RIGHT TO HEALTH AND FREEDOM OF CARE

By Silvia Demma

Focus

Stamina. This word has captured the attention of the Italians, more than any other, as to the issue of health 35 years after Law 833/78 establishing the (Italian) National Health System. A complex story whose chapters are outlined here to describe what is the state of the right to health in Italy: *freedom of care; access to care; quality of care*. Those chapters are to be contextualized in a scenario heavily influenced by economic recession, in which excellence and serious deficiencies coexist and where, finally, the deepest feelings - fear, hope, anguish, joy – reach their climax in a relationship with rationality that is not always easy.
Starting from the definitions we want to give here for the three issues, we briefly retrace the story of Stamina, although it is not over yet, as it exemplifies the roles of the individual stakeholders.
Freedom of care: a wide and sensitive issue, in which the law provides the limit of what is allowed with respect to health care. It includes the possibility to refuse treatment and access palliative care to contain the pain, alternative healing methods with respect to those proposed by allopathic medicine or, in extremely severe cases, compassionate care via procedures that are still in the experimental stage.

Access to care: this is based on the constitutional principle which is a cornerstone of the law establishing the (Italian) National Health System, which aims to afford all citizens equal rights to health, to smooth out disparities related to income or place of residence that might otherwise transform the opportunity to be treated into a kind of lottery for the happy few.

Quality of care: this has to do with the mechanisms to guarantee citizens in their relationships with the healthcare world, given the asymmetry – assumed to be likely – of technical and scientific skills between health care services and patient. Here information and transparency become tools to facilitate trust between the parties, the prerequisites for a therapeutic covenant in which error is left in the sphere of the imponderable.

The whole system underwent a deep strain with the Stamina case because the latter is related to high emotional impact events and involves patients in extreme clinical situations. Even if there is a specific law designed to reconcile the piety due under these circumstances with the protection from profiteers playing with patients' hope, the frantic sequence of events after the treatment was allowed by the NHS proved how difficult it was for the individual branches of the State to follow clear-cut, shared procedures in the approach to care.
The citizen's right to self-determination, a key element of the *freedom of care*, is far from being taken for granted in all its aspects in our legal system: it is enough to think of the so-called biological will to appreciate the reluctance of the lawgiver to step in where this freedom involves one's life. For the children involved in the Stamina case, who by definition cannot express their informed consent to the treatment, freedom of care seems to have prevailed over the attention paid to survival, to the precautionary principle that should protect minors in the first place. To date, in fact, there are no shared assessments on the efficacy of the therapy, let alone on its potential harmfulness. Standardized procedures at international level for which studies, publications, scientific debate and, unfortunately, years are necessary to avoid harmful treatments have been set aside: «It is important to consider that after over a year of administration of the stamina method at the defendant health care agency, no case of unfavourable or partially negative results has been report-

ed»: this can be read, for example, in the judicial order authorising the treatment. The same order limits the intervention of the Ethics Committee, which is another tool that is useful for protecting those who, in a desperate situation, would submit themselves voluntarily to any therapy and that should protect minors – possibly – also from the humanly understandable desperation of their parents: «Having considered (…) that (…) given the very serious conditions applying to the claimant (…) also the Ethics Committee's opinion cannot include a global, detailed evaluation as to the likely effectiveness of the treatment undertaken, requiring studies and trials that are in themselves incompatible with the tight schedule and the urgency of the case»[1].

Another well-trodden path is the judicial one, in Court, to get *access to care* at the "Spedali Civili", the public hospital at the centre of the controversy. Here, according to one of the protagonists, Stamina had arrived in September 2011 allegedly on grounds other than a disinterested scientific curiosity: «A manager of the Lombardy Region suffered from (...) a progressive neurological disease. He thought we could treat him and favoured the entry of our method at the "Spedali" of Brescia. Also local managers had brothers, brothers-in-law or husbands to be treated (…) therefore we decided to treat persons with connections first»[2]. In fact, until that time the costs for the treatment were borne by patients, who reportedly had to pay around €50,000[3].

On the other hand, there is the attempt made by the NHS - obliged to follow effectiveness criteria in providing care and to also ensure the sustainability of the system – to close the door to judicial interpretations on the comprehensive definitions of compassionate care

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[1] Court of Mantua, Order, proc. 1740/2013, 2/5/13, http://www.ilcaso.it/giurisprudenza/archivio/9036.pdf

[2] Interview of M. Andolina at Presadiretta, rai3, 14/01/14, quoted by national dailies. For the reconstruction of the very first steps of the story see also: Angelini L., *"Staminali, il giallo del primo paziente. I dati anagrafici del primo paziente coincidono con quelli di un alto dirigente regionale of the Sanità",* "Corriere della Sera"/Brescia, 7/12/12

[3] Mangili C., "*Stamina gratis? Era tutto a pagamento. Mio marito: ne approfittano. Poi è morto*", "L'Eco di Bergamo", 10/01/14; "*Stamina, inchiesta verso la chiusura. Fonti investigative: "Venti indagati*"", La Stampa, 18/1/14

and technical-scientific subjects. The bombshell exploded in May 2012 when AIFA (Italian Drugs Agency) ordered the treatments to be stopped. In August there came the first judgment which ordered the treatment to be recommenced for a little girl[4]. The appeals against the initial order then multiplied and the Decree of March 2013, converted into law in May, allowed completing the treatments already started - thereby introducing inequality among citizens with respect to access to care. This is no minor issue, so much so that a magistrate requested the opinion of the Constitutional Court[5]. It must be said that the views of the judges on this issue are split and therefore there are several judgments rejecting requests for access to this treatment on the ground of its poor scientific guarantees.
The impact of the appeals fell on the hospital in Brescia: Stamina used its laboratories for producing the mixture then administered in a department of the structure. The 12 patients of the group mentioned in the Decree were joined by other 350 on the waiting list who had lodged their appeals with the judiciary. This waiting list is likely to increase until uncertainty persists. This was a significant impact in many ways, not least on account of the costs: for hospitalizations (around 10.000 €/patient) and legal costs, and to challenge the applications for treatment (little less than €180,000 in 2013[6] and 500,000[7] in 2014).

The opposition by the "Spedali" highlights the *quality of care* issue and the procedures for assessing it, also in the context of compassionate care. Indeed, if current regulations were enough, AIFA's provisions would have cut the discussion on this matter short. Instead, the debate flared up and was also fuelled by the perhaps excessively optimistic tones of the supporters, according to whom the therapy would be a panacea for multitudes without care.

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[4] Court of Venice, Labour sect., order of 30/8/12

[5] Court of Taranto, Labour sect., order 23 of 24/9/13

[6] Dusi E., "*Stamina, gli Spedali Civili di Brescia: 'Basta, è un inferno. Situazione impossibile'*", "La Repubblica", 28/09/13

[7] Lozito F., "*Stamina, le sentenze del TAR del Lazio e il nodo giuridico*", *Lettera 43*, online daily newspaper, 25/12/13 http://www.lettera43.it/cronaca/stamina-le-sentenze-del-TAR del Lazio-e-il-nodo-giuridico_43675118566.htm

To settle the issue, Parliament in an exceptionally short time ordered the conversion of the Decree into law and the starting of a clinical trial, partially derogating from the provisions of the legislation in force.
A possible *deregulation* in the field of stem cells in Italy is observed with great concern also from abroad, because research is very active in this sector due to the advances in treatment it would appear to enable; however, reckless businessmen are also quite keen on this sector.

The invitation to recognize the importance of controls to protect patients[8] was accepted and therefore compliance was ensured with some key elements of clinical trials pursuant to international regulations. Essentially, at least one of the terms on which the debate is focused was clarified: the method cannot be equated to a transplantation, but – at least in theory – it is a drug, given the type of manipulation the cells undergo. However, the method never reached the clinical trial stage because it did not pass the preliminary assessment by the committee of experts appointed by the Ministry of Health.

Many members of the committee expressed their unfavourable opinion even before examining the study protocol in detail. According to the TAR (Regional Administrative Court) of Latium, this was an indication of unfair assessment; hence the Court ordered the appointment of a new committee «consisting of members, possibly also from abroad, who have not expressed their opinion on this issue or, where impossible, because all experts have already taken a stand, the Committee should include an equal number of experts who have voiced their support for the said method»[9] in order to reach a final opinion.

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[8] *"ISSCR Emphasizes Importance of Regulatory Oversight for Stem Cell Products for Clinical Use"*, Apr. 22, 2013

[9] TAR del Lazio (Regional Administrative Court for Latium), order 8730/2013

Besides, although the allegations of pressure exerted by the pharma industry are in general not unfounded, as the supporters of Stamina vigorously pointed out, the international debate focuses more on increasing the accessibility of the data than on blindly trusting the quality of care – which is apparently the preferred approach for the inventor of the method : «Clinical trials are just window dressing, a gift to the scientific community and transparency, but they are not for patients»[10].

For example, the international petition *All Trial,* goes in the direction of increased oversight and is supported by influential signatories to get transparency on investigational data. Sometimes these data were at least in part not disclosed, as the Tamiflu case highlighted, since the manufacturer – Roche – legally retained part of the data[11]. The same direction is followed by associations such as "Famiglie SMA" and "Luca Coscioni"[12], which more than once intervened also to oppose the exploitation of patients' suffering.

Pending new developments in the case, the story reveals how delicate a role the law plays when applied to reality and how much care the lawgiver should take in writing the laws, especially in this period. Streamlining, cuts to wasteful spending and sustainability have been the buzzwords in health care for the past few years, reinforced by the recession and the appeal to contain the budgetary deficit - which almost led to forgetting Article 32 of the Constitution, where health is defined as " *a fundamental right of the individual and as a collective interest".*

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[10] Declaration by D. Vannoni, Rome, ANSA, 1/8/13

[11] Maciocco G., "*Il caso Tamiflu*", com.unità, 3/2/13, http://salutepertutti.com.unita.it/sociale/2013/02/03/il-caso-tamiflu/

Godlee F., "*Clinical trial data for all drugs in current use*", 29/10/12, British Medical Journal

Goldacre B., "*It's a scandal drug trial results are still being withheld*", The Guardian, 5/1/14

[12] In this regard, see: http://www.famigliesma.org/index.php?option=com_content&view=article&id=400:famiglie-sma-perche-l-atrofia-muscolare-spinale-sma-and-esclusa-dalla-sperimentazione-stamina&catid=118:contenitore-ricerca-staminali&Itemid=654#.Uj78YobIbpU; http://www.associazionelucacoscioni.it/comunicato/smascherata-sul-corriere-la-malafede-di-vannoni

This right justifies the expenditure for medical care provided to individuals by way of the commitment undertaken in Article 3 of the Constitution "*to remove those obstacles of an economic or social nature which constrain freedom and equality of citizens, thereby impeding the full development of the human person and the effective participation of all workers in the political, economic and social organisation of the Country."* The organisation of a medical system capable of mitigating the substantial differences between individuals is considered an investment in favour of the community as a whole, as pointed out by the World Health Organization: «*A better medical system is fundamental for human happiness and wellbeing. In addition, it contributes significantly to economic progress, because healthier populations live longer, are more productive and can save more*."

Therefore, it is in the fragile balance between spending for pursuing health and the constraints imposed by the current economic situation that the struggle is being waged to ensure the current and future enjoyment of this right in Italy - a sort of indication of the orientation of relationships within society. Some data may help understand the complexity of the universe that revolves around the right to health and the barriers to its enjoyment.

Who works for health? At the end of 2012, the Italian National Health System had 672,051 employees[13] (in addition to doctors and nurses, administrative staff, technicians, veterinarians – the health of the animals is linked to human health, Bovine Spongiform Encephalopathy "*docet"* - porters, cooks and managers). In addition there are 60,000 chemists[14], pharma industry employees – about 60,000 more – plus as many workers in related industries, without forgetting the several thousand workers in subsidised healthcare facilities (hospitals, laboratories), social cooperatives and voluntary

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[13] The State's General Accounting Department, Analysis of some data of the annual General Statement of Accounts of the period 2007-2012, 16/12/13

[14] Data from: http://www.federfarma.it/Farmaci-and-farmacie/Notizie-and-dati-dall-Europa/Numero-di-farmacisti.aspx

work[15]. It is not just a matter of jobs, even though this is no secondary issue: research and innovation are strategic for economy as well as for health care and have in this field one of their natural locations. The above considerations lead one to shift the gaze to the future: of the little more than 59 million residents, over 12 million are older than 65[16], corresponding to 147.2 every 100 individuals under 15 years[17]. This is yet another challenge to the sustainability of the whole system, together with the exponential growth, for example, of the price of cancer drugs[18], for which sometimes progress is measured via a few weeks' increase in survival rates[19]. The very conformation of Italy's territory – about 20% of the population lives in mountain areas – is a challenge to the universality of the right to care in an age where expensive equipment and up-to-date medical teams are required to achieve excellent results.

A predicament not easy to sort out, given the broad array of byzantine bureaucracy, lengthy negotiations between the different political forces and interventions of the judiciary, overshadowing the results obtained in relation to expenditure, less than elsewhere as shown by data comparing the situation in Italy with that in the U.S.A. – where access to health care depends to a large extent on private insurance - and in two European countries that are often taken as terms of comparison.

Per capita GNP (US $)	32,400	35,910	40,230	48,820
Total per capita health expenditure (US $)	3,435.6	4,952.0	4,875.0	8,607.9
Quota paid by government bodies over the total health expenditure	77.2%	76.7%	75.9%	45.9%
Child mortality rate (under-5 per 1,000 live births)	4	4	4	8
Maternal death rate (per 1,000 live births). Data 2010	4	8	7	21
Life expectancy (years)	82	82	81	79

(Source: World Health Organization, data 2011, unless otherwise explained, http://apps.who.int/gho/data/node.main

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[15] UniCredit Foundation, "Ricerca sul valore economico del Terzo Settore in Italia", 2012

[16] Source: ISTAT, Resident population as of 1 January 2012 for age, gender and marital status in Italy, (my data processing)

[17] Istat, Noi Italia

[18] http://www.mskcc.org/research/health-policy-outcomes/cost-drugs

[19] Hall S. S., *The Cost of Living*, New York, Oct 20, 13

Discriminations and violence

More than just a review of the cases in which the right to health was violated or discrimination occurred, one can provide "clues" about the grey areas that affect prevention and care, with a warning: some victims may not perceive to be such, others – aware of the violence suffered – may not have the strength or the means to denounce, others found the courage to speak up just for "one day" and then seem to fall into oblivion for the rest of the year.

6 January 2013. **Rome. Barriers to health care: language**. A research highlights the embarrassment of British patients to ask for an explanation on diagnosis and treatment. Interviews to Italian physicians confirm: the problem is widespread even among young patients and has consequences on the outcomes of treatments also involving the taking of drugs.

23 January 2013. Rome. Ethics is missing: bribes for treatment. An Italian out of 10 has allegedly paid bribes to access health care services. The figures emerged at the First Italian Meeting on Ethics in National Public Health sponsored by ISPE (Institute for the promotion of ethics in health care). Corruption in health care was said to amount to 10 billion Euro/year in Italy.

1 February 2013. Drugs in Italy: The survey by OsMed (Observatory on the use of medicines) is published. The data for the first nine months in 2012 are as follows: Italians spend out of their own pocket more than € 5.5 billion in drugs, in part (651 million) to purchase the branded product instead of the generic one. Consumption increases: on average, one dose a day per capita, with substantial regional variations. The boom of antidepressants continues and the use of antibiotics decreases for the first time: -6.4%. While AIFA (Italian Medicines Agency) highlights the effect produced by the decrease in the prices of subsidized drugs on the containment of expenditure, Federfarma (Italian National Association of Owners of Pharmacies) stresses the lack of access to new medicines on the

Italian market in 2012, including anticancer drugs and drugs against hepatitis C.

16 March 2013. Brussels. **Pollution:** costs for health. Because of coal power plants Italian health is said to pay € 857 million.

This estimate is shown in the report by *Health and Environment Alliance*, active in 26 European countries. Italy ranks reportedly 10th among EU member states for health care costs related to this cause. 6,000 deaths and over € 10 billion would be saved in Italy if thin dust particles were reduced by 50%.

28 March, 2013 Racale (LE). Freedom of care: the first "Cannabis social club" is discovered. Over 1,000 patients joined for the cultivation of cannabis for therapeutic use. According to the organizers, patients turn to the "black market" because the legal purchase of the substance is very complicated.

A few days later, **on 4 April**, only one drug of this category obtained the marketing authorisation by AIFA (Italian Medicines Agency)[20], with stricter procedures than those for opioids. This is paradoxical when compared with the news on the legalization of cannabis for recreational use coming from the United States.

1 April 2013. Italy. Access to care: illegal migrants penalized. A study on "Lancet" at European level confirms Italian data: migrants' health, basically good on arrival due to the fact that sick migrants rarely leave, tends to worsen after their arrival[21]. Among the causes, in addition to poor living conditions, there are their difficulties in accessing public services of medical care.

9 May, 2013 Bologna. Recession: children care also cut. Some signals were highlighted at the National Congress of Sip (Italian Society of Paediatrics): the early use of cow's milk is on the rise for saving purposes; some infectious diseases are increasing also due to the reduced recourse to paid vaccinations, for instance in

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[20] O.G. No. 100, 30/4/13

[21] Ministry of Health, "Relazione sullo stato sanitario del Paese 2011"

the case of bacterial meningitis that mainly affects children under one year and can be deadly.

The situation of chronic diseases worsens: support services decrease, there may be more problems in the supply of the so-called "orphan" drugs – often very expensive - to treat rare medical conditions. A 20-40% decrease is estimated in visits to outpatient clinics subject to payment of a fee ("ticket"), which is confirmed by the 10% increase of the visits by Italian families to free-of-charge outpatient clinics as recorded by INMP (National Institute for Health, Migration and Poverty – NIHMP).

28 June.2013 Rome Guidelines not implemented: the case of rheumatic diseases (700,000 patients). At the Conference "The suitableness of prescribing biologic drugs as means of saving for the community" experts denounced that only one third of the 150,000 patients suffering from severe chronic disabling rheumatic diseases can access the new treatments indicated by national and international guidelines. These are expensive treatments: about € 10.000/ patient/year, but after a year of therapy they can reduce severe disabilities and, consequently, impact on the quality of life. The cost of sick leaves and lower productivity was estimated to be about €1.7 billion/year. The news are related to another piece of information dating back to 14 January: Apmar (Association of People with Rheumatic Disease) denounced a series of thefts of biological drugs for rheumatoid arthritis, psoriasis and Crohn's disease from in-hospital pharmacies in various areas in Italy.

29 July. 2013. Italy cost-saving strategies: oncological patients. «Linear cuts threaten oncological treatments, which are already inadequate in several regions. Instead, we agree on making a more efficient use of resources». The President of FAVO (Federation of Italian Voluntary Associations in Oncology) declared the above at the hearing of the joint Committees for Budgetary and Social Affairs at the Chamber of Deputies and he recalled that deaths in acute care wards entail much higher costs because there are no home-care facilities.

24 September. 2013 Perugia. Health care risks: insurance policies. No insurance company entered bids at the call for tenders for the coverage of "catastrophic" risks with damages exceeding € 800,000 (4-6 cases per year). The Region directly pays damages under that threshold.

9 October 2013. Italy. **Access to care: eye diseases**. On the occasion of the World Sight Day, the Soi (Italian Society of Ophthalmology) denounced: the low cost drug that can stop age-related macular degeneration is not available.

22 November. 2013. Italy. Planning of Expenditure: hepatitis. Considering the data, we need a National plan against hepatitis: Italy has the highest mortality rate for hepatocellular carcinoma in Europe; every day there are about 30 deaths from cirrhosis and hepatocellular carcinoma; there are 1.8 million of hepatitis C carriers. For the World Day, Epac (a non-profit association supporting patients with liver diseases) highlighted that only 9 Regions prepared diagnostic and care pathways for gaining access to new drugs.

14 November 2013 Senate; 26 November 2013 Chamber of Deputies. **Discriminations: Neonates.** Bills were submitted to ensure that all Regions should enable neonatal screenings to detect rare metabolic diseases with often disabling symptoms, especially if not recognized so soon. Currently this type of screening is only available in Tuscany, Umbria and Sardinia.

31 December 2013: Drawing the balance. The National Health Plan (Pact for health) and the update of LEA (Basic levels of health care) - expected, among others, by a 1 million and a half people with rare diseases (as estimated by Minister Balduzzi in February) – were postponed. The distorting effect of the regionalization of health care services is confirmed, so much so that the fruition of health care services is a variable depending on a person's residence[22].

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[22] Ministry of Health, Fulfilment of the "continuity in the provision of LEA (Basic levels of health

The differences are related to the cuts to health care and the payback plans for the Regions in deficit; however, they are also a direct consequence of the multiplication of procedures and the difficult coordination to be achieved via the State – Regions Conference.

While Italians do without treatments or "manage" somehow to get them – with the help of *coupons* for discounted services[23] and aid from the Banco Farmaceutico (a non-profit foundation that collects medicines for indigent people)[24] - one of the causes of the demand for health care is made clear: «Who does defend the doctor from the "blackmail" by the patients, who, if they do not get what they want, apply to be assigned to another doctor? »[25].

This year started with an estimated debt towards suppliers of about € 40 billion. The State Auditors' Court can hardly manage to understand the financial statements: «By virtue of a mistaken notion of autonomy each Region has adopted its own systems»[26], a problem that might be solved in 2014 (Legislative decree No. 118/2011); it seems that «often, regions use resources allocated to health care to face liquidity needs of other sectors»[27].

This is a paradoxical approach when, in fact, maximum rationality would be necessary to know where and how to reduce spending. All this is happening among oranges, azaleas and whatever other thing can be relied upon to fund research and care. [Note: The latter sentence refers to the many initiatives waged by foundations and associations to collect donations in exchange for small gifts like potted plants, bags of fruit, etc.]

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care)" through the indicators of the LEA grid, Methodology and Results for 2010, March 2012

[23] Data from the Groupon site: 300,000 in 2012 for dental treatments and physiotherapy, cardiology visits, echographies, psychological counselling and psychotherapy, Ansa, 20/1/13

[24] The Foundation collects, every year in February, C-group drugs for the less affluent. In the province of Naples aid requests increased by 146% in 6 years, Ansa, 11/10/13

[25] Del Barone, National President of SMI (Italian Medical Doctors' Union), Ansa, 4/10/13

[26] State Auditors' Court, Autonomies Section, "Relazione sulla gestione finanziaria delle regioni esercizi 2010 – 2011", page 281

[27] State Auditors' Court, Autonomies Section, "Relazione sulla gestione finanziaria delle regioni esercizi 2011 – 2012", page 354

Legislation and policies

Considering the anniversary, here are some historical notes: the Italian National Health System was established by Law 883/1978 that came into force on 1 July 1980. The old system was superseded. The previous system was mainly based on the health care funds of various categories of workers and was fragmented, marked by severe budget deficits and, above all, by wide disparities in access to care, linked to the performance of the different funds[28].

Law 883/78 introduced the financing of the health care through general taxation and during the first phase afforded a totally free service. The State was responsible for the general planning and the Regions for the implementing actions. Later, tickets (fees) were introduced and the role of the Regions became more substantial following fiscal federalism and the constitutional reform[29]. This led to the current scheme, with 21 Regional Services and funding divided between the State and the regions.

There are still differences between regions with a special status and the remainder. In general, the Regions count on revenues determined autonomously, coming from taxation (IRAP, regional corporate income tax; regional surtax on IRPEF personal income tax; quotas on VAT and specific surtax on fuel) and from services (tickets and revenues from fees levied on in-hospital specialist care). Finally, the State intervenes with the help of general taxation to compensate for the differences, through equalization instruments at national level.

With the National Health Plan, a 3-year planning tool, established in agreement with the Regions, the uniform delivery of LEA should be achieved. The criteria[30] to include the services provided in the LEA are *efficacy* (scientific evidence demonstrating a significant

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[28] Masulli I., "Cittadinanza and stato sociale in Italia: azione sindacale and politiche governative negli anni Sessanta and Settanta"; Ascoli U., "Il modello storico del Welfare State Italiano", by Sorba C., in "Cittadinanza. Individui, diritti sociali, collettività nella storia contemporanea", proceedings of the annual conference of SISSCO, Padua, 2-3 December 1999, Ministry of Cultural Heritage and Activities, DG for Archives, Rome, 2002

[29] Law 133/1999; D. Lgs. 56/2000; Const. Law 3/2001

[30] Decree-law No. 502 of 30/12/1992

benefit in terms of health, at individual or community level, in comparison with the resources provided), *appropriateness* (for the specific clinical condition the recommended indications are applied), and *efficiency* (where efficacy is the same, the less costly type of care is chosen both in medical protocols and in the organization and provision of services). In addition, each Region may, through its own resources, expand the LEA offered to residents.

Even if lower than in the reference countries, health expenditure went from € 112.889 billion in the 2011 State's balance [31] (1,862 Euro per capita) to about 111 billion in 2013[32]. For 2014 the apportionment is expected to be around 109 billion[33], with a reduction that went unnoticed in the troubled political season of end 2013. This is shown by the approval of the Stabilisation Law[34] consisting of a single Article with 749 paragraphs, among which there is a decrease from 19% to 18% of the deduction allowed for health care costs. These choices were made in the framework of a crisis that began in 2008 and reached its peak (- 3.6%) in the first quarter of 2009[35]. The measures concerning health care in Decree-law 98/11, Decree-law 95/12 and in the Stabilisation law for 2013 are drastic: minus 900 million in 2012, 4,900 in 2013 and 8,000 in 2014[36]. The above amounts have been the subject of constant negotiations, difficult to describe due to their complexity, which does not make it easy to anticipate where and how they will be actually impacting. For example, Decree-law 98/11 provided for increases of € 2 billion in 2014 on health care fees ("tickets"), which could be avoided thanks to the pronouncement 197/2012 by the Constitutional Court.

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[31] "Relazione generale sulla situazione economica del Paese", Ministry of Economy, page 179

[32] Economic and Financial Document 2013

[33] *Budget and Financial Stabilisation Law. Lorenzin: Fondo sanitario 2014 è di oltre 109 miliardi* Daily newspaper Sanità , 27/11/13

[34] Law 147/13

[35] Istat, "Conti economici trimestrali", 10/09/13, page 5

[36] Source: Ministry of Health, Uscire dalla crisi: chiarezza sui numeri della sanità , Health Minister's press conference, 19/12/12

Above all, the new National Health Plan (now called Pact for Health) has not been defined yet although it was supposed to be launched in early 2013.
This time, the Pact should have 5-year duration and the firm intentions seem to be to overcome linear cuts in order to rationalize expenditure: for example, the reduction of hospital beds should be accompanied by a strengthening of local care and the reshaping of LEA. Several reasons may account for the delay, not least the recent political uncertainty that still persists. For example, to identify the three benchmark Regions for the services to be provided in terms of efficiency and appropriateness[37], there was a confrontation among the five Regions selected by the Ministry at the end of July (Umbria, Emilia Romagna, Marche, Lombardy and Veneto) [38].
"Costi standard. Le Regioni Benchmark 2013 saranno Emilia Romagna, Umbria and Veneto", ("Standard costs. The benchmark regions 2013 will be Emilia Romagna, Umbria and Veneto"): this was the headline of a newspaper on 5 December 2013[39].

The delay is reflected in the territories, some of which are heavily affected by plans to cut spending undertaken in ten Regions (since 2007: Abruzzo, Campania, Latium, Liguria, Molise, Sardinia, Sicily; 2009: Calabria; 2010: Piedmont and Apulia). The goal was achieved by Liguria and Sardinia at the end of 2010[40]. For the remainder, five regions have been administered by a governmental commissioner as to health care: Latium since 2008; Campania and Molise since 2009; Calabria since 2010 and Abruzzo since 2012.

The issue is complex given the many interests involved – not always legitimate[41] – that juxtapose in the immense field of action of the Na-

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[37] Resolution of Prime Minister's Office 11/12/12, Definizione dei criteri di qualità dei servizi erogati, appropriatezza ed efficienza per la scelta delle regioni di riferimento ai fini della determinazione dei costi and dei fabbisogni standard nel settore sanitario. (13A04967)

[38] Turno R., "*Sulla sanità derby tra regioni leghiste*", "Il Sole 24 Ore", 31/7/13

[39] Quotidiano sanità

[40] Health Minister's press conference , quote.

[41] Coripe Piemonte, Consorzio per la Ricerca and l'Istruzione Permanente in Economia" (Consortium for Research and Lifelong Training in Economics) and Associations: Libera, Avviso

tional Health System, where the many stakeholders try to steer the decisions in their favour. If, then, the application of Law 190/2012 ("Disposizioni per la prevenzione and la repressione della corruzione e dell'illegalità nella pubblica amministrazione" – "Measures for the prevention and suppression of illegality and corruption in the public administration") is provided for also with regard to health care companies, many issues are still open to negotiation. It is a context in which several rights come into play: the right to health and care, the right to education – as to university training in hospitals - and the right to work, also due to the consequences of Fornero's reform[42].

The debate on reducing costs unfolds just as painstakingly in the Regions (more than 70% of their budgets are related to health care); since each develops its own social and health care plan, there are significant differences between them and this impacts the three areas identified above.

Access to care.

It starts from the Health Card, indispensable to have access to health care, which is issued also to those not in compliance with the residence permit in Italy ("STP" card, i.e. the card issued to Aliens Temporarily in Italy by ASL – Local Health Units) by virtue of the State-Regions Agreement of 20/12/2012[43] reaffirming the universal nature of this right and explicitly forbidding reporting to the police - which settled the doubts raised by the immigration law.

However, not everyone holds a chip card that would, among other things, enable booking visits and exams on-line (Decree-law 78 of

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Pubblico , Gruppo Abele , La Prevenzione e il Contrasto dell illegalità nella tutela della salute . Introductory Report Illuminiamo la salute per non cadere nella ragnatela dell illegalità , Rome, 27/6/13

[42] Basic forms for the new Health Care Pact, Reports by the Health National System/University and Health Research, in: ESCLUSIVA Patto per la salute, le ipotesi su cui decidono i governatori. Farmaci, ospedali, medici, università, dispositivi: dove affonda il bisturi , Il Sole 24 Ore Sanità , 30/10/13

[43] Proceedings Ref. No. 255/CSR (State-Regions Conference), "Indicazione per la corretta applicazione della normativa per l'assistenza sanitaria alla popolazione straniera da parte delle Regioni and Province autonome"

31/5/10, conversion law No. 122/10). If in Friuli[44] and Lombardy[45], for example, the health card seems to be widespread and used also for other services, in other Regions citizens are likely to wait until 2016: the decree provides for the gradual replacement of expiring cards. Oddly, since the Decree proposed the above cards as a means for saving: «no less than € 600 million on an annual basis that shall remain at the disposal of regional health services» (section 7). Another tool is the "electronic prescription" for the "dematerialization" of medical prescriptions, mentioned in Decree-law 179 of 18/12/12 with the following time schedule for implementation: «60 per cent in 2013, 80 per cent in 2014 and 90 per cent in 2015» (section 13, paragraph 1). As for waiting times, on-line booking procedures, where available, vary from Region to Region[46].

The path of Fascicolo Sanitario Elettronico (FSE) (Electronic Health Record) is rougher. It is only accessible to the concerned party and to those authorised and should file all contact with the NHS – medical records, certificates, prescriptions – and the willingness to donate organs[47]. In theory, diagnostic errors could be reduced as resulting from gaps in the patient's medical history and the data, stripped from references to the specific individual, could allow detecting anomalies in the incidence of diseases or planning the range of services to better meet patients' needs. Costs could be contained by monitoring the appropriateness of treatments. Finally, there would be immediate benefits for both the NHS – less paperwork and counters – and citizens, at least those provided with the card, as waiting times and costs (travel, queues) due to the bureaucratic aspect of the treatment could be basically zeroed. The privacy guidelines date back

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[44] http://cartaservizi.region.fvg.it/CrsCentralService/areaPubblica/CrsPublic/CrsHome/?page=FEServiziDisponibili

[45] http://www.crs.lombardia.it/ds/Satellite?childpagename=CRS%2FCRSLayout&c=Page&pagename=CRSWrapper&cid=1213350950929

[46] The procedures of Latium and Piedmont were tested as a sample. http://www.poslazio.it/opencms7/opencms/sociale/pos/cittadino/Servizi_al_cittadino/Prenotazioni_prestazioni/ https://secure.sistemapiemonte.it/health/prenotazioni/CsiConnectionController

[47] The citizen could supplement the "Fascicolo" (Electronic Health Record) also with medical reports by private specialists. Thus, for example, in Emilia Romagna.

to 2009[48] and are accompanied by these words: «In this way, once more, the Authority plays a role of "substitute" pending the enactment of appropriate legislation»[49]. In actual fact, already in 2008, some Regions tested the EHR[50], but the guidelines of the Ministry came in 2010[51] and the project became part of the plan only through the provisions for re-launching economy (Section 12, Decree-law No. 179 of 18/10/12; Section 17, paragraph 1, of Decree-law No. 69 of 21/6/13). In the meantime, several regional systems have been implemented presumably fraught with compatibility issues.
The measures that could allow rational cuts require time, investments and negotiations [52] to be implemented. It was "a urgent priority" and the right – defined by the Constitutional Court "financially conditioned" - became even more insecure (Constitutional Court 248/11); indeed, this interpretation had already surfaced in 2005: «the need to ensure universality and thoroughness of care in our country collided, and is still colliding, with limited financial resources» (Judgment No. 111).

The "clues" provided above describe the effects produced on health by the joint action of the decreased income and the public finance measures; they are confirmed by Istat (Italian National Institute of Statistics) as for the increase of social and territorial inequalities,[53], by Censis[54] (Italian socio-economic research institute) as for the ef-

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[48] Italian Data Protection Authority, "Linee guida in materia di Fascicolo sanitario elettronico (Fse) e di dossier sanitario" – 16/7/09 (G.U. n. 178 3/8/09), Register of Resolutions No. 25 16/7/09

[49] "Fascicolo sanitario elettronico: il Garante approva le Linee guida". Press release, 11/8/09

[50] Di Giacinto A., Randazzo M. P., "Il Fascicolo Sanitario Elettronico", Basilicata Region Workshop 2009

[51] Ministry of Health, "Il Fascicolo Sanitario Elettronico", National Guidelines, 11/11/10

[52] By way of example, three Regions: Latium: "Medici di famiglia: Conclusa la riunione in Regione: raggiunto un accordo", 28/3/12. http://www.smi-lazio.org/modules.php?name=News&file=article&sid=465
Campania: Decree No. 87, 24/07/13, Supplementary Regional Agreement for General Medicine. Approval.
Veneto: Regional Resolution No. 1753, 3/10/13

[53] Istat, "La salute e il ricorso ai servizi sanitari attraverso la crisi", Year 2012 (September-December average), provisional data, 24/12/13

[54] *"27% of Italians noticed that the ticket (fee) to be paid for a health service was higher than the cost to be incurred in the private sector, i.e. than paying it out of their own pockets (the percentage rises to 37% in Regions with Plans to Cut Spending, where public health has been affected more by cuts).*

fects produced by the increased fees on medical services ("tickets")[55] and by Agenas[56] (Italian National Vocational Training Agency for Regional Health Services) regarding the decrease of the specialist services provided by the NHS which is only partially offset by *intra-moenia* (NdT services provided by Italian doctors outside their working time but in public hospitals) or private services. These outcomes are very different from those of a universal health care system in which the careful application of health care fees [57] helps manage the demand in an equitable manner. Taking into account the general impoverishment of the population[58] and that deductible medical costs (including tickets) require the immediate availability of cash, it is highly likely that the number of citizens obliged to do without care, at least in part, because of their income will be on the rise.

With the crisis, also the waiting time makes the system more unfair because waiting time is another instrument to manage the demand. In theory, it should "convince" wealthier people to use paid services and medical insurance services; in practice, it forces employees on short-term contracts or low-income self-employed people to pay for such services because they need to get well quickly to avoid a work stoppage and, therefore, a further reduction of their revenues.

At the moment, it is a paradox related to low-tech investigations but it should not be underestimated". Censis, Fuga nel privato per curarsi: 12,2 milioni di Italiani hanno aumentato il ricorso alla sanità a pagamento, Press release for the presentation of a RBM Sanità-Censis Research on the role of health insurance schemes, Rome, 4/6/13

[55] 35% are exempt due to low income or specific conditions (Ministry of Health, Uscire dalla crisi: chiarezza sui numeri della sanità, quote). Exempt due to low income: up to 6 years and over 65, family income under € 36,151.98; unemployed and seniors over 60 years, family income under € 8,263.31, up to € 11,362.05 with spouse (+ € 516.46 for a dependent child).

[56] Agenas Report (National Agency for Regional Health Services) illustrated by the President, G. Bissoni, during the hearing of the joint Commissions for Social Affairs and Budget at the Chamber of Deputies (Indagine sulla sostenibilità del Servizio sanitario nazionale), Rome, 10/9/13

[57] Rebba, V., "*I ticket sanitari: strumenti di controllo della domanda o artefici di disuguaglianze nell'accesso alle cure?*" In "Politiche sanitarie", vol. 19, No. 4, 2009, pages 221 - 242

[58] In 2012, the relative poverty threshold lowered (€ 990.88 for a two-person household, - 2% since 2011). The threshold is parameterized to the general expenditure capacity, in this case it is decreasing: if the threshold had been kept in line with inflation (+ 3%), the number of families in relative poverty would be higher - rising from 3,232 million to 3,592. Data by Istat, La povertà in Italia, Anno 2012 , 17/7/13

The issue is exacerbated in the event they need hospital services: the phenomenon of medical migration from southern regions to those in the north [59] remains substantial and can be only partially justified by the flow towards centres of excellence at national level. In these cases, mobility penalizes poorer citizens more: trips and, sometimes, extended stays often require at least one companion with all the resulting expenses.

As for *hospice care*, if one assumes that the relevant benchmark (1 bed/100 deceased patients) is appropriate, the goal seems to have been achieved: 2,524[60] for 173,000[61] deaths, but 744 of the former are in Lombardy and the deaths occurred all over Italy. So, one third of the patients die in hospitals, in 2011 only 55,242 received home care and even fewer, 40,564, palliative care. We continue to heavily rely on the volunteering sector, also active in fundraising (almost € 20 million in 2011[62]), even though the first law dates back to '99[63]. A tiring and slow pace: the regulations on the qualifications to be held by medical doctors in order to administer palliative care appeared in the Stability Law (paragraph 425).

Freedom of care.

As for the possibility to reject treatment, the reference benchmark can be found in Article 32, paragraph 2, of the Constitution: *"No one may be obliged to undergo any health treatment except under the provisions of the law.*

The law may not under any circumstances violate the limits imposed by respect for the human person." together with Article 13 of the Constitution ("*Personal liberty is inviolable."*) and Article

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[59] Viaggiare per la salute , La mobilità sanitaria , Proceedings of the Agenas-AIE-AIES Conference, Rome 3-4/5/11, I quaderni Monitor , Supplement to No. 29 of 2012

[60] FCP - Federazione Cure Palliative (Palliative Care Federation), - Database January 2014

[61] Report to the Parliament on the implementation of Law No. 38 of 15 March 2010, year 2012, Tables 1, 13, 14

[62] Data concerning only organizations pertaining to FCP, Report to Parliament, quote, page 79

[63] Min. Decree 28/9/99, "Programma nazionale per la realizzazione di strutture per le cure palliative"

33 of Law 833/78 (*medical investigations and health treatments are usually voluntary*). The Court of Cassation confirmed the principle[64]: informed consent is essential, it has to be based on detailed information, explicit (tacit or alleged consent is excluded), specific (for each specific treatment).

In the event of *end of life* treatments there is a legal void: early elections have shelved the controversial bill by Mr. Calabrò, written during the last frantic stage of the Englaro case, strongly limiting individual freedom.
The only reference is to the pronouncement of the Court of Cassation[65], which is however only applicable for suspending hydration and nutrition to those who have expressed unambiguously their will beforehand and are in an irreversible vegetative state. Several local authorities[66] have set up registries and associations have prepared forms available online to collect explicit wills. Without a specific law, however, documents and procedures are heterogeneous and expressions of a person's wishes are automatically enforceable only in the cases provided for by the Court of Cassation. The range of clinical conditions and medical treatments, by contrast, is much wider, as in Mr Welby's case. Mr Welby underwent treatments contrary to his will while he was in a state of temporary unconsciousness and they allowed him to survive for a long time against his will. The doctor who enabled him to die, however, was prosecuted on charges of murder of a consenting victim, although the charge was finally dismissed (Rome, 23/7/2007). In the legal void, the only further guideline is the Medical Code of Ethics (Article 38, Autonomy of the citizen and advance directives), but the procedures for ascertaining a person's wishes (even where an agent/guardian is available) are difficult to reconcile with the need for promptness of some medical procedures in emergency cases, such as after a trauma. Maybe, citizens may file their will with the Fse, when it is active.

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[64] Court of Cassation, judgment 20894, 27/11/12, Civil sect. III

[65] Court of Cassation, judgment 21748, 16/10/07, Civil Sect. I

[66] Biological Will, Turin, March 2011; Prior Declaration for Treatment, Province of Pisa, Nov. 2009; Prior Provision for Treatment, Bologna, Nov. 2011

The voter initiative bill *"Refusal of medical treatment and the legality of euthanasia",* signed by more than 65,000 Italian citizens[67] and filed in Parliament on 13/9/2013, is a qualitative leap forward.

The law would be directed only to adults able to express their wishes autonomously or, if unconscious, through a trustee. Said bill, if approved[68], would lead to the legalization of euthanasia, a rather difficult goal to achieve, considering that end of life issues have sparked major confrontations such as to make the political debate rather sterile so far.

Regarding alternative treatments, the regulatory framework shows some novelties concerning homeopathic medicines as used by millions of Italians[69].

The matter was already partially disciplined since 2006[70] by the legislation aimed at regulating all the medical drugs sector. However, there was no procedure for registering homeopathic and anthroposophic drugs with AIFA (Italian Medicines Agency), which only became possible in 2012[71]. Therefore, by the end of 2015, about 25,000 pharmaceutical products [72] should be submitted to a simplified registration[73] procedure certifying only they are not toxic, and comply with quality requirements, to safeguard consumers[74], whilst their efficacy will not be certified as is the case of allopathic specialties. In fact, double-blind vs. placebo or standard therapy trials are not required.

This innovation allows solving the problem of provisional authori-

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[67] Data disclosed by the promoting committee, "Eutanasia Legale" http://www.eutanasialegale.it/

[68] Proposal for the inapplicability of the provisions of Sections 575, 579, 580 and 593 of the Criminal Code to medical staff

[69] Italians using homeopathic remedies are reportedly about 7 million. See *"Omeopatia. Si cambia. Anche in Italia nuove regole"*, in "Quotidiano sanità", 4/12/12 CHECK

[70] Legislative Decree No. 219, implementation of directive 2001/83/CE - and subsequent amendments – on an EU Code concerning drugs for human consumption and directive 2003/94/CE

[71] Section 13, Decree Law 158 13/9/12, Conversion Law No. 189 of 8/11/12.

[72] AIFA, ibidem

[73] AIFA, "Calendario per la presentazione delle domande di regolarizzazione dei medicinali omeopatici in commercio", page 27, 10/9/13

[74] Section 16 of Legislative Decree 219/06

zations[75], but it aroused very negative reactions in the sector because of the registration rates[76] and the reduced annual fees. Representatives of the sector consider them high, such as to endanger businesses and employment[77]. There are several initiatives – an appeal to the Regional Administrative Court for the Latium[78], a petition[79] - contrary to the procedures by AIFA. Therefore, it is possible that the set deadline is not met.

As regards the right to be treated through non-conventional medicine, one should distinguish the issue of citizens' right to self-determination from the right to receive care from the National Health System. With regard to the former, the limit is not imposed on the citizen-patient, but on the caregiver: medical practice is reserved only for those registered with the relevant Professional Roll and it is not enough that a patient is aware of being treated by a person who is not a medical doctor[80]. For the moment, these practices are regulated by the Code of Medical Ethics[81] and by the decisions of the courts[82]: there is no national framework law on non-conventional drugs, which is mandatory in all EU Member States[83]. In order to safeguard patients, 28 associations and Italian schools signed a

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[75] AIFA, Medicinali omeopatici - Modalità di presentazione delle domande di registrazione semplificata" – Section 17, paragraph 2 of Legislative Decree 219/06 (final extension: Article 6, paragraph 8-undecies of Law No. 17/2007, for the "Conversione in Legge, con modificazioni, del decreto-legge 28/12/06, n. 300, recante proroga di termini previsti da disposizioni legislative. Disposizioni di delegazione legislativa").

[76] AIFA, "Tariffe per la registrazione dei farmaci omeopatici"

[77] Calderola B., "*Spunta la tassa sull'omeopatia, i produttori: a rischio migliaia di posti di lavoro*", "Il Giorno" (Milan), 19/9/13

[78] Contro il decreto Omeoimprese (l'associazione di categoria) ha già presentato ricorso al TAR del Lazio (sentenza di merito attesa per il prossimo Gennaio) news disclosed by several Internet websites concerning the sector, for example see http://www.pharmaretail.it/articoli/2013-09-02-omeopatia.aspx

[79] Omeocom (Homeopathy Defense Committee), Petition: together for Homeopathy, September 2013, http://www.omeocom.it/

[80] Court of Cassation, Criminal Section VI, judgment No. 34200 of 6/9/07

[81] Federazione Nazionale degli Ordini dei Medici Chirurghi and degli Odontoiatri (National Federation of Physicians and Dentists), Codice di Deontologia Medica (Code of Medical Ethics), 16/12/06, Article 15

[82] Constitutional Court: judgments Nos. 300/07, 93/08, 40/06, 424/05; Court of Cassation: Criminal Section VI, No. 34200/07; Sect VI, No. 964/07; Criminal Section VI, No. 16626/05; No. 1735/03; Criminal Section VI, No. 9961/01; IV Criminal Section, No. 30/01; No. 500/82; Sect. VI, No. 2652/99

[83] European Parliament's Resolution No. 75, 29/5/97; Council of Europe, No. 1206, 4/11/99

Memorandum of Understanding[84] in 2012 aiming to standardize training.

Regarding the latter aspect, the National Health System expressly excludes non-conventional medical care and services from LEA[85]. Tuscany is the exception: several years ago it included a number of treatments among its LEA[86] and it has a network of complementary medicine spread throughout its territory (108 public clinics)[87]. Its latest health care plan includes homeopathy, acupuncture and herbal medicine. In addition, since 2007 Tuscany has regulated the training of health care professionals (doctors, dentists, veterinarians and pharmacists) who use alternative medicines[88]. Finally, Tuscany regulated the so called bionatural disciplines (9 of them, including yoga, shiatsu and osteopathy), for safeguarding the quality of the services provided; the operators have to be included in a register after appropriate training[89].

The issue of *compassionate treatments/ care*[90] falls within the scope of freedom of care for patients suffering from severe or rare conditions or who are in life-endangering situations whenever no further valid therapeutic alternatives exist according to medical opinion, but the patients might benefit from therapies at an advanced stage of clinical trial (therefore, Stamina is not one of such treatments). In addition to the informed consent of the person concerned, full compliance with procedures and protocols is required along with the Ethics Committee's opinion, *consisting of medical and non-medical professionals tasked with ensuring the protection of the*

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[84] "Protocollo di intesa sulla definizione epistemologica e sulla formazione primaria della medicina omeopatica", Chianciano, 16/03/12

[85] Annex 2 to Prime Minister's Decree of 29/11/01

[86] Regional Council Resolution No. 655/05

[87] See: http://www.region.toscana.it/cittadini/health/medicine-complementari and Regional Health and Social Integrated Plan 2012 – 2015

[88] Regional Law 9/07

[89] Regional Council Resolution No. 9/10. A similar approach was attempted by Piedmont (Regional Law 13/2004), Liguria (Regional Law 18/2004; Regional Law 6/2006); Veneto (Regional Law 19/2006), but it was rejected by the Constitutional Court, which considered the legislation to be in breach of the powers of the State, competent for regulating professions.

[90] Ministerial Decree of 8/5/03: "Uso terapeutico di medicinale sottoposto a sperimentazione clinica."; Ministerial Decree of 5/12/06, "Terapia genica and terapia cellulare somatica.", Section 1, paragraph 4"

rights, safety and well-being of the probands and affording public guarantees thereof, for example by giving their opinion on the trial protocol, the suitability of the investigators, the adequacy of the facilities, and the methods and documents that will be used to inform patients and obtain their informed consent[91]. In addition, the manufacturer must commit to provide the treatment for free.

Quality of care.

Healthcare quality and "malasanità" (medical malpractice) is an inevitable pairing. Medical malpractice is a buzzword emerging in the news to cover the most disparate cases - from the doctor discovered eating at the pizzeria during working hours[92], to the tragedy of a woman deceased after a caesarean[93]; from misplaced blood units[94] to the time spent waiting to be visited at the Emergency Unit[95]. A proof of the uncertain quality of health services may be the number of complaints lodged in 2012 for damage suffered in public hospitals: they are more than 12,000, however over more than ten million hospitalizations per year and about one billion specialized services [96], whilst the percentage of claims settled without compensation is higher than 50%[97].

Behind the numbers there are citizens that have been awaiting the payment of damages for 10 years; doctors who are prosecuted as part of criminal proceedings; the NHS burdened by compensatory damages and the costs of *"defensive medicine"*; young people fleeing from specialized medicine due to hefty insurance premiums and insurance companies that, despite everything, withdraw from this sector.

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91 Legislative Decree 211, 24/6/03, Section 2, m).

92 *"Medico sorpreso al ristorante durante il suo turno di guardia"*, "La Repubblica" Naples edition, 1/4/13

93 Morta dopo parto cesareo: familiari, non è caso malasanità , Ansa, 2/11/13

94 The case took place in Grosseto on 25/8/13

95 *"Tor Vergata, allarme pronto soccorso mancano i posti letto, attese infinite"*, "La Repubblica", Rome edition, 4/10/13

96 Bissoni, G., Responsabilità professionale e diritti del cittadino , Monitor, year XII, No. 34, 2013

97 ANIA (Italian National Association of Insurance Companies) report 2013," L'assicurazione Italiana 2012 – 2013", page 218 -225, July 2013

Different options have been taken into account in recent years. For example, guidelines directed to medical staff, and recommendations for preventing errors[98] and risk management strategies were worked out, not uniformly[99], in the absence of a specific law on clinical risk which is still under way[100]. In addition, in the name of the respect for regional autonomy, there is a wide gamut of systems for the management of claims and procedure-specific policies whilst different data collection methods and glossaries have been implemented[101].

Although risk may be contained by respecting standardized procedures, developed in accordance with the best medical practices known, there is still the human error medical staff may be liable to as well[102]. The approach to such errors evolved from a highly indulgent orientation by criminal law courts to the opposite extreme due to the widespread application of the indictment for negligence[103]. From this interpretation along with the one followed in civil actions regarding the provisions for establishing and granting damages, there derive the effects gynaecologists[104] and orthopaedists[105] complain about – these two being the categories most exposed to criminal complaints and claims for damages.

Taking this situation into account, the provisions of Section 3 of Law 189/12 introduced the concept of "culpa levis" (minor negligence) which is not punishable by criminal law, to be applied to medical

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[98] National Guidelines, Sistema nazionale per le linee guida (SNLG - Guidelines National System) worked out by: Istituto superiore di sanità (ISS National Institute of Health), Centro nazionale epidemiologia, sorveglianza and promozione della Salute (CNESPS – National Centre for Epidemiology, Surveillance and Health Promotion)

[99] Parliamentary Investigation Committee on Errors in Healthcare and the Reasons for Regional Health Deficit, Final report, 22/1/13, page 180 and following ones.

[100] Chamber of Deputies. Bills: No. 1324; No. 259; No. 262; No. 1312; No. 1581. Senate. Bills: No. S. 1134; No. S. 1025; No. S 90

[101] Agenas, "Indagine sui modelli regionali di gestione sinistri and polizze", Quaderno di Monitor 2013, Supplement to the quarterly magazine "Monitor"

[102] Ministry of Health, Quality Department, Healthcare Risk Management. "Il problema degli errori", March 2004, Rome

[103] Court of Cassation, Criminal Section IV, judgment 16237/13

[104] *Oggi sciopero ginecologi: 1.100 interventi rinviati. Adesione oltre il 90%. La protesta per la sicurezza delle cure, una nuova legge sulla responsabilità professionale and contro il caro assicurazione*", Quotidiano sanità, 12/2/13

[105] *Sciopero ortopedici del 1° luglio. Riconoscimento della responsabilità delle strutture nel risarcimento del danno* , Quotidiano sanità, 27/6/13

practitioners when they have acted in accordance with commonly received guidelines and good practices. The Court of Cassation and the Constitutional Court have already expressed their opinion[106], confirming the validity of the distinction. The issue of compensation has still to be clarified: the deadline for the compulsory stipulation of the policy for professional liability has been postponed to 15 August 2015, as has the establishment of a guarantee fund for harmed patients – initially set at June 2013. In addition, there are still no pre-defined tables for calculating damage that might add some predictability to the overall picture as well as expedite the payment of compensation[107]. In the meanwhile, it is estimated that the cost of *defensive medicine*, including evaluations and prescriptions useful for demonstrating professional zeal in the event of complaints rather than for safeguarding health, amount to €10 billion[108].

Recommendations.

1. Developing tools to strike the right balance between regional autonomy and national coordination so as to prevent re-introducing the substantial differences experienced by citizens as for public health care and the relevant fees (“tickets”).
2. Launching the National Health Plan, which was scheduled to be ready by January 2013, including Essential Care Levels (LEAs) that should be adjusted to afford all citizens full-fledged compliance with healthcare guidelines – including citizens affected by rare diseases.
3. Reconsidering the mechanisms underlying payment of fees (“tickets”) and waiting times, which are the “regulators” of the health care demand, as they are currently detrimental to those citizens that are close to the poverty threshold. It should be recalled that the latter include minors and even newborns.

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[106] Court of Cassation, Criminal Section IV, judgment 16237/13; Constitutional Court, order 295/13 CHECK

[107] Ania report, quote, page 223

[108] Parliamentary Investigation Committee on Errors in Healthcare and the Reasons for Regional Health Deficit, quote, page 55

4. Implementing the palliative care net throughout the national territory on the basis of standardised quality criteria (e.g., 24/7 availability, psychological support to patient and relatives).
5. Regulating the so-called biological will to enable citizens to exercise the right to express their wishes. Expediting the nationwide implementation of the Electronic Health Record which should include a dedicated section only accessible if urgency procedures prove to be necessary.
6. Providing that AIFA [Italian Drugs Agency] simplifies the procedures for drugs containing cannabis-derived active principles. The relevant measures should also provide for expanding the scope of treatable diseases to include, for instance, treatment of the side effects produced by chemotherapy.
7. Amending, where necessary, pharmacological vigilance procedures. Additionally, effective measures have to be taken regarding distribution of drugs to counter speculation related to price differences across European markets.
8. Developing the tables listing the damages payable based on medical risks, which are needed to enable fair as well as timely compensation. This should include additional measures to contain the costs of "defensive" medicine and foster safety (e.g., by way of investments into health care buildings, vocational training, etc.).
9. Disseminating initiatives to promote the right to health such as the PartecipaSalute project (http://www.partecipasalute.it/cms_2/) which allow spreading information and raising awareness. Informing patients of the costs of individual health care measures.
10. Developing practices aimed at mutually respecting competences - in the light of the rule of law, which can create trust in institutions. In this sense, attention should be paid to the debate within the Roll of Medical Doctors, who are engaged in redefining their ethics code. Also the Roll of Journalists should perhaps initiate a reflection on the role information plays in this framework and whether it might be useful to introduce

rules to reconcile freedom of the press with citizens' right to receive information that has been double-checked and is respectful of suffering.

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