4th International Focus Programme
Essay Competition on Health Law
2012

Obsessed for a perfect healthcare system

Second Runner Up

LIST OF ABBREVIATIONS

Giulia Funghi
Alessandro Rosanò

ELSA Italy

ACHR	American Convention of Human Rights
CEDAW	Convention on the Elimination of all forms of Discrimination Against Women
WHO	World Health Organisation
NHS	National Health System
R.A.Cs	Regional Administrative Courts
EU	European Union
TFEU	Treaty on the Functioning of the European Union
EEC	European Economic Community
TEC	Treaty on the European Community
IRAP	Imposta Regionale sulle Attività Produttive (Regional Tax on Productive Activities).

It is part of the cure to want to be cured.

SUMMARY

I. Judicial enforceability of the right to health. II. European Union. III. Juridical and financial consequences. IV. Conclusions.

I. Judicial enforceability of the right to health.

In a Welfare State, Government's action should aim at social cohesion, tending to prevent and reduce the conflict between single individuals and social classes. Such conflict arises from the so-called "natural lottery" and creates inequalities in income and wealth redistribution. The main tools to achieve this end are redistribution policies, which allow to transfer financial resources from one social class to another, compensating an otherwise rather "Darwinian" market tendency. As such, political freedom is based on freedom from all needs, that is a notion of social justice. Attached to this statement lies the idea of such rights as those to an education, work, social security, maternity safeguard and health; in brief, social rights.

It is precisely due to their nature of rights which need an external intervention in order to be enforced, or rather of a certain level of disbursement from the Government, that after having stated the existence of those rights one should interrogate oneself as to how to effectively enforce them. Indeed, it does not suffice that the public entities involved refrain from engaging in wrongdoings. The social and economic infrastructure of a country is questioned to the bottom of this very issue: the need to find the resources needed in order to implement those rights. For example, if in order to guarantee freedom of thought a State needed only to refrain from limiting or impeding the exercise of said freedom, safeguarding the right to health would necessarily imply allocating a certain amount of economic resources thereto. This way rights become a financial issue. It is no coincidence that article 6 of the 1994 WHO Declaration on the Promotion of Patients' Rights in Europe states the need to establish appropriate means (evidently, of a financial nature) in order to allow the exercise of the rights set forth therein.

The right to health is a vivid example of this statement insofar as it is a primary constitutional value referring to the safeguard of an individual's psycho-physical integrity and the undeniable relationship between health, safety and dignity. Defined by the Italian Constitution as a fundamental right of all individuals and an interest of the people, such right shall be construed as the right to access the healthcare system and, as such, it requires the legislative power to establish the tools, time-frame and manners for its implementation. This means that one should interpret it as a constitutional right subject to implementation by the legislator based on the amount of organisational and financial resources available at any given time. Properly so, one could suggest that the right to health and the right to healthcare treatments have the same extent only for the poorers, who are guaranteed free healthcare. As a matter of fact, it would be contradictory to speak of a right to health if patients did not have the means to pay for access to it.

In the years immediately following the enactment of the Constitution, the courts read the social rights set forth in Titles II and III of its first part merely as goals to be reached by a future legislator; they were surely seen as binding from the political point of view but could not be enforced in a court of justice as they lacked a specific action to claim performance. However, the Constitutional Court, in 1956, finally established that distinguishing between programmatic and preceptive provisions was pointless given that all provisions set forth in the Constitution are enforceable on their own via the legitimacy judgement entitled to the Constitutional Court itself. Once settled the hoary problem, the Italian courts concentrated their attention to the issue of keeping a balance between financial stability and the safeguard of the right to health. As a matter of fact, it was immediately after the enactment of the National Health Service Act no. 833/1978 that scholars started debating the choice between public and private healthcare facilities. After establishing the right of single individuals to chose their favourite facilities, both the Court of Cassation and the Constitutional Court found in favour of differentiating between the right to health entrusted on collectivity and a person's free choice. Indeed, the Constitution does not guarantee an indiscriminate right to be treated wherever a person pleases at the State's expense. Far from it, the State is due only for treatments offered by public facilities or private healthcare providers operating within the NHS. Thus, when the collectivity is paying for health expenses, the choice between providers is not absolute but shall be

confined within the limits drawn up by the applicable legal provisions. After all, before having to pay for treatments made by private providers it is reasonable that the State shall first attempt to use its own public facilities.

Given the limited amount of resources available, in the '90s the courts held that the Italian NHS should select the range of services provided. It was found that the Italian NHS is not in the position to provide indiscriminate services and citizens do not enjoy an absolute right to receiving all possible treatments available to date. The view embraced by the Court of Cassation and by various R.A.Cs., is that it is up to the Ministry of Health and to the Regions to choose the services to be provided according the extent that they are necessary and may not be easily substituted. This is to say, there is no such right to a full healthcare coverage, but only to receiving those services which are deemed necessary by a panel of physicians. So, even if the right to health is seen as the right to healthcare treatments, this should be coupled with the limitations imposed by limited economic resources. In 1993, the legislator intervened by establishing the so-called "joint funding" scheme: central government funding to the Regions are allocated so that they guarantee uniform coverage of minimum healthcare levels to all; insofar as more advanced healthcare services are concerned each Region has to provide autonomously with their own resources[1]. Confirming this line of reasoning, the Administrative Court of Tuscany held that the Italian NHS had duly denied health expense coverage for a treatment to be provided overseas insofar as said treatment was experimental and did not sufficiently ensure a successful outcome. The Court took into no account the fact that the overseas provider was much more specialised in treating the patient's illness than the Italian counterparts. That is, the Italian NHS may not found treatments whose clinical effectiveness is not guaranteed, a decision to be made on the merits by the patient's treating physicians.

Equally, the English courts provide an useful insight into this issue. In *R. v. Secretary of State for Social Services ex p. Hincks* (1979), a case involving four patients who had long been on the waiting list for orthopaedic surgery, the Court of Appeal underlined that the court's judicial review was justified only if it was demonstrated that the Ministry had allocated its resources unreasonably in a way to prevent the purpose of 1997 National Health Service Act. This is to say, the duty of the Secretary of State was and is to provide services "to such extent as he considers necessary to meet all reasonable requirements such as can be

1 Legislative Decree no. 502/1992, and then Legislative Decree no. 56/2000.

provided within the resources available". In *R. v. Central Birmingham Health Authority ex p. Walker* (1987) and *R. v. Central Birmingham Health Authority ex p. Collier* (1988), two cases involving children in need of heart surgery, it was held that the health authority may only act within the limits of the budget provided by the Department of Health. There follows that the judgement is subject to judicial review only when it is demonstrated that the government had acted unreasonably in allocating healthcare resources. Courts have thus refused to act as general controllers of the social policy in England[2]. From this consideration, it seems fair to define the right to health as the right to access a fair share of the healthcare resources.

II. European Union

The issue of social rights may be seen differently from the perspective of the EU's new welfare role. Much earlier than the provisions of art. 168 TFEU[3], it should be noticed that the first instances of an elaboration on the topic are linked to the need to guarantee the right to health within the framework of free movement of people, especially workers, in the Community. Article 7 (2) of Regulation (EEC) no. 1612/68 states that a worker who is a national of a Member State shall enjoy in the territory of another Member State the same social[4] and tax advantages as national workers, in order to overcome discrimination concerning work, remuneration and employment conditions.

Regulation (EEC) no. 1408/71 concerns the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community (and further to art. 2 its application extends to students, survivors of employed or self-employed persons and of students and retired persons).

2 Actually - despite a scarcity of court cases - it may be preferable to investigate the issue from the point of view of private law, entailing the right to compensation for breach of statutory law and negligence.

3 Which states that a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.

4 In *Even*, the Court of Justice extended the notion of social advantages, meaning all those which, whether linked or not to an employment contract, are generally attributed to National workers, in relation mainly to their state of workers or simply for their residency within the territory of a Member State, and found that extending those advantages to other EU member state citizens would facilitate their freedom of movement within the Community.

Article 4 limits the subject-matter of the Regulation to sickness and maternity benefits, invalidity, old-age and survivors' benefits, to benefits in respect of accidents at work and occupational diseases, death grants, unemployment benefits, family benefits and all general and special social security schemes, whether contributory or non-contributory. Given the basic principle of equality of treatment of all EU nationals (art. 3), the Regulation states that migrant workers are entitled to the same benefits as persons resident in the Member State concerning access to national health systems, when they become relevant for the purpose of the Regulation. Pursuant to art. 19, a worker residing in the territory of a Member State other than the competent State shall receive both cash benefits and benefits in kind, i.e. both access to healthcare and health insurance benefits.

As a matter of fact, the scope of Regulation no. 1408/71 should be evaluated according to its appreciation made by the courts with reference to article 56 TFEU (49 TEC), prohibiting any restriction on freedom to provide services within the Union in respect of nationals of Member States who are established in a Member State other than that of the person for whom the services are intended. The direct applicability of this provision prompts to the existence of a right to access healthcare services which may be enforced by courts. In its judgments *Kohll, Vanbraekel, Geraets-Smits and Peerbooms, Müller-Fauré and Van Riet, Inizan, Leichtle, Watts and Stamatelaki* the EU Court stressed that free provision of services is one of the main principles of EU Law and that healthcare services fall under the relevant economic activities of the provision. Furthermore, it was held that in order to safeguard the economic balance between the various national welfare systems, it was necessary to introduce a mechanism of prior authorisation and that there is a right to be reimbursed medical expenses incurred based on the tariffs of the country where one is insured. It may be worth mentioning one of these judgements in details. In *Vanbraekel* the Belgian social security institution refused to reimburse the costs of hospital treatment needed for an orthopaedic surgery occurred in France in lack of prior authorisation[5]. The Court touched on various issues before its bench: It was clarified that pursuant to art. 57 TFEU (50 TEC) all services provided for remuneration are services within the meaning of the treaty, in so far as they are not governed by the provisions relating to freedom of movement for goods, capital and persons. This is to say, also healthcare services are

5 Later the Belgian institution ruled that such refusal was unfounded.

included, notwithstanding whether they are offered by public or private providers. The Court further found that art. 56 TFEU (49 TEC) precludes the application of any national rules which have the effect of making the provision of services between Member States more difficult than the provision of services purely within one Member State; indeed such limitations could be justified pursuant to art. 52 (47 TEC) on grounds of public health in so far as it contributes to the attainment of a high level of health protection, which is essential for the public health or even necessary to ensure the survival of the population, or else based on the need to adjust the balance of the social security system[6]. When an insured person is authorised by its competent institution to be treated in the territory of another member state, the social security institution of the receiving country oughts to provide him/her with the same level of healthcare services as they provide to their citizens, as if the foreign insured person were enrolled with that social security institution. Where the request of an insured person for authorisation on the basis of Article 22(1)(c) of that regulation has been refused by the competent institution and it is subsequently established that such refusal was unfounded, the person concerned is entitled to be reimbursed directly by the competent institution by an amount equivalent to that which would have been borne by the institution of the place of treatment under the rules laid down by the legislation applied by the latter institution if authorisation had been properly granted in the first place.

Indeed, the issue at stake is far from trivial. For example, following the entry of new countries in the EU from Central and Eastern Europe, one should reasonably expect that the wealthier citizens of those States would more easily choose to receive medical treatment from another EU member state in order to access healthcare services unavailable in their home countries. It may be hard to foresee the results of this trend: needless to say, waiting lists for certain procedures will get longer, but it could also have a positive impact if resources were to be allocated more efficiently in *over-capacity countries*; however it may as well lead to a potentially catastrophic decrease in the quality of medical services offered by national providers given the need for cost-containment.

III. Juridical and financial consequences

6 In *Stamatelaki*, the Court clarified that in order to be fair limitations are to be proportionate to the means to be achieved.

From what we have stated, health is a merit good, that is a good encompassing non-negotiable ethical and civil values, as well as social and economic ones. One should understand that what we are looking at does not merely regards the enforcement of certain rights; rather it is an issue of costs - essentially their repercussion on public finance, and the need to span the divide between economic efficiency and the solidarity principles enshrined in the welfare system. Looking at the Italian case, public health expenditure equals to 111 billion Euros per year, and in certain Regions, notably in Southern Italy, as much as 80% of public funding is allocated to this sector. It is certainly excessive and this excess forces us into a reorganisation of our mid and long-term policies concerning the usage of public resources as well as implementing effective measures against waste and stealing in the health sector, for example against medical fraud. Regarding the latest, one ought to look the case of the USA following the enactment of the False Claims Act. Originally issued in 1863 as a response to fraud perpetrated by federal contractors against the military during the American Civil War, it has been increasingly applied to medical fraud from the '90s. The act imposes liability on any person who falsely submits a claim to the federal government knowing that it is false, such as when a physician claims reimbursement for unprovided medical treatments under the Medicare scheme. The corresponding penalty is equal to double the amount of damage suffered by the United States plus a lump fine of 2000 $ for each claim submitted. With the 2010 Fraud Enforcement and Recovery Act, liability was expanded to those who knowingly and improperly avoided or decreased an obligation to pay or transmit money or property to the Government. Another incentive to solve this issue is the *qui tam* rule contained therein, encouraging private individuals to bring actions on behalf of the government by ensuring them a share of any penalty imposed in case of successful prosecution.

Although with fair access to justice citizens are allowed to publicly deprecate the inefficiency of a healthcare provider, which in turn increases the overall quality of the system since some providers may be more inclined to take the necessary steps to improve their services and the safety of future patients, an excess may in fact yield to the contrary outcome.

A good example of this is provided by defensive medicine, which occurs when physicians order tests, treatments or visits (positive defence) or avoid treating their patients with high risk procedures (negative defence), mainly (although not necessarily exclusively) to reduce

their liability in case of malpractice suits. In the United States, between 79% and 93% of physicians concede to having practised a kind of defensive medicine, especially those practising emergency medicine, obstetrics and other high-risk specialist surgery. In Italy, 61,3% of physicians test their patients with unnecessary exams. Such a widespread misbehaviour leads to longer waiting lists and higher costs for the healthcare providers; yet it may finds its reason in the excessive tendency to file actions for damages in case of unsuccessful treatment. In Italy, for instance, between 1994 and 2007 the number of new civil actions being brought forward every year was between 10.000-12.000 in addition to 150.000 criminal count claims, for a total of 320.000 patients who suffered from hospital malpractice over an estimated number of eight million patients; consequently insurance premiums have increased by 1000% in fourteen years. This boost in lawsuits may originate from the court's shift from a doctor-friendly orientation based on the provisions of sec. 2236 of the Civil Code (limiting liability only to malicious and grossly negligent acts) to a different view which, referring openly to Article 32 of the Constitution, is more favourable to patients given the need to leave behind all paternalistic instances in medical practice and promote the latter's participation in the choice of treatment, in a position essentially equal to that of treating physicians.

Consequently, the practice of medicine is strongly discouraged given the high level of inherent risk and physicians have to carry a heavy burden on their shoulders - both judicially, financially and morally – which has got no equal in other professional services. In English-speaking countries this issue was felt to such an extent that dedicated risk management procedures were drawn up in order to trace the origin and consequences of adverse events and prevent their occurrence. We believe one ought to "depersonalize" doctors' liability in a way similar to what has been done with regards to liability claims from motor accidents: in such cases, the damaged party deals almost exclusively with the insurance company rather than with the party causing the damage. Likewise, patients should be allowed to bring action directly against the insurance company - not only the one of the physician causing the damage but also that of the hospital where such damage occurred, in light of the fact that only 20-30% of malpractice cases originate from mistakes of the medical personnel, while the other 70-80% is to be ascribed to lack of organisation of the medical facilities themselves. It is no coincidence that sec. 28 of Presidential Decree n. 761 enacted on 20.12.1979 allows Local Health Authorities to enter into a suitable

insurance to cover risks from medical practice liability. This would remove the risks associated to claims moved directly towards physicians, thereby allowing them to operate less stressfully and base their actions solely on their patient's best interest by reducing, if not erasing, the practice of defensive medicine. Additionally, it might be worth establishing a pre-trial arbitration proceeding similar to the one operating in France further to Act no. 2002/303 of 4.3.2002. After hearing from the parties involved, such body - made of impartial experts in the fields of law and medicine - should be responsible for evaluating the grounds of each malpractice claim and ascertaining the liability and damage thereto. In France, said experts are chosen from a national list of "medical accidents experts" and then assigned to each case by the regional committee receiving the patient's malpractice allegation: when professional liability is established, the insurance company involved is invited to make a compensation offer, otherwise the patient is indemnified by a national guarantee fund called Office national d'indemnisation des accidents medicaux.

IV. Conclusions

From what we have seen, it is possible to infer that as much as it is necessary to contain public expenditure, this should not come at the detriment of individual rights. How does this reflect in the right to health? One could suggest that the introduction of a mixed health system, i.e. public providers founded with taxation and social insurances, may lead to a new definition of the right to health. This would no longer be seen as divided between a right to have quality treatments and to equality in cost allocation and would reduce the danger for collectivity to sustain undue expenses. At present, the Italian national health system is mainly founded with IRAP, a tax paid exclusively by firms, which naturally do not benefit from the services provided. Excluding a considerable raise in taxation, the consequence of this policy is that public expenditure is fiercely reduced in an attempt at rationalization and savings, which in turn causes a reduction in the level of health services provided with a double negative impact: those who pay for it are not granted the service, while those receiving the service are forced to turn to private providers. A mixed system would allow the State to greatly reduce its share of contribution, as the system would mainly rely on insurance companies, which would then deduce their premiums from the insured personal income (Germany, France) or from families (Switzerland) or from both (Netherlands). The remaining taxes for health services should be used to grant health

coverage to all citizens, notably those who do not earn an income (unemployed and students), retired persons and the poors. If such a system were established, it would have to be designed as a mandatory insurance policy in which companies would not be allowed to deny insurance coverage to any citizen (principle of universality),with no limitations on previous or on-going diseases nor any period of observation. Furthermore, all services should be made reimbursable without a price cap on the payments and with several insurance companies competing for their market prices would tend to best economic balance. Undoubtedly, a private chain of management for those services would be more effective than a public system, thereby ensuring lower costs for the same services as well as the possibility for all to use them equally, since the assumption behind the system is that everybody may one day get ill.

LIST OF REFERENCES

ADAM R. - TIZZANO A., *Lineamenti di diritto dell'Unione europea*, 2nd ed., G. Giappichelli Editore, Torino, 2010, pagg. 41-49.

BACKMAN G. (and others), *Health systems and the right to health: an assessment of 194 countries*, in *The Lancet*, Vol. 372, December 13, 2008, pagg. 2047-2085.

BLACKBURN R. (edited by), *Rights of Citizenship*, Mansell, London - New York, 1993, pagg. 56-74.

BIN R. - PITRUZZELLA G., *Diritto costituzionale*, G. Giappichelli Editore, Torino, 2007, pagg. 47, 52-54, 517-519.

BUCHANAN A. E., *The Right to a Decent Minimum of Health Care*, in *Philosophy & Public Affairs*, Vol. 13, No. 1, Winter 1984, pagg. 55-78.

CALAMANDREI P., *Costituente e questione sociale*, in *Il Ponte*, Agosto 1945.

CARSON T. L. - VERDU M. E. - WOKUTCH R. E., *Whistle-Blowing for Profit: An Ethical Analysis of the Federal False Claims Act*, in *Journal of Business Ethics*, 2008, 77, 361-376.

DEN EXTER A. - HERMANS H., *The Right to Health Care: A Changing Concept?*, in DEN EXTER A. (edited by), *The Right to Health Care in Several European Countries*, Kluwer Law International, The Hague, 1999, pagg. 1-9.

FELDMAN R., *An Economic Explanation for Fraud and Abuse in Public Medical Care Programs*, in *The Journal of Legal Studies*, Vol. 30, No. S2, June 2001, pagg. 569-577.

FRANCE G., *The Changing Nature of the Right to Health Care in Italy*, in DEN EXTER A. (edited by), *The Right to Health Care in Several European Countries*, Kluwer Law International, The Hague, 1999, pagg. 39-55.

HERSCH J., *I diritti umani da un punto di vista filosofico*, Bruno Mondadori, Milano, pagg. 85-86, 90-93.

HERVEY T. K. - McHALE J. V., *Health Law and the European Union*, Cambridge University Press, Cambridge, 2004, pagg. 109-144.

HERVEY T., *The impacts of European Union law on the health care sector: Institutional overview*, in *Eurohealth*, Vol. 16, Number 4, 2010, pagg. 5-7.

HYMAN D. A., *Health Care Fraud and Abuse: Market Change, Social Norms, and the Trust "Reposed in the Workmen"*, in *The Journal of Legal Studies*, Vol. 30, No. S2, pagg. 531-567.

HULST E., *The Quality Dimension of the Right to Health Care*, in DEN EXTER A. (edited by), *The Right to Health Care in Several European Countries*, Kluwer Law International, The Hague, 1999, pagg. 11-16.

HURLEY J., *Ethics, Economics and Public Financing of Health Care*, in *Journal of Medical Ethics*, Vol. 27, No. 4, August 2001, pagg. 234-239.

IRWIN R., *EU Law and health: an introduction*, in *Eurohealth*, Vol. 16, Number 4, 2010, pagg. 1-2.

KELMAN M., *Health Care Rights: Distinct Claims, Distinct Justifications*, in *Stanford Law & Policy Review*, 1991, 3, pagg. 90-102.

MODUGNO F., *I nuovi diritti nella giurisprudenza costituzionale*, G. Giappichelli Editore, Torino, 1995, pagg. 40-49, 65-74.

MONTGOMERY J., *Health Care Law*, 2nd ed., Oxford Press University, New York, 2003, pagg. 67-80.

MORANA D., *La salute nella Costituzione italiana*, Giuffrè Editore, Milano, 2002, pagg. 36-41.

PALADIN L., *Diritto costituzionale*, Cedam, Padova, 1998, pagg. 675-677.

PALOMBELLA G., *L'autorità dei diritti*, Laterza, Roma-Bari, 2002, pagg. 11-34, 39-50.

PANNARALE L., *Giustiziabilità dei diritti. Per un catalogo dei diritti umani*, FrancoAngeli, Milano, 2002, pagg. 11-34.

PILLAY N., *Right to health and the Universal Declaration of Human Rights*, in *The Lancet*, Vol.

372, December 13, 2008, pagg. 2005-2006.

SEN A., *Why and how health is a human right?*, in *The Lancet*, Vol. 372, December 13, 2008, pag. 2010.

TRIPODINA C., *Articolo 32*, in BARTOLE S. - BIN R. (edited by), *Commentario breve alla Costituzione*, 2ª ed., Cedam, Padova, 2008, pagg. 321-332.

JURISPRUDENCE OF THE COURT OF JUSTICE OF THE EUROPEAN UNION

C-444/05, *Stamatelaki*, April 19th 2007.

C-372/2004, *Watts*, May 16th 2006.

C-08/02, *Leichtle*, March 18th 2004.

C-56/01, *Inizan*, October 23rd 2003.

C-385/99, *Müller-Fauré and Van Riet*, May 13th 2003.

C-157/99, *Smits and Peerbooms*, July 12th 2001.

C-368/98, *Vanbraekel*, July 12th 2001.

C-158/96, *Kohll*, April 28th 1998.

C-263/86, *Belgian State v Humbel*, September 27th 1988.

C-207/78, *Even*, 31 May 31st 1979.

JURISPRUDENCE OF THE ITALIAN COURT OF CASSATION

April 22nd 1994, n. 3840.

November 21st 1983, n. 6920.

November 16th 1982, n. 6129.

JURISPRUDENCE OF THE ITALIAN CONSTITUTIONAL COURT

May 15th 1987, n. 173.

June 14th 1956, n. 1.

JURISPRUDENCE OF THE ITALIAN REGIONAL ADMINISTRATIVE COURTS

RAC of Tuscany, November 28th 1994, n. 376.

RAC of Sicily, August 19th 1994), 1803 .

RAC of Tuscany, December 17th 1992, n. 508.