CROSS-BORDER HEALTH CARE IN THE EU AND THE ORGANIZATION OF THE NATIONAL HEALTH CARE SYSTEMS OF THE MEMBER STATES: THE DYNAMICS RESULTING FROM THE EUROPEAN COURT OF JUSTICE'S DECISIONS ON FREE MOVEMENT AND COMPETITION LAW

JOHAN W. VAN DE GRONDEN

ABSTRACT

This paper discusses the influence of European Union (EU) law on the organization of national health care of the Member States. On the one hand, Article 152(5) of the European Convention (EC) stipulates that the organization and delivery of health care is considered to be a responsibility of the Member States on a national level. On the other hand, it is clear from landmark European Court of Justice (ECJ) decisions that the Treaty provisions concerning free movement do cover national laws on health care schemes. This paper will look at how the health care systems of the Member States are affected by EU law on the internal market and competition in order to determine whether or not the way European internal market and competition law is applied to cross-border health care amounts to a harmonization of the national health care systems of the EU Member States.

Free movement rules have more influence on national health care systems than EU competition law does. The role of competition law is less important because many (public) bodies managing health care systems are not regarded as undertakings. However, according to settled ECJ case law, health services themselves do constitute economic activities and are, as a consequence, covered by the EU regime on free movement. With regard to non-hospital care, patients are free to choose between domestic and foreign providers. As for hospital care, Member States are forced to manage their systems properly, e.g., taking into account the interests of patients (e.g., no waiting lists, international medical standards, etc.). If they succeed in paying due consideration to these interests, the Member States are allowed to restrict the free movement of hospital services.

By examining whether the health authorities have managed their systems properly, the ECJ is setting standards for: reimbursement rates, waiting lists, and prior authorization procedures on a case-by-case basis. This approach leads inevitably to the harmonization of several aspects of the organization of the national health care systems of the Member States. From a patient's perspective, it could be argued that the ECJ case law forces the national authorities to respect principles of good-governance, while managing the national health care system. Therefore, the ECJ's approach should be welcomed.

Nevertheless, the steering capacity of the national authorities must be respected. Consequently, in the near future, points of concern will be the observance of the principle of subsidiarity in national health care and the planning of the national health care systems, which remain tasks of the Member States on a national level. Hopefully, the draft Directive on Patient Mobility will be capable of striking a good balance between the internal market and the national organization of health care.

INTRODUCTION

The aim of the present issue of the *Wisconsin International Law Journal* is to explore issues of cross-border health care. Patients seeking health care abroad may create various problems for Member States (for instance, difficulties related to the need to plan health care services). This paper will focus on cross-border health care services in the European Union (EU).

To start with, it must be noted that in the EU, the subject of cross-border health care is a delicate matter. On the one hand, it is a well known fact that one of the main objectives of the European Union is the establishment of an internal market. As a result, the treaties establishing the EU[1] lay down provisions that obligate Member States not to impede upon the free movement of goods, services, persons, and capital, and prohibit undertakings from distorting competition. Moreover, EU law has supremacy over national legislation according to settled European

[1] The EU Treaty and the EC Treaty will be changed by the Treaty of Lisbon. *See* Treaty of Lisbon amending the Treaty on European Union and the Treaty Establishing the European Community, Dec. 13, 2007, 2007 O.J. (C 306) 1, 10, 42 [hereinafter Treaty of Lisbon]. However, the basic provisions of free movement and competition will not be changed by the Treaty of Lisbon. In this regard, it should be noted that the EC Treaty is to be renamed 'Treaty on the functioning of the European Union' (TFEU).

Court of Justice (ECJ) case law.[2] On the other hand, pursuant to Article 152(5) of the European Community, the organization and delivery of health care is considered to fall under the purview of the Member States. Consequently, national law, rather than EU law, deals with the management of health care systems and sets out which treatments patients are entitled to. As a result, a diagonal tension exists between objectives related to the internal market and the national laws governing health care.[3] Therefore, it is clear from the outset that in the EU, issues of cross-border health care amount to a delicate interplay between the role of the Member States and that of the EU.

In many cases, it is difficult and sometimes nearly impossible, to draw a distinction between elements of the internal market and features connected with the organization and the delivery of health care. Ultimately, the provision of health care services is closely intertwined with economic activities, which implies that the EU internal market and competition law comes into play. It is clear from landmark decisions (such as *Kohll v. Union des caisses de maladie*[4] and *Decker v. Caisse de maladie des employés*[5]), that it is precisely for these reasons that the ECJ has taken the view that the Treaty provisions in the field of free movement do cover national laws on health care schemes. In cases involving cross-border health care, the ECJ applied those Treaty provisions to the organization of national health care systems, and, in doing so, it served a blow to the national health authorities. Since *Kohll* and *Decker*, the concerned national authorities now know that they have to give consideration to EU law. In other words, the health care systems of the EU Member States are in limbo just because two Luxembourg citizens sought medical care abroad, one by trying to purchase glasses in Belgium (*Decker*) and the other dental services in Germany (*Kohll*).

In light of the aforementioned discussion, the question arises as to how these systems are affected by EU law on the internal market and competition. In particular, it must be asked if the application of European internal market and competition law to cross-border health care amounts to a harmonizing of the national health care systems of EU Member States. Are Member States forced to align their national health

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[2] *See, e.g.*, Case 6/64, Costa v. ENEL, 1964 E.C.R. 585, 586; Case 26/62, N.V. Algemene Transport–en Expeditie Onderneming van Gend & Loos v. Nederlandse Administratie der Belastingen, 1963 E.C.R. 1, 2 [hereinafter Van Gend & Loos].

[3] *See, e.g.*, Costa, 1964 E.C.R. at 587; Van Gend & Loos, 1963 E.C.R. at 2-3.

[4] Case C-158/96, Kohll v. Union des Caisses de Maladie, 1998 E.C.R. I-1931.

[5] Case C-120/95, Decker v. Caisse de Maladie des Employés Privés, 1998 E.C.R. I-1831.

care systems with requirements developed at the EU level, despite the fact that Article 152(5) of the EC preserves the organization and delivery of health care to them? This paper addresses these questions by focusing on the influence of EU law on the organization of national and cross-border health care.

At the heart of this paper is the discussion of EU law on the internal market and on competition. The internal market regime encompasses both the EC Treaty provisions on free movement and EU harmonization measures taken by the European Community legislature. Since, in the case of cross-border health care, the landmark decisions of the ECJ deal mainly with free movement, the emphasis of this paper is on the analysis of that regime. EU competition law consists of rules directed at undertakings and rules directed at Member States.

Part I of this paper discusses the impact of the internal market law—most notably the provisions of free movement of the EC Treaty—on the national health care systems of the Member States. Part II deals with competition law and health care. This section examines whether EU competition rules give rise to cross-border health care and, as a result, puts pressure on the Member States' organization of health care. Part III of this article concludes by considering whether the EU internal market and competition law forces Member States to harmonize their health care schemes.

I. EU INTERNAL MARKET LAW AND CROSS-BORDER HEALTH CARE

The ECJ judgments in *Kohll* and *Decker* are important starting points in the case law with regard to cross-border health care. In deciding those cases, the ECJ began setting out the principles that would govern cross-border health care in the EU. The Court based these principles primarily on the Treaty provision of the free movement of services (Article 49 and further EC Treaty). Therefore, this section will first discuss the case law setting forth the principles for cross-border health care.

More recent ECJ rulings elaborate on these two landmark decisions by formulating rules which aim to facilitate cross-border care. Hence, the second and third subsections of Part I will discuss the case law providing these "facilitating rules." Then, Part I will address the harmonization measures that are relevant for cross-border care and which might influence the organization of national health care schemes.

The EC Treaty (EC) establishes provisions that prohibit Member States from restricting the free movement of persons, goods, services, and capital. Articles 49 to 55 of the EC in particular deal with the free circulation of services, whereas Articles 28 to 30 of the EC concerns the free movement of goods (non-tariff barriers). Articles 43 to 48 of the EC govern the freedom of establishment, whereas the free movement of persons is subject to Articles 39 to 42 of the EC. Finally, the provisions on the free movement of capital are laid down in Articles 56 to 60 of the EC.

Both distinctly and indistinctly, applicable national measures are prohibited under EU law. It could be argued that the ECJ applies a market access test:[6] national measures rendering the access of persons, goods, services, or capital coming from other Member States to the national market less attractive, fall within the scope of the prohibitions laid down in the Treaty provisions on free movement.[7]

Restrictions can be justified by exceptions established in the EC Treaty. Such exceptions include Article 46 of the EC (which *inter alia* refers to public health) and Article 30 of the EC (which *inter alia* covers the protection of health and life of humans), or as developed in the case law of the ECJ[8] (overriding requirements of general interest and is also referred to as the Rule of Reason).[9]

A national measure can only be exempted from the scope of a free movement prohibition if it meets the principle of proportionality. In this regard, in most cases, the ECJ deploys the test of the less restrictive means by examining whether the objective of general interest could also be realized by means that would make free movement less restrictive than the national measure concerned.

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[6] *See, e.g.*, Case C-302/97, Konle v. Austria, 1999 E.C.R. I-3099; Case C-55/94, Gebhard v. Consiglio dell'Ordine degli Avvocati e Procuratori di Milano, 1995 E.C.R. I-4165; Case C-415/93, Union Royale Belge des Sociétés de Football Ass'n ASBL v. Bosman, 1995 E.C.R. I-4921 [hereinafter Bosman]; and Case C-384/93, Alpine Invs. BV v. Minister van Financiën, 1995 E.C.R. I-1141.

[7] *See, e.g.*, PAUL CRAIG & GRÁINNE DE BÚRCA, EU LAW: TEXT, CASES AND MATERIALS 801-03, 831-34 (4th ed. 2008).

[8] *See, e.g.*, Case 120/78, Rewe-Zentral AG v. Bundesmonopolverwaltung für Branntwein (Cassis de Dijon), 1979 E.C.R. 649.

[9] *See, e.g.*, JOHN FAIRHURST, LAW OF THE EUROPEAN UNION 467 (5th 2006).

A. THE FIRST GENERATION CASE LAW ON FREE MOVEMENT AND HEALTH CARE: SETTING THE PRINCIPLES

The first generation of case law on cross-border health care may be considered from the perspective of the landmark decisions in *Kohll*,[10] *Decker*,[11] *Geraets-Smits v. Stichting Ziekenfonds VGZ and Peerbooms v. Stichting CZ Groep Zorgverzekeringen*[12] *(Smit-Peerbooms)*, and *V.G. Müller-Fauré v. Onderlinge Waarborgmaatschappij OZ Zorgverzekeringen UA*, and *E.E.M. van Riet v. Onderlinge Waarborgmaatschappij ZAO Zorgverzekeringen*[13] *(Müller-Fauré)*. It was in these cases that the principles for receiving health care services (and goods) from providers established in other Member States were set.

B. HEALTH CARE AND THE SCOPE OF THE TREATY PROVISIONS ON FREE MOVEMENT

In *Kohll* and *Decker*, the ECJ held that the fact that national rules governing cross-border health care fall within the category of social security regulations does not exclude them from the scope of the Treaty provisions on free movement.[14] The court held that since health care services (and goods) are usually provided for remuneration, they should be considered services within the meaning of Article 50 (and as goods in the sense of Article 28). In these cases, the ECJ built upon earlier rulings in which different kinds of health care services were regarded as economic activities.[15]

In *Smit-Peerbooms* and *Müller-Fauré*, the proper functioning of health care systems was at stake, which meant that the ECJ was again asked to examine carefully to what extent the EC Treaty provisions on the free movement of services were applicable. Both cases concerned the Dutch health care system that was in place during that time. Under that particular system, reimbursement for treatment abroad was subject to

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[10] Kohll, 1998 E.C.R. I-1931.

[11] Decker, 1998 E.C.R. I-1831.

[12] Case C-157/99, B.S.M. Geraets-Smits v. Stichting Ziekenfonds VGZ, 2001 E.C.R. I-5473 [hereinafter Smits-Peerbooms].

[13] Case C-385/99, Müller-Fauré v. Onderlinge Waarborgmaatschappij OZ Zorgverzekeringen, 2003 E.C.R. I-4509.

[14] *See* Kohll, 1998 E.C.R. at I-1943, paras. 20-21; Decker, 1998 E.C.R. at I-1845, paras. 23-25.

[15] *See, e.g.*, Case C-159/90, Soc'y for the Prot. of Unborn Children Ir. Ltd. v. Grogan, 1991 E.C.R. I-4685 [hereinafter Grogan]; Joined Cases 286/82 & 26/83, Luisi and Carbone v. Ministero del Tesoro, 1984 E.C.R. 377.

prior authorization by the sickness fund[16] the patient was affiliated with. The Dutch health care scheme involved a benefit-in-kind system: patients were entitled to receive health services only from providers with which their sickness fund had entered into agreements in advance.[17] At issue were medical treatments of Dutch patients in other Member States.

Without any hesitation, the ECJ ruled that according to its own settled case law, medical activities fall within the scope of the Treaty provisions on free movement.[18] It stated that the fact that hospital care is financed by sickness funds on the basis of agreements and pre-set scales does not remove the treatment from the sphere of services within the meaning of Article 50 of the EC.[19] The Court also held that it did not matter that the national health care scheme at issue provided for benefits-in-kind rather than reimbursement. Furthermore, the Court pointed out that both treatments inside and outside hospitals are covered by the EU regime on free movement.

In *Watts*,[20] the ECJ confirmed its rulings in *Smits-Peerbooms* and *Müller-Fauré*. However, it also differentiated its line of reason in a subtle way. In *Watts*, a British patient associated with the United Kingdom's National Health Services (NHS) sought hospital treatment in France for a hip replacement. In *Watts*, the ECJ repeated its previous holding that medical care provided for remuneration falls under the EU provisions on free movement.[21] The Court also held that refusal by a NHS entity to pay the costs connected with this treatment was covered by the Treaty provisions on free movement. The ECJ stressed the point that these provisions were applicable because Mrs. Watts went to another Member State in order to receive medical treatment there. The ECJ felt that there was no need to determine whether the provision of hospital services in the context of the British NHS, in itself constitutes services within the meaning of Article 50 of the EC. The cross-border aspects of the hospital service concerned were enough to establish the applicability of the EU rules on free movement.[22]

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[16] This term is quite common in Europe, it is equivalent to the term "public insurance companies" in the United States.

[17] *See* Smits-Peerbooms, 2001 E.C.R. I-5473, paras. 3-24.

[18] *Id.* paras. 53-59.

[19] *Id.* para. 56.

[20] Case C-372/04, Watts v. Bedford Primary Care Trust, 2006 E.C.R. I-4325.

[21] *Id.* paras. 86-92.

[22] *Id.* para. 90.

According to the approach of the ECJ deployed in *Watts*, the provision of health care services can be disconnected from the state body that administers the service. The service itself may constitute a "service" in the sense of Article 50, whereas the administering body does not fall within the scope of that provision. This implies that institutions managing national health care systems or other social security systems could restrict the free movement of services without themselves providing services covered by the EC Treaty.

A similar conclusion could be drawn from the ECJ's decision in *Freskot*.[23] In the *Freskot* case the benefits provided by a Greek social security system institution were not considered "services" within the meaning of Article 50 of the EC. However, the compulsory affiliation with the social security scheme managed by this institution restricted the free movement of services, provided that the benefits concerned constituted an insurable activity.[24] According to the ECJ, the health care services concerned were insurable, if foreign insurance companies were able to offer insurance similar to the insurance provided by the Greek social security scheme at issue against the risks in question.[25] Consequently, the Court felt that it could not be ruled out that compulsory social security systems that do not leave any room for competition could fall within the scope of the Treaty provisions on free movement. The key question is whether they relate to insurable benefits.

On the one hand, the *Freskot* judgment makes clear that these Treaty provisions are capable of interfering with the Member States' powers to regulate social security in a rather far-reaching way: from a free movement perspective, many compulsory social security schemes could give rise to restrictions. On the other hand, it is rather remarkable that in both academic circles and legal practice not much attention is paid to this judgment. This article advances the view that the debate should focus on both the consequences of the free movement rules for health care and the effects for other social security schemes. Case law such as *Watts* and *Freskot* demonstrates that these rules could open up social security arrangements.

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[23] Case C-355/00, Freskot AE v. Dimosio, 2003 E.C.R. I-5263.

[24] *Id*. paras. 61-63.

[25] *Id.* paras. 53, 62.

1. THE PROHIBITION FROM RESTRICTING THE FREE MOVEMENT OF HEALTH CARE SERVICES

In the landmark decisions on free movement and health care, the ECJ was asked to rule on the compatibility of national systems requiring prior authorizations for cross-border care with EU law. The national requirements obliging patients to apply for prior authorizations for treatments abroad were modeled in different ways.

In Luxemburg (*Kohll* and *Decker*), national legislation stipulated that the costs related to health services received in other EU Member States were only reimbursed if the patient's sickness fund had granted prior authorization for the services rendered. In the Netherlands (*Smits-Peerbooms* and *Müller-Fauré*), the benefit-in-kind system implicitly forced patients to request their sickness funds in advance to cover the costs of medical treatment in other Member States, as these sickness funds usually only purchase health care from providers established in the Netherlands. In the United Kingdom (UK), national legislation regulating the NHS imposes on the state the duty to provide the necessary medical health care. Hospital care is provided free of charge by the NHS organs, on a non-profit-making basis. As a result, patients were free to go to hospitals in other Member States, but could not receive medical treatment there at the expense of the NHS; whereas if they had received treatment in British hospitals, it would have been free of charge.

Unsurprisingly, the ECJ ruled that the explicit prior authorization scheme in Luxemburg restricted the free movement of services.[26] In EU law, such a national discriminatory measure is not in line with the prohibition against hindering free movement. However, other Member States, like the Netherlands,[27] claimed that their systems were different and that, therefore, the *Kohll* and *Decker* rulings had no significant consequence when applied to their systems. They stressed that the need of patients to apply for prior authorization for medical treatment abroad was "*merely the result*" of the structure of their national health system.[28] As a result, they argued, their national health care system did not fall under the prohibition not to restrict the free movement of services.

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[26] *See* Kohll, 1998 E.C.R. at I-1946, paras. 33-35; Decker, 1998 E.C.R. at I-1852-52, paras. 34-36.

[27] *See, e.g.*, Press Release, Ministry of Health, Welfare, and Sport of the Netherlands, Arresten Europees hof Hebben Weinig Gevolgen voor Ziektekostenverzekeringen [European Court Rulings Have Little Effect on Health Insurance] (Sept. 18, 1998), *available at* http://www.minvws.nl/persberichten/z/arresten_europees_hof_hebben_weinig_gevolgen_voor_ziektekostenverzekeringen.asp.

[28] *Cf.* Müller-Fauré, 2003 E.C.R. at I-4553, para. 29.

The ECJ rejected these arguments in *Smits-Peerbooms*, *Müller-Fauré* and *Watts*. In *Smits-Peerbooms* and *Müller-Fauré*, which concerned the Dutch health care scheme that was in place then, the ECJ ruled that the benefit-in-kind system amounted to a restriction of the free movement of hospital services, as prior authorization was only granted if the necessary medical treatment could not be provided by the hospitals under contract in the Netherlands.[29] Moreover, the ECJ felt that the Dutch government's argument that sickness funds could enter into agreements with hospitals established in other Member States, could not be upheld. After all, these entities mainly had contractual arrangements with hospitals operating within the territory of the Netherlands.[30] Therefore, the ECJ was of the opinion that the Dutch system deterred or even prevented insured persons from receiving medical treatment abroad. In *Watts*, the receipt of free hospital treatment did not depend upon prior authorization when provided by a British hospital, but such an authorization was required when provided by a hospital established in another Member State. The ECJ held that this led to a restriction of free movement of services. Apparently, it did not matter to the ECJ whether this restriction was inherent to the NHS system. What was important was that this system prevented patients from seeking treatment in other Member States.

The position taken by some Member States is not helpful. They argue that their health care system is different than the systems that are at stake in well known judgments of the ECJ. As long as a national system—explicitly or implicitly—requires prior authorization for medical treatment in other Member States or for reimbursement of the costs incurred by such treatment, the ECJ assumes that free movement is hampered. As a result, the only way a Member State can go unaffected by this significant development in EU law on free movement would be for it to attempt to argue that its policies regarding prior authorization fall under an exception.

2. EXCEPTIONS AND CROSS-BORDER HEALTH CARE

In the aforementioned case law, the ECJ accepted that restrictions to cross-border health care could be justified, if certain conditions

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[29] *See* Smits-Peerbooms, 2001 E.C.R. at I-5530-33, paras. 62-71; Müller-Fauré, 2003 E.C.R. at I-4557-58, paras. 41-45.

[30] *See* Smits-Peerbooms, 2001 E.C.R. at I-5531, para. 66; Müller-Fauré, 2003 E.C.R. at I-4557, para. 43.

are met. In this regard, the ECJ based its line of reasoning both on Article 46 of the EC (a Treaty exception) and on the Rule of Reason (an exception developed in the case law of the ECJ).[31] Restrictions to the free movement of health services may be justified either by the need to protect public health (EC Article 46) or the need to maintain the financial balance of a social security system.

Essentially, the ECJ has based its approach on a distinction between hospital care and non-hospital care (so-called "intramural" and "extramural" care). Most notably in *Müller-Fauré*, it became clear that Member States are not allowed to apply a prior authorization requirement to non-hospital care (e.g., services provided by medical self-employed professionals) but they may maintain such requirements with respect to hospital care. Accordingly, the ECJ has adopted a rather generous approach towards hospital care by allowing far-reaching restrictions on the free movement of services provided in a hospital.[32]

In the author's view, the main reason for this difference is that, according to the ECJ, *hospital care* needs to be subject to an advanced system of planning in order to ensure that a Member State is able to operate a network of hospitals covering its whole territory. In the words of the ECJ, ". . . the survival of the population. . . " of a Member State is even dependent on such a network, as the maintenance of treatment capacity or medical competence is essential for the public health.[33] In contrast, the ECJ held that the removal of the requirement of prior authorization for *non-hospital* care would not give rise to an enormous increase of patients traveling to other Member States and, consequently, such a removal would not put the financial balance of the social national security system under pressure.[34] The ECJ took the view that problems related to the cultural, linguistic, and geographical distance would prevent patients from crossing the borders of the Member States in large numbers in order to seek treatment by self-employed professionals. Thus, according to the ECJ, non-hospital care does not need to be subject of a system of planning.

The result of this perspective is that the national health care systems of Member States are liberalized in as far as they concern medical treatment provided outside hospitals. The national legal barriers to this

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[31] *See, e.g.*, Smits-Peerbooms, 2001 E.C.R. I-5533-34, paras. 73-75.

[32] Karl Stöger, *The Freedom of Establishment and the Market Access of Hospital Operators*, 17 EUR. BUS. L. REV. 1545, 1555 (2006).

[33] Smits-Peerbooms, 2001 E.C.R. at I-5533, para. 74.

[34] Müller-Fauré, 2003 E.C.R. at I-4573, para. 95.

health care category have been removed by the ECJ. Although Article 152(5) of the EC provides that national competences regarding the organization and the delivery of health care should be respected, the free movement EC Treaty provisions have considerable a impact, at least on the way non-hospital services are organized and delivered: the ECJ case law has led to a certain degree of harmonization of these "extramural" services in the EU.

The distinction between hospital and non-hospital care is of great importance. In some cases, this distinction is hard to draw, but the ECJ seems to be prepared to give a broad interpretation to the concept non-hospital care.[35] In *Müller-Fauré,* the ECJ stated that certain services provided in a hospital environment are also capable of being provided by a practitioner in his surgery or in a health center. These services could, therefore, be placed on equal footing with non-hospital services.[36]

It should be noted that the ECJ has not given a *carte blanche* to the Member States to regulate hospital services. The landmark decisions analyzed above do formulate several criteria that national health care authorities must comply with in order to prevent patients from being treated abroad. A successful invocation of a Treaty exception or Rule of Reason exception depends largely on the question whether the principle of proportionality has been observed.[37] Remarkably, while formulating the conditions connected with the justification of the restrictions of the free movement of hospital services, the ECJ did not explicitly refer to this principle. However, it is clear from the outset that these conditions are based on the presumption that a prior authorization requirement—from a EU law perspective, a far-reaching curtailment of the free movement services—is only justifiable if this requirement is proportionate.

The ECJ held that two conditions must be met. First, the waiting list for the hospital where the patient is seeking treatment must not be too long. The assessment of the question of the duration of such a list may only be based on medical considerations,[38] and not on costs related arguments.[39] Second, the necessity of the medical treatment must be evaluated on the basis of international (and not national) medical standards.[40]

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[35] Anne Pieter van der Mei, *Cross-Border Access to Medical Care: Non-Hospital Care and Waiting Lists*, 31 LEGAL ISSUES OF ECON. INTEGRATION 57, 65 (2004).

[36] Müller-Fauré, 2003 E.C.R. at I-4567, para. 75.

[37] The principle of proportionality is explained in Part I.A.

[38] *See, e.g.*, Müller-Fauré, 2003 E.C.R. at I-4571, para. 90.

[39] *See, e.g.*, Watts, 2006 E.C.R. at I-4416, paras. 120-22.

[40] *See* Smits-Peerbooms, 2001 E.C.R. at I-5539, para. 97.

It must be examined whether this treatment is sufficiently tried and tested by international and medical science.

It is apparent from these conditions that the case law on the Treaty provisions on free movement affects the organization and delivery of hospital care. Although this conclusion is burdensome for some Member States,[41] the considerable influence of EU law on cross-border health care cannot be denied. The case law forces Member States to solve capacity problems occurring in their hospitals. If they do not do so, they could be confronted with a flow of patients traveling to hospitals in other Member States. Such a development is capable of endangering the proper functioning of the planning system that is in place in the health care sector of a Member State. Furthermore, while assessing the necessity of hospital treatment, the competent health authorities must pay due consideration to the international state of science. As soon as a certain medical practice is accepted by a considerable number of professionals in several countries, this practice can no longer be rejected by a Member State.

Accordingly, the conditions requiring Member States to provide treatment in due course, and to assess the necessity of this treatment in light of international medical standards, enable EU law to intervene in the organization of hospital care in the Member States. They provide a basis on which an elaborative and detailed set of rules could be built upon. This is exactly what the ECJ did in its rulings subsequent to its earlier judgments.[42]

C. THE SECOND GENERATION CASE LAW ON FREE MOVEMENT AND HEALTH CARE: SETTING THE RULES AIMING TO FACILITATE CROSS-BORDER HEALTH CARE

After determining the main principles for cross-border health care in the EU, the ECJ was asked to clarify how these principles must be applied in practice. By elaborating on its landmark decisions, the ECJ has extended its influence on national health schemes.

In this respect, it must be noted that no clear dividing line exists between the ECJ's case law establishing the "cross-border health care

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[41] For example, the U.K. claims that it is still possible that restrictions to non-hospitals are justifiable in the view of the ECJ. *See* HEALTH AND CONSUMER PROTECTION DIRECTORATE-GENERAL, EUROPEAN COMM'N, SUMMARY REPORT OF THE RESPONSES TO THE CONSULTATION REGARDING "COMMUNITY ACTION ON HEALTH SERVICES" (2007) at 15 [hereinafter SUMMARY REPORT], *available at* http://ec.europa.eu/health/ph_overview/co_operation/mobility/docs/health_services_rep_en.pdf.

[42] *See, e.g.*, Smits-Peerbooms, 2001 E.C.R. at I-5539-40, paras. 94-98.

principles" and the case law which is presently being referred to, in which these principles are worked out in detail. The demarcation between these categories of case law is somewhat blurred. Nevertheless, it is useful to make a distinction between these categories, as each type of case law gives rise to different questions.

With regard to several issues, the ECJ explained in more detail how Member States have to deal with cross-border health care in the EU. These topics are discussed below. It should also be noted that what is put forward with regard to these topics, only holds true if the Treaty provisions on free movement confer upon a patient the right to receive medical treatment abroad.

1. REIMBURSEMENT RATES

Once it is established that a patient is entitled to receive cross-border health care pursuant to the Treaty provisions on free movement, it must be determined to what extent the managing body of the home state must pay the costs connected with this cross-border service. ECJ decisions on this matter could deeply interfere with the health care services of the Member States. However, these questions involving reimbursement rates must be tackled in order to ensure that patients can benefit from the rights they derive from the EU free movement regime.

In *Müller-Fauré*, the ECJ stated that it is up to the Member States to determine the reimbursement rates and to fix the amounts to be paid to patients.[43] As a result, the ECJ put forward that ". . . insured persons who go without prior authorization to a Member State other than the one in which their sickness fund is established to receive treatment there can claim reimbursement of the cost of the treatment received only within the limits of the cover provided by the sickness insurance scheme of the Member State of affiliation.[44] This gave Ms. Müller-Fauré a *Pyrrhus'* victory, because pursuant to the applicable Dutch rules, insurance coverage contributed only up to a maximum of EUR 221.03, whereas the costs incurred for the treatment by a German dentist were EUR 3,806.35.[45] At the end of the day, she had to bear most of the costs (and this after being involved in litigation for more than eight years).

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[43] *See* Müller-Fauré, 2003 E.C.R. at I-4576, paras. 105-07.

[44] *Id.* at para. 106. *See also* Elies Steyger, *National Health Care Systems Under Fire (but not too heavily)*, 29 LEGAL ISSUES OF ECON. INTEGRATION 97, 105 (2002).

[45] *See* Müller-Fauré, 2003 E.C.R. at I-4509, para. 106.

However, in *Müller-Fauré,* the ECJ also formulated conditions to be fulfilled by the Member States when shaping their reimbursement rates. National rules regarding these rates must be based on objective, non-discriminatory, and transparent criteria.[46] By stressing the importance of these criteria, the ECJ has given itself the opportunity to influence the way national health care systems are financed.

This is apparent from the *Vanbraekel* decision.[47] In that case, a Belgian patient residing in Belgium was treated in a hospital in France. According to French legislation, she was forced to pay her own contribution for the medical treatment. However, in Belgium, similar treatment was free of charge. The ECJ felt that there was no doubt that the free movement of services was restricted in this case, since the patient received a lower level of coverage when she was treated in another Member State's hospital than she would have received had she undergone similar treatment in one of her home state's hospitals. Moreover, she was prevented from applying for services offered by providers established in other Member States.

The ECJ decided that this restriction was not justifiable, as the financial equilibrium of the Belgian health care system was not at stake.[48] After all, the patient was entitled to receive hospital treatment abroad anyway and, as a consequence, the payment of an additional reimbursement, covering the difference between the systems of cover in France and Belgium, would not jeopardize the maintenance of a network of hospital services.

As a result, in *Vanbraekel* it was accepted that the EU regime on free movement not only entitled EU nationals to receive medical treatment in other Member States, but it was also capable of interfering with the national rules on the financing of health care treatment.

The question of reimbursement was very complicated in cases where a EU national sought medical treatment in a Member State that based its health care system on principles that were considerably dissimilar to the principles of the health care system of the Member State of residence. As a consequence, the question arose: how to connect these national systems? In *Watts*, a British patient underwent an operation in a French hospital. One of the questions that needed to be answered by the ECJ was the amount of the costs that the British authorities must pay to

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[46] *Id*. at I-4576, para. 107.

[47] Case C-368/98, Vanbraekel v. Alliance Nationale des Mutualités Chrétiennes, 2001 E.C.R. I-5363.

[48] *Id.* para. 51.

Ms. Watts. In France, a health insurance-like system is in place (*caisses mutuelles*), while in the UK, patients registered with NHS receive treatment free of charge.[49] Once it was established that the costs incurred by Ms. Watts in France must be reimbursed, the amount of this reimbursement had to be determined.

The ECJ had to express its view on the situation, in which the French health care legislation did not provide for the reimbursement in full of the cost of the hospital treatment concerned. Like the *Vanbrakel* case, at issue was the question of how the home Member State should deal with reimbursement requests of patients who were obliged to make additional payments under the health care system of the host Member State.

In the author's view, in the *Watts* case it was more difficult to cope with this question given the dissimilarities between the French and British health care systems than it was in *Vanbrakel*, where the French and Belgian systems were more alike. The ECJ has developed an approach based on the presumption that the patient must be placed in the position he would have been in had he undergone the operation under the British NHS. In the author's view, the rationale of this approach is the non-discrimination principle: a patient who is entitled to an operation in another Member State pursuant to EU law should not be treated less favorably than a patient who undergoes similar treatment in the home Member State.[50]

According to the ECJ, the NHS was obliged to compensate Ms. Watts for the additional payment she made, to a certain extent.[51] The competent authority must reimburse the patient the difference between the cost, objectively quantified, of the equivalent treatment under the NHS system, up to the total amount invoiced for the treatment received in the host Member State (in this case, France), and the amount that the competent Member State institution has paid on behalf of the NHS,[52] in so far as the first amount is larger than the second.

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[49] *See* Watts, 2006 E.C.R. I-4365, paras. 5-23.

[50] *See also* TAMARA K. HERVEY & JEAN V. MCHALE, HEALTH LAW AND THE EUROPEAN UNION 134 (2004).

[51] *See* Watts, 2006 E.C.R. I-4365, para. 131.

[52] The competent authority of the host Member State reimburses the cost of the medical treatment of a patient affiliated with the health care system of the home Member State. Subsequently, the host Member State will pass on these costs to the home Member State. *See* Council Regulation 1408/71 on the Application of Social Security Schemes to Employed Persons and Their Families Moving within the Community, 1971 O.J. (L 149) 2 (EEC) [hereinafter Council Regulation 1408/71].

Consequently, the ECJ forces the two Member States involved to carry out a comparative analysis of the costs. The host Member State is allowed to limit the total reimbursed amount to the level of the costs of the health care services of its own system, provided that these costs are objectively calculated. As a result, when the costs of the operation that Ms. Watts underwent in France are higher than the costs of a similar operation in a British hospital, the NHS was not obliged to compensate Ms. Watts completely for the additional payments made by her to the French authorities.

However, the *Watts* case shows that the Member States' rules on reimbursement rates are influenced by EU law. In the case of cross-border health care, Member States might be forced to come up with comparative analyses of the costs of different health care systems in Europe. The direct result of such analysis could be that additional payments made by patients when being treated abroad must be compensated. What is more, it is possible that the *Watts* case law—possibly leading to the benchmarking of several health care systems in Europe—would stimulate Member States to reconsider the cost efficiency of their health care services.

Another cost issue arose in relation to accommodation and traveling. Ms. Watts claimed that her travel and accommodation costs had to be reimbursed by the NHS. It is clear from the outset that patients seeking medical treatment abroad are confronted with considerable ancillary costs. However, these costs could cause problems for the national health authorities as well, since they have to control the expenditure on health care. Similar to the question of additional payment, the ECJ's approach towards this issue is based on the anti-discrimination principle. Whether such expenditure is covered depends upon the way the national health care systems involved deal with ancillary costs, such as travel and accommodation expenses.[53] A Member State is only required to reimburse these costs if similar costs are also reimbursed for treatments offered under its own health care system. If a national health care scheme does not provide for the reimbursement of costs, such as travel and accommodation expenses, that Member State is not required to compensate patients seeking medical treatment in another Member State for those costs. As a result, once a Member States has opted for a health care scheme that includes several ancillary costs, the amount of such expenditure could become even larger, when many insured persons from another Member

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[53] *See* Watts, 2006 E.C.R. at I-4366, paras. 139-40.

State cross the border in order to receive health care services. In contrast, if a Member State has excluded these costs from its health care scheme, it will not be confronted with the same expense when insured persons seek medical treatment abroad. Consequently, one could argue that the ECJ's "anti-discriminatory approach" actually contains an incentive to exclude ancillary costs from national health care systems.

The ECJ's approach towards ancillary costs in *Watts* is in line with its previous judgment in the *Leichtle* case.[54] There, the ECJ stressed that it is up to the Member States to limit the amount up to which expenditures on board, lodging, travel, visitors' tax, and the completion of a final medical report could be reimbursed.[55] However, if those costs are reimbursed for treatment provided under the health care system of the home Member State, the competent authorities of that state must also compensate patients undergoing similar treatment in another Member State for these costs.[56]

2. PROCEDURES AND CONDITIONS REGULATING THE GRANTING OF PRIOR AUTHORIZATIONS

In the case of hospital care (intramural care) the Member States are allowed to make cross-border health care subject to prior authorization. As long as Member States are able to provide the necessary hospital care to the patient without undue delay, they may even refuse to grant authorization for cross-border care.

However, in judgments delivered after *Smits-Peerbooms*, where it was accepted that the free movement of hospital services may be restricted by a prior authorization scheme, the ECJ formulated conditions to be met by such schemes. Consequently, the way the Member States model their authorization schemes in health care is partly influenced by EU law.[57]

Already in *Müller-Fauré*, the ECJ set some principles regarding the design of these schemes. It was stressed that a scheme of prior authorization cannot legitimize discretionary decisions taken by public bo-

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[54] Case C-8/02, Leichtle v. Bundesanstalt für Arbeit, 2004 E.C.R. I-2641.

[55] *Id.* para. 48.

[56] *Id.* paras. 48-50.

[57] *See also* Panos Koutrakos, *Healthcare as an Economic Service under EC Law*, *in* SOCIAL WELFARE AND EU LAW 117 (Michael Dougan & Eleanor Spaventa eds., 2005).

dies of the Member States.[58] Therefore, such a scheme must be based on objective and non-discriminatory criteria which are known in advance. These criteria should circumscribe the exercise of the national authorities' discretion and prevent the arbitrary use of power.[59] Furthermore, the procedural system at hand must be easily accessible and lead to decisions that may be challenged in judicial or quasi-judicial proceedings. In making their decisions, the health care authorities must take into consideration all of the circumstances surrounding each case: both aspects related to the patient's medical condition, including the degree of pain or nature of the patient's disability, and his/her medical history.

In *Inizan*,[60] the ECJ further built upon the procedural principles it laid down in *Müller-Fauré*. In *Inizan*, it was held that a request made by a patient for authorization in order to receive hospital care in another Member State must be dealt with objectively and impartially within a reasonable time, whereas a refusal to grant authorization must be subject to a procedure of judicial review.[61] In other words, the procedures relating to cross-border health care must meet fair trial like prerequisites.[62] Health care authorities must not only assess requests made by patients without any prejudice, but they must also proceed in handling these requests in a timely manner. In addition, the procedures themselves may not last too long.

In the author's opinion, the requirements concerning the speed of the procedure should be explained against the background of the ECJ's ruling that the free movement of hospital care may only be limited when the medical treatment that the patient needs can be given without undue delay. It goes without saying that the treatment cannot be given in a timely fashion when the prior authorization procedure is too time-consuming.

Furthermore, in *Inizan*, the ECJ decided that refusals to grant authorization, or advice on which these refusals are based, must refer to the

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[58] Müller-Fauré, 2003 E.C.R. at I-4569, para. 84. For ECJ's settled case law on the matter, see, e.g., Joined Cases C-358 & C-416/93, Criminal Proceedings against Aldo Bordessa, 1995 E.C.R. I-361 and Case C-205/99, Asociación Profesional de Empresas Navieras de Líneas Regulares v. Administración General del Estado, 2001 E.C.R. I-1271 [hereinafter Analir].

[59] Müller-Fauré, 2003 E.C.R. at I-4569, para. 85.

[60] Case C-56/01, Inizan v. Caisse Primaire d'Assurance Maladie des Hauts-de-Seine, 2003 E.C.R. I-12403.

[61] *Id.* para. 48.

[62] *See also* Anthony Dawes, *'Bonjour Herr Doctor': National Healthcare Systems, the Internal Market and Cross-border Medical Care within the European Union*, 33 LEGAL ISSUES OF ECON. INTEGRATION 167, 170 (2006).

specific provisions on which they are based.[63] These decisions must be well reasoned too, whereas the judicial bodies competent to review refusals to grant authorizations must be able to commission the advice of wholly objective, impartial, and independent experts.[64] As a result, it could be argued that, as was the case in *Inizan*, principles of good governance are developed for the health care sectors of the Member States. Hence, next to substantive rules regulating cross-border health care, principles forcing the Member States to design health care procedures properly are derived from the Treaty provisions on free movement.

In *Watts*, the ECJ applied these principles to the British NHS. The procedure of this national system was criticized because the regulations issued by the NHS do not set out criteria for the grant or refusal of prior authorization.[65] This deficit was described by the ECJ as a "lack of a legal framework"[66] (in the prior authorization procedure). Furthermore, the ECJ pointed out that the decision to grant or refuse authorization may not be merely based on the existence of waiting lists. The patient's medical condition must be taken into account too.[67] Accordingly, general observations related to the health care system of the Member State involved should not only play a role in the assessment carried out by the authorities, but arguments regarding the health of the patient applying for prior authorization must also be accommodated in the reasoning upon which the grant or the refusal of such an authorization is based.

3. NATIONAL POLICIES REGARDING WAITING LISTS

Waiting lists play an important role in the rulings of the ECJ. The free movement of hospital services may be restricted in order to maintain medical treatment capacity, in so far as the patient concerned does not need to wait too long for her or his treatment. However, in *Watts* the ECJ accepted that the national health authorities deploy waiting lists because they have to cope with the rising demand for hospital care and budgetary constraints.[68] It is clear from the outset that the bodies responsible for the provision of health care must be able to manage

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[63] Inizan, 2003 E.C.R. at I-12441, para. 49.
[64] *Id.*
[65] Watts, 2006 E.C.R. at I-4415, para. 118.
[66] *Id.*
[67] *Id.* para. 63.
[68] *Id.* para. 67.

the supply of medical services by setting priorities on the basis of the available resources and capacities.

However, in *Watts* the ECJ also formulated conditions that national policies regarding waiting lists must comply with.[69] First, a patient's waiting time may not exceed the period that is acceptable in the light of his/her clinical needs.[70] The question of whether a person can be treated without undue delay must only be assessed on the basis of medical arguments and may not be based on an economic line of reasoning.[71] Second, the waiting list must be set in a flexible and dynamic way, because the period of time the patient is initially told he or she will have to wait must be reconsidered if his or her state of health so requires.[72]

In cases in which a patient seeks hospital care in other Member States, it appears that waiting lists are not contrary to EU law. Nonetheless, the Member States' policies in regards to these lists must observe principles of good governance. The medical needs of the patients should be at the heart of the hospitals' waiting list policies.

4. THE PROVISION OF HEALTH CARE SERVICES BY PUBLIC AND PRIVATE HOSPITALS

In many EU Member States, people are not only treated in public hospitals but also in private hospitals. Therefore, the question arises whether the costs of treatments carried out by private hospitals in other Member States must be reimbursed. The ECJ addressed this question in *Stamatelaki*.[73]

According to the Greek legislation at issue in *Stamatelaki*, a patient affiliated with a Greek social security institution was entitled to hospital care provided by both domestic public and private hospitals free of charge. However, if he or she was treated in another Member State, her or his costs were only reimbursed when she or he had undergone the treatment in a public hospital. Services provided by private hospitals in

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[69] *See id.* paras. 68-71.

[70] *Id*. para. 68.

[71] *See also* CATHERINE BARNARD, THE SUBSTANTIVE LAW OF THE EUROPEAN UNION: THE FOUR FREEDOMS 398 (2d ed. 2007).

[72] *See* Watts, 2006 E.C.R. I-4365, paras. 69-71.

[73] Case C-444/05, Stamatelaki v. NPDD Organismos Asfaliseos Eleftheron Epangelmation, 2007 E.C.R. I-3185.

other Member States did not fall within the scope of the coverage of the Greek health care system except for children under the age of fourteen.[74]

In the view of the ECJ, such a health care system precluded insured persons from seeking medical treatment in other Member States and, as a consequence, amounted to restricting the free movement of services.[75] Furthermore, in the view of the ECJ, this restriction was not justifiable, as the principle of proportionality was not met. The ECJ felt that the absolute terms of the prohibition laid down in the Greek legislation were not appropriate to the objective pursued.[76] What is more, the ECJ rejected the Greek government's argument that the quality of foreign private hospitals could not be monitored by Greek health care authorities.[77] The ECJ pointed out that private institutions established in other Member States are subject to quality controls, just like the Greek institutions, whereas doctors of these foreign hospitals must comply with the applicable EU rules on medical professional skills.[78] Consequently, the Greek authorities had to recognize the inspections on quality carried out in other Member States and the national health laws (partly implementing EU directives on the free movement of doctors) of these Member States.

In *Stamatelaki*, the ECJ based its approach towards the reimbursement of costs of treatment in foreign private hospitals on the principle of anti-discrimination. These costs must be paid back only by the national health care authorities, if the cost of medical treatment undergone in a similar private domestic institution falls within the scope of the coverage of the national health care schemes. Therefore, it is up to the Member States to decide on the question of the reimbursement of the costs of services provided by private hospitals. But, as soon as the reimbursement of these costs is part of their own health care system, they cannot totally exclude the recovery of the costs connected with treatment in private hospitals in other Member States.[79] If the necessary hospital treatment cannot be given without undue delay by domestic hospitals, the Member States are obliged to compensate the costs of the treatment abroad, irrespective of whether this treatment was offered by a public or

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[74] *Id.* paras. 4-8.

[75] *Id.* paras. 25-28.

[76] *Id.* para. 35.

[77] *Id.* paras. 36-37.

[78] *Id.*

[79] In this respect, see also H.M. Stergiou, *´Kalimera' dear Doctor: het arrest-Stamatelaki en andere recente ontwikkelingen op het terrein van grensoverschrijdende patiëntenmobiliteit*, 11 NEDERLANDS TIJDSCHRIFT VOOR EUROPEES RECHT [DUTCH ILLUSTRATED MAGAZINE FOR EUROPEAN LAW] 238, 242 (Nov. 2007).

private institution. Furthermore, the Member States must trust the inspections on quality and the standards of the national health laws of their fellow Member States.

5. THE PATIENTS ENTITLED TO HEALTH CARE BENEFITS

On April 1, 2008 the ECJ rendered its judgment in the case *Regering van de Franse Gemeenschap, Waalse regering v. Vlaamse regering*.[80] In that case, the ECJ addressed the question of whether EU law requires Member States to insure certain groups of persons. Similar to the case law on reimbursement rates and on the provision of health care by private hospitals, the ECJ based its approach towards this question on the principle of non-discrimination.[81] The point of departure was that nationals of other Member States may not be treated less favorably than nationals of the Member State concerned.

In the case *Regering van de Franse Gemeenschap, Waalse regering v. Vlaamse regering*, the scheme for insurance of persons whose autonomy is reduced,[82] introduced by the autonomous Flemish community (a federal entity of Belgium), was at stake. According to this program, only persons working and residing in Flanders and persons working in Flanders but residing in Member States other than Belgium were insured. As a consequence, persons working in Flanders, but residing in other parts of Belgium (i.e., the Walloon and German areas of Belgium) were excluded from the scheme at issue.[83]

The ECJ explicitly stated that the free movement provisions of the EC Treaty were not applicable to purely internal situations.[84] Therefore, Belgian nationals working in Flanders and residing in the Walloon and German regions of Belgium could not invoke the Treaty provisions on the free movement of persons (Articles 39 and 43 of the EC). However, the situation was different for nationals of other Member States who work in Flanders and are residents in the other parts of Belgium. The ECJ ruled that it is possible for them to rely on the EU free movement rules.[85]

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[80] Case C-212/06, Regering van de Franse Gemeenschap v. Vlaamse Regering, 2008 E.C.R. __ (Apr. 1, 2008), 2008 O.J. (C 128) 4.

[81] *Id.* paras. 47-48.

[82] In this case, the ECJ used this term to describe people living with disabilities.

[83] *Id*. paras. 7-11.

[84] *Id.* para. 38.

[85] *Id.* paras. 41-42.

What is more, in the view of the ECJ, the Flemish scheme at stake had the effect of causing the nationals of other Member States to lose social security advantages. After all, if they lived in Belgian regions other than Flanders and decided to pursue employment or self-employment in Flanders, they were not able to claim the benefits of the Flemish scheme of care insurance. According to the ECJ, this fact was capable of impeding the exercise of the rights conferred by Articles 39 and 43 of the EC. Consequently, the Flemish health care insurance scheme was found in violation of these Treaty provisions.[86]

Remarkably, Belgium did not invoke an exception in order to justify the restriction of free movement. Rather, it only argued that according to the requirements inherent in the division of powers within the Belgian federal structure, the Flemish government was not competent to introduce health care schemes for persons living in other regions of Belgium. The ECJ did not accept this argument. In doing so, it referred to long standing and settled case law, which prevent Member States from basing their argument on practices that result from the constitutional organization to justify non-compliance with obligations arising under EU law.[87]

From this judgment it is apparent that Member States are obliged to grant to other Member States' nationals health care benefits similar to those that their own nationals are entitled to. Even if certain groups of their own nationals are excluded from these benefits, nationals of other Member States may not be denied access to the benefits concerned. Thus, EU law is capable of requiring Member States to extend the scope of national health care schemes.

D. SPECIAL SECOND GENERATION CASE LAW ON FREE MOVEMENT AND HEALTH CARE: RULINGS ON PATIENT MOBILITY AND SOCIAL SECURITY REGULATION

The rulings discussed above specify the rights of various categories of patients but, quite remarkably, the ECJ did not make use of the Social Security Regulation,[88] while setting the main principles for cross-border care. Yet, this piece of Community legislation also contains provisions on cross-border health care. Thus, after having set the main prin-

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[86] *Id.* para. 54.

[87] *Id.* para. 58.

[88] Council Regulation 1408/71, *supra* note 52.

ciples on the basis of provisions of the EC Treaty regarding free movement, the ECJ turned not only to these provisions but also to the Social Security Regulation, while elaborating on the rights of patient to receive access to health care in other Member States.

The relevant framework for cross-border health is founded in Article 22 of the Social Security Regulation.[89] According to Article 22(1)(a), a worker who stays outside his or her state of residence has the right to be treated in another Member State if his or her condition necessitates this medical treatment. Pursuant to Article 22(1)(c), health care authorities may give a patient authorization to go to the territory of another Member State in order to receive medical treatment. Article 22(2) stipulates that such an authorization may not be refused where the treatment cannot be provided in the state of residence.

In *Inizan* and *Watts,* discussed above, the ECJ based its rulings not only on the Treaty provisions on free movement, but also on these provisions of the Social Security Regulation. The ECJ judgment in *Keller* is noteworthy.[90] In *Keller,* the ECJ extended the right to receive medical treatment abroad even to situations where this treatment is provided in a third country (a EU non-member state). Ms. Keller, a German national, lived in Spain and, as a result, according to the system of the Social Security Regulation, the Spanish health care authorities were supposed to decide whether she was entitled to medical benefits or not. When she became ill, they authorized her to go to Germany in order to receive medical treatment in a hospital there. Due to the complicated character of her illness, the German doctors who treated Ms. Keller sent her to a hospital in Switzerland. Because Switzerland is not a member of the EU, the Spanish authorities refused to reimburse the costs of her treatment there.

The decision by Spanish authorities was, however, not upheld by the ECJ. The ECJ pointed out that the Spanish health care authorities were bound by the findings of the authorities of the state of stay (in this case, Germany) as regards the need for urgent, vitally necessary treatment.[91] The Spanish authorities must respect the decisions made by the doctors of the country of stay, even if this implies that the patient concerned must be transferred to a hospital in a country that is not a member of the EU. Hence, under certain circumstances, EU law obliges even the

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[89] *Id.*

[90] C-145/03, Heirs of Annette Keller v. Instituto Nacional de la Seguridad Social, 2005 E.C.R. I-2529 [hereinafter Keller].

[91] *Id.* para. 63.

Member States to reimburse costs of medical treatment received by a patient outside the territory of the EU.

Furthermore, the ECJ has used the Social Security Regulation in order to create extensive rights for retired persons. Article 31 of the Regulation provides that a pensioner who stays in a Member States other than the one in which she or he resides is entitled—with members of her or his family—to medical treatment in that state.[92] Unlike (the original words of) Article 22, this provision of the Social Security Regulation does not use the words "whose condition necessitates immediate benefits during a stay." In *Idryma Koinonikon Asfaliseon and Vasilios Ioannidis (IKA)*,[93] the ECJ deduced from the difference between both Articles that the right of a pensioner, when staying on the territory of another Member State—e.g., for the purpose of a family visit or to get medical treatment—is not dependent upon the immediate necessity of the treatment.[94] She or he has to right to receive medical treatment, for instance, in a hospital of the Member State of stay, irrespective of whether it is an emergency visit.

In this regard it should be noted that in *Van der Duin*,[95] the ECJ restricted the scope of the rights of pensioners. According to the system of the Social Security Regulation, pensioners who stay with members of their family in a Member State other than the one responsible for the payment of their pensions, enjoy, for themselves and members of their families, a right to benefits in kind from the relevant institution of the Member State of residence, as if they were pensioners under the legislation of that State. This implies that the authorities of the Member State of residence are able to issue permission for medical treatment in other Member States, even if this treatment takes place in the Member State that is liable for the payment of their pensions. In *Van der Duin,* a pensioner who enjoyed a pension under Dutch legislation, moved to France after retirement. Accordingly, she was obliged to apply for prior authorization for medical treatment in the Netherlands by the French authorities. However, because the pensioner failed to file an application, the ECJ found that the authorities had not violated EU law when they refused to reimburse the costs of the medical treatment received in a Dutch hospital.

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[92] *Id*. paras. 60-62. *See also* Council Regulation 1408/71, *supra* note 52, art. 31.

[93] Case C-326/00, Idryma Koinonikon Asfaliseon v. Ioannidis, 2003 E.C.R. I-1703.

[94] *Id.* paras. 39-43.

[95] Case C-156/01, Van der Duin v. Onderlinge Waarborgmaatschappij ANOZ Zorgverzekeringen UA, 2003 E.C.R. I-7045.

All in all, it could be argued that not only the Treaty provisions on free movement, but also the Social Security Regulation has inspired the ECJ to intervene in the national organization of the delivery of health care. The regime on cross-border health care established in the Social Security Regulation gives a lot of possibilities to elaborate on the main principles advanced in judgments such as *Decker* and *Kohll*.

It must also be pointed out that in the short run, the current Social Security Regulation will be replaced by Regulation 883/2004.[96] So far, however, it is not clear when the later regulation will enter into force. As for cross-border health care, the new Regulation will constitute an important change in law. Specifically, according to Article 19 of the new Regulation, insured persons and their families are entitled to benefits in kind when staying in Member States other than the one in which they reside. In order to get access to this medical treatment, proof that the treatment is immediately necessary is no longer required. Meanwhile, Social Security Regulation 631/2004[97] has already removed the word "immediate" from Article 22(1)(a) of the current Regulation, 1408/71. Because this provision regulates the rights of workers staying in the territory of another Member State, the "health care position" of workers is improved.[98] Thus, "the *IKA* approach" is extended from pensioners to all insured persons.

E. INITIATIVES AT THE EU-LEVEL THAT RESPOND TO THE CASE LAW OF THE ECJ ON HEALTH CARE

Thus far, the EU measures towards the national organization of health care are mainly "negative in form," they aim to remove obstacles to cross-border health care. But it is clear that issues of "a positive nature," like the setting of minimum quality standards and transparency requirements, need to be regulated as well. This is particularly true because Member States are not able to control these issues in the case of cross-border health care.[99] The consequence of ECJ case law is that the

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[96] Council Regulation 883/2004 on the Coordination of Social Security Systems, 2004 O.J. (L 166) 1 (EC).

[97] *See* Council Regulation 631/2004 amending Council Regulation 1408/71/EEC on the Application of Social Security Schemes, 2004 O.J. (L 100) 1, 2 (EC).

[98] *See* F.J.L. PENNINGS, GRONDSLAGEN VAN HET EUROPESE SOCIALEZEKERHEIDSRECHT 177 (2005).

[99] *See* Mel Cousins, *Patient Mobility and National Health Systems*, 34 LEGAL ISSUES OF ECON. INTEGRATION 183, 191 (2007); Gareth Davies, *Competition, Free Movement, and Consumers of Public Services*, 17 EUR. BUS. L. REV. 95, 103-04 (2006).

health authorities of the Member States have less discretion than was intended in order to restrict the number of patients seeking treatment abroad.[100]

Furthermore, some argue that the incremental development of the cases on health care and free movement gives rise to legal uncertainty.[101] So, it is no surprise that the ECJ case law on patient mobility has led to several EU legislative initiatives. In 2004, the Commission issued a draft Services Directive.[102] The aim of this Directive was to stimulate EU Member States' services markets. The Directive covers both the provision of services on a temporary basis (free movement of services) and on a permanent basis (freedom of establishment). The first version of this draft[103] included health services and harmonized the ECJ's case law on the free movement of services and patient mobility. According to the then-proposed Article 16, the providers of services would only be subject to the national legislation of their home country ("country of origin principle"), unless certain exceptions were applicable. Article 17 (paragraph 18) of the 2004 Draft stated that the country of origin would not apply to authorization schemes regarding the reimbursement of hospital care. As a result, all authorization schemes with regard to non-hospital care were not allowed to be applied to health care services by providers of other Member States.

However, the Commission faced a lot of resistance while defending its 2004 proposal; it was feared that the proposal would not lead to a proper balance between market forces and objectives of public interest.[104]

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[100] Christopher Newdick, *Citizenship, Free Movement and Health Care: Cementing Individual Rights by Corroding Social Solidarity*, 43 COMMON MKT. L. REV. 1645, 1663 (2006).

[101] Dawes, *supra* note 62, at 178-79. He also points out that the application of the EC Treaty provisions on free movement by national courts in various Member States has resulted in divergent interpretations of the case law of the ECJ. *Id.* at 174-78.

[102] *Commission Proposal for a Directive of the European Parliament and of the Council on Services in the Internal Market*, COM (2004) 2 final/3 (Mar. 5, 2004) [hereinafter *Draft Services Directive*].

[103] *Commission of the European Community, [Proposal for a Directive of the European Parliament and the Council on Services in the Internal Market]*, COM (2004) 621 definitief/2 (Feb. 25, 2004).

[104] In this respect the speech of the Commissioner for the internal market, delivered in the European Parliament on March 9, 2005 is illustrative. The resistance with regard to the Draft Services Directive "inspired" him to make the following statement: "However, I realize that the services directive as initiated has not a snowball's chance in hell of getting through either the Council of Ministers or the European Parliament." Charlie McGreevy, European Comm'r for Internal Mkt. Servs., Discussion in the European Parliament Plenary on the Services Directive, SPEECH/05/148 (Mar. 9, 2005). *See also* Stefan Griller, *The New Services Directive of the European Union: Hopes and Expectations from the Angle of a (Further) Completion of the In-*

As a result, the controversial country of origin principle has been replaced by the requirement imposed upon the Member States to respect the free movement of services. What is more, the health care sector has been excluded from the Services Directive:[105] Article 2(2)(f) now provides that health care services, whether public or private, do not fall within the scope of the Directive. Thus, in the author's view, the aim of this provision is to guarantee to as great an extent possible that the organization of health care systems of the Member States is not affected by the Services Directive.[106]

Conversely, in its press release[107] accompanying the amendments to the 2004 Draft, the Commission announced that it would come forward with a separate initiative in the field of health, covering, *inter alia*, the issues of patient mobility. Therefore, it was clear that the Commission did not give up its attempts to codify the ECJ's case law on patient mobility and to facilitate the exercise of the rights patients may derive from this case law.

F. THE DRAFT DIRECTIVE ON THE APPLICATION OF PATIENTS' RIGHTS IN F. CROSS-BORDER HEALTH CARE

In September 2006, the Commission started a consultation process and asked the Member States and other actors whether the EU legislature should become involved in the field of health services.[108] In its so-called Health Initiative, the Commission proposed to harmonize

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ternal Market, *in* FIDE XXIII CONGRESS LINZ 2008, CONGRESS PUBLICATION VOL. 3, at 381-82 (H. Koeck & M. Karollus eds.).

[105] Council Directive 2006/123 on Services in the Internal Market, 2006 O.J. (L 376) 36 (EC).

[106] However, the Commission points out that services that are not provided to a patient but to a health professional or to a hospital (such as accounting services and the provision of and maintenance of medical equipment) do fall within the scope of the Services Directive and are not excluded of its scope by Article 2(2)(f). *See* DIRECTORATE-GENERAL FOR INTERNAL MARKET AND SERVICES, HANDBOOK ON IMPLEMENTATION OF THE SERVICES DIRECTIVE 12 (2007), *available at* http://ec.europa.eu/internal_market/services/docs/services-dir/guides/handbook_en.pdf. Furthermore, it is put forward that the exclusion of health services only covers activities that are reserved to a regulated health profession. *Id.*

[107] Press Release, European Comm'n, Services Directive: Commission Puts Forward Amended Proposal (IP/06/442) (Apr. 4, 2006).

[108] *Communication from the Commission, Consultation Regarding Community Action on Health Services*, SEC (2007) 1195/4 (Sept. 26, 2006) [hereinafter *Community Action on Health Services*], *available at* http://ec.europa.eu/health/ph_overview/co_operation/mobility/docs/comm._health_services_comm2006_en.pdf. For a discussion of this regulation, *see, e.g.*, Frans Pennings, *Co-ordination of Social Security on the Basis of the State-of-Employment Principle: Time for an Alternative?*, 42 COMMON MKT. L. REV. 67 (2005).

certain matters related to cross-border health care. It was suggested that issues like liability and the provision of information could become subject to EU legislation.[109]

On April 20, 2007, the Commission published the results of this consultation process.[110] From these results it appeared that the case law of the ECJ gave rise to several problems—partly of a practical nature (for instance, lack of information) and partly of a legal nature (for example, questions related to liability). Therefore, many contributors shared the view of the Commission that some measures should be taken.[111] Yet, the opinions were divided as to the nature of the measures to be taken. The idea of the adoption of a specific directive on patient mobility was not supported by every Member State.[112] In this respect, it should be noted that for some Member States, the far-reaching consequences of the case law on the free movement of health services is hard to accept.[113]

In December 2007, the Commission announced that it intended to launch a draft legislative measure on patient mobility.[114] Due to some practical (and also perhaps political) problems, the launching of this proposal was postponed. On April 1, 2008 during a meeting with the Environment Committee of the European Parliament, the Commissioner for Health promised to publish a draft proposal in June 2008.[115] The Draft Directive on the Application of Patients' Rights in Cross-Border Health Care[116] was finally published on July 2, 2008.[117]

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[109] *Community Action on Health Services*, *supra* note 108, at 7-8.

[110] SUMMARY REPORT, *supra* note 41.

[111] *Id.* at 34.

[112] *Id.* at 34-35.

[113] As already stated, the official position of the U.K. is that it cannot be derived from the case law of the ECJ that patients may seek any non-hospital care in other Member States without prior authorisation. *Id.* at 15.

[114] Agenda, Top News from the Eur. Comm'n from 10 December to 6 January, at 11 (Dec. 7, 2007), *available at* http://europa.eu/rapid/pressReleasesAction.do?reference=AGENDA/07/43&format=HTML&aged=0&language=EN&guiLanguage=en

[115] Press Release, Eur. Parl., Summary of Hearing of Androula Vassiliou, Commissioner-designate for Health (Apr. 1, 2008), http://www.europarl.europa.eu/hearings/commission/2008/press/press_release_en.pdf.

[116] *Commission Proposal for a Directive of the European Parliament and of the Council on the Application of Patients' Rights in Cross-Border Healthcare*, COM (2008) 414 final (July 2, 2008) [hereinafter *Draft Directive*].

[117] *Id. See also* Europa – Public Health, New Commission Initiative on Patient's Rights in Cross-Border Healthcare, http://ec.europa.eu/health/ph_overview/co_operation/healthcare/proposal_directive_en.htm (last visited Oct. 24, 2008).

The objective of the Draft Directive is the establishment of a general framework for cross-border health care in the EU.[118] It contains some remarkable provisions. For example, pursuant to Article 5, the Member States—taking into account the principles of universality, access to good quality, equity, and solidarity—must clearly define quality and safety standards for health care provided on their territory and ensure that mechanisms are in place for guaranteeing that health care providers are able to meet such standards. Furthermore, Article 5 stipulates that compliance with the standards must be regularly monitored, health care providers give all patients necessary information, and patients have a means of making complaints and are guaranteed remedies and compensation when they suffer harm resulting from medical treatment. Moreover, Article 5 requires that Member States introduce systems of professional liability insurance, a guarantee, or similar arrangements. Additionally, the patient's fundamental rights to privacy regarding the processing of personal data and to equal treatment must be respected. In the author's opinion, Article 5 is a starting point for the development of basic principles and requirements for national health care systems in Europe. After all, it provides a common and general framework for the organization and delivery of health care.

Article 7 of the Draft Directive provides that a Member State may not subject to prior authorization the reimbursement of the costs of non-hospital care provided in another Member State. This requirement is in line with the settled case law of the ECJ.

Article 8 of the Draft Directive states that a Member State is allowed to provide for a system of prior authorization allowing for reimbursement of hospital care costs in other Member States, provided that the following conditions are fulfilled. First, the treatment concerned would have been assumed by the social security system of the other Member State if this treatment had been provided in its own territory. Second, the prior authorization scheme aimed at addressing the outflow of patients and preventing the serious undermining of (1) the financial balance of the national social security systems, (2) the planning and rationalization carried out in the hospital sector, (3) the maintenance of a balanced medical and hospital service open to all, and (4) the maintenance of treatment capacity or medical competence. According to Article 8, not all interests that may justify restrictions on the free movement of hospital services are mentioned by the ECJ in its case law. Judgments in

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[118] *Draft Directive*, *supra* note 116, at 4, 18.

cases such as *Smits-Peerbooms*, *Müller-Fauré,* and *Watts* focus mainly on arguments of planning and financial balance. In response to such arguments, the Draft Directive adds arguments such as a balanced medical and hospital service, maintenance of treatment capacity, and medical competence. From the perspective of the Member States, it could be argued that Article 8 broadens their possibilities to protect their hospital sectors.

Yet, it should also be noted that this provision adds a requirement to the assessment of prior authorization schemes, in the context of hospital care, which has not played a (significant) role thus far in ECJ case law. Under the Draft Directive, Member States may only protect their hospital sectors if the outflow of patients is capable of seriously undermining one of the interests mentioned above (e.g., financial balance, etc.). In its case law, the ECJ has not examined whether the outflow of patients may seriously undermine a national scheme of hospital care. It has simply put forward that the free movement of hospital services may be restricted, provided that the patient concerned can be treated without undue delay by a Member State hospital. In the view of the ECJ, hospital care must be subjected to an advanced system of planning. In this regard, the ECJ presupposes the serious undermining of hospital care as soon as a patient seeks treatment abroad. From this perspective, the Draft Directive limits the possibilities of the Member States to protect their hospital sectors.

Comparable to the second generation of ECJ case law discussed in Part I, Section B of this article, the Draft Directive sets rules which aim to facilitate cross-border health care. For instance, Article 6 elaborates on the case law dealing with reimbursement rates (such as the above mentioned judgments *Vanbraekel* and *Watts*). Furthermore, Article 9 formulates procedural guarantees regarding administrative procedures on the use of health care in another Member State. These procedures must, for example, be based on objective, non-discriminatory criteria which are published in advance and are necessary and proportionate. It could be argued that the provision aims at codifying the ECJ case law dealing with the procedures and conditions regulating the granting of prior authorizations. In addition, in my opinion, Article 12 of the Draft Directive is rather remarkable. It obliges Member States to set up national contact points for cross-border health care. Consequently, Member States are forced to encourage their citizens to consider undergoing medical treatment in other Member States.

The Draft Directive provides mechanisms for cooperation on health care between the competent authorities. Pursuant to Article 15, Member States must, for instance, facilitate the development of European reference networks of health care providers. The objective of these networks is *inter alia* to help to realize the potential of European reference networks regarding highly specialized health care and to help to promote access to high quality and cost-effective health care for all patients with special medical conditions. Another noteworthy provision of the Draft Directive is Article 14; prescriptions issued by an authorized person in another Member State for a named patient can be used in the territory of the Member State where the patient resides.

At the time this article was written (during the second half of 2008), the position taken by the Member States and other actors towards the Draft Directive was not yet clear. However, it goes without saying that this draft will be much debated and (probably even heavily) amended before it will be adopted.

G. OTHER HEALTH CARE INITIATIVES

In October 2007, the Commission published the White Paper "Together for Health: A Strategic Approach for the EU 2008-2013."[119] In that document, the Commission put forward several objectives for EU health policy: fostering good health in an aging Europe, protecting citizens from health threats, and supporting the development of dynamic health systems and new technologies.[120] The White Paper also stressed that issues of health policy should be integrated in other policy fields and, in order to realize this goal, "Health in All Policies" (HIAP) was launched.[121] The aim of he HIAP approach is to strengthen integration of health concerns into all policies at Community, Member State, and regional levels.

This integrated approach is already prescribed for in Article 152(1) of the EC Treaty, which provides that a high level of human health protection must be ensured in the definition and implementation of all EU policies and activities. Yet, the HIAP method not only encompasses the accommodation of health care objectives in other EU areas, but also encourages the involvement of new partners, such as non-

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[119] *Commission White Paper Together for Health: A Strategic Approach for the EU 2008-20013*, COM (2007) 630 final (Oct. 23, 2007).

[120] *Id.* at 7-10.

[121] *Id.* at 6.

governmental organizations (NGO's), industry, academia, and the media in EU health policy. [122] In other words, the Commission is attempting to set up a health care network consisting of both public authorities of the Member States and private actors at the EU level.

On March 25, 2008, the Commission launched a public consultation on patient safety. After this consultation, the Commission plans to publish a proposal for general patient safety issues.[123] The Commission puts forward that the aim of the proposal will likely be twofold. In the first place, the proposal will attempt to support Member States in their efforts to minimize harm to patients from adverse events in their health systems.[124] In the second place, the proposal will strive to improve the confidence of EU citizens about receiving good information on levels of safety and available redress in the EU health system.[125] This information must concern the activities of both health care providers in their own country and health care providers in other Member States.

H. EVALUATION

Consequently, although Article 152(5) of the EC preserves the organization of health services and medical care to the Member States, the Commission is working on a EU health policy that will have considerable impact on the organizational structure of the national health care systems. After stating that it wants to cooperate closely with the Member States in order to achieve the health care objectives of the Strategic Approach, the Commission suggested that it will come up with a "Structured Cooperation Implementation Mechanism."[126] Therefore, there is a chance that national health polices will be increasingly interlinked with the health policy developed at EU level. Furthermore, the Commission reaffirms that it intends to issue a framework for health services,[127] the aim of which is to further support areas where EC action can add value

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[122] *Id.*

[123] The Commission, however, pointed out in March 2008 that there is already legislation on issues related to patient safety at EU level. The Commission refers, *inter alia*, to Directives in the field of medical devices. *See* Europa-Public Health, Commission Launch of an Open Consultation on Public Safety, http://ec.europa.eu/health/ph_overview/patient_safety/consultation_en.htm (last visited Nov. 3, 2008).

[124] *Id.*

[125] *Id.*

[126] *Commission White Paper Together for Health*, supra note 119, at 10.

[127] *Commission Staff Working Document – Document Accompanying the White Paper Together for Health: A Strategic Approach for the EU 2008-2013*, at 19-20, SEC (2007) 1376.

(such as developing European networks of reference centers ensuring that patients have access to highly specialized care) and to clarify the application of EU law to health services.

Hence, EU law and policy measures developed by the Commission are creeping into national health law. A case in point is the remark on good governance made in the document containing the Impact Assessment of the Strategic Approach of the Commission.[128] Good governance is needed and therefore a coherent framework overarching all EU measures and documents with regard to health must be developed at the EU level. It is possible that such a framework will not only touch all sectors of EU health policy, but also national health care systems; it could be capable of setting references and standards that national health care policy makers will respond to.

It is clear that the ECJ's case law on patient mobility gave a significant boost to the expansion of EU health policy. It enables the Commission to start building a coherent framework for health care at the EU level.

Nevertheless, these developments are not in line with the ambitions of some Member States to revitalize the principle subsidiarity.[129] These ambitions are reflected in the drafting process of the Treaty of Lisbon (also known as the Reform Treaty). For instance, a protocol on the application of the principles of subsidiarity and proportionality is annexed to the Treaty.[130] The protocol introduces a procedure according to which national parliaments may intervene in the decision process at the EU level, if the principles of subsidiarity and proportionality are at stake in the view of these parliaments. However, in this regard, it must be noted that the status of the Treaty of Lisbon, including its protocols, was unclear at the moment that this contribution was written (second half 2008), because the people of Ireland, via referendum, voted against the treaty on June 13, 2008.[131]

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[128] *Commission Staff Working Document – Accompanying Document to the White Paper Together for Health: A Strategic Approach for the EU 2008-2013*, at 20, SEC (2007) 1374.

[129] According to the principle of subsidiarity, the Community shall take action ". . . only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States and can therefore, by reason of scale or effects of the proposed action, be better achieved by the Community." EC Treaty art. 5.

[130] Treaty of Lisbon, *supra* note 1, at C 306/150-51.

[131] Statement by José Manuel Barroso, President, European Comm'n, following the Irish Referendum on the Treaty of Lisbon (June 13, 2008), *available at* http://ec.europa.eu/commission_barroso/president/pdf/statement_20080613.pdf.

It could be argued that while drafting EU measures, the Commission should take into consideration the feelings of many national governments regarding the division of powers between the EU and its Member States. Otherwise, there exists the danger that several proposals submitted by the Commission to the Council and the European Parliament will be voted down.

II. COMPETITION LAW AND HEALTH CARE

Another EU regime that is capable of stimulating cross-border health care is competition law. This regime is laid down in Articles 81 and 82 of the EC, and in the Merger Control Regulation.[132] Patients could challenge restrictive measures taken by institutions such as sickness funds and insurance companies by claiming that these measures are contrary to EU competition rules. For instance, if insurance companies have agreed not to reimburse the costs related to cross-border care, a successful lawsuit against such an agreement may lead to a ruling that the practice is in violation of the cartel prohibition. Such a ruling might enable patients to receive health services abroad eventually. Consequently, from a theoretical point of view, the EU competition rules could foster patient mobility as firmly as the Treaty provisions on free movement do now.

Since private entities such as insurers, hospitals, and doctors play a significant role in health care, one may even expect that competition law is more appropriate than the EU free movement regime, in addressing issues of cross-border care. From the perspective of the framers of the original European Economic Community Treaty (Treaty of Rome), the competition rules are directed at undertakings—i.e., private parties—whereas the free movement provisions are aimed at regulating measures taken by Member States—i.e., public authorities. On the one hand, there is no denying that the demarcation between these regimes has been blurred. This is due in large part to the fact that the ECJ has developed concepts like the horizontal effect of some Treaty provisions on free movement,[133] which enables a private party to invoke a free movement

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[132] Council Regulation 139/2004 on the Control of Concentrations Between Undertakings (the EC Merger Regulation), 2004 OJ (L 24) 1.

[133] *See, e.g.*, Bosman, 1995 E.C.R. I-4921; Case C-281/98, Angonese v. Cassa di Risparmio de Bolzano SpA, 2000 E.C.R. I-4139; Joined Cases C-51/96 & C-191/97, Deliège v. Ligue Francophone de Judo et Disciplines Associées, 2000 E.C.R. I-2549; Case C-176/96, Lehtonen v. Fédération Royale Belge des Sociétés de Basketball, 2000 E.C.R. I-2681; Case C-438/05, Int'l. Transp. Workers' Fed'n v. Viking Line ABP, 2008 E.C.R. ___ (Dec. 11, 2007); and Case C-

rule vis à vis another private party, and the "useful effect" norm,[134] which applies the competition regime to measures stemming from state bodies. On the other hand, one might expect that, if "the state oriented free movement rules" increasingly contribute to the free movement of health services, the same will be true for EU competition law.

However, the ECJ's case law on the application of the competition rules to health care is far less expansive than its case law on free movement and cross-border health care. It appears that the ECJ is rather reluctant to make health care issues subject to competition law. This conclusion can be derived from its case law on the concept of undertakings.

The following section begins with a discussion of the rulings of the European courts with regard to the concept of undertakings. Then, an examination of the relationship between the substantive EU competition rules and cross-border care will follow.

A. THE CONCEPT OF UNDERTAKINGS

The subject matter of the prohibitions laid down in Articles 81 and 82 of the EC are undertakings.[135] According to settled ECJ case law, every entity engaged in an economic activity should be regarded as an undertaking.[136] Furthermore, economic activities are defined as the offering of goods or services on the market.[137] However, the exercise of competences that are typical of the public domain ("state prerogatives") does not amount to an economic activity.[138] Moreover, in social security cases, the ECJ has developed an approach that departs from the question of

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341/05, Laval un Partneri Ltd. v. Svenska Byggnadsarbetareförbundet, 2008 E.C.R. ___ (Dec. 18, 2007).

[134] *See, e.g.*, Case 267/86, Van Eycke v. ASPA NV, 1988 E.C.R. 4769; Case C-245/91, Criminal Proceedings against Ohra Schadeverrzekeringen NV, 1993 E.C.R. I-5851. According to this case law, Article 85 in conjunction with Article 5 of the EC Treaty prohibits Member States from depriving Article 81 or Article 82 of their useful effect. Such will be the case if a Member State requires or favours the adoption of agreements, decisions, or concerted practices in violation of Article 81 or reinforces their effects, or deprives its own legislation of its official character by delegating to private companies the responsibility for taking decisions affecting the economic sphere.

[135] Undertakings are companies or enterprises. The official term used in Articles 81 and 82 of the EC Treaty is "undertaking."

[136] *See, e.g.*, Case C-41/90, Höfner v, Macrotron GmbH, 1991 E.C.R. I-1979.

[137] *See, e.g.*, Case 118/85, Comm'n v. Italy, 1987 E.C.R. 2599.

[138] *See, e.g.*, Case C-364/92, SAT Fluggesellschaft mbH v. European Org. for the Safety of Air Navigation, 1994 E.C.R. I-43; Case C-343/95, Diego Calí v. Servizi Ecologici Porto di Genova SpA, 1997 E.C.R. I-1547.

how significant the role of the principle of solidarity is.[139] It has instead scrutinized how much room a national social security scheme leaves for competition in the implementation of a social security scheme, and what role the principle of solidarity plays.[140] When a social security scheme is almost completely based on solidarity, the institution managing the scheme cannot be regarded as an undertaking.[141] In contrast, if the implementation of a social security scheme is based on a mix of competition and solidarity elements, the institutions concerned do perform an economic activity and can, as a result, be seen as an undertaking.[142]

The ECJ has applied this approach towards the concept of undertakings in health care in several cases.[143] It is the author's belief that a distinction should be made between (1) rulings with regard to the question of whether entities administrating health care systems are engaged in economic activities and (2) rulings where it is decided whether this is the case with respect to health care providers.

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[139] *See, e.g.*, JOSE LUIS BUENDIA SIERRA, EXCLUSIVE RIGHTS AND STATE MONOPOLIES UNDER EC LAW 52-56 (Andrew Read trans., 1999).

[140] *See, e.g.*, Vassilis G. Hatzopoulos, *Killing National Health and Insurance Systems but Healing Patients? The European Market for Health Care Services after the Judgments of the ECJ in* Vanbraekel *and* Peerblooms, 39 COMMON MKT. L. REV. 683, 710-13 (2002); Elias Mossialos & Martin McKee in collaboration with Willy Palm, Beatrix Karl, & Franz Marhold, *The Influence of European Union Law on the Social Character of Health Care Systems in the European Union* (Nov. 19, 2001), *in EU Law and the Social Character of Health Care*, 38 WORK & SOCIETY 98 (2002); Sybille Sahmer, *Krankenversicherung in Europa: Die wettbewerbsrechtliche Stellung der Kranken- und Pflegeversicherungsträger im Bereich der freiwilligen Versicherung* [*Health Insurance in Europe: The Competition-Legal Position of the Ill and Nursing Care Insurance Carriers within Range of the Voluntary Insurance*], *in* 8 BONNER EUROPA-SYMPOSIUM, Die Krankenversicherung in der Europäischen Union [The Health Insurance in the European Union] 53 (1997).

[141] *See, e.g.*, Joined Cases C-159 & C-160/91, Poucet v. Assurances Générales de France, 1993 E.C.R. I-637; Case C-218/00, Cisal di Battistello Venanzio v. Istituto Nazionale per l'Assicurazione contro gli Infortuni sul Lavoro, 2002 E.C.R. I-691. *Cf.* UNIVERSITY LIBRE DE BRUXELLES & KATHOLIEKE UNIVERSITEIT LEUVEN, INTERNAL MARKET AND HEALTH CARE: A NEW BALANCE? 49 (Sept. 26, 2006), *available at* http://www.law.kuleuven.ac.be/int/europees/Nederlands/Onderzoek/Onderzoeksprojecten/health_services_co157 en.pdf; Davies, *supra* note 99, at 98-100.

[142] *See, e.g.*, Case C-244/94, Fédération Française des Sociétés d'Assurance v. Ministére de l'Agriculture et de la Pêche, 1995 E.C.R. I-4013 [hereinafter FFSA]; Case C-67/96, Albany Int'l BV v. Stichting Bedrijfspensioenfonds Textielindustrie, 1999 E.C.R. I-5751; Joined Cases C-115, C-116 & C-117/97, Brentjens' Handelsonderneming BV v. Stichting Bedrijfspensioenfonds voor de Handel in Bouwmaterialen, 1999 E.C.R. I-6025; and Case C-219/97, Maatschappij Drijvende Bokken BV v. Stichting Pensioenfonds voor de Vervoer-en Havenbedrijven, 1999 E.C.R. I-6121.

[143] *See* Hatzopoulos, *supra* note 140, at 703-10.

1. THE CONCEPT OF UNDERTAKINGS AND BODIES ADMINISTRATING HEALTH CARE SYSTEMS

The leading case on the application of the concept of undertakings to managing bodies such as sickness funds is *AOK Bundesverband and others v. Ichthyol-Gesellschaft Cordes, Hermani & Co. and others (AOK)*.[144] At issue in *AOK*, was the question of whether sickness funds were engaged in economic activities in Germany. These funds entered into agreements on the reimbursement rates of medicines purchased by patients. The agreements were part of the German health care system. In the first stage, the Federal Committee of Doctors and Sickness Funds had to decide for which groups of medical products fixed maximum amounts must be determined. In the second stage, the funds jointly determined the uniform fixed maximum amounts applicable to these groups of medicines. This procedure is an example of the "consultative" structure of the German health care system.[145]

The involvement of bodies operating independently from the government made this system vulnerable to litigation. To a certain extent, it is remarkable that the first case in which the German system was challenged in light of European competition law was brought before the ECJ not earlier than the beginning of this millennium. Pharmaceutical undertakings claimed that the agreements on the fixed amounts were contrary to the cartel prohibition of Article 81 of the EC. The competition rules of the EU provided them with legal arguments to contest the decisions on the rates of these amounts. As soon as they were of the opinion that the rate level did not match their expectations, they could challenge the decisions made by the German sickness funds by invoking EU competition law.

Since the consultative structure is a significant feature of the German health care system, the organization of this system was at stake. If the ECJ had found that the agreements concerned were in violation of Article 81 of the EC, this would have forced Germany to change constitutive elements of its health care system. As a result, the ECJ was con-

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[144] Joined Cases C-264, C-306, C-354 & C-355/01, AOK Bundesverband v. Ichthyol-Gesellschaft Cordes, 2004 E.C.R. I-2493 [hereinafter AOK].

[145] *See* Geert Jan Hamilton, Case Comment on the *AOK* Ruling, 3 TIJDSCHRIFT VOOR GEZONDHEIDSRECHT [J. HEALTH L.] 244, 244-58 (2004).

fronted with a politically sensitive question of how to strike a balance between the effective application of EU competition law and the Treaty principle of respecting the national organization of health care.

In his opinion in the *AOK* case, Advocate General Jacobs developed a sophisticated approach towards this question. On the one hand, he argued that the sickness funds were engaged in economic activities and that their agreements restricted competition. On the other hand, he was of the opinion that this restriction could be justified by Article 86(2) of the EC.[146] According to that Treaty provision, undertakings entrusted with special tasks may hinder competition (or free movement), provided that the proportionality principle has been met. The Advocate General suggested deploying a rather loose test with regard to this principle. He argued that, given the fact that EU law accords Member States the freedom to organize their health care systems, which implies a wide margin of discretion, the setting of fixed amounts only fall outside the scope of Article 86(2) of the EC if this method of determining the rates for reimbursement could be shown to be manifestly disproportionate.[147] Basically, the approach proposed by the Advocate General boiled down to a so-called "light control regime" that only disallowed exceedingly restrictive agreements concluded in the framework of the German health care system. According to this approach, the sickness funds are not totally "immune" from the application of the competition rules, but they are subject to a certain degree of judicial review in the light of those rules.

However, the ECJ opted for another solution in its judgment in the *AOK* case. It solved the tension between the effective application of the EU competition rules and the national organization of health care by completely respecting the regulatory powers of the Member States: In the view of the ECJ, the German sickness funds were not engaged in economic activities and, as a result, their agreements did not need to be reviewed in terms of European competition law.[148] Accordingly, the agreements that were challenged by the pharmaceutical companies were immune from the application of EU competition law.

In order to establish that the German sickness funds were not undertakings, the ECJ applied the principles that it had developed in its case law on social security schemes and competition. As already mentioned, this implies that the ECJ examined the role that solidarity plays in

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[146] *See* Opinion of Advocate General Jacobs, AOK, 2004 E.C.R. I-2493, paras. 24-103.

[147] *Id.* para. 95.

[148] *See* AOK, 2004 E.C.R. I-2493, paras. 45-65.

the social security scheme.[149] The ECJ based its decision (that German sickness funds are not undertakings) on three arguments.

First, the ECJ stressed that the benefits to which affiliated persons are entitled are fixed by the state as the funds are compelled by law to offer their members essentially identical obligatory benefits.[150] These benefits do not depend on the amount of the contributions.

Second, the ECJ held that the German sickness funds did not aim to make a profit. This consideration is remarkable because in a previous ruling, *FFSA*,[151] the ECJ held that bodies not aiming to make a profit could nevertheless be engaged in economic activities. From this ruling it could be derived that profit-making was not an element constituting the concept of undertakings. Nevertheless, it could be argued that, based on *AOK*, this element has made a come back.

Third, the ECJ referred to the system of risk equalization (*Solidargemeinschaft*) the German sickness funds were engaged in.[152] Funds whose health expenditure is high for the reason that they insure less healthy people (so called "high risks") are compensated for those risks by funds to which healthier persons are associated. It cannot be denied that in a risk equalization scheme the solidarity principle plays a key role.

On first impression, the decision of the ECJ seems to be based upon sound analysis. However, in the *AOK* judgment some astounding considerations can be found. It should be noted that the German sickness funds were free to set their own contribution rates. Consequently, the amount of the contributions to be paid by the insured persons differed from sickness fund to sickness fund. Unsurprisingly, German internet sites encourage people to switch to cheaper health insurers.[153]

The position that the ECJ took, regarding the freedom to set contribution rates is, at least for the author, hard to understand. The ECJ felt that the fact that sickness funds were engaged in some competition did not call into question the conclusion that they were not undertakings.[154] The ECJ went on to say that the German legislature introduced an ele-

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[149] *Id.* para. 51.

[150] *Id.* para. 52.

[151] FFSA, 1995 E.C.R. I-4013, para. 21.

[152] AOK, 2004 E.C.R. I-2493, paras. 53.

[153] *See, e.g.*, Health Insurance in Germany, http://www.billigerkrankenversichert.de/international/health-insurance.htm (last visited Nov. 3, 2008).

[154] AOK, 2004 E.C.R. I-2493, paras. 56-57.

ment of competition in order to stimulate the funds to operate in the most effective and least costly manner possible.[155] Considering that the legislature's aim was to promote the proper functioning of the German health care system, it could not be argued, according to the ECJ, that the nature of the sickness funds activities had changed. The author cannot support such a line of reasoning. After all, competition law is all about enhancing efficiency, which implies that as soon as a national legislature introduces elements of competition into a social security system, the competition rules should be applied to bodies managing that system. In the author's judgment, competition law must be regarded as the rules of the game for privatized sectors. Efficiency will only be enhanced if the key actors are required to observe the cartel prohibition, the prohibition on the abuse of dominant position, and the merger control regime.

Therefore, the author cannot help but think that the ECJ's decision in the *AOK* case was politically driven. Consultative mechanisms play a key role in German health care. If agreements concluded between sickness funds were caught by the EU competition rules, this would have endangered the proper functioning of the German system. Therefore, the ECJ shied away from a logical and consequent application of the EU competition rules to German sickness funds. The ECJ concluded, therefore, that even the so-called "light regime" that was proposed by the Advocate General—and would only have implied a ban on extremely restrictive practices—went too far.

The *AOK* approach gives rise to a remarkable conclusion: The free movement rules, which were originally directed at Member States, force sickness funds to consider whether the costs of certain cross-border health services should be reimbursed. However, the main aim of EU competition law, which is to regulate the conduct of private actors, does not impose such duties upon them.[156]

This somewhat remote approach towards the application of EU competition law in health care was confirmed in the *FENIN* cases.[157] Here, at issue was the question of whether bodies managing health care system should observe competition law when purchasing goods or ser-

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[155] *Id.*

[156] *Cf.* Markus Krajewski & Martin Farley, *Non-Economic Activities in Upstream and Downstream Markets and the Scope of Competition Law after* FENIN, 32 EUR. L. REV. 111, 118 (2007).

[157] *See* Case C-205/03 P, Federación Española de Empresas de Tecnología Sanitaria v. Comm'n, 2006 E.C.R. I-6295, paras. 26-37 [hereinafter FENIN (2006)]; Case T-319/99, Federación Española de Empresas de Tecnología Sanitaria v. Comm'n, 2003 E.C.R. II-357, paras. 25-26 [hereinafter FENIN (2003)].

vices. A decision taken by the Commission was challenged in this case, which meant that this case was not only subject to review by the ECJ but also by the Court of First Instance (CFI).

FENIN concerned the purchase activities of the Spanish NHS. Since, in a NHS system, the managing bodies are obliged to provide health care free of charge, it was not a surprise that in the view of both the CFI and the ECJ these bodies were not undertakings within the meaning of EU competition law. In such a system, the principle of solidarity is predominant and the NHS entities do not compete with each other.[158]

However, this point of view does not exclude the possibility that they do fall within the scope of competition law when they purchase goods or services from enterprises on the market. The purchase policy of entities such as NHS bodies or sickness funds have a considerable influence on various markets, since many suppliers of medical goods and providers of medical services are highly dependent upon them. If health care suppliers or providers are not engaged in business relations with these bodies, they are probably not able to operate on the market at all. Additionally, in many EU Member States, policy makers introduce incentives in the health care sector in order to enhance the functioning of purchase markets (markets on which health insurers and NHS bodies operate as purchasers).

If the ECJ and CFI had decided that the Spanish NHS bodies were undertakings as far as their purchasing activities were concerned, the outcome of the *AOK* case would have been mitigated.[159] However, both Community courts held that when an entity does not apply the purchased goods or services to a market on which it offers products itself, this entity is not an undertaking.[160] Accordingly, the status of the purchasing entity is entirely dependent upon the subsequent application of the goods and services it has acquired. The consequences are clear: bodies managing health care schemes in which the principle of proportionality is predominant are not subject to competition law neither when providing services to affiliated persons nor when buying products in order to carry out this task.

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[158] *See also* Andreas Bartosch, *Social Housing and European State Aid Control*, 28 EUR. COMPETITION L. REV. 563, 565 (2007).

[159] Somaya Belhaj & Johan W. van de Gronden, *Some Room For Competition Does not Make a Sickness Fund An Undertaking*, 25 EUR. COMPETITION L. REV. 682, 685 (2004).

[160] *See* FENIN (2006), 2006 E.C.R. I-6295, paras. 25-27; FENIN (2003), 2003 E.C.R. II-357, paras. 35-44.

However, bodies managing health care systems do not, as a rule, fall outside the scope of EU competition law. In fact, in relation to social health care schemes, the ECJ applies a concrete test: The applicability of competition law depends upon the way in which these schemes are modeled by the Member States. Consequently, if the national legislature has opted for a system which leaves much room for competition, these bodies must be regarded as undertakings within the meaning of EU competition law. For instance, in the Netherlands, since 2006, private insurance companies are the managing bodies of the Dutch health care system.[161] In carrying out this task, they are allowed to be for-profit. Accordingly, it may be assumed that these entities are engaged in economic activities. As soon as the Member States of the EU make their health care systems subject to a process of opening up, EU competition law provides the relevant framework for reviewing the agreements and other restrictive practices of health insurers. However, the "semi-private" health care system of the Netherlands is rather unique in Europe, because in other Member States public bodies and state authorities still play a dominant role. As a result, EU institutions do not have much experience in applying EU competition rules (e.g., anti-trust law, state aid, etc.) to health insurers.

2. THE CONCEPT OF UNDERTAKING AND HEALTH CARE PROVIDERS

Are providers of health care, like doctors and hospitals, undertakings within the meaning of Article 81 of the EC? It is apparent from cases like *Pavlov and Others v. Stichting Pensioenfonds Medische Specialisten*[162] that the ECJ applies a different test to these entities than it does to social security and health care schemes.

In *Pavlov*, the ECJ held that medical specialists are engaged in economic activities (in their capacity as self-employed economic operators) because they provide services for remuneration. The ECJ simply applied the "undertaking qualification" based on the fact that these doctors are paid by their patients (or their health insurers) for the services they provide, whereas these doctors have to bear the financial risks at-

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[161] This system is introduced by the Zorgverzekeringswet [Health Insurance Act]. For a brief description of this bill, see Geert Jan Hamilton, *A new Private Universal Health Insurance in the Netherlands, in* A. DEN EXTER, COMPETITIVE SOCIAL HEALTH INSURANCE YEARBOOK 2004, 8 (2005).

[162] Joined Cases C-180 & C-184/98**,** Pavlov v. Stichting Pensioenfonds Medische Specialisten, 2000 E.C.R. I-6451.

tached to the pursuit of these activities.[163] It is remarkable that the ECJ did not scrutinize the legal framework that was applicable to the medical specialists. For example, the ECJ did not examine whether this legal framework included enough room for competition or whether the principle of proportionality was predominant in this framework. Furthermore, the professional organization that the medical specialists were associated with was regarded as an association of undertakings despite the fact that it was governed by national public law.[164] The ECJ ruled that because this organization was not composed of a majority of representatives of public authorities and because it was not obliged to observe various public-interest criteria, it did fall within the scope of EU competition law.[165]

The ECJ followed a similar approach in *Ambulanz Glöckner v. Landkreis Südwestpfalz*.[166] At issue there was, *inter alia*, the question of whether medical aid organizations to which public authorities have delegated the task of providing a public ambulance service must be regarded as undertakings in the sense of EU competition law. As in *Pavlov*, the ECJ based its conclusion (that the entity at hand was engaged in an economic activity) on the finding that medical services concerned were provided for remuneration.[167] Moreover, it was stressed that these activities were not always and were not necessarily, carried out by public bodies.[168] It appeared from the files submitted to the Court that, in the past, private organizations provided ambulance services. Thus, the ECJ counted the possibility that the service at hand could possibly be provided on the market of great importance.

Quite remarkably, in the ECJ's view, the legal framework applicable to ambulance services and the way these services were modeled by the national legislature were not relevant. The ECJ explicitly stated that public service obligations may render the services at issue less competitive than comparable services rendered by operators not bound by such obligations, but that fact did not call into question the conclusion that these services do not constitute economic activities.[169]

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[163] *Id.* para. 76.

[164] *See id.* paras. 71-89.

[165] *Id.* para. 88.

[166] Case C-475/99, Firma Ambulanz Glöckner v. Landkreis Südwestpfalz, 2002 E.C.R. I-8089 [hereinafter Ambulanz Glöckner].

[167] *Id.* para. 20.

[168] *Id.*

[169] *Id.* para. 21.

So, when it comes to the question of whether health care providers are undertakings, in *Ambulanz Glöckner,* the ECJ deviated from its previous approach developed in cases such as *AOK* and *FENIN*. The ECJ did not look at the concrete legal framework that was applicable to those health care providers, but rather examined whether the medical services concerned could be provided on the free market.

Is it possible that these services are offered to end users via market mechanisms? If this is the case, the providers of these services do fall within the scope of competition law. To the author it seems that one could argue that, in an abstract way, the ECJ is examining whether health care providers are engaged in economic activities. Hence, the approach towards the application of the concept of undertakings to health care providers is dependent upon an abstract test. In contrast, as has already been advanced, the ECJ addresses the question of the concept of undertaking with regard to bodies managing health care schemes by taking into consideration the concrete (legal) framework, which boils down to the application of a concrete test.

Consequently, health care providers are more often than not confronted with the application of EU competition law than are bodies managing health care schemes. In the author's view, a judgment on competition law and health care providers is less capable of affecting the national health care organization than rulings in the field of competition law and managing bodies. After all, the position of these bodies is at the heart of the organization of the provision of health care as they decide on the reimbursement of medical treatment. Accordingly, at the present stage of the European integration process, EU competition law does not have much influence on cross-border health care. The ECJ is probably attempting to strike a balance between the internal market and national health care authorities. By applying the Treaty provisions on free movement to cross-border health care it takes account of the "internal market interest" and by exempting managing bodies from the scope of EU competition law, it observes the "health care organization powers" of the Member States.

Therefore, it cannot be ignored that rulings like *AOK* are politically driven. By examining whether the principle of solidarity is predominant in a national health care scheme, the Community courts are essentially basing their decisions in part on the perceived will of the national legislature. Competition law provides the rules of the game for

privatized sectors.[170] If a national legislature has introduced enough elements of competition in its health care system, the EU competition rules are applicable. If the national legislature did not intend to introduce a considerable amount of competition into such a system, the managing bodies did not fall within the ambit of the EU competition rules.

B. EU COMPETITION LAW AND HEALTH CARE

It is not a surprise that only a few precedents on the application of EU competition law to matters of cross-border care are available. Nevertheless, some cases are worth mentioning. First, this section will look at rulings on competition law and health care. Second, this section will discuss cases where EU competition law is applied to managing bodies that do fall within the scope of this field.

1. COMPETITION LAW AND HEALTH CARE PROVIDERS

In cases like *Pavlov* and *Ambulanz Glöckner*, policy measures with regard to health care providers were assessed in the light of EU competition law. However, *Pavlov* will not lead to more cross-border care, because it concerned agreements between medical specialists with regard to their pension schemes. Furthermore, according to the ECJ, these agreements did not violate Article 81 of the EC, as they did not restrict competition in an appreciable way.

In this regard, *Ambulanz Glöckner* is of more interest, since in that case, the ECJ dealt with an exclusive right given by a German federal state to a public undertaking to provide emergency ambulance services. As a result, other undertakings were not entitled to carry out these activities: both domestic providers and providers established in other Member States were prevented from entering the market. Hence, in *Ambulanz Glöckner*, the issue of cross-border care was approached from the "supply side" angle of health care (and not, like in free movement judgments, from the "demand side" angle, i.e., the patients).

In *Ambulanz Glöckner*, the market for emergency transport was reserved for one particular party. In contrast, state authorities could give other companies access to the market for non-emergency transport. However, before state authorities granted an authorization for this type of

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[170] Johan W. van de Gronden, *Purchasing Care: Economic Activity or Service of General (Economic) Interest?*, 25 EUR. COMPETITION L. REV. 87 (2004).

transport, they consulted the undertaking entrusted with the task of performing emergency ambulance services. If this undertaking regarded such an authorization as a danger to its special task (i.e., to transport patients in case of emergency), the German federal state refused to grant authorization to the applicant. Although this practice did fall within the scope of Article 86 (1) of the EC, which prohibits Member States from granting exclusive rights that are in violation of, *inter alia*, the prohibition on the abuse of a dominant position, the ECJ held that the exclusive right concerned was justifiable in the light of Article 86(2) of the EC. Pursuant to this provision, special rights violating the EU rules on competition were allowed, provided that they were necessary for a special task entrusted to the undertaking by a public body.

The proportionality principle must also be observed. In *Ambulanz Glöckner*, the ECJ took the position that the exclusive rights at hand were in accordance with this principle, enterprises had to be prevented from only offering transport by ambulance in non-urgent cases in urban areas, so that the undertaking that is entrusted with task of the overall ambulance transport would not be able to profitably offer its services in urgent cases during the night and in rural areas.[171]

It is apparent from the ruling in *Ambulanz Glöckner* that in other cases where EU competition law is applicable, the national authorities enjoy a wide margin of discretion. After all, it is clear that the ECJ did not apply a strict proportionality test in *Ambulanz Glöckner* in that it allowed the undertaking entrusted with the task of the emergency ambulance transport to monopolize the market for non-emergency transport.

Thus, under EU competition law, it is not very difficult for a Member State to restrict cross-border health care offered by providers established in other Member States. Apparently, the concept of Services of General Economic Interest, as provided in Article 86(2) of the EC, gives Member States the opportunity to regulate the national organization of the delivery of health care services in a far-reaching way. Consequently, at the present stage of the European integration process, EU competition law does not preclude Member States from introducing certain restraints on competition in their health care systems.

Furthermore, according to Article 87(1) of the EC, Member States are not allowed to give state aid to undertakings. The Commission is, however, able to approve financial advantages given to enterprises on the basis of Article 87(3) of the EC (which also mentions interests such

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[171] *See Ambulanz Glöckner*, 2001 E.C.R. I-8089, paras. 57-64.

as a significant project of common European interest, the development of certain economic activities or of certain economic areas, and culture) and Article 86(2) of the EC. Article 88(3) of the EC requires Member States to notify to the Commission of state aid measures before implementing them (the so-called "standstill principle").[172] In this respect, it should be noted that the ECJ has developed a special approach towards financial compensations for the performance of public service obligations.

In *Altmark Trans GmbH and Regierungspräsidium Magdeburg v. Nahverkehrsgesellschaft Altmark GmbH*,[173] the ECJ held that benefits granted by Member States to an undertaking entrusted with the execution of public service obligations do not constitute state aid, provided that the following four conditions are fulfilled (1) the undertaking is charged with the execution of a clearly defined public service obligation, (2) the parameters of the amount of the compensation are established objectively and transparently, (3) the compensation is proportionate, and (4) in the case of a public contract, the amount of the compensation is determined on the basis of the expenses a well run undertaking would have incurred.[174] If national compensation measures fulfill these conditions, they are not regarded as state aid and the Commission does not need to be notified of them.

In the author's view, the concept of public service obligations shares many similarities with services of general economic interest, as provided in Article 86(2) of the EC.[175] After all, the point of departure for both concepts is that a special task is entrusted to the undertaking by a public authority. The main difference is that the second and fourth condition of *Altmark* (the criterion related to objective and transparent parameters respectively, the criterion regarding the benchmark of the costs of a well-run company) do not play a key role in the ECJ's assessment under Article 86(2) of the EC.

Due to the fact that health services are often regarded as services of general economic interest in the EU (*Ambulanz Glöckner*), it is not a surprise that the concept of public service obligations is applied in health care as well. In 2005, the Commission adopted a Decision that elabo-

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[172] *See, e.g*, Case C-39/94, Syndicat Français de l'Express Int'l v. La Poste, 1996 E.C.R. I-3547.

[173] Case C-280/00, Altmark Trans GmbH v. Nahverkehrsgeselschaft Altmark GmbH, 2003 E.C.R. I-7747 [hereinafter Altmark].

[174] *See id.* paras. 88-93.

[175] *See, e.g.*, Case T-289/03, British United Provident Ass'n Ltd. v. Comm'n, 2008 O.J. (C 79) 25, para. 162 [hereinafter BUPA].

rates on the ECJ's approach in *Altmark.*[176] The decision allows Member States to grant state aid to hospitals.[177] The measures at play here are exempted from the obligation of notifying the Commission of state aid, in so far as the hospitals concerned are entrusted with the task of providing services of general economic interest. Thus, the state aid rules laid down in Articles 87 through 89 of the EC do not considerably interfere with the Member States' powers to finance hospital care.

2. COMPETITION LAW AND MANAGING BODIES

This point of view is confirmed by the recent decision reached by the Commission with respect to the Dutch health care system.[178] In the Dutch system, a considerable amount of room for competition exists and private insurance companies are the managing bodies for the provision of the basic health care schemes. However, these private actors must comply with certain criteria given in the *Zorgverzekeringswet* (Health Insurance Act).

For example, private actors are obliged to engage in a system of risk equalization. The discussion of the German *AOK* case has already made clear that such a system amounts to the transfer of money from insurers of more healthy persons to insurers of less healthy people ("high risks"). Under the Dutch *Zorgverzekeringswet*, an independent government public body is entrusted with the task of managing these fund flows.[179] As a result, a state body pays money to private insurance companies, whose health expenditure is high for the reason that many unhealthy persons are affiliated with them. Since Articles 87 through 89 of the EC preclude Member States from granting state aid to undertakings, unless the aid is approved by the Commission, the Dutch government informed the Commission of their plans to adopt a system of risk equalization.

In its decision, the Commission held that the payments made in the framework of the Dutch risk equalization scheme constituted state

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[176] *See* Commission Decision on the Application of Article 86(2) of the EC Treaty to State Aid in the Form of Public Service Compensation Granted to Certain Undertakings Entrusted with the Operation of Services of General Economic Interest, 2005 O.J. (L 312) 67.

[177] *See generally* Wolf Sauter, *Services of General Economic Interest and Universal Service in European Union Law*, 33 EUR. L. REV. 167, 191-92 (2008).

[178] *See* Commission Decision of 3 May 2005 on N 541/2004 & N 542/2004 on Retention of Financial Reserves by Dutch Health Insurance Funds and Introduction of a Risk Equalization System in the Dutch Health Insurance, 2005 O.J. (C 324) 28.

[179] See Article 3 of the *Zorgverzekeringswet*.

aid.[180] Furthermore, intra-Community trade was influenced and competition on the common market was distorted because the position of Dutch health insurers was reinforced by the state aid, compared to the position of similar undertakings in other Member States. However, the Commission held that the state aid was justified on the basis of Article 86(2) of the EC.[181] The Commission held that the Dutch health insurance companies were entrusted with a service of general economic interest such as the management of the basic health care program.[182]

However, a recent judgment of the CFI justifies the expectation that indeed the CFI would have found the Dutch system of risk equalization to be in accordance with EU law.[183] Until the Commission's decision in the case of the Dutch risk equalization scheme, this Treaty provision was only applied to a limited number of undertakings. At the moment of writing this article, a case brought against the Commission decision on the Dutch risk equalization scheme was pending before the CFI.[184] A case was brought against the Commission decision on the Dutch risk equalization scheme. Unfortunately, the parties concerned withdrew their appeal and the case was removed from the register of the CFI. So the Community does have the opportunity to to review the approach that the Commission adopted in this case.

From this standpoint, a recent judgment of the CFI justifies the expectation that indeed the CFI will find the Dutch system of risk equalization to be in accordance with EU law. A few years ago, the Decision[185] by which the Commission approved the risk equalization scheme of the Irish health care system was challenged by the British United Provident Association (BUPA). On February 12, 2008, the CFI delivered its judgment in the *BUPA* case.[186] In its sizeable judgment, the CFI upheld the decision of the Commission. However, unlike the Commission in the case on the Dutch risk equalization scheme, the CFI based its decision on the *Altmark* judgment. This implies that, according to the CFI, the Irish measure did not even constitute state aid within the meaning of Article

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[180] Sauter, *supra* note 177, at 18-25.

[181] *Id.* at 26-30.

[182] Case T-84/06, Onderlinge Waarborgmaatschappij Azivo Algemeen Ziekenfonds De Volharding v. Comm'n, 2006 O.J. (C 108) 27.

[183] *See* 2008 O.J. C327/41

[184] *Supra* note 181.

[185] Commission Decision of 13 May 2003 in Case N 46/2003, Risk Equalization Scheme in the Irish Health Insurance Market, 2003 O.J. (C 186) 16.

[186] *See* BUPA, 2008 E.C.R. __ (Feb. 12, 2008), 2008 O.J. (C 79) 25.

87(1) of the EC. Consequently, the regulatory scope of the Member States is rather broad in the setting up of a risk equalization scheme.

The CFI's considerations of the margin of appreciation are, moreover, in line with this observation. The CFI decided that the competent authorities enjoyed a wide margin of discretion in entrusting undertakings with special tasks.[187] The Community institutions' standard of review were limited to ". . . ascertaining whether there is a manifest error of assessment."[188] It may even be argued that the CFI's review of the Commission's assessment regarding national entrustment of a special task is subject to this standard of review. The CFI held, for instance, that it was only entitled to examine whether the Commission made a manifest error when it assessed the necessity and proportionality of the Irish measures.[189] One could argue that a "double layer of a wide margin of appreciation" exists under the approach adopted by the CFI in *BUPA*. Hence, the role of the Community courts is rather limited under this approach.

Considering one of the *Altmark* conditions concerned entrusting a public service obligation to a private company, the CFI had to examine whether the Irish health insurers were entrusted with a special task. The method followed by the CFI in its assessment confirms the conclusions of the CFI in *BUPA*, which considerably respected the regulatory freedom of the Member States.[190] In point 182 of the *BUPA* judgment, the CFI derived public service obligations from the general requirements laid down in national legislation.[191] The relevant Irish health law imposed upon all insurance companies the obligation to provide private medical insurance. In providing these services, they had to comply with obligations such as community rating, open enrolment, lifetime cover, and minimum benefits. All providers of private medical insurance were subject to these obligations.

Therefore, the CFI rather easily assumed the existence of public service obligations. Furthermore, it is of significant interest that the CFI accepted that a Member State may impose public service obligations upon an unlimited number of undertakings. In principle all health insurers may be entrusted with such tasks. Since the CFI ruled that the concept of public service obligations corresponded to that of the Services of

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[187] *Id.* para. 169.
[188] *Id.*
[189] *Id.* para. 220.
[190] *See id.* paras. 180-84.
[191] *Id.* para. 182.

General Economic Interest of Article 86(2) of the EC, it may be assumed that, in the view of this Community court, an open group of market operators may be entrusted with the performance of Services of General Economic Interest. Consequently, the *BUPA* judgment can be regarded as the first ruling in which a Community court applied the concept of Services of General Economic Interest to an unlimited number of enterprises.

As a result, the CFI has broadened the scope of this concept. In addition, the majority of ECJ case law on Services of General Economic Interest concerns network sectors. Services of General Economic Interest are usually imposed upon a limited number of operators by Member States in network sectors. Conversely, in sectors such as health care, an open group of enterprises and organizations are supposed to contribute to the realization of goals of general interest.

By accepting that Member States entrust an unlimited number of operators with the execution of Services of General Economic Interest, the CFI has paved the way for these services in the health care sector.

III. CONCLUSION

It is apparent that free movement rules have more influence on national health care systems than EU competition law does. The role of competition law is less significant because many public bodies managing health care systems are not regarded as undertakings. However, according to settled ECJ case law, health services themselves constitute economic activities. Yet, EU competition law comes into play only when national legislators deregulate and open up their health care systems. Consequently, if the process of deregulation taking place in the health care sector further takes shape in various Member States, competition law will become increasingly important. After all, the EU regime on competition provides the rules of the "free market game."

The applicability of EU competition rules to privatized health care systems is capable of causing much legal uncertainty as only a few precedents in the field of competition law and health care are currently available in EU jurisprudence. The concepts of Services of General Economic Interest and Public Service Obligations may provide more guidance on how the goal of the enhancement of competition and general interest issues may be reconciled. It is not a surprise that in the EU a de-

bate is on-going in regards to whether the EU should issue specific rules for Services of General (Economic) Interest.[192]

The Treaty provisions on free movement apply to the national health care systems of the Member States, irrespective of whether these programs are funded as reimbursement systems, benefits-in-kind systems, or as NHS systems. Some commentators have advanced the idea that health care services and goods are subject to these Treaty provisions when they are organized according to a system where payer and provider are separate and independent institutions.[193] However, this point of view can no longer be supported because in *Watts* the ECJ also applied the free movement rules to the refusal of a British NHS body to reimburse the costs of medical treatment received in France. After all, in a "state-based" system like the NHS there is not a clear distinction between providers and payers. Based on case law like *Watts* and *Freskot*, the EU regime on free movement is applicable to health care and other social security schemes that concern insurable benefits. This implies that national basic health care schemes fall within the ambit of this regime, as a rule.[194] Moreover, this should be considered in the context of the fact that the majority of the medical treatments covered by these schemes are insurable.

The ECJ's case law on free movement obliges the Member States to make a distinction between hospital and non-hospital care. With regard to non-hospital care, patients are free to choose between domestic and foreign providers. As for hospital care, Member States are forced to manage their systems properly, for instance, taking into account the interests of patients (e.g., in terms of waiting lists, international medical standards, etc.). If they succeed in paying sufficient consideration to these interests, the Member States are allowed to restrict the free movement of hospital services. In examining whether the health authorities have managed their systems properly, the ECJ is setting standards for: reimbursement rates, waiting lists, and prior authorization procedures on

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[192] *See, e.g.*, *Commission of the European Communities Communication Accompanying the Communication on "A Single Market for 21st Century Europe:" Services of General Interest, including Social Services of General Interest: A New European Commitment*, COM (2007) 725 final (Nov. 20, 2007).

[193] HERVEY & MCHALE, *supra* note 50, at 136; Davies, *supra* note 99, at 97-99; and Mark Flear, Case Note, *Case C-385/99 V.G. Müller-Fauré v. Onderlinge Waarborgmaatschappii O.Z. Zorgverkeringen U.A. and E.E.M. van Riet v. Onderlinge Waarborgmaatschapii Z.A.O. Zorgverzekeringen*, 41 COMMON MKT. L. REV. 209, 220-21 (2004).

[194] *Cf.* Maximilian Fuchs, *Free Movement of Services and Social Security–Quo Vadis?*, 8 EUR. L.J. 536, 544 (2002).

a case-by-case basis. This approach inevitably leads to the harmonization of several aspects of the organization of national health care systems.

However, several points are not clarified in the case law on cross-border health care. It is no surprise that the EU is about to harmonize these matters on the basis of Treaty provisions such as Article 95 of the EC. Matters to be covered are, in my view, patient information, definitions (e.g., what is hospital care), liability, and quality requirements. Another important issue is connected with the problem that too much movement of patients might result in the overburdening of some hospitals and corresponding under use of other hospitals.[195] In the case law, a lot of attention is paid to the aspects of under use (financial equilibrium). However, the question arises as to whether Member States are allowed to prevent patients residing in other Member States from receiving medical care in their hospitals if these hospitals are overburdened. It is clear from the outset that such a policy would amount to restrictions of the free movement of services (recipients of services would be hindered in the exercise of their free movement rights). Therefore, whether such restrictions may be justified by an exception should be resolved soon. It is a pity that the proposed Directive on patient mobility does not give much guidance on this point.

A certain degree of harmonization is inevitable but the organizational basis structure of health care remains within the ambit of the powers of the Member States. To what extent a national health care system is "vulnerable" to the application of EU law, depends on the way a particular Member States shapes and administers such a system, issues that must be addressed include (1) How are waiting lists addressed? (2) What is the role of planning? (3) How much room is left for competition? From a patient's perspective, it could be argued that the ECJ case law forces the national authorities to respect principles of good governance in the management of the national health care system. The well-being of patients must always be at the heart of Member States' policy. This conclusion is to be welcomed: health policy is essentially about curing ill people.

Nevertheless, the steering capacity of the national authorities must be respected. How to ensure an adequate balance between cross-border health care and the powers of the Member States to organize and deliver health care services is a difficult question. It is to be expected

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[195] HERVEY & MCHALE, *supra* note 50, at 139.

that this question will be high on the ECJ's agenda in the coming years. In this respect, it should be noted that the Treaty of Lisbon will change Article 152 of the EC. In particular, Section 7 of this Treaty provision will again stress that the EU should respect the competences of the Member States to regulate the organization of health care. However, compared to the present Treaty provision this section adds new elements to the principles governing the relationship between the EU and the Member States in the field of health care. It explicitly states that the responsibilities of the Member States ". . . shall include the management of health services and medical care and the allocation of the resources assigned to them."[196] It is clear from these words that the emphasis is put on the management of national health care and, therefore in the author's view, also on the steering capacities of the Member States. Consequently, points of concern in the near future will be the observance of the principle of subsidiarity in national health care, and the planning of the national health care systems, which will remain a task of the Member States. It is hoped that the proposed Directive on patient mobility will be able to strike a good balance between the internal market and the national organization of health care. Both the present version of Article 152(5) of the EC and the new version of this provision, as amended by the Treaty of Lisbon, do not preclude the EU legislature from adopting a Directive on patient mobility. As long as this directive deals with medical services that are services within the meaning of Article 49 of the EC, the EU has the power to regulate patient mobility.[197] Such services are in principle open to EU measures of harmonization taken on the basis of Article 95 of the EC.

In sum, it is time for the EU legislature to take action and to set clear standards for reconciling the free movement of health services and national measures in the health care sector. The incremental development of health care cases by the ECJ is no longer capable of addressing the challenges faced by the EU and the Member States. The EU legislature and the Member States must not shift the responsibility onto the ECJ, but should start developing a clear framework for health care services on their own.

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[196] Treaty of Lisbon, *supra* note 1, at C 306/84 (amending Article 152 of TFEU by renumbering paragraph 5 as paragraph 7 and stipulating that the measures taken by the EU may "not affect national provisions on the donation or medical use of organs and blood.").

[197] *See* Derrick Wyatt, *Community Competence to Regulate Medical Services*, *in* SOCIAL WELFARE AND EU LAW 131, 142-43 (Michael Dougan & Eleanor Spaventa, 2005).