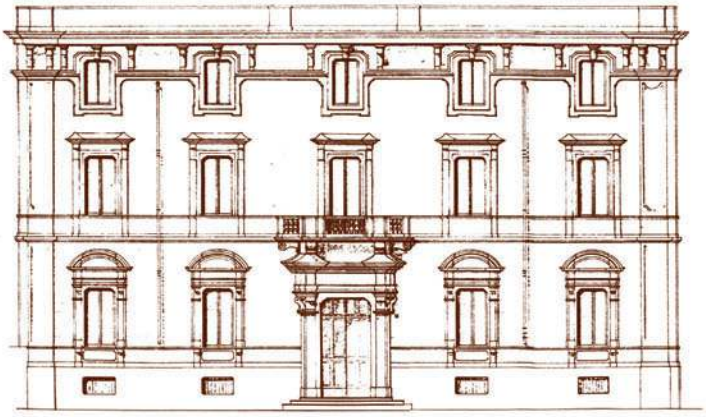
International Conference

HEALTH CARE POLICY AND FUNDAMENTAL RIGHTS IN EUROPE



Villa Spalletti Trivelli - Historic Mansion

The Lord John ALDERDICE OF KNOCK Emma BONINO Silvia BRUZZI
Giuseppe Maria CASSANO Giulio ERCOLESSI Giovanni GASBARRINI
Alexander GRAF LAMBSDORFF Andre KNOTTNERUS Enzo MARZO Attilio MASERI
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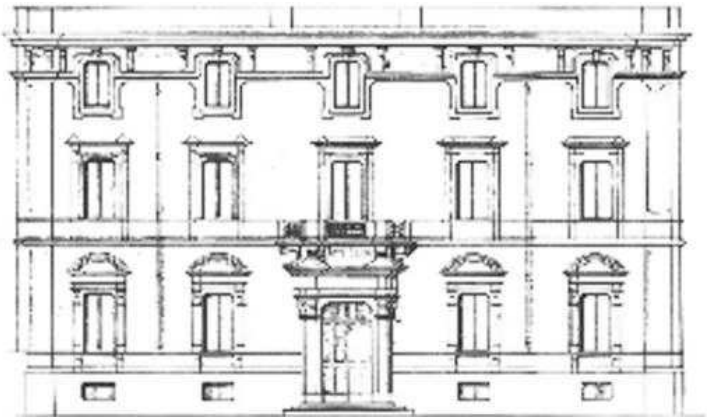
European Liberal Forum

The European Liberal Forum (ELF) was established in the autumn of 2007; it is a non-profit organisation, and its aim is to bring together think-tanks, political foundations and institutes from around Europe which work at promoting the different aspects of liberalism. ELF's aim is to provide for education, training, research and promotion of active citizenship, and also to contribute to the transfer of knowledge and experience, to contribute to the information of the general public, and to help establishing a truly European democracy. The role of the organisation is also to work as the meeting point, as the framework for national political foundations, think tanks, networks, academics and leading liberal personalities.

Fondazione Critica Liberale

Critica Liberale was funded in 1960s as independent liberal Press Agency; in 1974 appeared the first number of Critica Liberale Review. In 1994 was established the Fondazione Critica Liberale, with the aim of promoting liberalism through the organization of conferences, seminars, workshops, meetings, researches and study activities. Norberto Bobbio became its first honorary president.
The Foundation has continued the publication of the monthly review "Critica Liberale" and its quarterly supplement "Gli Stati Uniti d'Europa".
Fondazione Critica Liberale is member and co-founder of the European Liberal Forum asbl.



Proceedings of the

INTERNATIONAL CONFERENCE

Health Care Policy and Fundamental Rights in Europe

Thursday 27th November 2008

Villa Spalletti Trivelli

Via Piacenza, 4 Rome

Organised by the European Liberal Forum asbl
with the support of Fondazione Critica Liberale
Funded by the European Parliament

edited by
Beatrice Rangoni Machiavelli and Francesco Velo

INTERNATIONAL CONFERENCE

Health Care Policy and Fundamental Rights in Europe

Thursday 27th November 2008

The Future of Health Care in the European Union: Principles, Rights, Research and Prevention

Issues and Proposals

Foreword

Alexander Graf Lambsdorff*

The creation of a single European market in which European citizens enjoy the freedom to seek and obtain treatment across borders is a truly liberal project.

This project is finally on its way. In July 2008, the European Commission published a proposal for a directive on cross-border health care. The European Parliament recently voted in a first reading on this proposal, which is mean to enable patients to pursue their right to seek health care abroad more easily and to be reimbursed for the costs.

The European Liberal Forum (ELF) - with the support of its member organization Fondazione Critica Liberale - took the initiative to host an international conference entitled "Health Care Policy and Fundamental Rights in Europe" on 27 November 2008 in Rome. Beatrice Rangoni Machiavelli, chaired the Conference. Contributions were made by politicians and experts:

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* MEP, President of the European Liberal Forum. 1st Vice President of the Alliance of Liberals and Democrats for Europe (ALDE) in the European Parliament, Member of the Committee on Foreign Affairs and of the Delegation for relations with the People's Republic of China of the EP. Founding member, FDP LV Net

Androulla Vassiliou, European Commissioner for Health, Emma Bonino, Vice President of the Senate of the Republic of Italy as well as Lord John Alderdice, Psychiatrist and President of Liberal International, Umberto Veronesi and various others. The proceedings of this high level conference are now published by ELF and add a liberal point of view to the debate.

The European Liberal Forum is the European political foundation of the liberal family committed to liberal democratic values and funded by the European Parliament. As a network of national think tanks, political foundations and institutes from around Europe, ELF contributes to the debate on a variety of European public policy issues and the process of European integration. Hosting conferences and seminars, ELF informs the public about liberal perspectives, offers policy recommendations and involves European citizens in the construction of a united European democracy. At ELF workshops experts analyze policy developments, elaborate common positions and exchange experience and best practice. Last but not least, ELF also issues publications and conducts studies.

You can find more information on ELF and its activities on our website www.liberalforum.eu .

The ELF is particularly grateful to Enzo Marzo, President of Fondazione Critica Liberale and to Beatrice Rangoni Machiavelli, Member of the Board of Fondazione Critica Liberale for their great support in implementing the conference and in publishing the conference proceedings.

Freedom of Information

Enzo Marzo*

In recent decades, health care policies have provided fertile ground for comparison. But too often these topics, which are extremely complex and difficult to translate into terms easily comprehensible by public opinion and by voters, are portrayed, especially in Italy, in simplified propagandistic models, through which each pressure group vitally interested in the defence of its own role and its own interests is able to present that role and those vested interests as perfectly coinciding with the public interest.

I would like to underline one particular issue: enhancing and defending the right to information is essential in order to give effectiveness and provide efficiency to the participation of the entire civil society in the determination of decisions in health care issues.

It is essential to make the process transparent over a long period, to allow the decision on the various possible choices and to govern the process of their undertaking. That will be much more important from now on,

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as citizens in need of care can move throughout the European territory, in search of centres of excellence where a solution to their need for care can be found.

Only knowledge can guarantee an informed interaction between politics and science, between economics and society. With regard to patients, protection of the right to information represents the constitutional guarantee of citizens, and a fundamental requirement for making the right to choose effective.

Critica Liberale has been engaged for almost four decades in defending freedom of information. Funded in 1960s as independent press agency of the Italian Liberal Party, in 1994 Critica Liberale became a foundation. Fondazione Critica Liberale, together with Critica Liberale review, has always promoted the political and cultural tradition of European liberalism, laicity and illuminist values, the defence of civil rights and the federal integration of democratic Europe.

Critica Liberale is one of the founders of the European Liberal Forum in which we strongly believe and consider an important point of reference. You can find more information on Fondazione Critica Liberale and its activities on our website: www.criticaliberale.it .

As President of Critica Liberale Foundation, I am particulary grateful to Alexander Graf Lambsdorff and Susanne Hartig of European Liberal Forum, for their precious help and sustain, as to all the speakers and personalities who made this conference possible.

Promoting Citizens'Rights in Europe

Beatrice Rangoni Machiavelli*

Ladies and Gentlemen, dear Friends, on behalf of Critica Liberale Foundation, I have the pleasure to introduce the International Conference *Health Care Policy and Fundamental Rights in Europe*, organized by the European Liberal Forum together with Critica Liberale Foundation and funded by the European Parliament.

During the last century, health care systems have changed. The needs of citizens and costumers have evolved, growing in number and quality.

In 2010 we will celebrate the 60th anniversary of the Schuman Declaration, that is commonly assumed as the date of birth of the European Union. During all these decades, the European Institutions have always been engaged in the field of citizens' rights protection and enhancement.

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* Patron of Liberal International, very active inside European and International Liberal organisations where she respresents the Italian Liberals. Former President of the EU EcoSoc. Always involved in the promotion of the status of Women; in 2003 she was conferred by the EP the "Prix Femme d'Europe"

Nine years ago, the European Parliament, the European Council and European Commission solemnly proclaimed the *Charter of Fundamental Rights of the European Union*. Article three of the Charter, entitled *Right to the integrity of the person*, is destined to have a strong influence on heath protection. It statues that: "(1) Everyone has the right to respect for his or her physical and mental integrity. In the fields of medicine and biology, the following must be respected in particular: the free and informed consent of the person concerned, according to the procedures laid down by law (...) the prohibition on making the human body and its parts as such a source of financial gain (...)".

The Charter is now part of the Lisbon Treaty, and will be effective from its approval.

Today, we are called to enforce again the social and economic conquers of the past, as we need to respond to new emerging issues.

The demand for more complex health care services, the rising costs of health care technologies, the difficulty in raising the funds for health care expenditure have lead to the widespread appearance of new approaches: limited resources have to be used in a better way and more attention to efficacy and efficiency is to be paid.

In this framework, the European Union can and has to play a worldwide leading role: to achieve this result, the definition of a common Health Care Policy is needed.

The World Health Organization (WHO) has underlined this great opportunity. In Estonia, 25/27 June

2008, the WHO Conference on health systems approved the Tallinn Charter for "HEALTH and WEALTH". The purpose of this Charter is to commit Member States of the WHO in the European Region to improve people's health by strengthening health systems, while acknowledging social, cultural and economic diversity across the Region. The Tallinn Charter reaffirms and adopts the values embodied in earlier charters, conventions and declarations. All countries in the WHO European Region have to address major challenges in a context of demographic and epidemiological change, widening socioeconomic disparities, limited resources, technological development and rising expectations.

The basic conviction is that, beyond its intrinsic values, improved health contributes to social well-being through its impact on economic development, competitiveness and productivity. High-performing health systems contribute to economic development and wealth.

For all of these reasons, the proposal of the European Commission for a Health Care Directive, published in July 2008, represents a milestone along the path that leads to the construction of the European Health Care single market and to the definition of an European Health Care policy.

We know that there is still much to do. I have been President of the European Economic and Social Committee (EESC) and I remember we addressed problems relating to health and patient rights in a number of opinions.

Examining the proposal of Commissioner Vassiliou, the EESC has underlined the need for a coordination of European health policies in the Member States, and stresses the risk of widening differences among various groups in society. The more, the EESC would like the Directive to mention that care must be provided on the basis of the equal worth of all human beings and that people with the greatest need or the lowest level of social security cover must also be given priority access to care.

What can be foreseen, is that in the very next years single member states will act as pioneers, launching initiatives that will be the basis of the future European Health Care System. The Treaty of Nice foresaw the possibility of a reinforced cooperation among member States in fields related to further integration, statuing that at least eight countries have to be involved. Reinforced cooperation can be seen not as a treat but as an occasion for sustaining European integration.

The Core Europe can play, again, a leading role in European integration: it happened with the Treaty of Paris of 1951 (CECA) that lead six years later to the Treaty of Rome.

Having that in mind, we promote this International Conference on the future of health and health care in Europe, involving the highest European experts and researchers in this debate on the tools and the projects that can help develop a European Health Care System as a pillar of European Citizenship.

Health Care Policy in the European Union

Francesco Velo*

The Future of Europe

The European health care single market is becoming a reality. The efforts of Member States to keep national markets closed are destined to grow increasingly less effective: the rising mobility of Europeans, the strengthening of health care providers and the increasing dissemination of information are driving to the creation of a European health care system.

What happened in other sectors is happening today to health care, supported by the principle of the freedom of movement for citizens, services, technologies and resources among Member States.

In a true market several conditions need to be met.

A market exists only in the presence of institutions capable of ensuring compliance with shared rules and principles. Without shared principles and without an over standing Authority, the market loses its essential feature as a place where the interests of civil society,

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citizens, public and private institutions can be jointly reconciled.

Without this requirement, the market falls into a free space, where rules and behaviours are not aimed at the pursuit of a common interest but are rather driven by individual aspirations.

A truly liberal system requires the setting of those rules that allow everyone to live virtuously together, in the belief that only by abandoning the defence of corporative interests will it be possible to achieve superior goals with benefice of all stakeholders partaking in the market.

This goal must be supported by awareness. The market with no rules is exposed to the risk of anarchy and the rise of monopolies. The market does not come free: it must be set free.

Each Member State can seize the opportunities that the creation of the single health care market offers: the key condition is that the construction of the new order will have to come first, despite the a-priori protection of the equilibriums that characterize today's national systems.

Protectionism cannot coexist with the instances of freedom and equality of individuals as it simultaneously dooms the national systems to inefficiency and obsolescence. The history of the Twentieth Century has taught us the tragedy of protectionism and nationalism.

The achievements and the solutions implemented at the national level are a key asset that cannot be wasted or dispersed; in fact, these solutions need to play a fundamental role in the debate that will forestall the creation of the European health care system. This way only

will it be possible to protect the characteristics of universality, equality, solidarity and sustainability of the health and social model shared by all European countries.

This calls into question the role that the national health care systems will be called on to play in the new institutional framework in the making. Above all, this raises the question of identifying the shape, purpose and rules that the European Healthcare System will adopt.

It is realistic to expect that two will be the areas that will access the health care single market first. In addition to the prevention sector, which represents a fundamental area of health, and for which the need to define choices and guidelines at European level is becoming increasingly important, the segment that may at first catch our attention is hospital care.

In the two chief instances, the demand for cross-border hospital care can either arise from the emergence of a sudden health care need (as when a citizen from a Member State is out of his or her country of residence) or be a result of the demand for specialized health care services in response to an already known need.

This simplification allows us to identify in first approximation the two main tracks that will characterize the future European health care system.

The first track will be characterized mainly by organizational needs, the second by programming. On the one hand, the problem of managing available resources will come to the fore, while on the other hand the issue of funding investment in research, development and innovation will become apparent.

All countries, particularly some specific national areas, are experiencing the growing openness of their health care systems, whether as a result of their location within the European territory (e.g. border territories), or as a result of the ability to develop centres of excellence in the sector of health care provision and research capable of attracting patients from other countries or, conversely, because of the unavailability of highly specialized centres within their national system.

What becomes apparent is that each Member State will be increasingly less able to respond, independently and autonomously, to these challenges.

While markets are progressively opening up, national systems can counter integration in favour of a short-term policy aimed at making available to their own citizens a fair and universally accessible health care system, rather than a long-term strategy that aims at the development of research and health care quality.

Internal organizational issues can delay the adhesion to the single European health care market: this inclination is destined to perpetuate inefficiency and to facilitate the obsolescence of health care strategies.

The problem is not to deter potential patients mobility between European countries but rather to organize and to recognize the contribution of these cross-border flows and to make them part of a European health care system capable of generating value through them.

The structural solution to these challenges has to be European: this is the institutional level at which these

issues can be solved and at which innovation can be promoted. This process can and has to be guided.

From the viewpoint of the domestic market, this is an opportunity to reduce the imbalances that exist today between the different European Union Countries and within national systems themselves; it may also be a way to avoid the emergence or increase of imbalances between Member States. These policies need to be supported by specific tools and choices.

European integration is an opportunity to strengthen the health care sector as a whole, by putting together national health systems' resources, strengthening the ability to protect the right to health of citizens and by keeping the pace with the evolution of other advanced health systems in the field of research, United States above all.

The formation of an integrated European health care market is an opportunity for defining what strategic direction the European health care system will take within the world market of research and health care services provision; the key alternatives for Europe are either to develop his own ability to offer high specialty care and research, investing in the long term, or act on the international markets as a purchaser of services, while delegating to other systems the development of technologies and techniques and using European financial resources to acquire services for its customers on foreign markets.

These opposed solutions will condition the future of health care at the global level. Europe can play a key role in governing this process, by guiding it towards the extension of fundamental rights even beyond its own borders.

Encouraging integration, protecting and strengthening Rights.The Commission's Proposal for a Health Directive.

The Directive Proposal submitted by the European Commission lays the foundation for the future European health care market. More than the way suggested by the Directive for the harmonization of national health systems, its major contribution can be identified in the establishment at EU level of a specific terminology that helps identify not only the fact species but also the principles that will in perspective guide the actual achievement of the single health care market.

A few points deserve a special attention.

a) A sum total of national health systems. The overall framework of cross-border care is going to be established in compliance with Member States' competences regarding the organization and supply of health services and medical care. The Directive Proposal tends to balance the protection of the principle of freedom of movement and the protection of a minimum level of certainty about what each national authority will have to ensure in response to specific health needs in their territory.

This will inevitably lead to the emergence, at least initially, of a European health care system as the sum total of national health systems. It can be expected that this system will evolve gradually towards an articulated coherent structure, according to the constitutional principle of subsidiarity.

Another problem concerns the funding and controlling the expenditure of every subsystem that will make

up the European Health System, i.e. today's national health systems. In this context, we can reasonably expect that specific choices, such as the implementation of individual mandatory insurance systems or the financing schemes based upon general taxation, will live side by side in compliance with the aforementioned principle of subsidiarity. However, in the medium to long term, we will probably witness the proliferation of those models that will mostly be able to effectively support the new order.

b) Responsibility of States in protecting the rights of European citizens. As recalled by the Commission,

"Member States have implemented different provisions to ensure equity: some have chosen to express it in terms of the rights of patients; others in terms of the obligations of healthcare providers. Enforcement is also carried out differently; in some Member States it is through the courts, in others through boards, ombudsmen, or other mechanisms (...) However, it is necessary to ensure a more general and effective application of these internal market rights in practice, and to ensure that they can be exercised in a way which is compatible with overall health system objectives of accessibility, quality and financial sustainability".

The birth of a European Authority could not only play a coordinating and connecting role between national systems, but it may also steer and control a framework that, at least initially, will be fragmented. The problem arises in particular with reference to the potential con-

flict between national institutions, a conflict that will be all the more likely as the international mobility of patients will increase. This Authority will be in charge of the defence of the citizens' right to health and its relevance will grow, in perspective, even in comparison to that of other institutions in charge of monitoring compliance with the rules.

c) The planning of mobility. "In terms of patients seeking planned health care in another Member State, this ensures that if the appropriate care for the patients' condition cannot be provided in their own country without undue delay, then they will be authorised to go abroad, and any additional costs of treatment will be covered by public funds". This will allow patients to receive the same assistance they could obtain in their own country in any other Member State.

There is no denying that cross-border mobility is the consequence of the existing imbalance between national health systems.

As we refer to the possibility of receiving better care (more quickly and effectively) abroad, we implicitly admit the existence of organizational barriers and structural obstacles affecting national health systems.

The European system as a whole, however, is in danger of remaining incomplete without tools that can promote the adjustment and the increase in quality of those health care sub-systems where a structural deficit occurs. Obliging each national health system to formally arrange the provision of health care to their citizens opens the way to the reimbursement of cross-border

care, but leaves to market mechanisms the solving of rebalance.

d) The protection of economic sustainability of national systems. Patients will be allowed "to seek any healthcare in another Member State that they would have been provided at home and be reimbursed up to the amount that would have been paid had they obtained that treatment at home, but they bear the financial risk of any additional costs arising (...). Therefore this Directive does not introduce a general prior authorisation requirement but allows Member States to provide for a system of prior authorisation for assumption of costs for hospital care provided in another Member State, provided however, that Member States can provide evidence that the following conditions are met: (1) had the treatment been provided on its territory, it would have been assumed by its social security system; and (2) the consequent outflow of patients due to the implementation of the directive seriously undermines or is likely to seriously undermine the financial balance of the social security system and/or this outflow of patients seriously undermines, or is likely to seriously undermine the planning and rationalisation carried out in the hospital sector to avoid hospital overcapacity, imbalance in the supply of hospital care and logistical and financial wastage (...)".

Maintaining a balanced medical and hospital service open to all and the maintenance of care provision capacity or medical competence on the territory of the concerned Member State is a priority: the European

health care system cannot rise from the ashes of existing national health systems.

Similarly, we must also accept the fact that the weight of the limitations produced by budget constraints becomes significant as sustaining the extra costs not covered by national health care systems falls upon individual patients. If the need for highly specialized or experimental care programs is responsible for a relevant share of cross-border mobility, the risk of extra costs is undeniably high.

The solution chosen by Italy to compensate for the cost of mobility among sub-regional systems was the adoption of an ad hoc methodology for the assessment of the benefits and cares provided, via a system of tariffs that apply specifically to these cases. This way, the compensation is managed through an exchange balance based on cross-border tariffs, established in advance by an interregional Conference, which are independent of the tariffs established by each sub-system for the provision of health care services to their own resident citizen. This system allows both promoting transparency and facilitating compensation between regional systems.

Using a similar system at European level will require a careful assessment and evaluation of the health benefits provided, including in economic/monetary terms. This may truly be an enhancement of the European health care system. It would also make it possible to trigger a European-wide discussion on a common problem: the correct economic evaluation (DRG) of health benefits and cares provided by the various health care suppliers.

e) Coordination of National Authorities. The Directive acknowledges the role of Member States in (1) the definition of quality and safety standards, transparency for patients, applicable standards and monitoring, (2) the dissemination of information on the opportunity to obtain cross-border healthcare, (3) the safeguarding of the patients' rights.

Here, again, lies the opportunity for an effective and almost immediate action of a European Authority, capable of taking action on a major issue, namely the accreditation of facilities entitled for international care provision.

The possibility of applying "European prices" for the reimbursement of the health care services provided needs to be developed simultaneously with the establishment of a European quality accreditation system for care providers.

The authorization to mobility, currently competence of national authorities, could, in these cases, automatically be provided if European protocols of care were complied with and applied.

Prospective Scenarios for European Health Care

Three are the alternative scenarios for European health care:

- a "liberistic" (laissez-faire) system that rewards the best providers and that witnesses the transfer of resources to the most advanced structures and systems under the pressure of patients' mobility. In this scenario, the existing imbalances between areas could com-

promise the ability to deliver even non-high specialty health care services. The outcome, in the Italian case, has been the creation of a dual system that rewarded excellence while protecting the most inefficient health care clusters;

- a integrated confederated system where individual Member States act independently towards the improvement of the national health care systems' efficiency and effectiveness, promoting at the same time a formal integration at European level;

- a European system where the integration of national health systems is not only formal but substantial. In the field of research and high-specialty care there is room for the creation of a European health system that may operate above the national level and that may consist of institutes and research centres of excellence accredited at European level. This is the real alternative to the previous scenarios, the "liberistic" and the "confederated" models. The key point is to recognize that such market segmentation already exists in facts, but it has not yet been recognized at the institutional level.

The role of Member States and European institutions (both existing and still to be constituted) is obviously different in the three scenarios. A European health care system requires no doubt to be supported by an institutional architecture. This architecture varies as a function of the goals that can be set. As the Directive reads, "action by Member States alone or lack of Community action would significantly undermine both the safe and

efficient provision of cross-border health care, and would leave Member States without a clear capacity to manage and steer their health systems as a whole, as emphasised by several Member States during the consultation.

Cross-border health care has, as the name already predicts, many Community-wide transnational aspects. Both national government and individual citizens face in this field challenges that cannot be satisfactorily solved by Member States alone."

We have no doubt on the importance of prevention and territorial medicine, that are the fundament of every Health Care system. It is also true, indeed, that the European Health Care market will arise from those sectors where integration has already started.

This process can be driven, by setting rules and authorities entitled of enforce compliance and defend rights and freedom. The birth of a European project for and advanced health care and research, with its own autonomous budget, would further the emergence of a true system of centres of excellence, able to compete worldwide. This was the case forty years ago with Nuclear Research and physics.

In this sense, the steps to be taken are easily identifiable: market harmonization can provide the foundation on which to build Reinforced Cooperation projects, to be outlined around a European Authority and oriented toward a shared objective. Research and high specialty health care are the natural priority field of application for the development of these projects.

Improving Health Care for All

The Role of the European Liberal Forum

Annemie Neyts Uyttebroeck *

I would like to start by congratulating Beatrice Rangoni Machiavelli, her Family and all those who organised this important conference which takes place in these exceptional surroundings of Villa Spalletti Trivelli which is not only a piece of Italian heritage, but of heritage of humankind, so thank you very much for that.

I have the pleasure, Ladies and Gentlemen, to introduce the European Liberal Forum, and to tell you few things about it.

The Forum is still very young. It was established in the autumn of 2007; it is of course a non-profit organisation, and its aim is to bring together think-tanks, political foundations and institutes from around Europe which work at promoting the different aspects of liberalism. The role of the Foundation is to observe, ana-

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* President of the ELDR Party - European Liberal Democrats; Spokesperson on Foreign Affairs for the ALDE group in the EP and Member of the EP delegation for relations with NATO. Minister of State and President of the Belgian Foreign Trade Agency

lyse and contribute to the debate on European public policy issues.

Today's conference is a beautiful example of that, to provide for education, training, research and promotion of active citizenship, and also to contribute to the transfer of knowledge and experience, to contribute to the information of the general public, and to help establishing a truly European democracy.

The role of the Foundation is also to work as the meeting point, as the framework for national political foundations, think tanks, networks, academics and leading liberal personalities. The European Liberal Forum is still a very young organisation, it has been very active, we already have had a series of activities, more or less like this one, some having been opened to a larger public. We have so many activities that the three persons who are constituting the board of the Foundation (Alexander Graf Lambsdorff, myself and Thierry Coosemans) divide up responsibilities, so one goes there and the other goes still somewhere else, because it is impossible for all of us to be everywhere, as we simply have too many activities, and that is why I have the honour to be here today.

We are very proud that we have been able to contribute to this conference.

Now having said ladies and gentlemen that I would like, if I may, to do a few introductory comments on today's theme. I don't pretend to be a specialist in healthcare, I am not, my domain is foreign and security policy, so it's entirely different. It sets me thinking nevertheless, looking back to what I know about human history, I realised actually that healthcare, or aspects of health-

care have been a matter of public concern and public actions since a very very long time.

If you think that in the oldest cities we know of, because we discovered the ruins of them, we have found traces of sewage systems, of procuring water, we know that there have been waste treatment systems, we know of course about medicine, the very old medicine of Galenus and Hippocrates, and the principles of that, we also know from history, ad it is very adapt as I can say in Italy, if you remember the first chapter of Decamerone, then you have those very young noble men and noble women, who have retreated to the hills, outside of Florence, and why did they do it?

They did it to escape from the plague, the bubonic pest that started in Florence and they did want to escape from it. At the time people didn't exactly know how epidemics were propagated, but they had the feeling that it was important to isolate the sick persons. Remember the way our civilization has treated lepers, also isolating them, because once we realised that contact was dangerous, even if we didn't know how it exactly operated. Illness and certain epidemics were seen as punishments, depending on god's will. That was the religious system the society had. So curing the sick, and providing care for the sick has been seen as a deed of charity and a good work for a very long time.

All of this is just to say that whether we are liberals liberally inclined or otherwise, healthcare has been a matter that was seen as more than strictly individual since times in memory and so I believe, and these might be my concluding introductory remarks.

The European Liberal Forum, together with Critica Liberale, under the Chair womanship of Beatrice Rangoni Machiavelli is organising this conference, dedicated to the future of healthcare in the European Union.

Patients' Rights in Cross-border Healthcare

Androulla Vassiliou*

Madam chairman, Ladies and gentlemen, Liberal friends,

Thank you for giving me the opportunity to contribute to this important event. I am honoured to be able to participate in this seminar, which I understand is the first event on public health organised by the recently formed European Liberal Forum.

I would like to congratulate the Forum for taking this initiative, which provides a platform to debate these highly topical health issues of central importance to our citizens.

As European Commissioner responsible for health policy, it is my role to ensure that the highest level of public health is maintained in all EU policies and to provide real added value to national health policies.

Yes, national Member States are responsible for the **organisation** and **delivery** of healthcare in their countries, but the European Union **can complement** national activities and coordinate policy initiatives

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* European Union Commissioner for Health. Honorary President of the World Federation of United Nations Associations. Former Member of the Joint Parliamentary Committee of Cyprus and the EU, Alternate Representative of the Cyprus Parliament to the Convention for the Future of Europe

across the European Union. This is an important role, particularly in the areas of **health promotion** and **disease prevention**.

As the EU Health Commissioner, **I am firmly committed to making progress** across the range of important issues that fall within the health agenda, among which is the essential theme of **healthcare** and **patients' rights**.

This is not only about healthcare per se, but it relates to a much broader theme, which is what the European Union can do for the **general public**, and it is also about **fundamental rights** under EU law.

I would say that in the field of healthcare, there are **three fundamental dimensions** for each individual citizen:

- a question of clear and effective rights,
- a question of empowerment and access,
- a question of choice and opportunities.

These are **universal issues** – and history is made of revolutions, reforms and policy changes aimed at turning these fundamental issues into reality for our citizens. But, as the world and our societies change, they constantly take on a new relevance and **become challenges again**.

This is all the more true in the field of healthcare. We see **progress in technology, the individualisation of treatments and patients becoming informed actors**. This makes rights and mobility, and the right to mobility, essential.

Addressing **patients' rights in cross border healthcare** today is about just that.

The European Commission adopted its proposal for a Directive on the application of patients' rights in cross-border healthcare in July of this year. This is, without doubt, the most important initiative on health of this Commission. "**Why propose such legislation**," some may ask?

First of all, it follows **a number of decisions of the European Court of Justice** on the question of the inherent right of European citizens to seek healthcare in the Member State of their choice, in line with the provisions of the EU Treaty.

The Court clearly sets the record straight on this, but the reality is that many patients are simply **unaware** of their rights, and unaware that they are entitled to **reimbursement** for such treatment. Even citizens do know what they are entitled to, the rules and procedures are often far from clear.

Second, this draft Directive is the answer to a **specific request from the Council of Ministers and the European Parliament** for a proposal to regulate the right to cross-border health care, after the healthcare related provisions had been taken out of the Commission's proposal for a Directive on services in the internal market.

During the debate on the Services Directive, both EU institutions stressed the importance of addressing the **cross-border health** issue in a **specific legal instrument** taking into account patients' needs, commonly agreed principles on the provision of healthcare

and, finally, developments in medical science and technology.

Furthermore, a public consultation three years ago showed **legal uncertainty** was, indeed, considered to be a serious concern both for citizens and healthcare systems.

I would add to this the results of the **impact assessment** that we conducted in the preparatory phase. This showed that the overall impact of such legislation would be **limited**, as mobility of patients is a **limited** phenomenon. It represents only 1% of healthcare expenditure. By contrast, the individual impact for patients would be high.

The overall aim of the proposal is to provide patients with better opportunities and access to healthcare, regardless of their place of residence while, at the same time, fully respecting national responsibilities for healthcare.

It has three main objectives:

First - the directive clarifies the **conditions under which patients would be entitled to cross border healthcare**, should this be the best solution for them, and to be reimbursed accordingly.

Concretely, as long as the **treatment is covered under their national healthcare system**, patients would be allowed to receive the same treatment abroad and be reimbursed up to the cost of the same, or similar, treatment at home.

To avoid any potential risk of undermining national health systems, Member States would be allowed to introduce **limits on the right to reimbursement of hospital healthcare obtained abroad, in the form of a prior authorisation system, provided that they have evidence that their health care provision is at risk of being undermined by patient outflows**.

Let us be absolutely clear that this initiative is **not about harmonising healthcare systems**; nor is it about changing roles in the management of healthcare systems.

Member States are responsible for deciding themselves how to organise their respective systems, what benefits they provide to their citizens and what treatments and medicines they will pay for. **This remains the case**.

The second main objective of the proposal is to ensure **high quality and safe cross-border healthcare** throughout Europe.

It clearly re-affirms the common principles of all EU health systems: **universality, equity, access to good quality healthcare** and **solidarity**. It fully respects the principle that the Member State, on whose territory the healthcare is provided, is responsible for setting the rules and ensuring compliance with these common principles, as underlined by the Treaty and the European Court of Justice.

The European Commission has introduced a provision that aims to ensure that patients from other Member States benefit from **the same quality of care** as

enjoyed by nationals of that Member State. In this respect, we also propose that Member States *clarify* the standards for quality and safety in their respective healthcare systems to patients from other Member States.

Third – the proposal seeks to to foster **European cooperation** between healthcare systems, better to meet the challenges ahead.

This is done through streamlined and improved cooperation, through common technical guidance and through a systematic search for best practice.

Concretely, the proposal establishes a **new framework for European cooperation** in key priority areas, where we must act together at EU level:

- It aims to set up European reference networks, to enable the sharing of expertise, knowledge and skills in highly specialised medical fields. This should increase the availability of new treatment, which is particularly important, for example, for patients with rare diseases.
- It encourages health technology assessment, whereby experts from Member States would help to identify and share information on the most effective treatment available and ensure it is used in the most cost-effective, yet efficient, way.
- It promotes "e-Health", the use of information and communication technologies in health, opening up new possibilities to treat patients from abroad while the patient remains at home.

- Furthermore, the proposal would ensure a better co-ordinated approach at EU level on the collection of health data on cross border healthcare.
- Last but not least, the proposal allows for an easier recognition of medical prescriptions in all Member States.

But what are the actual benefits for patients ?

First of all, the directive will **empower patients** by providing them **with legal certainty** about their right to access the healthcare that they think is the best for their needs.

I believe this is a very important policy development as the patient is no longer a passive subject of treatment. He or she becomes an actor, who needs to be at the root of any decision on the care they receive.

Second, it underlines the importance of the **right to information**, which is essential in the case of healthcare.

How could someone make a choice on such a sensitive issue without being properly informed about the treatments available, their cost and how much they will be reimbursed? Or about the professional who will provide such treatment?

In the proposed Directive, information to patients is **not a vague goal but a concrete objective**. To underline this, national contact points would be designated to support patients and answer their questions.

At this point, I would like to pay tribute to the initiative taken by Mrs. Karin Riis-Jorgensen MEP and the ALDE Group in the European Parliament for creating a

Patients' rights website, with reference to the European Charter of patients' rights developed by the Active Citizenship Network. This is already a great step towards providing clear information to patients on their rights to cross border healthcare.

The draft Directive also emphasises the **right to confidentiality**, as well as the **right to see a complaint and request for compensation to be properly considered and addressed**.

Last but not least, it aims to **clarify the right to access quality and safe healthcare**.

In this respect, the added value of cross-border healthcare is particularly evident for **people in border regions**. Often, it may be easier to seek healthcare abroad rather than to travel long distances to their nearest relevant domestic health facility.

For instance, thanks to the outstanding cross-border cooperation established by Maastricht University Hospital, people in this region can benefit from high quality care, irrespective of which side of the border they live.

It also makes great sense to **people seeking highly specialised treatment**, which only a very limited number of medical practitioners in Europe can provide. This might be the case, for example, for rare diseases.

But ultimately, this proposal aims to offer **more opportunities to every one of us**. More opportunities to access the safest, best quality and most suitable treatment, wherever that treatment may be available in Europe, and whenever an individual thinks this is appropriate, according to their particular situation and preferences.

This proposed Directive is only one of many paths we are mapping out to move **towards a "Europe for patients"**.

Indeed, this proposal is part of a wider series of initiatives that together form our "**Europe for patients**" campaign. Let me just say a few words about it.

As a core subject and concern of the campaign, are **patients**, their rights, their needs and their expectations.

The method is simple and effective: **working together** towards **better healthcare for all in Europe**, and making sure this objective is shared and debated with citizens.

Our agenda is made up of **10 initiatives**, which are expected to be adopted in the course of the next 6 to 9 months in a variety of fields: cancer screening, patient safety, rare diseases, the health workforce, organ donation.

We have created a logo and the slogan "**Europe for Patients**" which clearly sets out our objective. To drive the campaign, a specific **website has been launched** as a centrepiece and a number of events are taking place to raise awareness of this initiative.

I invite you to go and take a look at it on the EU Health portal of the Europa website[1]. I hope this campaign will **provide useful information on what Europe can do for patients**, and I hope that you will be convinced that all these initiatives bring significant added value to health policies across the European Union.

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[1] http://ec.europa.eu/health-eu/europe_for_patients

The proposed Directive is already being discussed in the Council of Ministers and discussions begin shortly in the European Parliament. I am convinced that the objectives and principles of this proposal are fully in line with the Liberal agenda for European citizens, and I trust that you will support it.

Given the political sensitivity of this issue, it seems unlikely that the decision-making procedure will get much beyond a first reading of the European Parliament before the European elections next June.

So it strikes me as an excellent campaigning issue for the ELDR to use in the elections – vote for an ELDR member party, and you will help to elect an MEP who will vote in favour of legislation on patients' rights to cross-border health care.

I strongly believe that these proposed measures on cross border healthcare represent an essential contribution to a **"Citizens' Europe" in which individuals are able to design and master their own future.**

Once again, thank you for giving me the opportunity to talk to you today about this important subject.

I hope together, we can take the lead in creating a **"Europe for Patients"**.

I wish you the very best of luck for future events of the European Liberal Forum.

Thank you for your attention.

The European Health Care System as Network of Centres of Excellence

Umberto Veronesi*

This was a conference I could not miss attending. I could not miss it because I am proud of being and have always been a fervent Europeanist. For fifteen years I have also been the President of a great European project called Europe against Cancer, which I presided over for many years which was the first attempt to unite all European countries at the health care level to address one specific but extremely important disease, cancer.

I would like to start by observing that if it is our intention to start as soon as possible in creating a project for integrating health care, then we must above all listen to the citizens.

The great old top down project must now make way for the new bottom up projects.

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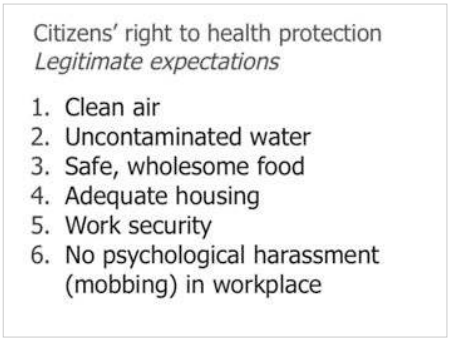
So as to understand people's needs it is necessary to start from here, to then build a pyramid that will certainly reach the summits.

As you see, we believe that citizens are stakeholders in the healthcare, treatment and diagnosis system, and therefore we must first of all understand what the expectations of the people rather than the sick are; the expectations of the general population.



These are expectations requiring an intelligent health system, one protecting health and providing prevention. I foresee a system that consists of breathing clean air, drinking clean water, eating safe food, having a clean home, safety at work (an important issue), as well as the equally important point of having no mobbing in the workplace.

It consists also of an efficient transport system, but also of periodical health checks; today we have extraordinarily efficient means, using both serological means as well as imaging, for checking the health of all individuals.

Naturally, one also needs an efficient treatment system and a general physician available, or more simply a family doctor. Satisfying these expectations expressed by people in Europe is a very complicated matter. Health is not the result of a single good health system. Ministries are needed, for welfare, labour – for example – a Ministry for Agriculture, one for food, and one for the environment, because that is one of the fundamental elements for our health, and a Ministry for research, because all this is conditioned by our capability to increasingly understand the factors and their impact on health.

Let us move on to the second stage. When a citizen falls ill, what are his rights?

- The right to be treated well in a scientific and not in a shoddy manner
- The right to a second opinion – and this should be more widespread than it currently is – because, unfortunately although I am a doctor who is friends with all doctors, but we know that it is right to get two opinions rather than one, at least for more delicate cases.
- The right to privacy, naturally.
- The right to know. The right to know everything about his disease. The doctor has the duty to provide all information with great care. I have always fought

Decalogue of patient rights

1. Right to scientifically-validated treatments
2. Right to a second opinion
3. Right to privacy
4. Right to know the truth about one's illness

for doctors not to be brutal or violent in providing information. But information, at least diagnostic information, must always be provided. One must step carefully – I am speaking of the doctors – with prognostic information, this because prognosis is difficult enough for us to communicate and can be incorrectly interpreted by the patient and cause depression or loss of morale.

- The right to be informed about treatment. It is called informed consent and is the right to accept treatment.
- The right to refuse treatment. This is a fundamental element in individual freedom and must be guaranteed in democratic countries.
- The right to express one's wishes in advance. We have been fighting for the implementation of the biological will, because it is an absolute right that provides people with consciousness and awareness and a chance to express their wishes that must be respected.
- The right to not suffer, the right to be pain-free. This is a fundamental right. When I was a Minister, I drafted laws to reduce pain in the sick to almost zero; I created a movement called "Hospitals without pain" – and it has been successful – based simply on the fact that all doctors and nurses must assess pain

from the moment the patient enters a hospital until he leaves according to a specific classification, so as to intervene instantly to block even the smallest pain.
- The right to respect and dignity.

As you see there are nine points in this set of rules, one is missing. I wrote it in and then I removed it. It is the right to die. The right to die, as mentioned by our European speaker, is the right to euthanasia. I know this is a controversial issue, not all countries in Europe accept this, some have solved the issue, others are debating it while others still reject it on principle. So I removed it from the set of rules. However, I am convinced that we all have the right to choose how to end our own lives in a moment of despair, when a disease is incurable.

So, if the expectations of European citizens are similar all over Europe, be they healthy or sick, then the rights of the sick person just described in the slideshow, I believe are shared all over Europe. I would describe the aforementioned as a summary of a European feeling.

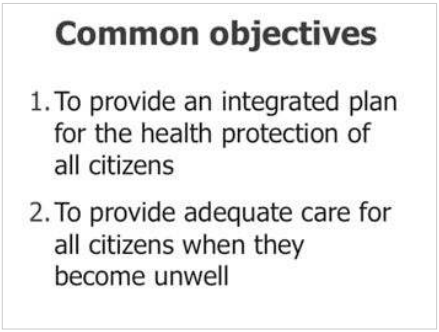
If all Europeans address the issue of protecting their health and defending themselves from diseases in the same manner, then the obvious conclusion is the need for a single, integrated homogenous system, in a manner that is egalitarian for everyone, not with one country treating the sick correctly and another doing it badly.

Hence, I believe I am correct in saying that this is the reason for this meeting, and it is one I share fully as do all those present.

We must therefore work to move towards a Health Plan for Europe, or one for the protection of health that is the same all over Europe.

So what is the problem? The great problem is that each country has a different system for health protection. There are countries with a national health system such as Great Britain and Italy; other instead that entrust people to a broadly extended and very effective insurance system, such as Germany; other countries instead have different kinds of mixed systems.

This situation is certainly an obstacle, but all European countries have shared objectives. What are these objectives?

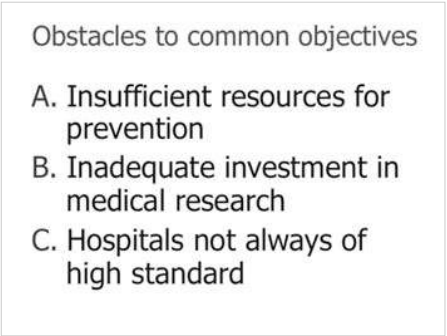


All countries pay great attention to having an integrated health protection plan for their citizens, and when a citizen falls ill, to be able to provide assistance and adequate treatment to all citizens, not only to a privileged few or distinguishing between the rich and the poor. This feeling is widespread in Europe.

However, there are a number of weak points in the European system and in the Italian one in particular. Not enough attention is paid to prevention.

I have spent a lifetime fighting for more prevention in Italy and Europe. Think of the economic resources available, 95% goes for treatment and 5% for prevention. Both Italy and Europe share this defect. One

should, I believe, overturn this data. There should be far more prevention, more controlled lifestyles, health checks for the population, and self-testing. A move from the welfare state to a welfare community, hence from the state offering protection and health to the community, to people checking themselves, assuming lifestyles and behaviour in line with maintaining good health.



There is never enough funding for research. As everyone knows, the situation in Italy is tragic, but the same applies to other European countries, although there are significant differences. Great Britain, for example, spends five times more than Italy in funding research. There are however also other countries that, like Italy, suffer from a lack of funding for research.

Furthermore, hospitals, not only in Italy but also in other countries, are not always up to adequate standards compared to what the sick deserve. The sick are often victims of a culture of the past that considers health care as an act of charity, as if treatment were something extra the patient should be grateful for. It is difficult to uproot this old culture that has historical roots. For many centuries that was the way things stood, but nowadays the right to treatment is an absolute right; the right not only to good treatment, but also the right to dignity. One

cannot have four people in one room with the bathroom at the end of a corridor, and yet in some hospitals this is still the case. Years ago I drew up a project with Renzo Piano in which everyone had their own private room, a small one, but with their own bathroom. If one goes to a hotel, even a one star hotel, I do not think one would be asked to share a room. One must be alone, have dignity, and be able to confide one's anxieties and fears to one's relatives, and be able to speak of private matters. The world has changed and one can no longer accept having more than one person in a hospital room. This is discrimination that shows the legacy of historical memories of a purely charitable form of care.

I would now like to provide you with some data from the Euro Health Consumer Index, an annual European verification on the state of health care in the various countries by listening to the opinions of the consumers themselves, the sick, the citizens. This study, which is published every year uses six different parameters. The patient's rights, whether they are respected or not, to what extent information technologies are used by hospitals, waiting lists, results of treatment; level of services and accessibility to drugs. These are the scores for thirty European countries (27 members of the Union plus Switzerland, Norway and Macedonia). There are certainly many differences:

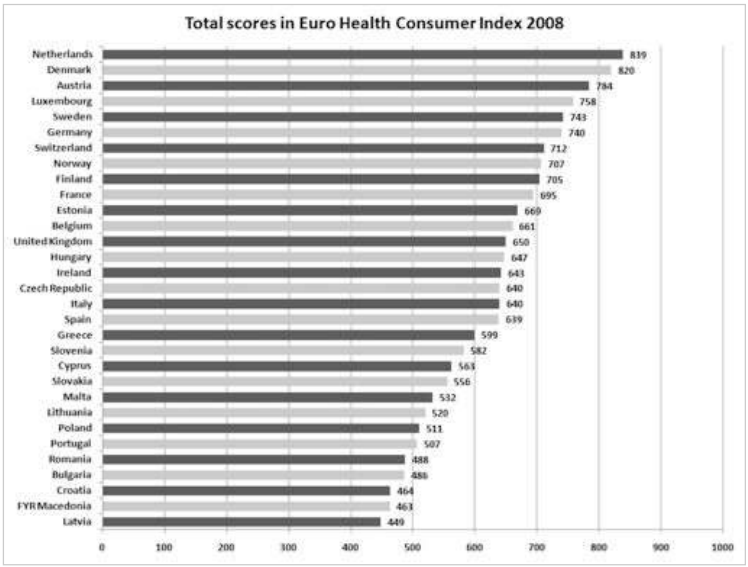
- Holland is rated best by consumers, as are in the following order Denmark, Austria, Luxemburg and Sweden.
- Then there are a significant number of countries that are midway, such as Italy, Spain, Ireland, Hungary,

and also Belgium, Estonia and France, all more or less equal.

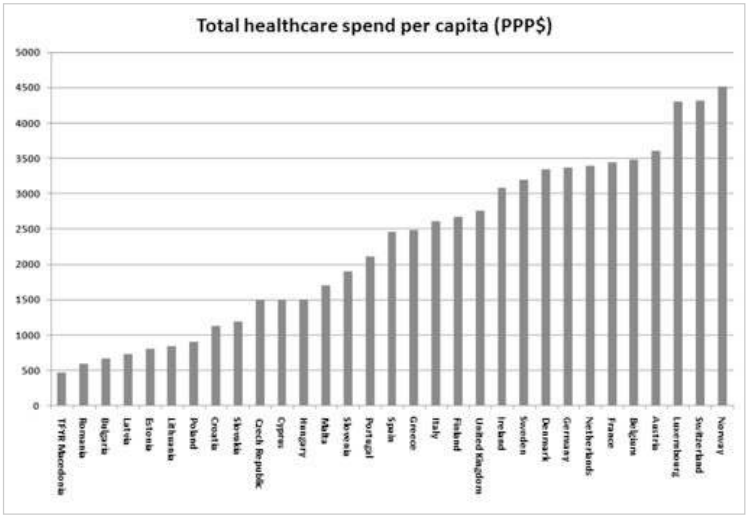
- Then come the countries that find it harder to have more acceptable health care.

What is instantly clear is that the result is proportional to the investment. This is the amount spent per person in various countries and those you see in the slide presentation on the right, and spend more, are generally speaking those with a better system.

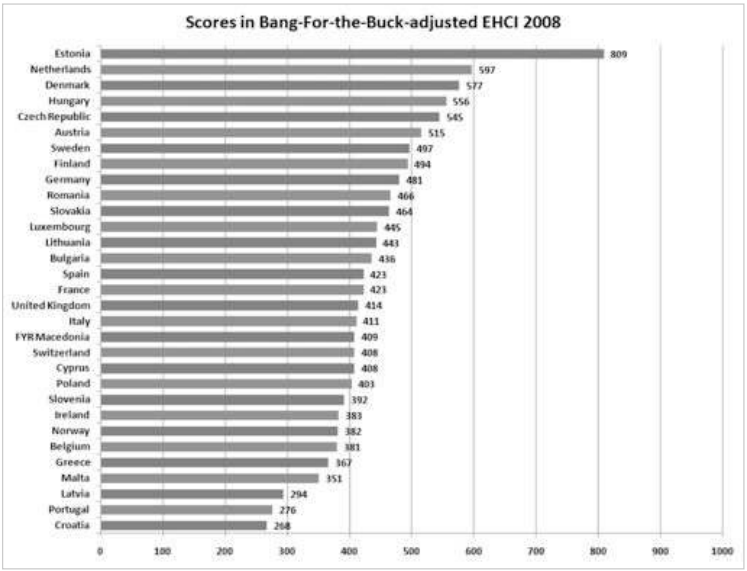
Euro Health Consumer Index – Total Scores



Euro Health Consumer Index – Total Healthcare Spend p.cap.



Euro Health Consumer Index – Scores in Bang-for-the-Buck



This is quite obvious, there are however exceptions. If you observe the next slide, comparing the quality of the system in relation to the investment, things change. Estonia, for example, a country that does not have a great health care system and a very low level of investment, is in first position thanks to the productivity of the investment.

This data emphasises that investing large amounts is certainly important, but it is equally important to use one's resources well. Wasted resources, channels that are not transparent, money that is used in the strangest of ways can all cause these kinds of problems.

One must bear in mind the revolutions taking place in the world of medicine so as to organise a health care system that is updated. Medicine follows science and science is experiencing a revolution, hence health care, which is at the service of good medicine must be continuously updated.

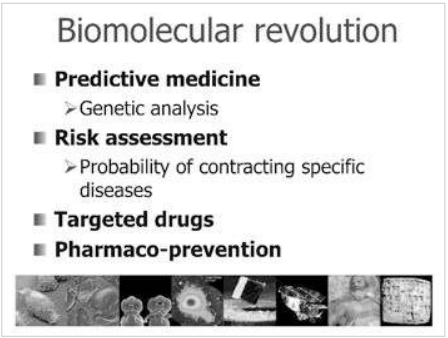
There have been many revolutions. The first one, the bio-molecular one, the decoding of DNA which took place nine years ago, totally transformed medicine. We must currently address the issues of a medical sector in which all past models must be renewed.

The revolution of diagnostics through imaging. As you know it is today possible to see three-millimetre tumours

in the remotest parts of the body, thanks to the application of IT to diagnostic systems.

The therapeutic revolution and technology's participation in medicine first with normal technology and then with nanotechnology. Nano-medicine is, in fact, becoming the great branch of the future.

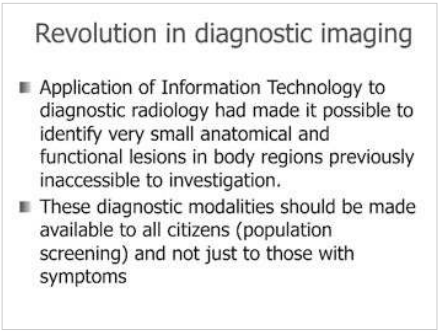
Finally, there has been an ethical and humanist revolution as briefly mentioned earlier on. Relationships with patients have changed. The aforementioned patients' rights are the result of this revolution, which is still ongoing and not complete.



I previously mentioned the biomolecular revolution. We have moved from prescriptive medicine to predictive medicine, and genetic tests will, in the future, provide us with a risk assessment for individual pathologies, in a very useful way as far as prevention is concerned, to try and anticipate systems for diagnosis, prevention and pharmacology. There is here with us today a great cardiologist who knows that one pill a day can be useful as protection from serious heart disease.

All drugs will undergo change, since we are moving from traditional chemical pharmacology to biological pharmacology, in which the drug will consist in a molecule that will attack one specific target, generally iden-

tified in changes in the DNA at the basis of that disease. This applies significantly to tumours and less to other diseases, but is, however, a great transformation that will also result in the preventive drugs I mentioned earlier.



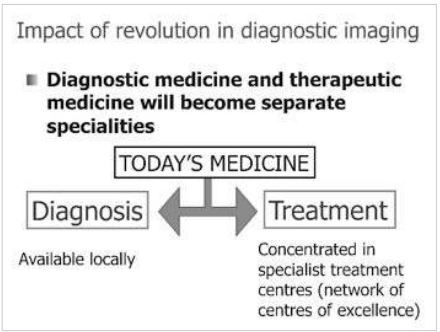
I have already mentioned that diagnostics using imaging will provide us with an increased capability to acquire greater, profounder andvery sophisticated information about our bodies. This will result in the entire population wishing to undergo diagnosis one a year to verify the state of their health. These special and fantastic machines such as magnetic resonance imaging machines, CAT and PET scanners, are now available and I believe that everyone, once a year will want to enter this magic box and come out with images of their bodies sectioned centimetre by centimetre, verifying that everything is in order.

This is the future. Today we have not yet reached this point, but we envisage progress in that direction. What will this result in? There will be a progressive division of modern medicine into two branches, diagnostic medicine and therapeutic medicine.

Diagnostic medicine will be widespread, available to everyone, close to individual homes so that everyone will easily understand the state of their own health.

Therapeutic medicine will instead move in the opposite direction. We will need fewer hospitals, but extremely well-equipped and technological ones, very advanced only accepting patients for treatment.

Treatment will be the specialisation of hospitals; diagnostics will remain peripheral and capillary. This is what is slowly happening, but it is the future of medicine, and therefore we will have to bear in mind these two different elements.



It is difficult to continue to imagine having hospitals that do everything. Diagnostics, prevention, screening and treatment. All this causes confusion. Doctors working in diagnostics are not motivated in the same way as those providing treatment.

Let us now speak of the revolutions taking place in treatment. First of all, the use of one day treatment has increased enormously both for medical treatment and for surgery. Nowadays almost everything can be done as day surgery. Anaesthetics

can be used, even general anaesthetics, and the patient can return home in the afternoon. Hernias, appendixes, gall bladders can all be operated in day surgery as can thyroids as well as many mammary pathologies.

This totally changes the approach. Leaving aside the fall in costs for surgery, everything is quicker and easier. This, however, poses a problem. The need for nearby reception facilities, a sort of hotel built in agreement with the hospital, where the patient can spend a night in case of need.

This also applies to patients who have been hospitalised for more serious surgery. Health care costs are very high because patients are often kept in hospital for a week because one does not feel confident sending them home, if for example they live two hundred kilometres away. A nearby hotel where patients could go and stay two days after surgery, seeing the closeness of the facility, would allow any complication to be quickly addressed. Suddenly health care's immense costs, about one thousand Euros a day for hospitalisation, would drop to one hundred Euros using the hotel.

Two final points:

- Earlier I spoke of technology. There is the role played by robotic surgery, and all surgery will become robotic. This because the robot is a fantastic instrument. In my institute we have a school of robotics and use robots for most of our surgery, at least for abdominal and thoracic surgery, because the small hands of these robots have extraordinary capabilities. Our hands cannot do more than a certain amount. The robot instead, if necessary, can carry out twenty

operations. Everything becomes easier, safer, and hospital stays are much shorter because only two or three small incisions are made and therefore one can say that this revolution will seriously benefit patients.

- Another point I wish to make is that in the future all hospitals will have to have a research department. One cannot envisage medicine without research. A hospital must have research, also because research is integrated. Nowadays medicine itself is research. It is adequate clinical research. If we have a new drug that needs testing we must do this in a rational and scientific manner, organising clinical research. If we have a laboratory that can help us and support this research, all will go well. We must resign ourselves to having research in hospitals. This is still at a very embryonic stage in many hospitals, but in my opinion it is what the future holds. The new model for a hospital I created with Renzo Piano about ten years ago, as mentioned previously, is still a valid one.

The hospital of the future will be very human, with the patient at the centre of everything. When I created the European Institute of Oncology I discussed the matter with the architects who had designed it thinking of the centrality of the doctors. I told them to overturn all their concepts;

the patient is at the centre. Think of something patients will like, that will be pleasant and useful to them, not to the doctors. It was a revolution. Those who come to my hospital see a very different kind of institution. A very small one with a great deal of horizontal connections, very few lifts that divide and make relations difficult. It has escalators like a department store to make everything easier, simpler and ensure that patients feel at ease throughout the hospital. Of course it is a small cog in a large machine.

I have already mentioned turnover. Patients should spend little time in hospitals; doctors must be there full-time. It is unacceptable for doctors to spend a few hours in a hospital with sick patients and then look at their watches and rush off to operate in private clinics. This is wrong. It is a phenomenon that has vanished in Europe, with the exception of Italy. On the contrary, here it has recently been confirmed as a model and this pains me greatly, because we are going against the trend; it is an anti-historical decision. It is as if Pirelli had a CEO who at a certain hour of the day went to work for Michelin. This is what happens in Italy. It is one of the reasons for which state hospitals don't work properly. Richer patients, and possibly with less serious needs, go to private clinics, while those with compli-

cated and expensive diseases end up in hospital. This is our health system's great defect.

And of course clinical research in laboratories must be integrated.

These are the conclusions for this brief introduction on Europe's future in the health sector.

The entire hospital system must be changed. It is necessary to invest more in prevention, more resources are needed for clinical and laboratory research, and – as previously mentioned – I am delighted, and this is a fundamental point, that there is free circulation of doctors and patients. This is the future.

If we manage to create a Europe in which these few things are achieved, we will really be moving towards a united and integrated Europe.

Science, Research and Citizens' Rights in Europe

Emma Bonino*

I have always addressed these subjects, and still do, from a number of political viewpoints, not only because of my family background, but also because, when speaking of Europe as we are doing today, I believe that the most important issue often emphasised today by Umberto, is that of freedom, freedom of choice. This, because without freedom, Europe cannot exist.

Freedom, however, does not mean 'taking liberties', freedom means responsibility, and usually a burdensome one. This is why freedom does not always mean happiness.

Freedom is at times an unhappy responsibility. Hence, there are a series of stereotypes that revolve around the concept of freedom, which in my opinion is something else.

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* Vice-President of the Senate of the Republic of Italy. Former European Commissioner for Humanitarian Aid, Fisheries, Consumer Policy, Consumer Health Protection and Food Safety. She was Head of the European Commission Delegation to the Rome Diplomatic Conference of Plenipotentiaries on the Establishment of an International Criminal Court in 1998

Europe is a constitutional state, it is freedom, it is a political project that does not intend as others have done, to move towards being a welfare state without freedom. Whatever the system may have been in other regions of the world, going by the names of communism, socialism or something else, they were after all at least in theory, welfare systems without freedom; a top-down approach or whatever you may choose to call it.

The European Union presents itself in a different manner, and this, I believe, is the difference between the EU and other institutions or other regional political associations.

My second observation is that, due to the financial crises, in the course of twenty-four hours eternal eurosceptics have become last minute euro-enthusiasts. But since these people are Europe's neophytes, they are enthusiastic for a Europe that does not exist, nor is it the kind we should create on the basis of updating the dream of the founding fathers.

The third, simple element is that because we are in Italy, it is obvious that we have an additional problem we must address. I speak to Umberto because we share some of these feelings. Beatrice says that, as the European electoral campaign opens, she hopes that health and welfare will be issues in the electoral debate. I am an optimist, but I am not exactly unrealistic. Hence I fear that, as always, that our agenda in this European election campaign will only address Italian issues and party controversies, and that we, or rather the political class of leaders, will be unable or unwilling to seize this opportunity to speak of Europe. I believe they have not reflected a great deal on this subject and would have little to say.

I remember the last electoral campaign, held only six months before addressing one of the most important and difficult decisions, that of opening negotiations with Turkey, something I am in favour of. When I tried to speak of this during electoral debates I was stared at as if I had just come from outer space and was inventing weird issues. I fear that efforts must be made, otherwise we will experience a similar situation.

I was saying that, as Italians, we experience an additional problem. We are, in fact, immersed in a culture, a scientific environment, or perhaps an anti-scientific one, an atmosphere in which science has suddenly become a frightening issue. Any research, any cure that is discovered leads to a return to stereotypes that few question, such as, for example, "natural means healthy". No, natural means natural. Healthy means something different. Cholera has been extremely natural but I would not describe it as healthy. I say this because, for example, another battle we have undertaken is the one in favour of research on green biotechnologies, in particular on genetically modified organisms.

I recently took part in a controversial debate precisely on this type of stereotype, describing it as Frankenstein's food. As soon as an innovative discovery is made in a laboratory it is instantly labelled as Frankenstein's food! Human beings have always experimented. My father, who was a poor farmer, also experimented, attempting to do his own grafting; it was a pity that only one out of ten attempts succeeded.

"Natural means healthy" is one of those stereotypes that are hard to overcome. Nor is "Nature equals motherhood" always true. Out in the jungle nature is a step-mother. For

three thousand years we have attempted to govern nature. Hence, I repeat, we are immersed in an a-scientific atmosphere, not to mention an anti-scientific one.

Another issue is that there is often the tendency, particularly in Italy, to impose a religious option as binding for all concerned. With all due respect for the various religions, I believe that a citizen may be a believer or a non-believer while remaining a decent human being. And I believe that this situation is one we must change.

We all agree on free circulation of the patients, but not when they are obliged to make this choice.

Free circulation and obligation are two very different issues. If one lives in a country which obliges its citizens to travel to Spain to receive artificial insemination, this is not free circulation but rather an obligation to embark on "health tourism", which is totally different.

As always, those with money can afford it, while those without funds end up in less desirable institutions in other parts of Europe.

I therefore would like to add, as far as Italy is concerned, just one concern in addition to those described by Umberto. Yes to an integrated system, because this leads to integration, and of course citizenship. But one should make sure one also learns from other European areas – I see our English colleague here – where they are more open to research than we are, with fewer fears, without stereotypes, because researchers do have a code of conduct and they are responsible people. Prohibitions are different since they imply a fear of research or of scientific results.

Finally, I repeat, beware of ideological impositions or religious restrictions affecting the centrality of the patient.

If it is the citizen who is at the centre of a responsible choice involving freedom, this free area must obviously be guaranteed. It must include the right to and the responsibility for a dignified death; this is a right that belongs to human beings.

Europe is also this; freedom and a constitutional state.

Compulsion, Confidentiality and Consent Three Current Dilemmas for Liberals in the Field of Human Rights and Mental Disorders

The Lord Alderdice FRCPsych*

It is a great delight to be present at this international conference on Health Care Policy and Fundamental Rights in Europe with such eminent colleagues from around the EU, under the auspices of the European Liberal Forum which I would like to congratulate for supporting the event. It is especially good to be with our friends of the Fondazione Critica Liberale to whom we owe enormous gratitude for their excellent organization and generous hospitality. I have always been deeply in the debt of Italian Liberals, from the legendary Senator Giovanni Malagodi, who first invited me to become involved in Liberal International and welcomed me to LI many years ago, to the equally legendary Contessa Beatrice Rangoni Machiavelli who has been a constant source of inspiration and support to me throughout my time and especially dur-

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ing my Presidency of Liberal International. Italian Liberals may not always be large in numbers but they are great in intellect, character and heart, and I wish to say a sincere thank you.

In considering European Health Policy and the current proposal for an EU Health Care Directive we can easily as liberals focus our attention on competitiveness and freedom of movement of people, or even the free movement of infections and pollution with the resulting spread of epidemics and disease within and beyond the Single European Market. However these issues largely apply to acute medicine and surgery and public health matters. A vulnerable person with a chronic disorder which needs long-term regular treatment or care, such as is the case in many mental illnesses, is unable to seek care in another part of their own country much less travel to another country for care, precisely because of the frequent, regular and on-going nature of the treatment or care required. What then are the key issues for other fundamental rights and healthcare policy in Europe especially in chronic disorders? This is especially a concern for me in the case of psychological and emotional aspects of physical illness and particularly in the field of mental illness and disability, which is my own special professional interest.

There are already many international human rights instruments and some of the articles they contain are of particular relevance to persons suffering from mental disability however, though we may relatively easily set down ideals, implementing them is another matter entirely. A Right to Health for example is easily proclaimed, but how can it be obtained, for it is not the

same thing as a Right of Access to Health Care, and access in principle is not at all the same thing as access in practice. In the case of mental health, in addition, there is not unanimity among professionals about what causes mental illness. There is also little agreement about what management or treatment will best promote mental health or a return to mental health in any particular individual with mental disabilities – even setting aside the many sad circumstances where there is no prospect whatever of achieving good mental health, no matter how excellent the care and treatment available.

I do not propose in this short paper to dwell on such wide issues of debate but rather to present three specific areas that concern me greatly in the field of Mental Disorder and Human Rights. They are serious current issues, though in some of our countries they may be a more present danger than in others, and I would readily admit that I am heavily influenced by developments in the United Kingdom where I live and work as a psychiatrist and as a legislator with an interest in human rights. At the same time I have good reason to believe that my concerns are widely shared by other professional and voluntary colleagues involved in mental health care, as well as by a number of human rights activists in other parts of the EU.

I must also make clear that in presenting these concerns I am very aware that they could be misunderstood as being in conflict with some more traditional human rights preoccupations. I do not see them in this way, but rather hope that what I say will be set alongside, rather than in opposition to, long-standing commitments.

The first threat to the rights of mentally disordered persons which I discern comes from the growth of a risk-averse society. It is now common place to find that any unfortunate happening is followed by an attribution of blame, in which it is assumed that the adverse event occurred because someone in authority failed in their duty to prevent it. If a child is abused the focus of blame sometimes shines less on the abuser than on an under-resourced social services department which failed to detect and prevent it. Whether or not it is found that there was a failure to observe current best practice, the post hoc enquiry will inevitably produce recommendations for further regulations and more monitoring, which restrict the freedom of carers and those cared for without much evidence of effectiveness. A very obvious outcome of this process, which is evident in every aspect of public and professional life, was apparent in the Draft Mental Health Bill in the United Kingdom. This proposed to widen the definition of mental disorder to include any disorder where mental functioning is impaired. This could include disorders such as diabetes and epilepsy, as well as learning disability, alcohol and drug abuse and sexual deviancy. It then proposed to create a legal requirement on mental health professionals to compulsorily refer and admit to mental hospitals for a one month assessment anyone who fulfils the requirements that they are suffering from a mental disorder, warrant provision of treatment and are a substantial risk to themselves or anyone else, but notably without any requirement that this be in the best interests of the patient, or that it is of direct therapeutic benefit to the patient.

The reason for this approach was the wish of the British Government to ensure that people with what is described as Dangerous Severe Personality Disorder (DSPD) would be able to be incarcerated by psychiatrists before they committed any crimes, rather than by courts through due process after a breach of the criminal law - a prospect that horrified the Royal College of Psychiatrists and its members. Articles in Royal College of Psychiatrists publications suggested that, even within high-risk groups, 100 patients would have to be detained unnecessarily to prevent one suicide and 2000 people detained to prevent one homicide.

The historic fear of the mentally ill combined with a more recent generalized aversion to uncertainty and risk is opening the door to illiberal and authoritarian legislation which will profoundly adversely affect the rights of people with a wide range of disorders, and will likely overburden health care systems to the point of them being overwhelmed. There are other ways in which the reasonable concerns of the population could be addressed, and which in the long run would be likely to be much more effective. One such line would be to adopt a more sensitive approach to the assessment of impaired decision-making by patients, and by maintaining professional flexibility under a 'least restrictive alternative' requirement for compulsory treatment. *A risk-averse attitude in society combined with an authoritarian approach by government is a danger to the rights of the mentally ill.*

My second concern is based on a more recent development which emerges from the catastrophic events of

September 11, 2001. Many of us, even as we watched the unfolding of the horror before our eyes in real time on satellite television, felt a cold chill as we sensed that the terrible suffering of the families of those killed and the fear generated in the community by the prospects of further terrorist attacks, would be used to justify a rolling back of the human rights agenda. We did not have long to wait. Around the world Justice, Home Affairs and Interior Ministries dusted down proposals that had lain on shelves for years because of their public unacceptability, and presented them to Ministers with briefs spiced up to make them relevant to the current crisis. One important example was that loss of personal privacy and confidentiality was presented as a small price to pay for security against another 9/11 or worse.

Combined with a more long-standing and constructive view that sharing of patient information between agencies was the way to better health care for patients, there is now pressure for legally binding compulsion of mental health care workers, including doctors, to provide confidential information not only to other health care agencies, but to the police. I believe that not only is this straining to the limit the interpretation of Article 8 of the ECHR, but it will inevitably lead to patients withholding information in ways which will profoundly damage the prospects for their treatment, and in the end for public safety. *Fear generated by terrorism should not be the excuse for destroying confidentiality and trust between patients and professional carers.*

My third area of concern is perhaps the most difficult to outline, but the most essential to an understanding of

the dilemmas of human rights and mental health. The stigma of mental disorder and the disabilities and discrimination suffered by mentally disordered people are in some measure shared by many other groups of disabled people. Working together in campaigns to improve human rights using a common disability model has led to the achievement of significant progress in the welfare of all disabled people and more can still be achieved by pursuit of this important path. At the same time it must be recognized that mental disorder is different from other disabilities because it makes a more fundamental attack on the person than any other disability for it damages some of those aspects of the person which we regard as distinctively human. One of the central features of our work in human rights is our determination to maintain the freedom, dignity and autonomy of the individual person, and all of these are jeopardized in mental disorder. Let me take as a brief example the autonomy of the person suffering from a psychotic illness. Their autonomy, an essential feature of their human rights, is not only at risk from external compulsion, neglect or injury, but also damaged to a greater or lesser extent by the dissolution of their mental functioning from within. We can address external problems by law, but internal damage and dissolution of the personality is another matter entirely.

It is here that the principle of human rights is most important and most complex, but this is also the point where a legal implementation is most difficult. It is not easy to judge the welfare of the patient in a psychotic state and to balance it against that of their family, even when we set aside the more gross and less common cases

where the risk of violence is apparent. The patient's capacity to think freely is damaged by the process of dissolution of their mental function by the illness. Their relation to reality and their volitional capacities are disturbed. This situation is also fluid. At times they may be less incapacitated, and at other times profoundly disturbed. The law generally wants to know whether the patient wants this, or that - yes or no - and is not generally constructed to be sympathetic to the double bookkeeping which is an essential feature of much of human life and all mental illness. The fact that a patient may say one thing, and mean another, or say one thing at one time and then something completely contradictory in five minutes time, is common-place, but a legal conundrum. There have been a number of efforts to address this. The most obvious and least satisfactory is to assume that the patient, if not deranged, would have the same view as their medical attendants. This may be made more acceptable by broadening the field to include the family or close confidantes. In such a case the doctor would consult with colleagues and with the patient's circle of family and friends, and then assume that their shared judgment approximates to what the patient would have wanted had they been well. We only need to reflect for a minute on our own feelings about our wishes being subjected to such a set of criteria to know that it is a very crude approximation. An improvement in the context of a relapsing illness may be the adoption of 'Advance Statements' by patients, in which they may declare in a signed statement how they would wish matters to be handled in the event that they fell ill again. This may not just be in connection with their medical

care, and whether they should be prescribed medication against their will as expressed during a period of incapacity, but also matters such as childcare arrangements and their financial affairs, which may be particularly problematic during certain acute psychotic episodes – for example in hypomanic states patients who are otherwise careful with their money may, during the acute illness, spend irresponsibility and then deeply regret what they have done when they subsequently recover.

Advance Statements do not entirely resolve the problem however, even in those recurrent conditions where they could be applied, for they do not of themselves take account of the complexities of management and judgment which are necessary. In illness what emerges is not just an expression of illness but also a release of certain genuine but inhibited parts of the personality - for good and for ill. Anger expressed against a relative during illness (as is also the case during inebriation) for example, may well be genuine and even deeply felt. In health it may have been inhibited for the sake of the relationship, but released during an acute episode of illness, with untoward consequences if it is taken as a genuine expression. Close relationships have the possibility of being part of the patient's problem as well as part of their sustaining support during difficult times. *The law finds such internal dissonance and complexity difficult to handle because they represent mixed and conflicting wishes. The law wants clarity and a singular view from the patient.*

These then are the three current issues which I wish to draw to your attention – Treatment under Compulsion,

especially where it is not demonstrably effective or in the interest of the individual patient concerned - Limits to Confidentiality, and the potentially disastrous consequences this may have not only on treatment but on the very public safety in whose service it is demanded, and - the Problem of Achieving Consent and the door this issue opens into the dilemmas of using legal instruments to address the conflicts and complexities of the mind, especially in serious mental illness.

These three dilemmas which I have tried to sketch out are all expressions of what Baroness O'Neill described in the Reith Lectures in 2002 as 'A Question of Trust'. She pointed out that for the last fifty years we have tried to use human rights law and democratic accountability to address the gross breaches of trust represented by human rights abuses, inequity of social and economic opportunity and the damage caused by war, criminal acts, misjudgments and simple tragedy. Unfortunately human rights law and democratic accountability have not succeeded in regenerating the trust that was lost. Rather trust has been replaced by regulations and law as the basis of public relationship, and trust is now almost absent in political, professional and public life. Relationships of course cannot survive only on law in the absence of trust and no life is worth living, or perhaps ultimately even possible to live, without some relationships of trust. In pursuing our concern for the human rights of those suffering from mental disorder we must try to ensure that the valuable legal mechanisms which we are using for the protection of those who are human, do not themselves come to jeopardize the very humanity which they seek to protect.

Improving Health and Healthcare across Europe: an Integrated Approach

André Knottnerus*

Fundamental rights, health and societal development

The three first articles of the Charter of the Fundamental Rights of the European Union are directly relevant for the domain of health and healthcare: Human dignity, the Right to life, and the Right to integrity of the person(1)

This emphasizes the enormous responsibility of all those in charge of providing good healthcare, directly and indirectly.

Accordingly, in the domain of healthcare, concrete rights to be achieved for European citizens are:

- availability of and good access to health protection, prevention and essential healthcare;

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- good quality healthcare provision, which includes effective, safe, and ethically justified prevention and care;
- No inequity in access and quality of these services

From the societal perspective, healthcare must be efficient as well, that is, providing value for money, to enable also other societal priorities to be optimally achieved. But in contrast to what many believe, this should *not* be in conflict with good healthcare for all: on the contrary, good prevention and healthcare for all is, in addition to being good in itself, increasingly recognised as an effective and efficient societal investment.(2) For example, economic research showed that investments in health in the western countries explain about 20-30% of the income and productivity per capita, which is about the same impact as education.(3) Obviously, human health is an important motor of participation in and contribution to society, as we saw this in history, and see that today – unfortunately too often in a negative sense – in low income countries. So, we should not only think about *what the market can do for health*, but maybe even more importantly, about *what health can do for the market* in its broadest sense. This insight adds to the relevance of good prevention and healthcare in Europe, which means that we really speak about a border crossing issue.

Against this fundamental background, we can distuinguish various specific challenges in the health domain in the context of an integrated European approach.

Border crossing issues

First, there are health threats that are inherently transnational, such as environmental health risk factors like air pollution and climate change, and infectious diseases like bird flu and the related threat of a pandemic among humans. These problems can only be tackled by well organised public health actions across Europe. Also cross-border mobility needs attention, not only of patients, but also of professionals. The latter for example may have reasons to move related to professional misconduct, which has already evoked collaborative European actions to protect the patient.

Another category of health issues is not inherently border crossing, but is represented in many member states in a similar way, such as ageing and health, the increase of chronic illness and obesity, and new medical technologies that pose complex ethical questions. Regarding these topics scientists, healthcare providers, and policy makers can exchange knowledge and experience, to learn from one another and collaborate to improve policy and practice thoughout Europe.

Third, there are healthcare challenges that need to be tackled internationally. For example, adequate provision of highly advanced clinical care requiring complex and very expensive infrastructures and scarce expertise, often need to be approached internationally instead of nationally. The same is true for dealing with very infrequent severe disease. For example, in the Netherlands, not more than 10 to 15 very young children per year are candidates for heart transplantation. Even if these procedures are carried out in one centre, this number is probably too low to reach the routine for a state-of-the-

art and safe performance, given the so called volume-outcome relation. In such cases, it is better to collaborate with a much larger centre in Europe. with much more routine. In this context, centers of excellence with a supranational function are essential for good patient care.

A fourth field relates to health services provision throughout Europe. This is a subject of increasing importance for national governments, not only because of cost implications, but first and foremost to enable patients to be optimally served. In view of the human rights in Europe, in combination with the free movement of persons, goods and services, we will move forward towards equal accessibility of health services in the European Union. This both requires and evokes cross-border health insurance coverage for the citizens in all member states, and more convergence of essential content and quality of the provided services. How to get there in a reasonable time is in fact a matter of implementation. In this context, healthcare institutions working in internal border areas have already shown to play an pioneering role. Until now, rulings of the European Court of Justice have given important guidance, but instead of awaiting such corrections based on retrospective review, also proactive and visionary leadership was required. Therefore I applaud the European Commission's Draft Directive of 2 July 2008, taking a vital formal step towards healthcare without borders.(4)

A final border crossing topic is health system performance throughout Europe. To evaluate this, we require comparative investigations, for example in the context of the Commission's Framework Programme.

Such studies can transparently relate data on relevant determinants (such as degree of primary care coverage, type of insurance, and copayments) and outcomes (mortality, life expectancy, morbidity, quality of life, and cost), to see what characteristics are important for an effective and efficient healthcare system, and what can be learnt from best practices. It is not to be expected that this will easily lead to a one and only best ever system. Rather, it will yield an evolving evidence base to include a range of effective system options that will give guidance to policy makers to improve system performance and make further adaptations. However, cumulated evidence base don good science will without doubt contribute to convergence over time.

Variety as a creative source

Of course, speaking about convergence, longstanding cultural differences between states, essential national traditions, and ethical diversity are to be respected. One can think at the fields of perinatal technologies, embryonic stemcell research, and dealing with end-of-life questions (the latter becoming increasingly relevant given our ageing societies). But at the other hand, it is precisely in such fields that cross -border European debates have added value for mutual understanding and learning.

An example where looking at variety can be helpful to strive for the better is antibiotic resistance. It has, recently again, been shown that the percentage of resistant bacterial strains shows huge differences between states: from a few to tens of percents. This cannot be explained by demographic an epidemiological variation, and it is

likely that prescribing policies and veterinary habits in use of antibiotics play an important role. As this problem is likely to occur again with new antibiotics to be introduced, there is an urgent need for mutual learning in an open international exchange.

Acceptance standards of medications for the market varies between states. In an open European context, some drugs enter the market after acceptance by some countries although they might not have been accepted by others. An example is rivastygmin, an anti-Alzheimer drug that has very limited effects and relatively many adverse effects. In fact, there are are two challenges here for the common market: first, to strive for a policy where the highest quality acceptance standards will be leading, not the lowest. And second, to stimulate international clinical guideline development leading to effective and critical cross-border treatment practices.

Organ donation: there is a large variety of national policies ranging from fully opting-out to opting-in systems. There are also intense debates on what is the best approach, from both the clinical and ethical perspectives, also within countries. Given the increasing pressure from those in need for organs on countries with a more favourable pool of donors, and in addition, the growing interest for commercial organ donation practices exploiting people from low-income countries, a more integrated international approach must urgently be considered.

There is quite some diversity between states as to primary care coverage, while there is important evidence as to the positive impact of a strong primary care basis for effective and efficient health care. This is really

an issue to think about proactively, rather than wait and see, and to anticipate what the future position of primary care in Europe should be.[5]

Market orientation

In a number of countries there is growing interest in shifting from mainly publicly financed healthcare towards a more market oriented approach. In The Netherlands, in 2006, concrete steps have been made in this direction. Without going into detail, it is interesting to mention the principles as also other European countries have expressed interest in these:

- The public sick funds have merged with private insurance companies
- A basic health insurance package for all citizens was introduced covering essential health care services and with acceptation without selection by risk
- A fixed annual premium is paid, on which insurers have to compete annually
- There is an annual own-risk coverage of 150 euros
- Low incomes receive a subsidy for the premium
- There is an optional additional package for nonvital extras
- Long-term institutional and nursing home care are covered by mandatory special national insurance (income-dependent).

As insurers must accept all applicants for the basic insurance package, the system represents a *regulated* rather than a fully open market. What has been achieved is[6]

- Increased competition among insurers and among providers

- Providers must negotiate with insurers over price and quality of care
- Providers must document quality of care, using performance indicators
- Hospitals compete by setting prices for services on the basis of predefined Diagnosis-Treatment Combinations
- The percentage of uninsured (1.5%) is somewhat lower than before
- No indications for risk selection in relation to basic package

Although the first results seem to be favourable as to perceived quality, consumer appreciation, and premium setting, it is still too early for an overall evaluation. However, the experience suggest that this regulated market approach, with safeguards as to equity, yields indeed better cost containment with more patient-friendly care.

Also other European countries have recenty reformed or are doing so. It is therefore now an appropriate period to exchange, with a view on good learning points for Europe's future.

Will we have a single, comprehensive market?

Having discussed the strong movement towards cross-border healthcare, and issues for mutual learning, and exchange, what about the central question whether we are going to a single European healthcare market?

My short answer is: yes we are, but I would rather speak about a c*omprehensive* European market. We see it contours appear, but to make it a predictable success,

it is wise to build this up from its most obvious and strongest pillars, guided by vision and evidence.

It is helpful to distinguish the content and financing of the healthcare market.

As to *content*, important steps have already been taken by the Commission and the Member states, recognizing the continuity between prevention and healthcare. As an example, in the field of infectious diseases, we have now the European Center of Disease Control (ECDC) which is developing strongly both in guidance of and networking with national health authorities. In the field of medical care an important step has been to establish the European Medicines Agency, aimed to foster scientific excellence in the evaluation and supervision of medicines, for the benefit of public health. Also, many productive collaborations from the professional healthcare domain have been established , for example on improving cancer care and on formulating and improving evidence-based clinical guidelines, both in primary and specialised care, having great authority in the field.

Many actors in the professional and policy field, including the European Commission, are very actively involved in developing, testing and implementing new knowledge for practice, and promoting quality and safety in healthcare. In addition, it is to be expected that, especially for advanced and complex medical technologies and rare diseases, acknowledged European centers of excellence and reference networks will increasingly established. Such developments will lead to strong international quality standards and further convergence of

the content of both prevention of care, especially in those field where cultural and diversity between member states do not play an important role. In the latter situations, mutual respect and taking time for discussion and learning from one another is the appropriate strategy. So, in the field of the content of care I am confident that healthcare provision meeting the best international standards is strongly on its way, and that-within five to ten years - the variety in the provision of essential care between members states will generally not be larger than it is within states.

As to the other side of the coin, the *financing system* to make this all happen, the market will now be formally more open, expecting that the July 2008 Draft Directive of the Commission will be endorsed by member states. This is a power in itself towards a comprehensive market, led, in fact, by the patient's choice. In addition, experiences in member states with system reforms need to be intensively analysed, discussed, and compared internationally, with the Dutch experience as one of the inputs, so that also in this respect, evidence-based policy solutions will prevail more than in the past. If this expertise would be concentrated in a European expertise center for health system comparison and reform, this would this be an extra driving force.

I expect that progress based on a combination of top-down and bottom-up forces, implies in itself a characteristically European solution. The question whether this would then be really called a single market is less important than the actual content. I would go for a comprehensive 'regulated' market context, in which various arrangements can be offered, but with one common ba-

sic package for essential healthcare to be available throughout Europe. There should be room for ambition and competition, with safeguards for accessibility, equity, and quality, to provide the best possible care to all European citizens.

Independent scientific advice on health

Given the exponentially growing body of knowledge, scientific advice on health issues to national governments and parlements and to European policy makers is of vital importance for optimal decision making to improve health both at the national and European level.

Strong links between national and transnational science advice, with collaboration between national and European agencies based on complementarity, will help to achieve maximal quality and efficiency. For this purpose, a solid common methodological basis for science advice will be important. In addition, in an international context of economic, political or commercial interests, and the increasing societal interests involved, independence of science advice is a key issue.

Accordingly, the European Science Network for Health (EuSANH), consisting of independent statutory advisory bodies, has been initiated to share expertise and to collaborate on border-crossing European issues, and to organise the independent voice of the European scientific community in the field of health.

Notes

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For an Open Debate on Health Policies

Giulio Ercolessi*

Even more than for other sectors, there is a need for an open debate on health policies in Europe and above all in Italy. This is an extremely complex subject and one unsuited to being reduced to the guidelines within which other social policies are debated. For years it has been hostage to a primitive debate in which each vested interest and pressure group has developed an almost diabolical capability to present its own particular point of view assumed to be the best able to identify with public interest. This applies to professional politicians, political parties, politically appointed administrators, bureaucrats, trade-unions, professional categories and their sub-groups, entrepreneurial or cooperative organisations, players variously qualified as non-profit organisations, religious or profiteering-religious bodies.

This game works extremely easily since this is an objectively complicated subject and any non-trivial discussion concerning it requires the counterpart to pay seri-

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ous attention that goes well-beyond the two/three minutes attention span that the average TV viewer is ready to apply before grabbing the remote control to find something more relaxing, or something that is comforting in confirming acquired platitudes. Most viewer may also search for something that reassures them since they presume to be already equipped with the necessary and sufficient information for navigating the various political-ideological ideas on offer they presume they can master.

If this is the state of an average citizen who has no immediate need of health services, health service users – call them patients or customers – find themselves in weak positions and with very little information when instead they find themselves in the hands of others and in times of need. They naturally tend to form an opinion only through the interpretative filter provided by an individual health operator, from among those they come into contact with, and with whom they establish a higher level of syntony and empathy. Usually they have no clear idea at all of the overall way the system works, and above all of its costs and relative efficiency or inefficiency compared to costs.

Often, however, their immediate interlocutors also have no idea on the matter. Our social systems are based on the principle according to which all health needs must be met – a sacrosanct principle and one to be defended and implemented literally, but with answers that do not fall from the heavens above. In many countries health care is also an absolute right established by the constitution.

But all players in the health sector, with the exception

of those required to provide financial resources and those required to provide health care within the limits of their budget, tend to widely underestimate the problem of costs and long-term sustainability and often not only the long-term.

What economists call "moral hazard" is not only the attitude people display, usually with little or no subjective awareness, when they tend to exploit even beyond their real needs and advantages all services provided free of charge, but also an attitude widely shared by those who directly provide these services. This happens when they are not aware of the costs, as often happens, and also not aware that the resources needed are always, by definition, limited resources and always inadequate compared to the needs.

The current primitive debate, in Italy and not only, indicates that there are basically only two alternatives up for discussion. These are on the one hand the privatisation of health care, identified *tout court* with the almost total deregulation seen in the American model, and, on the other, the all-out defence of the existing system, with the exception of a few shareable but marginal ideas for patching it up.

And yet there are objective reasons that will impose, and are in fact already imposing, changes that, if not properly managed, will very soon result in a progressive collapse of the current system. These are technological progress – which everyone expects to be supplied as soon as they are available – increased life expectancy – partly a consequence of improved technology but also involving a further inevitable rise in costs – and the changed demographic situation, which, in spite of the

decisive and beneficial presence of immigrants, will inevitably lead to an increased number of users and a fall in the number of those paying for costs. Furthermore, in these conditions investing in research will become increasingly difficult also for those European countries that, unlike Italy, have not yet totally given up; and this will be one of the most important sectors in international economic competition over the coming decades.

These are the reasons that already make it increasingly arduous to keep the promise of providing effective and quick universal coverage of a person's needs, as established by the European social model, and that is now considered part of the constitutional pact.

This is also due to the impossibility of increasing spending without limitations, as that would imply unsustainably ever growing taxation: that being impossible within an international context of open markets, the system's economic sustainability is increasingly conditioned by its efficiency.

The costs of the system's party-political and monopolistic management, structurally less interested in and not very capable of economic efficiency, in fact turns into an effort to contain expenditure, effectively pursued by a creeping and progressive reduction of services (that in Italy is mostly not even declared). This is a reduction that does not at all consist only in restricting services to the currently guaranteed basic level of care. This is implemented by effectively making the guaranteed services inaccessible, due to long waiting lists, and often through a unstated attempt to restrict these for those less able to demand them. This because they are deprived not only of the financial but also of the cultural

means needed to understand that they can demand these services, how to do so, as well as with what degree of individual freedom. This freedom is often legally guaranteed, but its putting into practice is often not recommended by those with far greater competence than the users, but who do not always share their interests and priorities.

Although with significant differences between the various regions (and obviously with exceptions resulting from the personal and unusual dedication of individuals capable of more demanding standards of professionalism, never totally absent even in circumstance of great degradation) almost everywhere the direct political management of the Italian Health System is basically now in the hands of the regional administrations and the managers of the Local Health Authorities (ASL). These have proved to be not at all or little intentioned or capable of confronting widespread electoral, patronising, territorial and vested interests pressure, in some extreme cases even strictly criminal or linked to local mafias, which have resulted in an inevitable and immeasurable waste of public money.

The frequent attempt to re-create artificially for the managers of the Local Health Authorities, or at times even for the general practitioners, mechanisms similar to that of profit in the private sector, guaranteeing them performance bonuses, based only on curbing expenditure, has provided a further incentive for a non-declared reduction in services, exclusively damaging citizens incapable of defending themselves.

In some regions, health costs have spiralled totally out of control, taking these regional administrations to

the brink of bankruptcy, at least until the arrival of inevitable rescue packages from the state that presumably once again will appear in election times, if opinion polls suggest a favourable electoral effect for the national majority coalitions. (And it will be interesting to see how these rescue packages, habitually also delivered to the advantage of friendly territorial administrations, will be justified in the near future by the supporters of "fiscal federalism" – the general public, however, not directly involved for vested interests reasons, will not even become aware of this, just as almost no one, for example, knows about repeated state lavish rescue packages for the city administration of Catania).

Keeping open irrationally small establishments, or those in irrecoverable conditions, patronising political recruitment, the creation of pointless hospital wards and management offices, the multiplication of bureaucracy, favouritism towards personal political clients and interference in the correct economic management of public health services – and even private ones operating within the national health service – are present almost everywhere, although at a very different level in the different geographical areas, and rather the rule than the exception.

Even if one wished to ignore cases involving real corruption, which have often made the health services a privileged channel for illegally financing the political class and political parties, this reality is mainly the inevitable consequence of the monopolistic party-political management of the health market, especially by an establishment, which, particularly in recent decades, has fallen below any possible Western public ethics stan-

dard.

In truth this has not caused too many jolts to public opinion which on the one hand is used to this situation, and on the other is stultified by popular media and TV: the latter largely serves the interests of politics and its masters, and also to a great extent connives with the political class with which it shares public ethical standards that for some time have no longer been Western standards.

In these conditions, the basic monopoly for buying health services guaranteed to citizens, currently the responsibility of representatives managed by the current party-political system in the regions and in Local Health Authorities, is a fundamental element in the web between politics and business, in that mingling of powers that, reducing its polyarchic characteristic, makes Italian society the less "open" in Western Europe. It is commonplace objecting to this on the basis of the mere principle, according to which health is a primary need, and this sector therefore needs rules capable of entirely removing it from the so-called "logic of profit." Food too is a primary need, but removing from the "logic of profit" the production and distribution of food, certainly did not lead to greater satisfaction of alimentary need where this was attempted.

On the other hand, the only model for privatising health care considered in the current rough public debate has been the one in use in the United States, and, not unreasonably, is considered a remedy worse than the problem by most Europeans, Italians included. Michael Moore's amusing film, "Sicko", which was released in 2006, may have been wrong in not even addressing the

problem of the costs of the European health services (and even taking seriously the presumed efficiency of the Cuban health service), portrayed well the failure of the American model, based on "free" individual bargaining between single customers and private insurance companies.

The American system is capable of ensuring America's success in achieving excellent result and an uncontested primacy in research. It does not however even address the objective of guaranteeing adequate health care to all the citizens of the most powerful nation on this planet.

In this sense, it is even less economically efficient than that of all countries in Western Europe in terms of the cost-benefit ratio, at least as far as the protection of its people's health is concerned (anyway, one cannot assess the efficiency of the American system in terms of results achieved in the real and current protection of the people's right to health care). Americans spend a great deal for health care in proportion to GDP, much more than Western Europeans. However, more than 40 million Americans have no health insurance and at best make do with what is provided by charitable organisations. It is also, and above all, for this reason that the average American's life expectancy is far lower than that of all Western Europeans.

Unacceptable from a European perspective, the reasons for this result are well-known. A system based on individual bargaining between individual citizens and private insurance companies is ruled by the mechanism of "adverse selection". The private insurance company is most of all interested in acquiring as clients precisely

those young and healthy individuals who are statistically less costly, but for this very reason also have less need than others of health insurance coverage. In the event of unexpected accidents, these insured parties will often be guaranteed the most excellent standard of care (as often also happens to foreigners who stipulate a temporary health insurance policy with travel agencies when they travel to the US). It is precisely those in greater need of health insurance – those suffering from chronic or recurrent illnesses or the elderly or those at risk – who are instead clients the private insurance companies wish to avoid.

Hence not only the refusal or the unsustainability of insurance costs for citizens belonging to these categories, but also the inevitability of real and proper reciprocal swindles. On the one hand the insurance companies entice people into signing standard form contracts filled with unconscionable clauses, often impossible to understand for those without expertise in this field and destined to leave the innocent clients with no coverage for many serious and even disabling illnesses. On the other hand, it is equally obvious that this sort of system also encourages those wishing to underwrite a policy to behave in an equally dishonest manner.

Generally speaking, clients tend to hide their conditions or lie about risk factors when signing the contract. Hence the need for a large number of preliminary medical tests before signing a contract, many often useless and possibly even potentially harmful to the would-be client's health, but necessary in the exclusive interest of the insurance companies. These tests are entirely paid for by the actual clients and that results in sky high over-

all costs for health care in the US.

To these additional costs to the system, useless for the protection of the health of individuals, one must add those of the immense cost of litigations due to the inclination of insurance companies, in the absence, or virtual absence, of effective public regulators, to pay for as few services as possible, at times also immobilising competition by cartel agreements that are obviously difficult to discover for both consumers and regulatory agencies, and this increases costs even more.

Even federal programmes providing health insurance for the elderly and the poorer (*Medicare* and *Medicaid*) and for war veterans, do not compensate for these disadvantages, nor do they spare the American health care system its enormous costs, which are much higher than European ones, or its profound social iniquity.

To present only one example, one should think of cases involving young children of disadvantaged families with no insurance, to which one cannot even apply the excuse, typical of excessive social Darwinism, according to which each person must always be considered responsible for their own destiny, regardless of the different opportunities they have been offered. And yet the immense economic and lobbying influence of insurance companies over American politics has so far even managed to prevent the extension of federal insurance to minors in disadvantaged conditions. Lastly, a recent attempt in this sense by Congress was vetoed by President Bush Jr.

Last but not least, the entire system based on individual negotiations between the insured party and private insurance companies is bound to become increasingly

unfair as a consequence of predictive medicine. If mapping the individual genome will in the future provide an increasingly precise identification of risks, it will be the very mutualistic character of the insurance principle that will disappear. Those at risk of developing expensive diseases, or maybe incurable ones, not only will be unable to obtain insurance for at least alleviating the consequences, but will also unnecessarily and inevitably be placed in the anxious condition of having to be informed about their unhappy destiny years or decades in advance, without being able to do anything at all to prevent those events.

It should be noted that also within European health systems, Italy included, the very fact that the public health service is obliged only to provide basic levels of care (hence not stating the aforementioned non-declared creeping cuts in services owed) – levels presumably destined, *rebus sic stantibus*, to suffer significant reductions in the future – will inevitably involve an increasing rise in the numbers of those resorting to integrating private insurance, restricted to all that is not guaranteed by the public service, but not for this reason less necessary for guaranteeing tolerable life conditions.

Consequently, the risk is to remain subject to the disadvantages presented by both systems. Hence patronage, waste, corruption, the cost of politics and bureaucracy will increasingly be added to those caused by the "adverse selection" mechanisms.

While all European countries have for years been attempting to preserve the system based on universal coverage by excogitating remedies that are mainly patches

destined in the long-term to be insufficient, the most intelligent and original reform experiment has come in our opinion from the 2006 Dutch reform.

The Dutch reform did not question the European social model, and universal health coverage, available and accessible to everyone, as one of its fundamental pillars. On the contrary, it created the premises for such coverage being guaranteed with greater security also in the future, abolishing at root-level all the costs of political intermediation in the direct management of health services, and yet promoting an almost total privatisation of the system, both for insurances and for services provided.

This however is organised with strict regulations that, far from compromising the correct functioning of market mechanisms, allow on the contrary its real existence in a sector where entrusting events to *laissez faire* policies, for the aforementioned reasons, prevents its functioning. In the Netherlands rules have been laid out for the development of real competition, for the best possible containment of costs and for investing with responsibility all those providing services.

The reform envisages a compulsory and universal insurance system for all residents in the Netherlands, and also the obligation to sign a contract respecting equal treatment and conditions from companies offering health insurance.

This excludes all pointless and damaging tests as well as the costs and iniquities that characterise adverse selection. The contents of basic care provided are defined by law. Fees comprise a fixed sum (sc. nominal part), which is the same for all those insured and paid directly

to the insurer, and a sum that is based on income and is redistributed by the state to the insurance companies to compensate for financial imbalances deriving from the obligation to enter a contract with anyone requesting it regardless of one's health conditions. Hence the mutualistic principle is safeguarded in the allocation of costs. Minors are exempt from paying insurance fees, as are those people with low incomes, in proportion to their financial means. Insurance companies cannot fix the nominal part of the fee at a cost superior or inferior to a modest percentage of that annually established by the state for basic care (1051 Euros for 2007). They can however compete freely in offering integrative insurance policies (which can include dental insurance, physiotherapy and visual aids also for adults, or alternative medicine and plastic surgery. These are cheap enough to be bought by over 90 % of the population). Insurance companies can choose the providers from which they buy the health services – and in this case, differently from political bodies, choices will be made exclusively on the basis of the quality-price ratio offered by those providing services. They may also, however, allow those insured to choose freely their medical doctors and hospitals (this is what has mainly happened so far). The insured can choose between various insurance products and have the right guaranteed by law to change insurance company every year at no additional cost. They also have the right to be compensated for care received abroad within the expense limits established for these same services in the Netherlands.

The first two years under this new Dutch system have proved right the promoters of this reform, which, in

spite of its profoundly innovative characteristics, has been appreciated from the very start by a large majority of the Dutch. In the future, of course, the effectiveness of monitoring competitiveness between insurance companies will play a very important role, as will the public control over the quality of the services provided, and the quality, availability and accessibility of information for the public.

For the moment, however, only a little more than 1 % of Dutch citizens have violated the obligation to buy insurance, which is punished with a fine amounting to 130 % of the cost of the basic insurance policy. Most of these people are part of the extreme fundamentalist Christian minority who believe that they should not receive treatment because diseases are God's will. The same percentage of citizens habitually refuses free and compulsory vaccinations.

The Dutch reform has for the moment proved that it is both possible to avoid waste and the risk of embezzlement and abuse that characterise party-political management of health services, along with the diseconomies and iniquities that characterise the total deregulation of the American health care system.

From our own point of view of liberals it also has the not unimportant merit of once again reminding us that the free market is not purely a synonym for *laissez faire*, and that *laissez faire* is no synonym for liberalism.

We are realistic enough not to be under any illusions. We know well that in Italy, before persuading politicians and vested interests pressure groups in abandoning ship, we would have to be on the brink of a final and ir-

reparable financial collapse of the entire system.

It is however the duty of small think tanks such as ours to put up for discussion, perhaps even a future debate, solutions that politicians – and above all politicians of the lowest level in Europe such as the Italians, led by demagogues and outlaws or inept followers basing their choices on opinion polls, rather than by responsible leaders and elites – do not have the strength or the will to address, until inescapably obliged by the coercive force of events: in this case, by the decreasing sustainability of the current health system's costs over time and the political impossibility to cut services below a certain level.

The Future of Health Care in the European Union:
Principles, Rights, Research and Prevention

Promotion of Knowledge Networks

Attilio Maseri*

Thank you very much for inviting me to this conference. I was rather worried because I was not sure how to contribute to this ambitious project, which involved providing strategies for changing our approach to caring for the sick. Then, while listening to the extremely interesting papers presented this morning, I realised that perhaps I can contribute in some way, attempting to draw on my wanderings and so many different experiences. From Padua I moved to Pisa, because in Padua I had studied medicine on books written by professors from Pisa and I wanted to work with them. From Pisa I moved to Columbia University in New York and then to John Hopkins. I then returned to Pisa, and while there I must have done something as I received an invitation from London when I was 42 years-old to hold the most prestigious cardiology chair in England. I spent twelve wonderful and very stimulating years there. Then I

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moved once again to work at the Gemelli for ten years and again to the San Raffaele where I spent seven years.

I had received a great deal from cardiology and felt obliged to give something back. I have seen a great deal in the course of my career. At times, when trying to decide what steps to take next, it is helpful to look back at history. If there are success stories there, why not try and repeat them? As mentioned earlier by Veronesi, one path to success has been research.

When I started to work in the research sector, our problem was to understand what problems led the patient to come to us. We had to understand what was wrong. Did patients come because they had chest pains? It was research that allowed the identification of the problems linked to the symptoms. Thanks to research, it has been possible to refine diagnostic techniques and start to treat these people. Now we are very good at identifying problems and correcting them. All this if one is in time, because when it is too late – as Veronesi mentioned early on the subject of cancer - for heart and cardiovascular problems one, can patch things up a little but one cannot do a great deal. If one is in time then something can be done.

What lessons are there to be learnt? It has been research that has allowed us to recognise problems and, having done so, research also allowed us to develop the increasingly reliable and precise diagnosis technologies. This has been possible because research identified what we needed to look for. This is of great importance.

One achieves the same level of success with an early diagnosis, which allows a problem to be effectively rectified. Success of course generates success. Having

achieved an objective stimulates more ambitious projects. What is the most ambitious project? As mentioned by Veronesi, the most ambitious project is predictive medicine.

Predictive medicine is a very wonderful thing. However, if one reflects seriously on this subject, one comes to the conclusion that, at least for the moment, it is a half-filled glass. Allow me to try and explain, because this may reveal the direction we should follow.

For example, we have identified risk factors, conditions that especially when added up significantly raise the possibilities that a person may have a problem. If we analyse these and observe them from a distance, we realise that most risk factors are the result of a person's maladjustment to the environment surrounding him.

Hypertension, a change in fat levels in the blood, diabetes, obesity, smoking and above all a lack of exercise, are all conditions associated to an increased risk of cardiovascular problems. But this happens above all when these risk factors are all present together, hence when there is an alteration of fat levels in the blood, as well as diabetes and obesity. Why is this? This derives from the fact that a person starts to smoke and continues to do so because they are out of tune with their environment. This problem is linked to maladjustment to their environment. People eat more because they are maladjusted. Men were created to work and hunt and matters were more balanced then. Now there is neither the time nor the wish to undertake such physical activity. As previously mentioned children are now overweight. Of course people say, in the United States. No, in Italy too they are

now starting to be overweight. Why? Because they sit in front of the TV or a computer, or even both. On TV all they see are snacks they cannot resist, and therefore instead of being part of sport activities they ask their mother for a snack. So as not to have to listen to their complaints the mother instantly gives them one.

So, we must address the problem of reducing risk factors.

When these risk factors become such they require treatment. If a person develops hypertension, become diabetic, in addition to already having very high cholesterol, they can go on a diet. At this point however it is hard to correct matters. Drugs will be needed. Medicines and drugs are a very large market for this industry. Predictive medicine, as discussed by Veronesi, works on a statistical basis. It is possible to identify a group of people who, if they smoke, have diabetes, hypertension and are overweight and over 50 years old, have a 30% chance of experiencing a cardiovascular event in the next five years.

And so one must work to reduce the risk factors.

Let us address for moment the meaning of these statistics. Thirty percent of those with these problems will experience an event over the next five years. There is, however, a problem. Seventy percent will not, and if one could identify this 70%, one could above all avoid them experiencing fear. Living in fear and worrying about an event is not at all pleasant. Furthermore, this would save a great deal of money. In this case, however, the market for that specific drug would instantly drop by 70%, a tragedy.

This is the problem. If one wants to implement prevention, one must first of all try and correct the lifestyles of our children. A strategic alliance is needed between the Health Ministry, the Ministry for Education, the Regions and local educational superintendents so that they may encourage a positive role model for children.

There is no point in telling a child "don't do this, don't do that". A joke I greatly enjoy about children goes as follows, "What do you want? Do you want to go to the soccer match? Do you want to go to the cinema? No, no – answers the child. What do you want? – asks the mother. I want to disobey." That is what children are like. There is no point telling them not to overeat or in advising them to do sport. It is far better to create positive role models.

I still remember the role models we were provided with during the Fifties. There was the man in the Camel cigarette advertisements. Smoking was seen as something of great importance and it is a legacy we still carry with us today. A role model created during the Fifties.

Envisaging prevention that starts in schools is a considerable commitment, as is inventing role models that will captivate children. It is a significant problem that someone must try and solve, inventing, for example, a cartoon providing an attractive lifestyle for children.

The other thing - as Veronesi said - is check-ups, early diagnosis, using these new technologies that slice up every centimetre and even every two or three millimetres. The problem? Let us remember what I said earlier. It has been research that has identified the problems. Then knowing what the problem to be identified was, it

became possible to establish the means one would use to identify it.

One could for example order a multi-slide CAT scan – from head to foot – but what would one be looking for'? One would look for what is known, not instead things that remain for the moment unknown and hence cannot be looked for.

There are therefore two problems:

First, for those who start to suspect something. It is necessary to educate people. Teach them what little red lights might appear on the dashboard. If they appear then a check-up is needed. Secondly, one must identify new red lights that are still not known so as to establish the need for other tests. This can take place because we have invented another marker, a high-risk indicator.

This is the problem with research, this is what we must invest in. But how? Let us now discuss biological research, genetic research and genomic research. But first of all, any kind of research addresses a problem. This might be a problem that was interesting 20 years ago. The biologist knows his target and what he continues to analyse in increasing detail. The problem is that in clinical application we must look to the patients, and also have a statistical approach. We identify the prevalent symptom and that is what we treat. That is what tells us what the prognosis is "on average," what risk there is "on average." If we prescribe medication we see that this medication is effective because it reduces the risk "on average."

The problem is that there are also 'outsiders'; those who react in total opposition to what one had expected.

Those who should be seriously ill and instead are fine, or those who we think would be fine and instead something happens to them. Why? A reason must be found. "Everything was perfect, there was nothing wrong with him. He had a heart attack when he was 40, but there was nothing wrong with him. Why? Did his wife smoke? Yes. Well then that is the reason."

Wanting to explain everything with what we already know means not stimulating the brain to question things. We must question things. This has already been emphasised by Professor Veronesi. Each case is different, or almost. It is clinical research that leads doctors to look for differences between one patient and another, to concentrate on these differences and try to understand what they mean.

An inquisitive mind leads to another aspect emphasised by Veronesi. There must be a relationship between patient and doctor. One cannot only use guidelines. Of course, using this method means processing many more patients more quickly. In reality however, this is a disservice to the sick, because the doctor-patient relationship becomes impersonal. The doctor is transformed into a surrogate chemist handing out prescriptions, rules dictated by guidelines. This cannot be the right way to work. One must try and stimulate the doctors' activities and try to understand what it is that makes one person or patient different to the other. Not all cases of course can be seen to with this approach. But at least the more extreme ones should be. Doctors should look for the more extreme cases. In the past clinicians isolated the "particular" patient; they observed the characteristics and the disease. They observed the patient clinically

and this was sufficient for discovering a disease. Today's diseases bear the names of clinicians who worked like that!

One must rediscover this way of working; have a clinical interest, be interested, and have the courage to do research. It is not enough to simply say "apply genomics." One must also know how to decide whom it should be applied to.

If I intend to study anaemia, I do not only observe those with a haemoglobin count of 5. Haematologists would ask me, "are you crazy? Look at the red blood cells." One must therefore isolate a homogenous group of patients, otherwise one will not find the common denominator in the absence of a group with a homogeneous phenotype.

To conclude, look at this photograph. An image is worth a thousand words.

This is the Island of Palmarola in the summer. I observe the photograph, I believe I see something here. There are two possible approaches. I can move increasingly closer to see what it is, or I can use binoculars and enlarge the image more and more to see what there is in that area.

But there is an alternative. The alternative I propose consists in reawakening and thinking that by observing the same things from different points of view means seeing them in a much easier and clearer manner. Instead of using increasingly powerful binoculars, one could do something different and change one's perspective. This (the photograph) is the same image seen from 90°.

This problem is this. I left the university, the San Raffaele, to work for this foundation with these hospital cardiologists, there are 6000 and have a network of 700 units linked on line. When working alone one might see one strange case every year. But when linked to a network of 700 units it is possible to observe about twenty, of one kind or another.

This means returning to clinical observation. Of course the instruments are no longer those of once upon a time, with notes on the patient's medical records. Today there are computerised medical records, and the patients are followed from the moment they enter the hospital until they leave. This way one could manage to understand where the differences lie.

It is innovation in cardiological research that needs something more, because with cancer one can take small pieces of tissue of the metastases and obtain information. For those of us who are cardiologists this is not possible and we have to make do with what we have. However, if we do not try we will never succeed.

If we try and we cross our fingers, we may succeed.

Thank you

Enhancement of Human Resources

Giovanni Gasbarrini*

An interesting subject often debated in Italy is that of the brain drain. I do not wish to be trivial. There are so many brilliant Italian brains abroad who are loved, sought after, paid and who want to return to Italy. Later I will name one.

It is obvious that when one is presented with the opportunity to allow a researcher like Attilio Maseri to return home, the answer is "yes", and one finds the money to do it. We are now debating the situation in Europe, but we must not lose sight of our own interests. For other member states the problem is less serious. Those who go abroad return home more easily, while when we wish to recall people we must be able to pay them more.

Today the conference is also devoted to improving health services and health care. International mobility of doctors and researchers can help in this. My university has a research programme and a funding initiative. At-

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tilio will say that "these funds are insufficient" – and we know that. There is also an international mobility programme. At the moment nine of my collaborators are abroad. I will introduce one of them to you, and in a sense I am desperate I cannot end my career by bringing them all back to Italy.

You know there is a controversy about 'easy' professorships, and for two reasons. For the useless and expensive professorships and those not assigned to important people. Let us analyse the figures for a university that works well compared to others. In addition to the figure on the number of beds, Catholic University, which I belong to has 68 first level professors, 220 second level professors, 480 researchers, contract researchers etc. Over the past ten years, Catholic University has achieved first and third place in Italy in many sectors, such as for gastroenterology, which I prefer, cardiology and others. In our institute there are 72 tenured professors, of which 8 are heads of hospital departments. There is a multidisciplinary department that includes oncology, and on this subject there are many questions I would like to ask Veronesi, and 72 post-graduates.

These 72 post-graduates provide scientific production that allows me, the person responsible for these papers, to achieve the impact factor I have. Most of the merit goes to them, to the candidates' for doctoral degrees, to those specialising.

Let us now address the issue of our "brains abroad," and their own personal experiences. These people come to me, or go to another professor in our University, after having waited one or two years before managing to enter

a University hospital. Then comes the six-year-long degree course and after that specialisation which lasts between two and four to five years depending on the subject. During these years one starts to observe them and think that 'this one is good' or 'not so good' and so on. Then what does one give them? One gives them a PhD, which lasts three years, and then they start to ask if they can go abroad.

Let us clarify further. Why do they go abroad? Why? And here there is a primary difference that those who are part of our environment are aware of. First of all it is far easier to go abroad for those who have money, or a father. There are dynasties that have formed for reasons that are also financial and not simple based on privilege. I have a son who has spent three years as the director of liver transplants in Pittsburgh, and now he has returned to Italy. I was able to send him to America.

Allow me a digression. Many newspapers have recently published reports about funds for EU researchers. Requests are presented in Italy, and our country presents the most, while Holland is in last place for numbers of requests presented. We are not good at exploiting them, but that is another problem. Secondly, the winners. Remember that Italians are among the winners, in second position after Great Britain. And what country is the one that attracts most in Europe? Leaving aside the United States, statistics show that it is without doubt Great Britain.

A few days ago, the President of the Republic said that we must promote "synergies between the private and the public sectors so as to incentivise research." In a university that is half private and half public this synergy

exists. But does the private sector, that complex of powerful private companies, communicate with the Ministry for Health and the Ministry for Universities? I fear not much. I know that research means freedom. But what kind of freedom? The first commitment should be to work on the basis of meritocracy. Sixty-three percent of Italians would prefer to be treated abroad. Excuse me, but do we want to bring in more patients from abroad? Are we capable of exploiting our capabilities? Allow me to provide one example of what we work on regenerative medicine, as an example of research at the service of practical medicine and care. Regenerative medicine, the field Professor Maseri works in and has cooperated with Antwerp for many years, has allowed the identification within our bodies and our organs of nuclei of cells that are the ancestors of cancer. This is real preventive medicine, not what we consider as such. Regards to colon cancer, do we undergo a colonoscopy every five years? No, that is not preventive medicine, it is early diagnosis. Preventive medicine would be the analysis and study of these cells and of how they regenerate. In our research we have used them for a case of fulminating hepatitis. They recreated a woman's liver with cells from an umbilical cord. The patient is now in good health. This is just one case, but it shows to what extent research is needed as the basis for care! This is why my proposal states that if we want to bring our best minds back from foreign countries, we must first of all search for new ways of doing this.

So let us return to the problem of having our researchers return to Italy. Let us take, for example, cooperation with industry. Our young men who go to the

United States come home filled with enthusiasm, but many of them are placed, as in a puzzle, within one of the university's great projects. One cannot allow these young people to think they are geniuses just because they work abroad. Furthermore, I am in favour of direct recruitment, but not without verifying how a person can be fitted into a project, and this is lacking in Italy. You go abroad, and you learn. Many return to Italy and do not apply what they have learned. One must make sure that these "brains" are capable of and able to apply what they have learned.

It is the case of my very young friend Doctor Cremonini, who graduated at Catholic University Hospital and then went to America, where is now Professor of gastroenterology at Harvard University. I believe that the most noticeable difference with the United States is organizing capability. In Italy funds are lacking, but for our researchers there is always the joy of being able to return home. That is why institutions must instead show rigour and openness in providing every opportunity there is abroad, allowing our researchers to work as clinicians, and be able to do research without having to lose themselves amidst paperwork, tasks and situations that have nothing at all to do with research.

Thank you.

A Project for Clinical Research

Claudio Rugarli*

I will discuss the relationships between research and clinical medicine, obviously from a European point of view. Research is per se international and thus moves beyond European borders. Researchers exchange the results of their research all over the world and this happens very quickly and in a widespread manner. However, the fact that research takes place in a given location, in particular research on certain subjects, does not only depend on the free ideas of researchers, but also on funding. These are no longer the times of Koch, who, after being given a microscope by his wife, discovered the tuberculosis bacillus in his kitchen. Nowadays things are far more complicated and a great deal of money is necessary for research. Hence, funding influences research. As I will mention a little later on, the European Union is active in this sphere.

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One interesting point is that Europe is also a cultural aggregation as far as research in general is concerned, and especially biomedical research. I researched the list of online magazines for our university, just to see how many had a title including the word European. Well, there were 168 magazines with the adjective European preceding other specifications. Of these 168, some were not biomedical, but most were and there were over 100. I also looked at the indexes of some of these magazines and noticed that they had authors from every country in Europe with an authentic scientific community and brotherhood.

The most important point concerning Europe is funding provided by the framework programmes published every few years. We are now at the seventh framework programme. These are research programmes that do not only address biomedical research, but more broadly also medical subjects. The really interesting point is that the seventh framework programme, which is the last one, has created a particular programme called IDEAS, mentioned also by Professor Gasbarrini and that I would like to discuss, since it seems to be an extremely important subject.

IDEAS consists of funding provided by the European Research Council, making available to research groups 7.5 billion Euros, a significant amount of money. Allow me to read to you some of the data in the announcement for this very innovative programme. "The objective of the specific programme 'Ideas' is to reinforce excellence, dynamism and creativity in European research

and improve the attractiveness of Europe for the best researchers from both European and third countries, as well as for industrial research investment, by providing a Europe-wide competitive funding structure, in addition to and not replacing national funding, for 'frontier research' executed by individual teams.". This is an absolute novelty, because funding is usually approved for research on a predetermined subject. The area of research is usually specified, while here instead what counts are innovative ideas and all that matters to gain support and funding, is they really be innovative. "And therefore – the announcement states - The IDEAS programme proposes a trans-European mechanism to support creative scientific research. This 'frontier research', which will be at the heart of the Ideas programme, is a new approach to basic research that is, by virtue of its nature, risky and cuts across established disciplinary boundaries and national borders. [risk means that a proposal is very innovative, hence there is the risk that it may later be disproved. However, innovative ideas would never be verified if one did not run such a risk and therefore research carried out in the absence of risk is worth little.]"

As mentioned by Professor Gasbarrini, with 19.2% of all requests, Italians lead the classification for the number of requests for this programme. Why is this? One could imagine that it depends on the fact that perhaps Italians are particularly creative, or perhaps they cannot obtain adequate funding in their own country. Perhaps both these elements come into play.

However, these requests, as also mentioned by Professor Gasbarrini, were certainly seriously interesting, since 58 Italian projects have been funded, in second

position behind English projects. Hence Italian science is capable of formulating brilliant ideas.

Another important aspect of this funding is that it can be used by researchers wherever they wish and not necessarily where they usually work . I am sorry to say that a number of Italian researchers who received funding have decided to develop their projects abroad. Among the researchers who received funds, there is also a young woman who works with me, Patrizia Rovere, and she had decided to stay in Italy.

I mentioned this programme to emphasise the importance of European institutions as far as research is concerned in all European countries and also in Italy. I would now like to address a more specific subject, that of the links that exist between research and clinical medicine, a problem I am particularly interested in since I am a professor of clinical medicine.

You will have recently read in the papers that in the thoracic surgery department at Barcelona University, an Italian surgeon performed an operation involving a trachea transplant. Leaving aside the technical difficulties in transplanting a trachea, the technique used was very innovative. In fact, the trachea was taken from a donor – hence from a cadaver – then the donor's cells were completely removed, leaving only the support structure, the connective tissue and the cartilages, and recreating a layer of cells on this. These cells had been obtained from the receiver's stem cells so as to avoid compatibility problems. This alone was a significant result, but the important point is that it was obtained thanks to cooperation between the surgery department in Barcelona,

the Milan polytechnic (with bio-engineers capable of handling these tissues to then cover then with stem cells), Bristol University and Padua University.

Therefore trans-European cooperation led to a great clinical result, but this was certainly preceded by an important scientific result through research on stem cells. I therefore consider this as a model; an example of how basic research can influence clinical medicine. In this case in a therapeutic manner, but clinical medicine is, of course, also influenced in other ways. Professor Veronesi spoke of the distinction between diagnostic procedures and therapeutic ones. It is worth bearing in mind that as far as diagnosis is concerned , which also derives from an understanding of what illnesses are, basic sciences have provided fundamental contributions, and these have come above all from genetics and molecular biology.

One normally thinks of genetics as the study of the transmission mechanism of hereditary characteristics. This is classical genetics, but the important point is that now that there is adequate knowledge of molecular biology and how genes work, which molecular structures it codifies, it is now possible to recognise the proteins codified by a gene.

This leads to an understanding of the pathological mechanisms deriving from genetic diseases and this is of fundamental importance. I could provide many examples, but will use only one so as not to take up too much of the time available. There is a disease that consists of metabolic anomalies, resulting in problems of the metabolism, hence in the chemical transformation of an amino acid called methionine found in all the proteins

we eat. The body then changes methionine into another amino acid called cysteine with extremely important functions. In the absence of certain enzymatic actions [enzymes are organic catalysts that encourage certain reactions] the methionine only develops to an intermediate stage called homocysteine. Well, homocysteine is damaging and therefore, if it accumulates within the body because of a genetic defect in the functioning of a number of enzymes important in this process, the result is a disease.

In the so-called homozygote form, inherited from both parents, this causes a serious disease that appears during childhood and affects development, growth and causes a series of corporeal anomalies, among them, to mention only one, ectopia lentis, the crystalline lens is not in its normal position.

Until recently it was thought to be a recessive hereditary disease and that therefore if inherited from only one parent everything would be fine. It is now clear that even if inherited from only one parent there are a few small anomalies. The increased presence in the blood of homocysteine is marginal and even modest in these cases, and yet this favours thrombosis. Hence, people with this anomaly are more likely to suffer from coronary thrombosis, cerebral thrombosis and so on.

It is important that this problem be acknowledged since it can easily be cured by administering vitamins such as folic acid, vitamins B12 and B6. This disease is therefore very easy to cure, but it must be diagnosed so as to implement the prevention discussed this morning. This is an example in which laboratory results were applied to clinical medicine. In fact, it was laboratory work

that made known a clinical condition that totally escaped superficial observation.

Things are certainly simpler when dealing with monogenic disease, one deriving from a single gene. At times, however, diseases are the result of a combination of genes that can be inherited in various assortments and in different ways; hence, the transmission of the disease cannot be traced following specific rules, known as Mendel's Laws. In these cases it is more difficult to trace the causes of diseases. One sees, however, that in certain families there is a recurrence of certain pathological forms, more than in the general population. These are usually polygenic diseases and this is a field in which a great deal of work needs to be done. Research also sponsored at a European level is therefore necessary.

Allow me to present examples in the sector of diseases I have most worked on. In his introduction, the moderator for this session mentioned scientific organisations I belong to; and for example the Society of Internal Medicine, which I care greatly about because I am proud of being a specialist in internal diseases. The moderator however also mentioned organisations that deal with immunology. In fact, although I am specialised in internal medicine, I cannot avoid also being specialised in a specific sector of Internal Medicine.

In fact, I mainly work in the sector of clinical immunology, also a very vast sector within which I have carried out research in a number of specific areas. From a clinical point of view, the diseases I have been most interested in are mainly linked to mechanisms involving polygenic transmission, such as, for example, the case of

systemic lupus erythematosus or certain kinds of endocrine diseases that depend on auto-immunity mechanisms. Among these diseases I would place those of the thyroid in first position since it can be influenced in various ways by autoimmune processes. Immunity is needed to protect us from external aggressions by microbes, but within an imperfect system it can make mistakes and these same reactions can be directed against "constituents of itself", hence also against the thyroid.

There are antibodies that stimulate it and this is the origin of what is known as Basedow's Disease - which the Anglo-Saxons call Graves Disease - or there can also be cells called lymphocytes, that destroy it – this is also at the origin of a disease known as Hashimoto's Thyroiditis, one of the most common causes of hypothyroidism. In this case there is a very close family link, although hereditariness is not seen using Mendel's Laws.

Family links are also present in other endocrine diseases, such as, for example, diabetes in the young which is also an autoimmune disease, in which cells in the pancreas known as Langerhans cells and are those that produce insulin. In the form experienced in maturity this depends even more closely on hereditary mechanisms. Here too there is a degree of familial links less close than for the thyroid. These are mysteries that must be clarified at a genetic and molecular level.

Furthermore, predisposition to disease must also be researched. This is what is meant when preventive medicine is referred to. On this subject too there is data already acquired that must be better clarified. For example, everyone knows that to transplant of organs or tissues there have to be compatibilities between donor

and receiver that are analogous, although with greater complications, to those that are necessary for blood transfusions necessitating blood group compatibility. As far as transplants are concerned, compatibility is needed for substances placed on the surface of cells; these are called histocompatibility antigens and they are hereditary. Some of these are linked to a predisposition to certain diseases, for example, those with the HLA-B27 histocompatibility antigen are 300 times more likely than those without it to fall ill with a disease called ankylosing spondylitis. It is not written in their destiny that these people will fall ill, but they have a strong predisposition for developing this disease. The same applies to other diseases, but it would be a little too complicated to discuss them at length on this occasion.

For the moment I have discussed the path from the laboratory to clinical medicine, from the laboratory bench to the sickbed. However, I believe, and this opinion is shared by many clinicians, that there is also a path moving in the opposite direction, from the sickbed to the laboratory. Clinical medicine in the past was founded exclusively on observation of the sick, on what appeared from a phenomenological point of view, and this was how a diagnosis was made and how diseases were classified, without understanding what was going on inside the organism. Progress made by modern medicine has instead allowed us to understand many things, but not everything. There are still diseases for which clinical diagnoses are made just as they were in the past, without understanding the mechanisms. Therefore, es-

pecially for these diseases, we have a significant need to understand what is happening.

Before pausing to reflect on this subject, I wish to first reflect with you on the meaning of the word disease. We all know what the word means but in fact the concept is a little ambiguous. It can have two meanings at least. For the person who is ill, at an individual level, it has an existential meaning, it is a personal experience. From a doctor's point of view, however, there is a need for objectification; there is a need for nosological classifications.

Nosology is the classification of diseases. If one takes a textbook and looks at the index one will see a list of diseases corresponding to current nosology. These classifications are made indicating classes of groups of sick people who share certain criteria, that can be the cause or the mechanism of the disease, or how organs work in the presence of this disease. Hence these are generally criteria that vary over time. When I was a student I studied diseases that have now been deleted from textbooks, not because they have vanished – smallpox for example has vanished but is still studied – but because they are now classified in a different manner. In the past at times an illness was diagnosed as just one disease, while nowadays instead ,it is known that this can be divided into three or four nosological categories, which may have ended up in other sectors.

Before the discovery of certain enzymes in the blood called transaminases or aminotransferases, and before liver biopsies were performed, chronic hepatitis was practically unheard of. There were people who were

living happy lives believing they were healthy while instead they were suffering from chronic hepatitis; this disease is now acknowledged and provided significant impulse for the discovery of hepatic viruses and the immunological mechanisms of chronic hepatitis.

This is a sector of medicine that has made great progress and shows clearly how nosology changes over time and can change a great deal with help from laboratory work. Instead of thinking that discoveries made in laboratories are those that provide us with new ideas about the diseases we observe in those who are ill, it is also necessary to believe the opposite. We observe clinical cases that are strange and this can provide ideas for research projects.

So medicine in the future will be profoundly different from current medicine. When we make a diagnosis we intend the sick person for whom the diagnosis is made to be included in the group classified with a given name, according to currently accepted nosological classification. However, we all know that sick people differ one from the other, and in the future they will seem increasingly different because we will achieve the ideal discussed this morning. In practice for each sick person there will be a molecular genetic profile defining his/her personal predispositions. So the doctor of the future will need far greater knowledge of the basic sciences, and will have to analyse in greater depth data for clinical diagnosis, also bearing in mind a number of particular aspects with which diseases manifest themselves. For example, in the presence of an inflammation there

are two laboratory indicators that increase, you will certainly have heard of them, the sedimentation rate, hence the speed at which red blood cells sediment in anticoagulated blood - erythrocyte sedimentation rate in English - and levels of protein C reactive in the blood. One observation that remains an empiric one is that if the disease is infectious these two indicators increase in parallel, while if the disease is immunological the sedimentation rate increases in proportion far more than the reactive protein. Why? Nobody knows.

There is one disease among those I work on called Horton's Disease, giant-cell arteritis, which is an inflammation of medium-sized arteries localised mainly in the cephalic area. This disease only appears after the age of 50 and not before. Why? This is another answer we do not yet have.

So clinical medicine is really full of question marks, of questions in need of answers. So what is the problem? The problem is that a clinician has neither the equipment, the funding, the laboratories, the cooperation nor the possibility to study the problem his attention is drawn to in the same location in which he observed it. However, someone out there in the immense world may be interested in these clinical problems. Hence information, even concerning individual sick people but with singular characteristics, should be made as widely available as possible. If there were a network gathering all this information, it would reach a centre where a researcher might find the idea interesting and try to study it in depth.

This is what is lacking, and so nowadays there is a large amount of clinical information that is literally thrown away and this really is a waste. Of course, nowadays the creation of such a network would not be all that complicated thanks to IT means, although there would be serious organisational problems. I put forward the idea for organising something along these lines in the Lombardy region, but not enough people listened. On the other hand perhaps Lombardy is too small an area for a project of this kind.

One can only hope that in the future, somewhere, a few new ideas linking clinical medicine with research will be cultivated, and hence, in this sense, I believe that Europe has the cultural backdrop and the organisational structure to provide support in the future for new research ideas suggested by clinical medicine, and this is what we hope.

Perspectives for a European Pharmaceuthical Market

Silvia Bruzzi*

The socio-economic systems in post-war industrialised countries are characterised by a different application in the relationship between health and the pharmaceutical sector. It can be shown, in fact, how faced with common motivating principles, the health of citizens, the improvement of the living conditions of the population, particular decisions have been made to influence the ability of the two sectors to pursue their fundamental aim.

The path followed in health and the pharmaceutical sector in some cases diverged. The European experience, in particular, shows how, in some systems, health policy has shown itself, above all, attentive to the containment of expenses, aiming to reduce costs for provision of services. There has been less concern in understanding how the evolution of the social and demo-

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graphic context, techniques and research could change the needs and procedures of providing health services. That has seemed more and more obvious, thanks to the opportunity of implementing innovations to diagnosis, prevention and the possibility of developing less invasive and more effective treatments.

As a consequence, in these systems, a strong attention has been paid to consumptions, which became the core of the public institutions' intervention, aiming at a short-term equilibrium between the needs of the population and the containment of costs, while there has been less concern in emphasizing the role of scientific research, so generating a breakdown in demand/supply relation.

The same was, mutatis mutandis, for the pharmaceutical sector, where the absence of institutions capable of guiding the processes at a global level, together with the reduction of available resources for the State budgets, has led to both a delegation of the definition of research guidelines to large industry groups, as well as closing the national systems in a protectionist sense, in order to control costs and favour the most reduced groups. That has led to the creation of a dual system, hastening the crisis. Symbolic at this regard that the European Commission's initiative in favour of constituting a Single Market in pharmaceuticals found an obstacle in the national price control policies, aimed at controlling the health expenditure.

The crisis of the two sectors offers today the opportunity to redirect the respective strategic decisions according to a long-term vision, appreciating the points of intersection between the two experiences; the objective

is to kick start synergies, which are capable of relaunching both sectors. Innovation and research and in particular the relationship between pure and applied research represent the main point where provision of health services and pharmaceutics meet: the demonstration of this is given by the fact that in the most advanced systems, this relationship has become ever more critical for health in the future (it is enough to think of the field of biotechnology and experimental treatments).

In this context, a reflection on the relationship that is wanted in Europe between various bodies, public and private, of health and pharmaceuticals, research and treatment, prevention and information, need to be developed, asking at the same time what role the public and private institutions can place, not only for funding, but above all to guide the emergence of a new system.

Delay must be avoided. If, indeed, in the area of treatment, public involvement in the regulation of direct performance of services has always been present in political and scientific debate, it has not the same for the pharmaceutical sector.

Today, we are talking about understanding if and in what way a renewed European policy can redesign a virtuous model in which public and private research centres, universities, associations and public and private institutions can develop in a complementary way, supporting and feeding each other.

The crisis which all countries are today living through has led to a discussion of the role and funding of research institutions (particularly public bodies and institutions); likewise, equal pressures are affecting businesses and private groups, who are today experiencing

the effects of a general and widespread economic crisis on a global level, which puts competitiveness in the market into discussion.

This is not simply about finding the resources to restart the system: it is, now more than ever, defining a strategy and creating the institutions that are capable of governing such processes. In this perspective, the current historical phase, where the crisis of health and the pharmaceutical sector coincides with the relaunching of a new European integration phase, offers important opportunities.

The US experience. In the case of the US experience, a government at the federal level with powers relating to research and industrial policy has realised how to sustain the innovative capacity of an entrepreneurial fabric of continental dimensions. The federal US government has assumed a fundamental role in driving forward economic development, mainly through an industrial policy supporting research and development activity, which makes use of two main tools: research funding and patent policy. Through research funding, the federal US government has provided enormous support since the end of the Second World War for research and the commitment of the pharmaceutical industry in research. The federal government has in fact opened a virtuous circle through the funding. That appears obvious considering the evolution of the federal funding throughout time: if, after the Second World War, the federal government made up the main funder of research, today the federal government would fund basic research almost exclusively, leaving to the industry applied research and development. Through the patent policy, strengthened

in the second half of the 1980s, the federal government instead encouraged the commitment of all players involved in R&D (universities, research centres, public agencies, industry) according to a systemic logic consistent with the enormous commitment of resources.

The European Experience. The process of European unification provides an answer to the delay of the European economic system and the limit that the national policy dimension has shown regarding an issue of global dimensions. The pharmaceutical sector may represent a laboratory of primary interest in the definition of a broader industry policy of a continental scale, capable of sustaining the European economic system, through the appreciation of research. The path in this direction seems to have been undertaken; some steps have already been taken: a) at the European level, it is worth observing how research in health has already been given, in the past, a primary role in the Framework Programs; today the Seventh Framework Program and the very recent establishment of the joint undertaking for funding of biopharmaceutical research (IMI) seem to be acting in the direction of strengthening an approach in favour of a European industry policy supporting research in this sector; IMI could assume an important guiding function of the European research activity, assisting development of public-private and research-industry partnerships; b) the recent Commission's Communication on rare diseases shows the engagement of the European institutions in favour of defining a global Community strategy in a specific segment of the pharmaceutical sector; c) the text of the proposal of the European Directive on cross-border healthcare with respect to pharmaceuti-

cals goes in the direction of the creation of a Continental market for consumers of pharmaceuticals which, if realised, could strengthen the prospect of European action; d) the European Medicines Agency (EMEA) shows in itself that a European market for pharmaceuticals already exists and requires a unified regulation for the security of European citizens; e) at the national level, the presence of countries such as France and Germany, where strong public policies sustaining research and development match with expansion strategies developed by the big national champions, offers important opportunities for Europe. The commitment of these two countries suggests that the Franco-German axis can, as in the past, assume a strategic function as an engine of European initiatives which allow the pharmaceutical industry to assume an effectively continental dimension.

The areas to test the definition of a true European industry policy in the pharmaceutical sector appear to be obvious; the obstacles to be overcome are still very important: a) the funding commitment set aside for the IMI seems to be insufficient in making up the difference with respect to the US experience; as a consequence, coordination with other funding measures will be necessary; b) the IMI's experience will show if the great European pharmaceutical industry and other players in the system of European research are able to move in a coordinated way, thereby starting the necessary process of cultural renewal aimed by IMI; c) the legal reference point of pharmaceutical businesses remains the national level; the regulation for patent protection, which is shown as being a decisive incentive for innovation in the pharmaceutical sector, retains in fact a national dimen-

sion, in spite of the Commission's proposal aiming at instituting a Community patent, confirming the traditional fragmented legal reference point, which is therefore not very attractive for businesses that want to invest. Tax policies, used as an indirect funding tool for research, remains within the national sphere and therefore confirms fragmentation within Europe; d) still, the make up of a European market for the consumption of pharmaceuticals is expected to continue to find an obstacle in the welfare policies of individual Nation States, which remain anchored to a short-term protectionist logic.

The development of a new, unitary political vision, which recognises the tight link between health policy (protecting the demand) and industry policy (supporting and directing the supply system) would contribute to increasing the effectiveness of Community initiatives, placing the pharmaceutical sector at the starting point of a new European model of socio-economic growth.

Issues and Proposals

On the Modernisation of National Systems on the Eve of the European Health Care Single Market

Fondazione Critica Liberale

In the next few years, national health care systems will have to face the challenge posed by the birth of a single European market for health care.

In recent decades, health care policies have provided fertile ground for comparison. But too often these topics, which are extremely complex and difficult to translate into terms easily comprehensible by public opinion and by voters, are portrayed, especially in Italy, in simplified propagandistic models, through which each pressure group vitally interested in the defence of its own role and its own interests is able to present that role and those vested interests as perfectly coinciding with the public interest: political class, spoil system appointed civil servants, bureaucracies, unions, professional groups and subgroups, entrepreneurs' organisations, real and fake non-profit organisations, religious organisations or religious businesses. Public opinion is, for the most part, unaware of what is at stake in research and international competition; and it is likewise unaware of the effective cost of health care (citizens are generally not even aware of the effective costs borne by health care systems for the services performed in their

own individual interest). Thus public opinion has, in recent years, been caught between two alternatives, often portrayed as the only available options: on the one hand privatisation, identified with the worst aspects of the American system that are furthest away from the European social tradition, and, on the other hand, the defence to the death of existing systems, with their increasingly unfulfilled promises of effective and timely universal cover: between the reality of a system in which privatisation proceeds only as a consequence of the inability of public services to satisfy such promises and the warning that the increase in costs cannot but bring growing recourse to individual insurance covers, albeit limited to the integration of the basic services assured by the public system (with growing regional and national differences), on the basis of individual agreements between citizens and private insurance companies: with all the added costs, widespread injustice and other typical risks of exclusion inherent to such model. Many problems still need to be faced today: in the first place, scientific, demographic and institutional evolution imposes an endless reassessment of the arrangements that have allowed health care systems to evolve to their present state. Some problems can best be jointly resolved at the European level, others at a national level, even in different ways, as long as consistent results are achieved.

The protection of the citizens' right to health must be regarded as a founding element of democracy, of justice, and of the liberty of European citizens.

1. Promoting Public Interest

In all European countries political choices in health care issues are aimed at protecting the achievements made in the course of the preceding decades.

"Good politics" in health care coincides with the protection of citizens' health, with the goal of guaranteeing the characters of fairness and universality typical of the European model.

A series of barriers have so far protected the health care sector at regional and national level, limiting the competition that, in different forms, has affected other economic sectors that first had to face the competition brought by the growing openness of markets.

One first step towards the modernisation of the systems coincided with their growing subsidiary transformation, reinforcing the role of local institutions, and with a progressive admission of private profit and non-profit operators in the number of health service providers. At the same time, central institutions have increasingly taken on the task of general regulators of national systems.

Such trends paradoxically had a greater impact on the organisation of the systems than on the individual elements that make them up. Today politics should pursue such changes also at the peripheral level in the best public interest.

Today the preservation and enhancement of the principles of justice and universality require new arrangements, so that the constitutional right to health can be protected in the new ways made necessary by a continuously evolving situation.

Such demands can be satisfied through a better control and management of resources, stricter responsibility of administrators and service providers, proper investment choices, a new role for the public and private sectors: the challenge is effectively enforcing the citizens' right to health.

In some countries, beginning with Italy, alongside obstacles relating to the organisation and financing of the health care system, others concerns are growing, especially in recent years, of a purely ideological and religious nature. In Italy in particular, the abandonment by the large majority of the political class of the idea that there is no equal social dignity of citizens without the most rigorous respect for religious neutrality on the part of public institutions, is creating obstacles of all kinds, legal and factual (at times even resulting in discrimination on the basis of different regional policies), to those medical practices, or even to health information campaigns, which are for various reasons opposed by the Catholic hierarchy (sexual education in schools, availability of condoms, contraception and especially emergency contraception, prevention of STDs, abortion, prenatal diagnoses, IVF, legal recognition and respect of living will, euthanasia, self-determination of individuals in ethically controversial matters). No less serious are the capriciously placed obstacles preventing scientific research and, therefore, the international competitiveness of the country, especially in the area of embryonic stem cells, aimed at satisfying the interests of Catholic religious pressure groups, to whose service a large part of the political class is bound.

2. Protection of the Right to Information

Enhancing and defending the right to information is essential in order to give effectiveness and provide efficiency to the participation of the entire civil society in the determination of decisions in health care issues.

It is essential to make the process transparent over a long period, to allow the decision on the various possible choices and to govern the process of their undertaking. That will be much more important from now on, as citizens in need of care can move throughout the European territory, in search of centres of excellence where a solution to their need for care can be found.

Only knowledge can guarantee an informed interaction between politics and science, between economics and society.

With regard to patients, protection of the right to information represents the constitutional guarantee of citizens, and a fundamental requirement for making the right to choose effective.

For the system of health providers, this represents an instrument by which they can adjust the defence of their professional exigencies to the protection of public interest. Respect for such a principle can strengthen prevention and care, as well as provide guidance on the direction and promotion of research.

3. Modernising Health Care Systems

Problems arising from the need for the coordination or the creation of a European system cannot but provide another incentive towards an ever more urgent reflection

on the competitiveness and the sustainability of the models that currently govern individual national health systems. However, monitoring health care costs represents only one of the essential aspects which can be recalled. The fundamental problem is even wider and concerns what kind of goals European states want to pursue in the overall use of the resources at their disposal, balancing internal, national and European issues. The fundamental decision concerns what resources to allocate to research and long term investment, and what to the current functioning and to correcting the flaws in the system, thus putting off the transition towards an efficient and balanced system.

Recent experience has shown that, in the absence of a clear regulatory role for institutions, the market is not capable of autonomously guaranteeing the secure development of the system. In order for a modern health market to be set up, it is necessary to reassess funding, management, performance and control, and to establish a clear assignation of responsibilities and tasks. Various solutions are viable: but political intermediation in health care policy should find its most essential role in defining the rules capable of sustaining the health model we want to develop for the future. A priority, especially critical in the Italian case, is to stop politicians and political parties from further continuing to carry out a role of direct management, which is today mainly parasitical, and frequently even illegal.

The aim should be to avoid the spreading of inequality and injustice, which would inevitably weigh on weaker individuals and, at the same time, put at risk the survival of the system as a whole. The principle of fairness typical

of the European model can and must be reinvigorated, by reassessing a great deal of the established arrangements, in search of a new deal capable of guaranteeing that the protection of fundamental rights regarding the health of Europeans be more sustainable in the long term.

The Dutch experience, in particular, makes an important contribution to the debate, above all in the light of some recent choices which in our opinion were instrumental in safeguarding, even more than in the past, the principles that are widely recognised as foundations of the European social model, such as universal access, fairness in the partition of costs and orientation towards quality. The Netherlands have encouraged the formation of a system in which health providers and insurance companies are granted greater freedom and responsibility, favouring in this way a greater awareness in the use of resources, in the control of costs and about the impact that such decisions have on care and insurance mechanisms. Such principles, which inform the entire national health system, have found further application in the Healthcare Insurance Act, passed in 2006.

The Dutch case is an important example of how differently European values can be implemented at the national level. Still, defending autonomy without creating internal imbalances, and within the broadest system in which the nation is inserted, appears problematic. Such difficulties are obvious in the very words of the Dutch Government, where it claims for the individual responsibility of national governments in order to organise, protect access to health care services of excellence and guarantee the financial sustainability of the system. Such questions should, however, in our opinion, find a satis-

factory institutional solution only at a higher, European, level.

Countries small in size often appear reluctant to consider the solutions successfully experimented by them as interesting models also for other countries that face the same problems. Perhaps for this reason too, the Dutch reform has not yet been the object of the due discussion it deserves in our opinion. The Dutch reform has redesigned the regulatory role of public institutions, in such a way as to exclude political meddling in choices where politics has no competence (choices which have extremely serious economic and managerial consequences in some countries, beginning with Italy): introducing a mandatory individual insurance (with no possibility for insurance companies to refuse contracting), which is private but strictly regulated and based upon the principle of mutuality on a national basis, assisted by adequate guarantee funds, which could avoid the negative consequences - inequality, injustice, incomplete universal cover, exponential increase of overall costs - typical of a laissez faire system, strictly regulating agreements between individuals and insurance companies, and thus integrating the welfare principle of the European model with the need for economic viability which can only be provided by effective competition: a competition that must be well regulated, well supervised by effective mechanisms of governance of the market ensuring the safeguard of citizens' rights and the fulfilment of universal cover, equity and effectiveness that are typical of the European social model, while relieving all political or corporate burden affecting the system.

Although aware of how difficult it is even to propose the discussion of a reform that challenges most of the vested interests of so many political and economic stakeholders currently involved in the management of health services, we hold that the inevitable increase in foreseeable costs in the near future, which is also a consequence of objective factors, such as the progressive increase in life expectancy and technological advance, and the need to find resources capable of sustaining research and development, will force our countries increasingly to take a clear position on what kind of health policy they want to implement at the national and supranational level.

Giuseppe Maria Cassano*

This initiative can be seen as one of the tunnels in the Alps regions that allow us to glimpse Europe.

This is even more important for us Italians, when we consider the backlog and delays that, in every field, characterise our nation.

For Italy, modernity and innovation are more often been the effect of the European example, or a consenquence of the obligations imposed by our participation in the European integration process.

Looking at indicators that describe the efficiency of the various European health systems, shown during the conference, ald particularly looking at the ratio between provided benefits and costs, we discover that Italy is unexpectedly placed in a not bad position.

We have to keep in mind that these are average figures: if we compare Italian regions, we find out that while in some regions of Italy we face more than acceptable standards, other regions (like Sicily, Calabria, Puglia, Campania, and maybe others) are characterized by levels worthy of the most backward and corrupt countries of the Third World.

This happens, incidentally, in those areas of the country in which is more extensive and penetrating the stifling interference of local politics in managing the health system.

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* President of Alleanza Lib-Lab

This should make us reflect on the Italian situation, in terms of non-inevitability of inefficiency and mismanagement and in terms of the positive effects of applying the ever-expanding concept of modern federalism, subsidiarity and responsibility. But if autonomy means the further reduction of real time control, the result could be disastrous from the point of view of citizens / users as well as from the institutional point of view.

I see the health care system of entire regions into the hands of colluding interests of bad business and bad administrators. I live in a region, Sicily, where public Health Care is the largest business. The intertwining of private providers and local politics are the focus not declared, but no less real, of the debate and of the political balance: the control of locals social and health authorities (ASSL), the contracts between them and the clinics, laboratories and private diagnostic centres are the crib that nourishes a political class greedy for money and power. Their mixed interests, legal and illegal, develop in general connivance: to pretend not to see and not know is the main task of those politicians who instead see and know very well, and consume their clashes in this environment.

Looking at the "the Italian case", we can see that the ability of the State to address, control and guide is no longer in the three areas where inefficiencies bring irreversible consequences, since remedies are always late and ineffective.

These three areas are: justice, education and, specifically, health. The consequences for the citizen who suffers the effects of these inefficiencies, regardless of the degree of gravity, are still and always severe.

We must seek then for effective remedies. If we open any newspaper, not a day passes without a few episodes of robbery, inefficiency, neglect, injured rights, often with tragic outcomes.

The battle for Health is not just a matter of efficient spending taxpayers' money, but first and foremost it is a battle for justice, equity and rights.

One of the battles on which a liberal movement should feel involved.

Giovanni Vetritto*

As a manager, civil servant and a liberal, I intend to address very briefly the issue of health policies within the general framework of state policies and in particular the situation in Italy.

A number of issues on this subject have already emerged over the course of the day.

First the absence at this time of specific ministerial responsibility on the subject of health care. This is a choice resulting from the unfortunate reinstatement, implemented by the last budget by the previous centre-left government, of the 1999 plan for ministerial organisation already greatly criticised at the time. This was a plan to incorporate all state departments linked to health under one single, enormous and probably rather vague Welfare Ministry.

The current government further compounded the damage resulting from this choice as it did not even reinstate the position of a junior health minister, although this would have been permitted under the same 1999 laws ...not to mention the further extravagance seen in the Premier acting as proxy for the Ministry for Relations with the Regions as far as control over spending in the health sector is concerned.

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This is a purely an accounting proxy role and totally unlinked to any competence regarding the quantity and quality of health services.

All in all, as far as organisation of health care is concerned, the scenario of state institutional players certainly does not favour incisive reprogramming of the system as envisaged by many of today's speakers.

There are also other elements of great uncertainty on this subject.

For example, one cannot forget how it is literally impossible to understand from the state's balance sheet (both the estimated one and even more so the final balance) what investments in policies have actually been implemented.

Within the framework of overall reform of the public administration, during the Nineties the muddled and not very transparent Italian budget was the object of a debate that was sadly far too weak. This was a debate centred on the need for a reclassification of the state balance sheet.

The debate was based on choosing between the idea of a budget organised according to spending sectors (defended effectively by the State Accounting Agency with all its ancient ideological paraphernalia) and another idea for a balance sheet organised according to target functions, and hence according to policies (supported instead by a number of the administration's great innovators over the past forty years – and especially by a lead player in programming during the Sixties such as Manin Carabba and some of the magistrates in the State Auditor's Department).

The result of this debate – I repeat, rather a weak one – has been insignificant and in Italy the State's balance sheets continue to be drafted according to the rules of the 1923 Royal Decree, written by Alberto De Stefani on the basis of the powers just bestowed upon Mussolini after the March on Rome. Obviously this is not remotely suited to modern, transparent policy management.

There is, in addition, a third element of uncertainty regarding state policies, health care in particular, consisting of the decentralisation of state power to various levels of government. Obviously, this too is the result of modernity and hence it is pointless to object to this.

One should, however, reflect more at length on the fact that Italy is the only European country that has three other levels of government, in addition to central government.

Usually, in addition to the State within Europe, there are also the Regions and the communes, or provinces and communes, and no country except Italy has regions and provinces and communes beneath the state. This would be acceptable if there were at least established communications systems, which are instead very weak and forever boycotted by institutional players.

Such a situation has extremely serious effects specifically in the health sector, which comes under the competence of all levels of government... this, in spite of the trivial but unavoidable fact that, when things are bad in Rome, they are so in the city, in the province, in Latium and in Italy.

This should induce us to make every possible effort (which, by contrast, is lacking) to preserve a unity of policies within the fragmentation of the systems.

A further element of criticality – that could simultaneously also become a solution to these problems, from a liberal policy viewpoint – is that of the progressive success at a global level of functional modules of inclusive public administration.

State policy programming (in general, but even more so in cases now symbolising efficiency in the public sphere over the last fifteen years – such as the "Barcelona case" for example) is increasingly more often implemented with powerful, organised and transparent involvement of social interest in inclusive decision-making processes.

This is a completely new direction for administrative systems that, for example, can offer the prospect of a solution to these remarkable issues often mentioned involving conflict of interests with transparent dynamics and procedures to address any interests involved.

The old administration, which should in theory make decisions in private, but in reality is swayed by vested interests in efficient state systems gives way to an administration that tries to be fair in taking into account social interests. If anything, it makes an effort to include the most diverse interests and ensure transparent dialogue between them to reach a collective decision, one that is as broadly shared as possible.

This is also what we mean when using the word 'governance' instead of the old expression 'government'. This is for public power a profoundly liberal way of working and a possible institutional instrument for solving a number of the significant problems debated

here today. One cannot, however, help but emphasise that with regard to this difficult but promising evolution, Italy is accumulating a serious and irresponsible delay.

In view of these considerations, it is obvious that Europe is an indispensable instrument for solving this multifaceted Italian deficit, as well as many other inadequacies and misalignments of individual national states with the stated objective of enhancing its capability to preside over efficient public policies at a continental level (as far as health care is concerned and in other respects also).

In a different context, I was recently accused of being a "mourner of European federalism," an expression that takes for granted that the European federal idea is dead. Without analysing this point in depth, and therefore without reasserting the federal idea, (to which I remain faithful), it seems impossible to deny that in this historical period, experiencing the problematic but also unequivocal creation of increasing but simultaneously even more closely linked layers of government, one can no longer accept that some major public policies in Europe are the subject of Treaties, while others are not. It is also impossible to complete the definition of these policies at a national level.

We need more European involvement, more of Europe in the health sector. There is already more European imput within the practising clinical community, and today we have heard some extremely prestigious examples, as in all other sciences and professions.

There are now in all sectors extremely strong European cultural and operational koiné, while institutions – and all too often only institutions – stop at the Alps or at the Pyrenees.

All this can no longer be tolerated.

Even if wishing to renounce a debate on federalism, so as to not be judged as old "stick-in-the-mud spinellians," one must acknowledge that modern multilevel governance of public policies must start with a stronger bond with Europe – this with Europe playing a leading role, as a far more influential player than it currently is in current issues, as well as playing a guarantor's role in the broadening and transparency of public participative decision-making processes.

Even without at any price representing the federal option as the only solution, one must acknowledge that the reconstruction of more effective public policies (in the health sector and not only here) can follow one of two paths. We are planning policies that are on one hand more inclusive (and, as such, more liberal), and on the other, clearly organised at a super-national European level.

On this point allow me to close with a brief comment.

It is probably time for everyone to stop complaining that politicians, everywhere and above all in Italy, are now oblivious to this need for Europe and only follow anti-European demagogy, popular dissatisfaction and fear of the Euro. This is true and everyone is aware of it and as voters we all try to reward those who do not fall into such traps.

However, once again from a liberal point of view, it really is time to stop always blaming everything on the political class.

There must be some other kind of player who can in turn lean on politicians and persuade public opinion to request more European involvement; foundations, professionals, cultural magazines, civil society in all its manifestations.

Let us all, whatever social class we may belong to and whatever professional position we have, once again start to request more European involvement, more unitariness, greater functionality, more openness and transparency in public policies.

Let us bet strongly on Europe so as to achieve this.

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In the last years national health care reforms have pursued the common goal of improving health care management, by promoting competition between the players that offer health care services. At the same time, the role of national authorities as the financing of health care expenditure have been evolving.

We are now at a turning point: the proposal of the European Commission for a Health Care Directive, published in July 2008, represents a milestone along the path that leads to the construction of the European HealthCare single market, and to the definition of an European HealthCare policy.

European integration may reinforce the right of access to health care services, as a pillar of the right of citizenship. The transformations currently in progress may make health care become a mover of development and economic growth, without contradicting its historical solidarity roots.

Our intention is to focus on the trends and initiatives that can support the integration of health care within the single market, reinforce the competitiveness of European services on the international health care sector and promote the development of a fair health care European System.

The aim of this Conference is the promotion of the debate between the highest European experts and researchers on the tools and the projects that can help develop a European Health Care System as a pillar of European Citizenship.