we] have a choice […] It's not an initiative of the commission to create any new right, [but] offering legal certainty' (Markos Kyprianou, Quoted in EU Observer 7 February 2008).

On 2 July 2008, the Commission was finally successful in proposing the directive on patient mobility. The final directive proposal is not fundamentally different from the version set to be presented in December 2007.[xiv] The amendments seem rather minor to the December version, however, the timing as well as the reactions from the members of the European Parliament were quite different.

In the proposal, the Commission tried to manage the conflicts and diverse interests previously expressed, by 1) referring to the 'voice of law', by 2) requiring evidence to justify eventual deviations from internal market principles and 3) by postponing salient conflicts to the implementation stage.

Regarding the 'voice of law', the final version maintains its heavy reliance on the decision making of the Court. The need to regulate is presented on the basis of the Court's interpretations. The reasoning in the proposal is therefore that whereas the individual cases are clear in themselves, there is a need to translate these individual rulings into a general framework and thereby improve their general clarity. The reasoning of the Court is ever present in the proposal and establishes the main justification as put forward in the background and preparatory work for proposing the directive. The proposal initiates with reference to the Court's ruling and the judicial interpretations substantiate the need to regulate throughout the proposal with reasoning such as: 'as the Court has held', 'as confirmed by the Court', 'as was recognised by the Court', 'as established by the Court', 'as already addressed by the Court', 'in the light of the case law', and 'in order to achieve a more general and

effective application of principles developed by the Court'. In this way the Commission tries to manage the potential conflict on competences by the rule of law, and it tries to downsize political conflict by presenting its aims through the more neutral voice of law. Member states are left with less choice when decision-making options are so clearly framed and reduced on the grounds of the Court's previous interpretations.

Evidence constitutes the other frame of reasoning through which the Commission launches its proposal. In the first pages of the proposal's background, various surveys, analyses and impact assessments are presented together with stakeholders' contributions. In addition, a specific impact assessment on the proposal has been done.[xv] One of the main conflicts of interests in the proposal is whether prior authorisation is a justified barrier to the cross-border provision of services. In addressing this conflict, the Commission constructs a delicate balance. As in the earlier draft, this proposal reemphasises that prior authorisation is not generally prohibited for hospital care – but if member states wish to maintain a system of authorisation, the justification for such necessity must be *evidence-based*.[xvi] In this way, the Commission's evidence requirement has strong resemblances to the Court's principle of proportionality, according to which national measures must be appropriate and necessary. Requiring proportional national measures is likely to be just as powerful an instrument in administrative politics as it is in judicial politics, since it puts the Commission in the position to review whether national measures pass the test of suitability and the test of necessity.[xvii]

Furthermore, conflicts are postponed to the implementation stage of the proposal. When member states in the future are to notify the way they have implemented the directive, they have to inform the Commission whether they have maintained or introduced a prior authorisation procedure. It is in the post-legislative phase the Commission comes in as authoritative reviewer, in a position to demand evidence to justify such barrier to the free movement of services.

National authorities must provide evidence that:

> the consequent outflow of patients due to the implementation of the directive *seriously undermines* or is likely to seriously undermine the financial balance of the social security system and/or this outflow of patients seriously undermines, or is likely to seriously undermine the planning and rationalisation carried out in the hospital sector …
>
> (COM (2008) 414 final, p. 14).

Also it is noticeable that the Commission is there first with evidence-based arguments to the contrary. The Commission repeats that on the basis of its own impact assessments, it holds it unlikely that patient mobility will endanger the balances of national healthcare organisations. Thus the proposal represents evidence-based policy. Conflicts are put aside. Political positions will not stand unless they are accompanied by evidence, put in a scientific way.

Furthermore, with direct reference to the proportionality doctrine, the Commission emphasises that the possibility of introducing and justifying prior authorisation is severely limited by the case law of the Court:

> In such cases, and according to the relevant jurisprudence, the introduction of a prior authorisation scheme, which will limit the exercise of rights conferred upon the citizens directly by the EC Treaty, *must be proportionate and justified by imperative reasons* as those mentioned in the same case law
>
> (COM(2008) 414 final, ibid, emphasis added.).

While the Commission admits that there may be exceptions to the general rule, it at the same time puts the 'burden of proof' for such exceptions on the member states. Furthermore, such proof shall be evidence based – and take previous case law into account. The restrictions on the executive autonomy of the member states are thus high.

Finally, as with the justification of prior authorisation, the severe conflict on where in practice to draw the line between hospital and non-hospital care is postponed to the implementation process. In several member states' hearing contributions, opposition was expressed regarding what was considered a crude Court distinction between hospital and non-hospital care. In the proposal, the Commission addresses this conflict and aims to manage it by, eventually, allowing certain cost-intensive or highly specialised forms of non-hospital care to be defined as hospital care, and thus allowing – if justified and proportionate – prior authorisation procedures.[xviii] In order to manage the conflict between national and supranational preferences, the Commission allows for a list of special forms of non-hospital care to be adopted. The list will be developed in the implementation phase under the administration of the Commission and supervised by member state representatives under the Commitology regulatory procedure.[xix] The Commission thus proposes that a committee should , through deliberation, achieve a compromise between salient conflicts of interests (cf. Joerges and Neyer 1997).

With its regulatory proposal, the Commission attempts to bridge law and politics. On the one hand, the existing Court rulings already constitute a legal framework; on the other hand the judicial process is not in itself a regulatory framework, since it has no mandate to set up the regulator. The Commission's proposal contains several such regulators, including a European reference network to coordinate healthcare that requires particular expertise or resources, a network on health technology assessment to support cooperation between national authorities and a commitology committee to formulate the list for special regulation of certain non-hospital treatments as described above.[xx] Giving form and task to such future regulators means that the Commission proposes to take the interpretations of the Treaty's article 49 'incomplete contracting' out of the judicial space and into the regulatory sphere. In this way, it invites member states' representatives to re-enter the scene.

Concluding remarks

Welfare regulation in the European Union continues to push forward, albeit in fragmented manner. Despite strong political preferences to maintain national competence, regulation finds its way into redistributive policies.

The key findings of the analysis carried out are that regulatory competences may be extended through a powerful interplay between the European Court of Justice and the European Commission. Through the way that the regulatory proposal is reasoned on the basis of previous case law, the Court becomes an institution which takes part in policy-shaping and frames policy options. The impact of Court rulings moves from ex-post interpretation of regulation in force into ex-ante validation of new regulatory activities. Despite the initial political response after the first rulings where politicians argued that the Court had to be reined in, this proposal is not braking or rolling back judicial decision-making, but instead codifying and in part progressing what the Court has laid down. The Court's interpretations feed regulatory actions. The Court's interpretations identify regulatory problems to be undertaken and lend regulatory formulations to the Commission. Proposing cross-border healthcare in the European polity, however, implies redistributive consequences and thus implications for the traditional allocative mechanisms of national welfare communities. Such implications raise severe and intense conflicts of interests which the Commission has to manage. It does so by at least three means: the voice of law, the requirement of evidence-based policy-making, and the postponement of central conflicts to the implementation stage.

In the literature on the regulatory state, the Commission is often found to be a uniquely powerful agency (Majone 1996; Lodge 2008), in large part insulated from majoritarian democratic control (Mabbett and Schelke 2009, this issue). However, in the analysis conducted here, its power is conditioned by its ability to manage conflicts effectively. The Commission as the European executive does not act on the basis of classic leadership, as a political entrepreneur presenting clear visions and directions. Instead the Commission presents its regulatory proposal as a sheer necessity, reasoned from a coherent set of landmark rulings by the Court, which leave no other choice. Instead of being an entrepreneur, its strategy seems to act as a manager between strong positions and conflicts. As manager of conflicts, the Commission abstains from the ownership of the idea behind the proposal. Instead of putting forward a vision of leadership in granting rights to the citizens of Europe, the main justification for the proposal is that the rule of law has spoken. The more neutral voice of law is one prism to bend political conflicts. The other is evidence-based justification. Here the Commission relies on the Court's principle of proportionality and introduces a very powerful means to evaluate the suitability and appropriateness of national measures. The Commission itself will become the reviewer and evaluating regulator. The Court's use of proportionality has been described as the most far reaching ground of review and the most potent weapon for the judge to use against a public policy (Tridimas 1999). The weight of an administrative proportionality test may prove very heavy, since few national measures are likely to pass the tests of necessity and suitability when they run up against the fundamental liberties of the EU.

The Commission has already developed a strong platform of evidence-based arguments. It is there first with its reasoned opinions, which set or limit the way positions can be presented. Political assumptions, ideological or passionate viewpoints cannot do it in the long run. The main conflicts in the proposal are postponed to the implementation phase which is where evidence is set to rule. Only what is justified by imperative reasons, and documented in a scientific way will withstand the burden of proof. The implications for the input-legitimacy of the political process are clear. The scope to build up political arguments is reduced before negotiations even start, since the argumentative scene is framed a priori by law and evidence. Whether the Commission has selected the right logic of reasoning and will be successful as conflict manager in the case of cross border healthcare remains to be seen in the negotiation processes ahead. However, one crucial factor which increases the likelihood of success is that an administrative, regulatory space is more tractable and controllable for politicians than the judicial space, which is further beyond the political realm. To re-regulate is the 'lesser evil' than uncontrollable judicial integration (Schmidt 2000; Schmidt 2004). For this

reason, politicians may accept the invitation to re-enter the scene and re-regulate European healthcare.

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[i] Regulation (EEC) No. 1408/71 of the Council of 14 June 1971 on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community. The regulation has recently been substantially reformed with the adoption of Regulation 883/2004. Although adopted 29th April 2004, Regulation 883/2004 has not yet entered into force as it awaits the adoption of the implementing regulation, which is currently under negotiation.

[ii] In the cases C-120/95, *Decker*, [1998], ECR I-1831 and C-158/96, *Kohll*, [1998], ECR I-1931.

[iii] See Kohll, para 41, 50, 51; Smits and Peerbooms, para 72, 73, 74; Müller-Fauré and Van Riet, para 67, 73; Watts, para 103-105.

[iv] It can thus be argued that the majority of member states at first found themselves shielded from internal market pressures by the features of the national health care model. EU healthcare families can roughly be divided into two models/basic institutional design (Ferrera 2005, p. 124). One model is organised as a *National Health Service*, covering the residing population universally and offering healthcare as benefits in kind. The other model is organised as a *social insurance/Bismarkian model*, structured on performance or income reflecting criteria. The social insurance model can further be divided into two sub-categories. One which supply healthcare as *benefit in kind*, and another based on *reimbursement*, i.e. where the patient is subsequently reimbursed for healthcare cost by her/his healthcare insurance fund. For a division of healthcare supply across the EU member states (EU-25), see Martinsen 2007, pp. 23-24.

[v] Case C-157/99, *Geraets-Smits* and *Peerbooms*, [2001], ECR I-5473.

[vi] For the proportionality principle, see paras. 75 & 82 of the *Smits-Peerbooms* cases; paras 68 & 83 of the *Müller-Fauré* cases and paras 106 and 114 of the *Watts* case. .

[vii] Case C-385/99, *Müller-Fauré and Van Riet,* [2003], ECR I-4509.

[viii] Case C-372/04, *Watts,* [2006], ECR I-4325.

[ix] COM (2004) 2, 5 March 2004. Proposal for a Directive of the European Parliament and of the Council on Services in the Internal Market.

[x] For an analysis of the high political salience of the service directive, see Schmidt (2009), this issue.

[xi] The Communication is SEC (2006) 1195/4, 26 September 2006.

[xii] Fintan Farrel, president of Social Platform, quoted in EU Observer, 19 December 2007. URL: [http://euobserver.com/?aid=25361].

[xiii] Christel Schaldemose, PES member of the European Parliament, quoted in Dagens Medicin, 1 February 2008. Author's translation from Danish, emphasis added. URL: [http://www.dagensmedicin.se/nyheter/]

[xiv] Proposal for a directive of the European Parliament and of the Council on safe, high quality and efficient cross-border healthcare (2007).

[xv] SEC (2008) 2163 final. Commission staff working document - Accompanying document to the proposal for a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare - Impact assessment.

[xvi] Evidence-based justification regarding prior-authorisation is treated pp. 13-16 of the proposal, point 7.1-7.4. See also especially article 8.3.b, 8.4 and 8.5 of the proposal.

[xvii] For the two tests which the ECJ uses to apply the doctrine of proportionality, see de Búrca 1993 and Tridimas 1999.

[xviii] See point 7.3, page 15, point 30, page 27 and article 8.1.b and 8.2, p. 38 of the proposal.

[xix] See article 8.2 of the proposal.

[xx] Respectively laid down in article 15, 17 and 8.2 of the proposal.