

## JUSTICIABILITY OF THE RIGHT TO HEALTH CARE



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Peculiarities of the justiciability of the right to health care are elucidated in article through the prism of a courts practice. Case-law of the constitutional courts of former socialist countries i.e. Poland, Czech Republic, and Slovenia and legal positions of these courts towards implementation of systems of medical insurance are analyzed. Legal position of the courts in Germany and the Netherlands as regards to providing access to high-cost medicines is described. The situation under which constitutional control is lacking like it is in the Netherlands, as regards to enforcing the right to health care by the courts is analyzed. Certain issues of justiciability of the right to health care at the European level are elucidated in article as well. In particular accent is made on the case-law of the European Court of Human Rights. Attention is also paid to realization of the right to health care by the asylum-seekers within the context of the European Court of Human Rights case-law.

*Key words:* health care, justiciability, access to health care.

The term 'justiciability' refers to the ability to claim a remedy before an independent and impartial body when a violation of a (human) right has occurred or is likely to occur.\* In case of the right to health care, on several occasions, domestic and international courts held claims on health care access justiciable, providing an effective remedy to enforce its realization.\*\* Nonetheless, courts recognize that the necessary means are not

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\* International Commission of Jurists, Courts and the Legal Enforcement of Economic, Social and Cultural Rights. Comparative experiences of justiciability, Geneva 2008, p.6.

\*\* For an interesting overview read C. Flood, A. Ayal (eds), *The Right to Health at the Public/Private Divide: A Global Comparative Study* (CUP) 2014, describing national experiences on litigating health care access such as: *Minister of Health v. Treatment Action Campaign* (TAC) 2002 5 SA 721 (CC) South Africa; Colombian Constitutional Court ruling T-760/08, 31 July 2008, etc.

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infinite. Therefore, concepts such as progressiveness, core obligations, proportionality, and the state's margin of appreciation provide important tools to mitigate excessive health care claims. Hereafter, selected cases adjudicate the constitutionality of the right to health care or related rights-claims, such as the right to (private) life and equality; either or not by referring to international human rights treaties. The examples are merely illustrative for the – innovative – approach applied by the judiciary when reviewing the constitutionality of health insurance reforms, and in case of enforcing health care access, notably in case of access to new medical treatment methods and high-cost medicines.

### **Issues of Justiciability at Domestic Courts**

#### *Triggering the constitutionality of health insurance reforms*

In former socialist countries, newly established Constitutional Courts held that the introduction of a public health insurance system, restricting existing benefits and introducing cost-sharing measures, may be regressive by nature, but not necessarily unconstitutional. Measures adopted by the state, restricting the content of entitlements already guaranteed by legislation have been upheld when constitutional principles have been respected and essential elements are protected, not arbitrary, thus necessary and non-discriminatory. For instance, the Polish Constitutional Tribunal confirmed that Article 68(2) of the Constitution (i.e., the right to health protection) allows the legislature with a far-reaching discretionary power within the condition of considering other constitutional principles and norms. 'This means that the legislature can modify social rights, both in favour or to the detriment of individuals as long as it does not deprive the right from its essence, that is guaranteeing a right or benefits necessary for a basic minimum of existence'.\* A similar reasoning has been applied by the Czech Constitutional Court when reviewing the constitutionality of introducing patient own payments for medicines under Article 31 of the Human Rights Charter.\*\*

So far, Constitutional Courts provided 'mere' procedural protection against violations of the right to health care. More rigorously was the Slovenian Constitutional Court when it annulled a retrogressive measure by means of substantial review, since the reduction of medical care to

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\* CT Ruling K 8/96, 275 and K7/95, 414.

\*\* Pl. US 1/08, 23 September 2008. The CC applied the reasonableness test, i.e. i. defining the essence (essential content) of the social right i.c. Art. 31 Charter; ii. whether the statute (health care reform) does not affect the essential content; iii) when confirmative, the court applies the proportionality test, i.e. Whether the interference of the essential content is based on the absolute exceptional current situation, which could justify such an interference. Since the measure did not violate the essential content of public health insurance (limiting excessive use of health care services), furthermore pursued a legitimate aim and was considered reasonable, the court upheld the constitutionality of the statutory reforms. For a similar approach, see Decision no 2, 22 February 2007 on CC No 12/2006 of the Bulgarian Constitutional Court, deciding that more restrictive rules on health insurance introduced by the National Health Insurance Fund were not unconstitutional.

emergency care was held unconstitutional and unjustified.\* Similar cases striking down retrogressive legislation have been found in Portugal and Belgium.\*\* These examples confirm that constitutional review may provide an effective remedy to enforce (components of) the right to health care.

*New medical technologies and limited cost-effectiveness*

In the *Nikolaus* case, the German Constitutional Court interpreted the progressiveness-concept by lifting the ban on reimbursement of experimental treatment methods.\*\*\* A young patient suffers from a Duchenne Muscle disease (DMD), a progressive and lethal illness. At present, there is no effective therapy for DMD available. Reimbursement of cost of a new treatment method, the so-called immune biological therapy, was rejected by the social insurance fund since it was not evidence-based (“wirksamkeit» criterion). The Court ruled, however, that statutory criteria for limiting health benefits (i.e. ‘ausreichend, zweckmässig, wirtschaftlich’) should be interpreted in line with constitutional values such as the right to life, bodily integrity and the welfare (or social) state principle.\*\*\*\* More specific, in case of life-threatening diseases for which medical treatment is lacking according to general medical standards, except availability of experimental treatment with curative or positive effect (“spürbare positive Einwirkung») on the disease course, this alternative cannot be excluded in the absence of scientific evidence. The alternative’s effectiveness could be based on other evidence, for instance expert opinions and medical practice.\*\*\*\*\* With this ruling the Court has, although in exceptional cases, extended health care access to newly developed, and in most cases extremely expensive diagnostic and treatment methods that are likely to have a positive effect (‘spürbare positive Einwirkung’) on the disease course.\*\*\*\*\* It means that when scientific evidence is absent, the required probability standard of effectiveness is rather flexible: the more severe, the more hopeless the situation, the less stringent the likelihood standard. And although the Court recognized the «Wirtschaftlichkeitsgebot», (Art. 12 SGB V), and the need for cost (or cost-benefit) considerations,\*\*\*\*\* these criteria were not decisive.

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\* U-I-390/02-27, example derived from I. Blaz, ‘Constitutional Review of the Slovenian Health Law’, (2007) 14 EJHL, 342.

\*\* Portuguese Constitutional Tribunal, Decision No. 39/84, 11 April 1984 on abrogating the National Health Service; Belgium Constitutional Court (previously Court of Arbitration) 27 Nov. 2002, no. 169/2002 and 14 January 2004, no. 5/2004.

\*\*\* Case BvR 347/98, 6 December 2005, also known as the ‘Nikolausbeschluss’.

\*\*\*\* Idem para 55.

\*\*\*\*\* Para 66.

\*\*\*\*\* See also Art. 12 (3) SGB V incorporating the Nikolaus ruling; Examples accepted under this provision concern an experimental combined therapy for Ovarian cancer (€15,000 p.m) BvR 2045/12, 26 February 2013; experimental stem cell transplantation LSG Baden Württemberg, 13. November 2012, L11 KR 2254/10.

\*\*\*\*\* Note 71 at 57-59.

The *Nikolaus* ruling stirred feelings in German legal doctrine.\* In essence, it shows that despite the legislature's (c.q. G-BA) discretionary powers to formulate binding guidelines on evidence-based medicine and applied selection criteria, standards should ultimately comply with constitutional values.

How different is the outcome in the *Myozyme* case from the Swiss Supreme Court.\*\* In appeal, a Swiss health insurance fund challenged the court order of the Insurance Tribunal to continue reimbursement of an experimental treatment for Morbus Pompe, a rare and life-threatening disease. The Supreme Court annulled the Tribunal's ruling by reasons based on both lacking clinical effectiveness ("Wirksamkeit") and cost-effectiveness (i.e., a limited cost-benefit ratio rated in so-called 'quality-adjusted life years', or QALYs). The costs of treatment were calculated at CHF 700,000 per year (€565,000). Because general criteria to assess cost-effectiveness were absent, the Court applied a – controversial – cost-benefit analysis, concluding that the excessive costs of treatment would be disproportionate compared to the benefit (i.e. only relieving the symptoms of the disease, not postponing or preventing its fatal outcome). Moreover, approval would violate the equality principle when a disproportionate amount of scarce resources would be allocated to a certain individual but not to others who are the same position.\*\*\* This line of reasoning has been criticized by legal scholars.\*\*\*\* Although cost-benefit/effectiveness analysis is relevant at macro level (benefit package decision-making), it seems less appropriate at the individual doctor-patient level since it will ultimately force the judiciary to decide about society's willingness to pay for rare diseases, which can only be answered by the legislature. Different from the *Nikolaus* case, the Swiss Supreme Court declined to review the constitutionality of denial under the right to life, personal freedom and the right to assistance when in need.\*\*\*\*\* Unfortunately, as these rights were not challenged at the Supreme Court, it could abstain from such a human rights assessment. Ultimately, this case triggered public deliberation which resulted in a Federal by-law providing a legal basis and guiding principles of cost considerations in coverage de-

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\* J. Huster, 'Anmerkung', *JuristenZeitung* 9 (2006): 466-468; G. Dannecker, A.F. Streng, 'Die Bedeutung des Nikolaus-Beschlusses für die Priorisierungsdebatte', in *Priorisierung in der Medizin. Kriterien im Dialog*, ed. B. Schmitz-Luhn & A. Bohmeier (Berlin: Springer, 2013): 135-146.

\*\* Judgment of the Federal Supreme Court of Switzerland of 23 November 2010 (BGE 136 V 395).

\*\*\* Idem 7.7-7.8

\*\*\*\* E.g., F. Kesselring, First Fundamental Decision of the Federal Supreme Court of Switzerland on Cost-Effectiveness in the Area of Human Healthcare, (2011) 3 EJRR , 442-446; S. Huster, A. Bohmaier, Die Myozyme-Entscheidung des Schweizerischen Bundesgerichts aus der Perspektive des deutschen Verfassungs- und Krankenversicherungsrecht, (2012) 106 ZEFQ 443-448

\*\*\*\*\* Articles 10 and 12 of the Swiss Federal Constitution.

cision-making, but without setting a threshold.\* Instead, health insurance funds are supposed to review (partial) reimbursement of expensive interventions on a case-by-case basis, applying cost-effectiveness evidence.

*Reliance on international law*

When constitutional review is absent, as in the Netherlands, the judiciary has frequently applied international human rights to enforce the right to health care. The Dutch Central Appeals Tribunal's (CRvB) case law on long-term care reveal an emerging interest in international treaty law, both human rights treaty law (ECHR)\*\* and international social security law (ILO Conventions and the European Code of Social Security),\*\*\* whether or not combined with general non-discrimination treaty provisions (e.g., International Covenant on Civil and Political Rights, Article 26).\*\*\*\* In practice, such appeals based on international treaty norms are only successful in exceptional circumstances, but the impact can be considerable. In 2006, the CRvB concluded that the European Code of Social Security included some self-executing treaty provisions (articles 32 and 34), which prohibit co-payments in terms of occupational health related injuries.\*\*\*\*\* As a direct consequence of this ruling, the Dutch Parliament agreed to partially denounce the European Code (part VI) and simultaneously ratify the Revised Code, which allows more flexibility in terms of co-payments.\*\*\*\*\* A similar response was considered in 1996, when the CRvB also held that the ILO-Convention 102/103 (Article 10) was self-executing, thereby prohibiting cost sharing in terms of in-patient maternity care.\*\*\*\*\* The criteria used by the CRvB to determine whether norm setting treaties or treaty provisions are self-executing include the nature (instructive or imperative), and the specificity of the wording of the specific provision. Therefore, the reliance

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\* Federal By-law on Health Insurance AS 2011 654 (Explanatory note), Art. 71a (3) KVV, reading: 'Die zu übernehmenden Kosten müssen in einem angemessenen Verhältnis zum therapeutischen Nutzen stehen (...)', which can be interpreted as an implicit cost-benefit assessment, idem Art 71 b (3) KVV; confirmed by the government's reply on Parliamentary question no 11.3154 (6 June 2011), in particular question no 4.

\*\* A and others v. UWV, 18 October 2007 (ECLI:NL:CRVB:2007:BB6578); X v. CIZ, 9 May 2012 (ECLI:NL:CRVB:2012:BW5345); X v. Agis, 6 June 2012 (ECLI:NL:CRVB:2012:BW7707)

\*\*\* A v. Achmea Zorgverzekeringen, 8 September 2006 (ECLI:NL:CRVB:2006:AY8221); C. v. BAZ Nijmegen, 29 May 1996 (ECLI:NL:CRVB:1996:AL0666)

\*\*\*\* In case of differential treatment of cost sharing: A v. NUTS, 13 December 2001 (ECLI:NL:CRVB:2001:AE8567).

\*\*\*\*\* See note 86, 8 September 2006.

\*\*\*\*\* Termination Part VI European Code of Social Security, Stb. 474, 2009. Upholding ratification would cause an estimated loss of maximum €80 million. Parliamentary Proceedings II (2007-8) 31 267, no 6, p. 4, Ratification European Code on Social Security (revised).

\*\*\*\*\* F v. BAZ Nijmegen (note 86). Although in this particular case, co-payments were based on the former Health Insurance Act (ZFW). Denunciation was allowed at the end of any successive period of five years after ratification and thereafter. Since that period was expired, denunciation failed.

on the direct effect of ILO social security treaties provide Dutch citizens with a limited claim to enforce the social right to health care before domestic courts. Conversely, the judiciary rejected such reliance repeatedly in case of the ICESCR, since its provisions are insufficiently precise, and the instructive nature provides States with a broad margin of appreciation to fill in the necessary steps in order to realise these rights.\* So far, the judiciary has continued that line of reasoning and is not willing to incorporate the concept of «progressive realization» of social rights.

In case of immigrants without a residence permit (irregular migrants), however, the Dutch CRvB seems more generous, notably when children are concerned. Though illegals are by law excluded from long-term care under the AWBZ-scheme, on several occasions the CRvB annulled that rule based on Article 8 of the European Convention (right to private life, ECHR), but only in a very exceptional case, where the humanitarian grounds against the removal are compelling.\*\* These cases concern aliens with life-threatening diseases who are facing deportation, where it is clear that the necessary medical facilities and family support are not available in the individual's home country.\*\*\* The Tribunal has confirmed the European Court of Human Rights' doctrine that the Convention may create a positive obligation to provide access to necessary care.\*\*\*\* Furthermore, inherent to Article 8 of the Convention is a search for a fair balance between the demands of the general interest of the community and the requirements of the protection of the individual's fundamental rights. Withholding necessary care under these exceptional circumstances cannot be considered as a 'fair balance'.

### **Issues of Justiciability at European level**

#### *Non-listed treatment methods and the ECHR*

Apart from domestic courts, the European Court of Human Rights has also dealt with the adjudication of health care access claims, although rarely successful.\*\*\*\*\* In case of non-available or excluded medical services or medicines, the Human Rights Court has linked the right to health care with the Convention's right to life (Article 2), prohibition of torture (Article 3), and private life (Article 8). For instance, it is nowadays accepted that under the Court's jurisprudence, the right to life is not limited to refraining from taking life intentionally and unlawfully but also implies the States' duty to take appropriate steps to safeguard the lives of its

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\* X v. Maastricht, 14 December 2010 (ECLI:NL:CRVB:2010:BO6734).

\*\* See also, A. den Exter. Health Care Access in the Netherlands, in: CM Flood and Aeyal (eds) *The Right to Health at the Public/Private Divide: A Global Comparative Study* CUP 2014

\*\*\* X v. Achmea, 9 September 2011, ECLI:NL:CRVB:2011:BT1738; X v. Agis, 4 August 2011 (ECLI:NL:CRVB:2011:BR5381; X v. Agis, 20 October 2010 (ECLI:NL:CRVB:2010:BO3581); contrary: X v. Achmea 6 June 2012 (ECLI:NL:CRVB:2012:BW7703).

\*\*\*\* See D v. UK, App. No. 30240/96 Eur. Ct. H.R. 25 (1997) (St Kitts) though the Court used Article 3 and not article 8 of the Convention.

\*\*\*\*\* However, in case of vulnerable groups and health care needs, such as prisoners, the ECtHR appears more generous.

citizens.\* In the health care context, this could mean that the refusal to make life saving medicines available under the social health insurance scheme, is considered as an act of omission under Article 2. In *Panaitescu v Romania*, the Court confirmed domestic courts' ruling that the State had failed to provide adequate treatment, putting the patient's life at risk.\*\* In this particular case, the lifesaving cancer drug Avastin was not yet registered on the list of medicines covered by the health insurance scheme but already approved by the National Medicines Agency at the time of the domestic procedure started. Still, the Health Insurance Fund refused to enforce the domestic court order for providing the necessary anticancer treatment for free. According to the Human Rights Court, the patient's right to free medical care was more than once hindered, mainly on bureaucratic grounds, which ultimately resulted in the patient's death. The Court concluded that since there was no justification for the State's conduct and given the gravity of the illness, the authorities failed to take timely measures (i.e. listing and providing Avastin for free), therefore – unanimously – holding a breach of Article 2. In this exceptional case of unreasonable obstruction of enforcing a court order, the State has not adequately protected the patient's right to life.

In another case, *Hristozov v. Bulgaria*, the applicants complained that the Bulgarian authorities refused authorisation for using a non-registered and untested medicine in case of a life-threatening disease.\*\*\* According to the Court there was no breach of the Convention's right to life, prohibition of torture, nor private life. It is true that the positive obligations under Article 2 include a duty to regulate the conditions for market entry of medicines. Clinical trials, testing the product safety and efficacy, are an essential part of the market authorization procedure, therefore market access. By exception, non-registered medicines could be granted market access but only in case.

itis undergoing clinical trials in other countries. In this particular case that was not the case. In the Court's view, Article 2 does not impose an obligation to regulate access to unauthorised medicines for terminally ill 'in a particular way'.\*\*\*\* Based on a survey, it appeared that the regulatory requirements allowing untested medicinal products outside the clinical trials differ by country.\*\*\*\*\* Member states have a wide margin of appreciation setting the conditions for such medicines. That being so, the applicants argued unsuccessfully that the Bulgarian rules were 'overly restrictive', thus rendering meaningless the exceptional nature of such permission. The Court's majority view was criticised in two dissenting opinions by using the safety valve of a «wide margin of appreciation» *before* analysing the scope and purposes of the positive obligations undertaken under Article 8 of the Convention, 'leaving the impression that this phrase has been

\* See for instance, ECtHR App. No. 32967/96 (*Calvelli and Ciglio v. Italy*), para 48-49.

\*\* ECtHR App. no 30909/06, *Panaitescu v Romania*

\*\*\* ECtHR App. no. 47039/11 and 358/12.

\*\*\*\* *Ibid*, Para 108

\*\*\*\*\* Para 54, 55.



interpreted not in a sense of evaluation of merit, but as an instrument to justify national authorities' complete failure to demonstrate any appreciation whatsoever of the applicant's right to personal life, or to strike the requisite balance between this right and the presumed counterbalancing public interest.'\*Although the dissenter recognises the potential public health threat of untested medicines, extending the exception clause can be justified when the risks posed by the product are not unreasonable, do not outweigh the risks posed by the disease, and is recommended by the treating physician. In addition, the physician should explain extensively the (un)known risks, and access to unauthorised medicines remains an option of last resort.\*\* The counterargument that access to unauthorised medicines may hinder clinical trials, seems rather unfounded since it remains a strict exception to the general rule. Similar to the argument that access would undermine patient's willingness to participate in future clinical trials. When conventional therapies are not effective, 'desperate' patients will remain available volunteering in such trials. Compassionate use of unauthorised medicines remains an *ultimum remedium* for life-threatening situations only. Under these conditions, widening the exception clause seems justified. Unfortunately, in *Durisotto v Italy*, the Court's latest ruling on compassionate use, it abstained from such a review on the merits and confirmed the Member states' wide the margin of appreciation formula under Article 8, therefore, denying patient's access to unauthorised medicines.\*\*\*

Without doubt, both *Panaitescu* and *Hristozov* are tragic cases though with different outcomes. This can be explained by the fact that Avastin was already approved by the Romanian Medicine Agency but not yet covered by the list of reimbursed medicines. Therefore, Avestin can be classified as a regular and authorised medicine, which was not the case in *Hristozov*. Secondly, in *Panaitescu*, the breach of Article 2 was based on 'bureaucratic unwillingness' to put Avestin on the positive list for reimbursement, as concluded by the national courts. 'Listing', therefore, could be considered as a positive obligation, whereas refusal to act was a breach of the State's procedural obligations under Article 2.

In case of non-listed medical devices, the Strasbourg Court leaves Member States a similar wide margin of appreciation. Illustrative is the *Sentges* case requesting a highly expensive medical device (robotic arm) that was neither approved nor listed as a health insurance entitlement.\*\*\*\* Under those circumstances, the Court does not interfere in the State's margin of appreciation in determining the scope of the health insurance entitlement.

#### *Medical asylum cases*

By exception, the Human Rights Court has accepted a claim on health care access based on the prohibition of inhuman and degrading treatment,

\* Partly Dissenting Opinion Judges Kalaydjieva, Gaetano and Vicinic.

\*\* Dissenting Opinion Judge Vicinic Para 8

\*\*\* ECtHR App No. 62804/13 (*Durisotto v Italy*), 6 May 2014, para 36. Although the medicine was in a clinical trial stage, the Court abstain from a so-called «merits review» of the applicable conditions.

\*\*\*\* *Sentges v. the Netherlands* (dec.), no. 27677/02, 8 July 2003.

in case of an alien facing deportation to his home country. In *D v. the United Kingdom*, the applicant was arrested at the UK airport for the possession of cocaine, and sentenced to a three-year term of imprisonment. Immediately prior his release immigration authorities gave directions for the applicant's deportation. Pending his removal, he requested to remain in the UK since he was suffering from AIDS in an advanced and terminal stage, arguing that his removal to St. Kitts would entail a loss of medical treatment he was receiving in the UK. Unsuccessfully for the national courts, he applied to the Strasbourg Court arguing, inter alia, that his removal to St. Kitts would be an Article 3 violation.

So far, Article 3 has been applied in the context in which the individual has been subjected to harmful treatment emanating from intentionally inflicted acts of the public authorities. In this case, the Court applies Article 3 in another context, i.e. the situation where the harm would stem from withholding life-saving treatment when expelling the person outside the territory. By interpreting Article 3 in a more flexible manner, the Court 'must subject all the circumstances surrounding the case', such as the advanced stage of a terminal and incurable disease, the absence of adequate healthcare facilities in the home country which will hasten his death, and the lack of evidence of any support from relatives or any other form of moral or social support in St Kitts. Based on these exceptional circumstances, the decision to expel the applicant would amount to inhuman treatment by the Contracting state, therefore considered a violation of Article 3. According to the Court, a breach of Article 3 for medical asylum cases can be established only on the application of this so-called 'exceptional circumstances' test.\* With this ruling, one may criticize the Court since finding a breach of Article 3 in the present case would open up the floodgates to medical immigration and make Europe vulnerable to becoming the «sickbay» of the world'. However, the «floodgates» argument seems totally misconceived given that since this judgment, the Court has never concluded a proposed removal of an alien from a Contracting State to give rise to a violation of Article 3 on grounds of medical asylum.\*\*

Although incomplete, this survey on the enforcement of the right to health care components illustrate how the judiciary carefully manoeuvres between justified individual requests for life-saving treatments and respecting state's duty to guarantee equal access to basic health care for all. The outcomes show that in some occasions courts have upheld the right to health care, and in individual cases, have even promoted health care rights by judicialization. But the price can be high as seen in the Netherlands: triggering the political debate on sovereignty as in the Nether-

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\* Para 52-53.

\*\* See for instance, *Karara v Finland* Appl. no. 40900/98 (HIV); *SCC v Sweden* App no. 46553/99 (HIV), *Bensaid v the UK* Appl. No 44599/98 (schizophrenia); *Arcila Heneao v the Netherlands* App.no. 13669/03 (HIV-positive); *N v UK* 26565/05 (HIV positive). Examining the facts of each case, they all were HIV positive or had a serious psychiatric disorder, but not close to death, whereas treatment was 'in principle' available in the home country, and/or having relatives able to support the applicant

lands. On other occasions, the Constitutional court has been criticized by crossing the boundaries of what society can effort (e.g. *Nikolaus* ruling in Germany). Even more delicate is triggered the question of the maximum costs of individual health care intervention in the court; a political issue not to be decided by the judiciary. But what if politicians are reluctant or unable to decide about the threshold? As such, the Swiss Supreme Court acted as substitute legislator by applying an economic analysis and setting the maximum. Finally, the innovative approach of the European Human Rights Courts by adopting expansive definitions of civil rights does not necessarily provide a functional remedy since the safety valve of margin of appreciation denied the enforcement of many health care claims.\*

Summing all it up, it worth noting that adjudicating health care access in the court appears to be successful. But whether these landmark cases have galvanized more equitable access for all remains unclear. Nonetheless, these cases triggered a social debate on new health technologies accessible for all.

**Екстер А.**

### **Судовий захист права на охорону здоров'я**

Особливості судового захисту права на охорону здоров'я висвітлені крізь призму аналізу судової практики. Проаналізовані приклади судових справ здебільшого ілюструють інноваційні підходи, які суди застосовують під час розгляду справ щодо конституційності реформ у сфері охорони здоров'я, забезпечення доступу до медичної допомоги, зокрема, з акцентуванням на забезпеченні доступу до нових методів лікування і дорогих медичних препаратів. Проаналізовано судову практику конституційних судів країн постсоціалістичного табору – Польщі, Чехії, Словенії та їх позиції щодо запровадження систем медичного страхування, обмеження чинних прав. Наголошено на тому, що вжиті державою заходи, які обмежували гарантований законодавством обсяг прав, знаходили підтримку конституційних судів за умови дотримання закріплених у конституції принципів.

З'ясовано правову позицію судів Німеччини і Швейцарії стосовно забезпечення доступу до дорогих медичних препаратів. Німецькі суди тлумачать законодавчі критерії обмеження виплат допомоги у зв'язку із захворюванням з урахуванням таких закріплених конституцією цінностей, як право на життя, фізичну недоторканність і добробут. Водночас суд Швейцарії вказав на те, що надмірні витрати на лікування можуть бути неспівмірними отриманому результату, яким є усунення симптомів захворювання. У Нідерландах, де інституту конституційного контролю немає, суди у вирішенні питання про забезпечення прав людини у сфері охорони здоров'я покладаються на норми та принципи міжнародних стандартів.

Висвітлено питання судового захисту прав людини у сфері охорони здоров'я на європейському рівні, зокрема правові позиції Європейського суду з прав людини, який за умов відсутності або обмеженої кількості медичних послуг і лікарських засобів пов'язує право на охорону здо-

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\* Although this is different in case of prisoners and health care access.

ров'я із закріпленими у Європейській конвенції правами на життя, заборону катувань і повагу до особистого життя. Окремо проаналізовано позицію Європейського суду з прав людини щодо забезпечення права на охорону здоров'я осіб, які шукають притулку.

*Ключові слова:* медична допомога, судовий захист, доступ до медичної допомоги.

**Екстер А.**

### **Судебная защита права на охрану здоровья**

Особенности судебной защиты права на охрану здоровья освещены сквозь призму анализа судебной практики. Проанализированные примеры судебных дел в основном иллюстрируют инновационные подходы, применяемые судами при рассмотрении дел о конституционности реформ в системе здравоохранения, обеспечении доступа к медицинской помощи, в том числе с акцентированием на обеспечении доступа к новым методам лечения и дорогостоящим медицинским препаратам. Проанализирована судебная практика конституционных судов стран постсоциалистического лагеря – Польши, Чехии, Словении, и их позиции относительно внедрения систем медицинского страхования, ограничения существующих прав. Сфокусировано внимание на том, что государственные меры, ограничивающие гарантированный законодательством объем прав, получали поддержку конституционных судов при условии соблюдения закрепленных в конституции принципов.

Выяснена правовая позиция судов Германии и Швейцарии относительно обеспечения доступа к дорогостоящим медицинским препаратам. Немецкие суды рассматривают законодательные критерии ограничения выплат помощи в связи с заболеванием с учетом таких закрепленных конституцией ценностей, как право на жизнь, физическую неприкосновенность и благополучие. Суд Швейцарии указал на то, что чрезмерные расходы на лечение могут быть несоизмеримыми полученному благу, например, такому, как устранение симптомов заболевания. В Нидерландах, где институт конституционного контроля отсутствует, суды при решении вопроса об обеспечении прав человека в сфере охраны здоровья полагаются на нормы и принципы международных стандартов.

Освещены вопросы судебной защиты прав человека в сфере охраны здоровья на европейском уровне, в частности, правовые позиции Европейского суда по правам человека, который, в случае отсутствия или ограниченного количества медицинских услуг и лекарственных средств, связывает право на охрану здоровья с закрепленными в Европейской конвенции правами на жизнь, запрет пыток и уважение к личной жизни. Отдельно проанализирована позиция Европейского суда по правам человека относительно обеспечения права на охрану здоровья лиц, ищущих убежища.

*Ключевые слова:* медицинская помощь, судебная защита, доступ к медицинской помощи.

infinite. Therefore, concepts such as progressiveness, core obligations, proportionality, and the state's margin of appreciation provide important tools to mitigate excessive health care claims. Hereafter, selected cases adjudicate the constitutionality of the right to health care or related rights-claims, such as the right to (private) life and equality; either or not by referring to international human rights treaties. The examples are merely illustrative for the – innovative – approach applied by the judiciary when reviewing the constitutionality of health insurance reforms, and in case of enforcing health care access, notably in case of access to new medical treatment methods and high-cost medicines.

### **Issues of Justiciability at Domestic Courts**

#### *Triggering the constitutionality of health insurance reforms*

In former socialist countries, newly established Constitutional Courts held that the introduction of a public health insurance system, restricting existing benefits and introducing cost-sharing measures, may be regressive by nature, but not necessarily unconstitutional. Measures adopted by the state, restricting the content of entitlements already guaranteed by legislation have been upheld when constitutional principles have been respected and essential elements are protected, not arbitrary, thus necessary and non-discriminatory. For instance, the Polish Constitutional Tribunal confirmed that Article 68(2) of the Constitution (i.e., the right to health protection) allows the legislature with a far-reaching discretionary power within the condition of considering other constitutional principles and norms. 'This means that the legislature can modify social rights, both in favour or to the detriment of individuals as long as it does not deprive the right from its essence, that is guaranteeing a right or benefits necessary for a basic minimum of existence'.\* A similar reasoning has been applied by the Czech Constitutional Court when reviewing the constitutionality of introducing patient own payments for medicines under Article 31 of the Human Rights Charter.\*\*

So far, Constitutional Courts provided 'mere' procedural protection against violations of the right to health care. More rigorously was the Slovenian Constitutional Court when it annulled a retrogressive measure by means of substantial review, since the reduction of medical care to

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\* CT Ruling K 8/96, 275 and K7/95, 414.

\*\* Pl. US 1/08, 23 September 2008. The CC applied the reasonableness test, i.e. i. defining the essence (essential content) of the social right i.c. Art. 31 Charter; ii. whether the statute (health care reform) does not affect the essential content; iii) when confirmative, the court applies the proportionality test, i.e. Whether the interference of the essential content is based on the absolute exceptional current situation, which could justify such an interference. Since the measure did not violate the essential content of public health insurance (limiting excessive use of health care services), furthermore pursued a legitimate aim and was considered reasonable, the court upheld the constitutionality of the statutory reforms. For a similar approach, see Decision no 2, 22 February 2007 on CC No 12/2006 of the Bulgarian Constitutional Court, deciding that more restrictive rules on health insurance introduced by the National Health Insurance Fund were not unconstitutional.

emergency care was held unconstitutional and unjustified.\* Similar cases striking down retrogressive legislation have been found in Portugal and Belgium.\*\* These examples confirm that constitutional review may provide an effective remedy to enforce (components of) the right to health care.

*New medical technologies and limited cost-effectiveness*

In the *Nikolaus* case, the German Constitutional Court interpreted the progressiveness-concept by lifting the ban on reimbursement of experimental treatment methods.\*\*\* A young patient suffers from a Duchenne Muscle disease (DMD), a progressive and lethal illness. At present, there is no effective therapy for DMD available. Reimbursement of cost of a new treatment method, the so-called immune biological therapy, was rejected by the social insurance fund since it was not evidence-based (“wirksamkeit» criterion). The Court ruled, however, that statutory criteria for limiting health benefits (i.e. ‘ausreichend, zweckmässig, wirtschaftlich’) should be interpreted in line with constitutional values such as the right to life, bodily integrity and the welfare (or social) state principle.\*\*\*\* More specific, in case of life-threatening diseases for which medical treatment is lacking according to general medical standards, except availability of experimental treatment with curative or positive effect (“spürbare positive Einwirkung») on the disease course, this alternative cannot be excluded in the absence of scientific evidence. The alternative’s effectiveness could be based on other evidence, for instance expert opinions and medical practice.\*\*\*\*\* With this ruling the Court has, although in exceptional cases, extended health care access to newly developed, and in most cases extremely expensive diagnostic and treatment methods that are likely to have a positive effect (‘spürbare positive Einwirkung’) on the disease course.\*\*\*\*\* It means that when scientific evidence is absent, the required probability standard of effectiveness is rather flexible: the more severe, the more hopeless the situation, the less stringent the likelihood standard. And although the Court recognized the «Wirtschaftlichkeitsgebot», (Art. 12 SGB V), and the need for cost (or cost-benefit) considerations,\*\*\*\*\* these criteria were not decisive.

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\* U-I-390/02-27, example derived from I. Blaz, ‘Constitutional Review of the Slovenian Health Law’, (2007) 14 EJHL, 342.

\*\* Portuguese Constitutional Tribunal, Decision No. 39/84, 11 April 1984 on abrogating the National Health Service; Belgium Constitutional Court (previously Court of Arbitration) 27 Nov. 2002, no. 169/2002 and 14 January 2004, no. 5/2004.

\*\*\* Case BvR 347/98, 6 December 2005, also known as the ‘Nikolausbeschluss’.

\*\*\*\* Idem para 55.

\*\*\*\*\* Para 66.

\*\*\*\*\* See also Art. 12 (3) SGB V incorporating the Nikolaus ruling; Examples accepted under this provision concern an experimental combined therapy for Ovarian cancer (€15,000 p.m) BvR 2045/12, 26 February 2013; experimental stem cell transplantation LSG Baden Württemberg, 13. November 2012, L11 KR 2254/10.

\*\*\*\*\* Note 71 at 57-59.

The *Nikolaus* ruling stirred feelings in German legal doctrine.\* In essence, it shows that despite the legislature's (c.q. G-BA) discretionary powers to formulate binding guidelines on evidence-based medicine and applied selection criteria, standards should ultimately comply with constitutional values.

How different is the outcome in the *Myozyme* case from the Swiss Supreme Court.\*\* In appeal, a Swiss health insurance fund challenged the court order of the Insurance Tribunal to continue reimbursement of an experimental treatment for Morbus Pompe, a rare and life-threatening disease. The Supreme Court annulled the Tribunal's ruling by reasons based on both lacking clinical effectiveness ("Wirksamkeit") and cost-effectiveness (i.e., a limited cost-benefit ratio rated in so-called 'quality-adjusted life years', or QALYs). The costs of treatment were calculated at CHF 700,000 per year (€565,000). Because general criteria to assess cost-effectiveness were absent, the Court applied a – controversial – cost-benefit analysis, concluding that the excessive costs of treatment would be disproportionate compared to the benefit (i.e. only relieving the symptoms of the disease, not postponing or preventing its fatal outcome). Moreover, approval would violate the equality principle when a disproportionate amount of scarce resources would be allocated to a certain individual but not to others who are the same position.\*\*\* This line of reasoning has been criticized by legal scholars.\*\*\*\* Although cost-benefit/effectiveness analysis is relevant at macro level (benefit package decision-making), it seems less appropriate at the individual doctor-patient level since it will ultimately force the judiciary to decide about society's willingness to pay for rare diseases, which can only be answered by the legislature. Different from the *Nikolaus* case, the Swiss Supreme Court declined to review the constitutionality of denial under the right to life, personal freedom and the right to assistance when in need.\*\*\*\*\* Unfortunately, as these rights were not challenged at the Supreme Court, it could abstain from such a human rights assessment. Ultimately, this case triggered public deliberation which resulted in a Federal by-law providing a legal basis and guiding principles of cost considerations in coverage de-

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\* J. Huster, 'Anmerkung', *JuristenZeitung* 9 (2006): 466-468; G. Dannecker, A.F. Streng, 'Die Bedeutung des Nikolaus-Beschlusses für die Priorisierungsdebatte', in *Priorisierung in der Medizin. Kriterien im Dialog*, ed. B. Schmitz-Luhn & A. Bohmeier (Berlin: Springer, 2013): 135-146.

\*\* Judgment of the Federal Supreme Court of Switzerland of 23 November 2010 (BGE 136 V 395).

\*\*\* Idem 7.7-7.8

\*\*\*\* E.g., F. Kesselring, First Fundamental Decision of the Federal Supreme Court of Switzerland on Cost-Effectiveness in the Area of Human Healthcare, (2011) 3 EJRR , 442-446; S. Huster, A. Bohmaier, Die Myozyme-Entscheidung des Schweizerischen Bundesgerichts aus der Perspektive des deutschen Verfassungs- und Krankenversicherungsrecht, (2012) 106 ZEFQ 443-448

\*\*\*\*\* Articles 10 and 12 of the Swiss Federal Constitution.

cision-making, but without setting a threshold.\* Instead, health insurance funds are supposed to review (partial) reimbursement of expensive interventions on a case-by-case basis, applying cost-effectiveness evidence.

*Reliance on international law*

When constitutional review is absent, as in the Netherlands, the judiciary has frequently applied international human rights to enforce the right to health care. The Dutch Central Appeals Tribunal's (CRvB) case law on long-term care reveal an emerging interest in international treaty law, both human rights treaty law (ECHR)\*\* and international social security law (ILO Conventions and the European Code of Social Security),\*\*\* whether or not combined with general non-discrimination treaty provisions (e.g., International Covenant on Civil and Political Rights, Article 26).\*\*\*\* In practice, such appeals based on international treaty norms are only successful in exceptional circumstances, but the impact can be considerable. In 2006, the CRvB concluded that the European Code of Social Security included some self-executing treaty provisions (articles 32 and 34), which prohibit co-payments in terms of occupational health related injuries.\*\*\*\*\* As a direct consequence of this ruling, the Dutch Parliament agreed to partially denounce the European Code (part VI) and simultaneously ratify the Revised Code, which allows more flexibility in terms of co-payments.\*\*\*\*\* A similar response was considered in 1996, when the CRvB also held that the ILO-Convention 102/103 (Article 10) was self-executing, thereby prohibiting cost sharing in terms of in-patient maternity care.\*\*\*\*\* The criteria used by the CRvB to determine whether norm setting treaties or treaty provisions are self-executing include the nature (instructive or imperative), and the specificity of the wording of the specific provision. Therefore, the reliance

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\* Federal By-law on Health Insurance AS 2011 654 (Explanatory note), Art. 71a (3) KVV, reading: 'Die zu übernehmenden Kosten müssen in einem angemessenen Verhältnis zum therapeutischen Nutzen stehen (...)', which can be interpreted as an implicit cost-benefit assessment, idem Art 71 b (3) KVV; confirmed by the government's reply on Parliamentary question no 11.3154 (6 June 2011), in particular question no 4.

\*\* A and others v. UWV, 18 October 2007 (ECLI:NL:CRVB:2007:BB6578); X v. CIZ, 9 May 2012 (ECLI:NL:CRVB:2012:BW5345); X v. Agis, 6 June 2012 (ECLI:NL:CRVB:2012:BW7707)

\*\*\* A v. Achmea Zorgverzekeringen, 8 September 2006 (ECLI:NL:CRVB:2006:AY8221); C. v. BAZ Nijmegen, 29 May 1996 (ECLI:NL:CRVB:1996:AL0666)

\*\*\*\* In case of differential treatment of cost sharing: A v. NUTS, 13 December 2001 (ECLI:NL:CRVB:2001:AE8567).

\*\*\*\*\* See note 86, 8 September 2006.

\*\*\*\*\* Termination Part VI European Code of Social Security, Stb. 474, 2009. Upholding ratification would cause an estimated loss of maximum €80 million. Parliamentary Proceedings II (2007-8) 31 267, no 6, p. 4, Ratification European Code on Social Security (revised).

\*\*\*\*\* F v. BAZ Nijmegen (note 86). Although in this particular case, co-payments were based on the former Health Insurance Act (ZFW). Denunciation was allowed at the end of any successive period of five years after ratification and thereafter. Since that period was expired, denunciation failed.



on the direct effect of ILO social security treaties provide Dutch citizens with a limited claim to enforce the social right to health care before domestic courts. Conversely, the judiciary rejected such reliance repeatedly in case of the ICESCR, since its provisions are insufficiently precise, and the instructive nature provides States with a broad margin of appreciation to fill in the necessary steps in order to realise these rights.\* So far, the judiciary has continued that line of reasoning and is not willing to incorporate the concept of «progressive realization» of social rights.

In case of immigrants without a residence permit (irregular migrants), however, the Dutch CRvB seems more generous, notably when children are concerned. Though illegals are by law excluded from long-term care under the AWBZ-scheme, on several occasions the CRvB annulled that rule based on Article 8 of the European Convention (right to private life, ECHR), but only in a very exceptional case, where the humanitarian grounds against the removal are compelling.\*\* These cases concern aliens with life-threatening diseases who are facing deportation, where it is clear that the necessary medical facilities and family support are not available in the individual's home country.\*\*\* The Tribunal has confirmed the European Court of Human Rights' doctrine that the Convention may create a positive obligation to provide access to necessary care.\*\*\*\* Furthermore, inherent to Article 8 of the Convention is a search for a fair balance between the demands of the general interest of the community and the requirements of the protection of the individual's fundamental rights. Withholding necessary care under these exceptional circumstances cannot be considered as a 'fair balance'.

### **Issues of Justiciability at European level**

#### *Non-listed treatment methods and the ECHR*

Apart from domestic courts, the European Court of Human Rights has also dealt with the adjudication of health care access claims, although rarely successful.\*\*\*\*\* In case of non-available or excluded medical services or medicines, the Human Rights Court has linked the right to health care with the Convention's right to life (Article 2), prohibition of torture (Article 3), and private life (Article 8). For instance, it is nowadays accepted that under the Court's jurisprudence, the right to life is not limited to refraining from taking life intentionally and unlawfully but also implies the States' duty to take appropriate steps to safeguard the lives of its

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\* X v. Maastricht, 14 December 2010 (ECLI:NL:CRVB:2010:BO6734).

\*\* See also, A. den Exter. Health Care Access in the Netherlands, in: CM Flood and Aeyal (eds) *The Right to Health at the Public/Private Divide: A Global Comparative Study* CUP 2014

\*\*\* X v. Achmea, 9 September 2011, ECLI:NL:CRVB:2011:BT1738; X v. Agis, 4 August 2011 (ECLI:NL:CRVB:2011:BR5381; X v. Agis, 20 October 2010 (ECLI:NL:CRVB:2010:BO3581); contrary: X v. Achmea 6 June 2012 (ECLI:NL:CRVB:2012:BW7703).

\*\*\*\* See D v. UK, App. No. 30240/96 Eur. Ct. H.R. 25 (1997) (St Kitts) though the Court used Article 3 and not article 8 of the Convention.

\*\*\*\*\* However, in case of vulnerable groups and health care needs, such as prisoners, the ECHR appears more generous.

citizens.\* In the health care context, this could mean that the refusal to make life saving medicines available under the social health insurance scheme, is considered as an act of omission under Article 2. In *Panaitescu v Romania*, the Court confirmed domestic courts' ruling that the State had failed to provide adequate treatment, putting the patient's life at risk.\*\* In this particular case, the lifesaving cancer drug Avastin was not yet registered on the list of medicines covered by the health insurance scheme but already approved by the National Medicines Agency at the time of the domestic procedure started. Still, the Health Insurance Fund refused to enforce the domestic court order for providing the necessary anticancer treatment for free. According to the Human Rights Court, the patient's right to free medical care was more than once hindered, mainly on bureaucratic grounds, which ultimately resulted in the patient's death. The Court concluded that since there was no justification for the State's conduct and given the gravity of the illness, the authorities failed to take timely measures (i.e. listing and providing Avastin for free), therefore – unanimously – holding a breach of Article 2. In this exceptional case of unreasonable obstruction of enforcing a court order, the State has not adequately protected the patient's right to life.

In another case, *Hristozov v. Bulgaria*, the applicants complained that the Bulgarian authorities refused authorisation for using a non-registered and untested medicine in case of a life-threatening disease.\*\*\* According to the Court there was no breach of the Convention's right to life, prohibition of torture, nor private life. It is true that the positive obligations under Article 2 include a duty to regulate the conditions for market entry of medicines. Clinical trials, testing the product safety and efficacy, are an essential part of the market authorization procedure, therefore market access. By exception, non-registered medicines could be granted market access but only in case.

itis undergoing clinical trials in other countries. In this particular case that was not the case. In the Court's view, Article 2 does not impose an obligation to regulate access to unauthorised medicines for terminally ill 'in a particular way'.\*\*\*\* Based on a survey, it appeared that the regulatory requirements allowing untested medicinal products outside the clinical trials differ by country.\*\*\*\*\* Member states have a wide margin of appreciation setting the conditions for such medicines. That being so, the applicants argued unsuccessfully that the Bulgarian rules were 'overly restrictive', thus rendering meaningless the exceptional nature of such permission. The Court's majority view was criticised in two dissenting opinions by using the safety valve of a «wide margin of appreciation» *before* analysing the scope and purposes of the positive obligations undertaken under Article 8 of the Convention, 'leaving the impression that this phrase has been

\* See for instance, ECtHR App. No. 32967/96 (*Calvelli and Ciglio v. Italy*), para 48-49.

\*\* ECtHR App. no 30909/06, *Panaitescu v Romania*

\*\*\* ECtHR App. no. 47039/11 and 358/12.

\*\*\*\* *Ibid*, Para 108

\*\*\*\*\* Para 54, 55.

interpreted not in a sense of evaluation of merit, but as an instrument to justify national authorities' complete failure to demonstrate any appreciation whatsoever of the applicant's right to personal life, or to strike the requisite balance between this right and the presumed counterbalancing public interest.'\*Although the dissenter recognises the potential public health threat of untested medicines, extending the exception clause can be justified when the risks posed by the product are not unreasonable, do not outweigh the risks posed by the disease, and is recommended by the treating physician. In addition, the physician should explain extensively the (un)known risks, and access to unauthorised medicines remains an option of last resort.\*\* The counterargument that access to unauthorised medicines may hinder clinical trials, seems rather unfounded since it remains a strict exception to the general rule. Similar to the argument that access would undermine patient's willingness to participate in future clinical trials. When conventional therapies are not effective, 'desperate' patients will remain available volunteering in such trials. Compassionate use of unauthorised medicines remains an *ultimum remedium* for life-threatening situations only. Under these conditions, widening the exception clause seems justified. Unfortunately, in *Durisotto v Italy*, the Court's latest ruling on compassionate use, it abstained from such a review on the merits and confirmed the Member states' wide the margin of appreciation formula under Article 8, therefore, denying patient's access to unauthorised medicines.\*\*\*

Without doubt, both *Panaitescu* and *Hristozov* are tragic cases though with different outcomes. This can be explained by the fact that Avastin was already approved by the Romanian Medicine Agency but not yet covered by the list of reimbursed medicines. Therefore, Avestin can be classified as a regular and authorised medicine, which was not the case in *Hristozov*. Secondly, in *Panaitescu*, the breach of Article 2 was based on 'bureaucratic unwillingness' to put Avestin on the positive list for reimbursement, as concluded by the national courts. 'Listing', therefore, could be considered as a positive obligation, whereas refusal to act was a breach of the State's procedural obligations under Article 2.

In case of non-listed medical devices, the Strasbourg Court leaves Member States a similar wide margin of appreciation. Illustrative is the *Sentges* case requesting a highly expensive medical device (robotic arm) that was neither approved nor listed as a health insurance entitlement.\*\*\*\* Under those circumstances, the Court does not interfere in the State's margin of appreciation in determining the scope of the health insurance entitlement.

#### *Medical asylum cases*

By exception, the Human Rights Court has accepted a claim on health care access based on the prohibition of inhuman and degrading treatment,

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\* Partly Dissenting Opinion Judges Kalaydjieva, Gaetano and Vicinic.

\*\* Dissenting Opinion Judge Vicinic Para 8

\*\*\* ECtHR App No. 62804/13 (*Durisotto v Italy*), 6 May 2014, para 36. Although the medicine was in a clinical trial stage, the Court abstain from a so-called «merits review» of the applicable conditions.

\*\*\*\* *Sentges v. the Netherlands* (dec.), no. 27677/02, 8 July 2003.

in case of an alien facing deportation to his home country. In *D v. the United Kingdom*, the applicant was arrested at the UK airport for the possession of cocaine, and sentenced to a three-year term of imprisonment. Immediately prior his release immigration authorities gave directions for the applicant's deportation. Pending his removal, he requested to remain in the UK since he was suffering from AIDS in an advanced and terminal stage, arguing that his removal to St. Kitts would entail a loss of medical treatment he was receiving in the UK. Unsuccessfully for the national courts, he applied to the Strasbourg Court arguing, inter alia, that his removal to St. Kitts would be an Article 3 violation.

So far, Article 3 has been applied in the context in which the individual has been subjected to harmful treatment emanating from intentionally inflicted acts of the public authorities. In this case, the Court applies Article 3 in another context, i.e. the situation where the harm would stem from withholding life-saving treatment when expelling the person outside the territory. By interpreting Article 3 in a more flexible manner, the Court 'must subject all the circumstances surrounding the case', such as the advanced stage of a terminal and incurable disease, the absence of adequate healthcare facilities in the home country which will hasten his death, and the lack of evidence of any support from relatives or any other form of moral or social support in St Kitts. Based on these exceptional circumstances, the decision to expel the applicant would amount to inhuman treatment by the Contracting state, therefore considered a violation of Article 3. According to the Court, a breach of Article 3 for medical asylum cases can be established only on the application of this so-called 'exceptional circumstances' test.\* With this ruling, one may criticize the Court since finding a breach of Article 3 in the present case would open up the floodgates to medical immigration and make Europe vulnerable to becoming the «sickbay» of the world'. However, the «floodgates» argument seems totally misconceived given that since this judgment, the Court has never concluded a proposed removal of an alien from a Contracting State to give rise to a violation of Article 3 on grounds of medical asylum.\*\*

Although incomplete, this survey on the enforcement of the right to health care components illustrate how the judiciary carefully manoeuvres between justified individual requests for life-saving treatments and respecting state's duty to guarantee equal access to basic health care for all. The outcomes show that in some occasions courts have upheld the right to health care, and in individual cases, have even promoted health care rights by judicialization. But the price can be high as seen in the Netherlands: triggering the political debate on sovereignty as in the Nether-

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\* Para 52-53.

\*\* See for instance, *Karara v Finland* Appl. no. 40900/98 (HIV); *SCC v Sweden* App no. 46553/99 (HIV), *Bensaid v the UK* Appl. No 44599/98 (schizophrenia); *Arcila Heneao v the Netherlands* App.no. 13669/03 (HIV-positive); *N v UK* 26565/05 (HIV positive). Examining the facts of each case, they all were HIV positive or had a serious psychiatric disorder, but not close to death, whereas treatment was 'in principle' available in the home country, and/or having relatives able to support the applicant

lands. On other occasions, the Constitutional court has been criticized by crossing the boundaries of what society can effort (e.g. *Nikolaus* ruling in Germany). Even more delicate is triggered the question of the maximum costs of individual health care intervention in the court; a political issue not to be decided by the judiciary. But what if politicians are reluctant or unable to decide about the threshold? As such, the Swiss Supreme Court acted as substitute legislator by applying an economic analysis and setting the maximum. Finally, the innovative approach of the European Human Rights Courts by adopting expansive definitions of civil rights does not necessarily provide a functional remedy since the safety valve of margin of appreciation denied the enforcement of many health care claims.\*

Summing all it up, it worth noting that adjudicating health care access in the court appears to be successful. But whether these landmark cases have galvanized more equitable access for all remains unclear. Nonetheless, these cases triggered a social debate on new health technologies accessible for all.

**Екстер А.**

### **Судовий захист права на охорону здоров'я**

Особливості судового захисту права на охорону здоров'я висвітлені крізь призму аналізу судової практики. Проаналізовані приклади судових справ здебільшого ілюструють інноваційні підходи, які суди застосовують під час розгляду справ щодо конституційності реформ у сфері охорони здоров'я, забезпечення доступу до медичної допомоги, зокрема, з акцентуванням на забезпеченні доступу до нових методів лікування і дорогих медичних препаратів. Проаналізовано судову практику конституційних судів країн постсоціалістичного табору – Польщі, Чехії, Словенії та їх позиції щодо запровадження систем медичного страхування, обмеження чинних прав. Наголошено на тому, що вжиті державою заходи, які обмежували гарантований законодавством обсяг прав, знаходили підтримку конституційних судів за умови дотримання закріплених у конституції принципів.

З'ясовано правову позицію судів Німеччини і Швейцарії стосовно забезпечення доступу до дорогих медичних препаратів. Німецькі суди тлумачать законодавчі критерії обмеження виплат допомоги у зв'язку із захворюванням з урахуванням таких закріплених конституцією цінностей, як право на життя, фізичну недоторканність і добробут. Водночас суд Швейцарії вказав на те, що надмірні витрати на лікування можуть бути неспівмірними отриманому результату, яким є усунення симптомів захворювання. У Нідерландах, де інституту конституційного контролю немає, суди у вирішенні питання про забезпечення прав людини у сфері охорони здоров'я покладаються на норми та принципи міжнародних стандартів.

Висвітлено питання судового захисту прав людини у сфері охорони здоров'я на європейському рівні, зокрема правові позиції Європейського суду з прав людини, який за умов відсутності або обмеженої кількості медичних послуг і лікарських засобів пов'язує право на охорону здо-

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\* Although this is different in case of prisoners and health care access.

ров'я із закріпленими у Європейській конвенції правами на життя, заборону катувань і повагу до особистого життя. Окремо проаналізовано позицію Європейського суду з прав людини щодо забезпечення права на охорону здоров'я осіб, які шукають притулку.

*Ключові слова:* медична допомога, судовий захист, доступ до медичної допомоги.

**Екстер А.**

### **Судебная защита права на охрану здоровья**

Особенности судебной защиты права на охрану здоровья освещены сквозь призму анализа судебной практики. Проанализированные примеры судебных дел в основном иллюстрируют инновационные подходы, применяемые судами при рассмотрении дел о конституционности реформ в системе здравоохранения, обеспечении доступа к медицинской помощи, в том числе с акцентированием на обеспечении доступа к новым методам лечения и дорогостоящим медицинским препаратам. Проанализирована судебная практика конституционных судов стран постсоциалистического лагеря – Польши, Чехии, Словении, и их позиции относительно внедрения систем медицинского страхования, ограничения существующих прав. Сфокусировано внимание на том, что государственные меры, ограничивающие гарантированный законодательством объем прав, получали поддержку конституционных судов при условии соблюдения закрепленных в конституции принципов.

Выяснена правовая позиция судов Германии и Швейцарии относительно обеспечения доступа к дорогостоящим медицинским препаратам. Немецкие суды рассматривают законодательные критерии ограничения выплат помощи в связи с заболеванием с учетом таких закрепленных конституцией ценностей, как право на жизнь, физическую неприкосновенность и благополучие. Суд Швейцарии указал на то, что чрезмерные расходы на лечение могут быть несоизмеримыми полученному благу, например, такому, как устранение симптомов заболевания. В Нидерландах, где институт конституционного контроля отсутствует, суды при решении вопроса об обеспечении прав человека в сфере охраны здоровья полагаются на нормы и принципы международных стандартов.

Освещены вопросы судебной защиты прав человека в сфере охраны здоровья на европейском уровне, в частности, правовые позиции Европейского суда по правам человека, который, в случае отсутствия или ограниченного количества медицинских услуг и лекарственных средств, связывает право на охрану здоровья с закрепленными в Европейской конвенции правами на жизнь, запрет пыток и уважение к личной жизни. Отдельно проанализирована позиция Европейского суда по правам человека относительно обеспечения права на охрану здоровья лиц, ищущих убежища.

*Ключевые слова:* медицинская помощь, судебная защита, доступ к медицинской помощи.