LAW AND ETHICS IN RATIONING ACCESS TO CARE IN A HIGH-COST GLOBAL ECONOMY

2nd Biennial Seminar in Health Law and Bioethics

edited by
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Law and Ethics in Rationing Access to Care in a High-Cost Global Economy

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Preface

Paula Lobato de Faria

The Second Biennial Seminar in Health Law and Bioethics on "Law and Ethics in Rationing Access to Care in a High-Cost Global Economy" was held on May 30 and 31 in Boston, US. This seminar was a joint venture of the Boston University School of Public Health department of Health Law, Bioethics, and Human Rights (directed by Edward R. Utley Professor George J. Annas) and the Discipline of Health Law, Ethics, and Biolaw of the National School of Public Health of the New University of Lisbon *(Universidade Nova de Lisboa)* — Portugal.

The first seminar was held in 2005 in Lisbon and resulted in the publication of the book *The Role of Health Law, Bioethics and Human Rights to Promote a Safer and Healthier World,* a collaborative look at the issues presented at the mentioned colloquium with the same title.

These series of seminars are designed to create scientific and academic bridges between US and Portuguese institutions in the fields of health law, bioethics, and human rights.

The 2007 seminar focused specifically on issues surrounding the rationing of health care within perspectives from both sides of the Atlantic.

The United States has dealt with rationing in the past, such as the well known case, in the late 1960s, of the Seattle medical community struggling to determine which renal failure patients to give preference to for the limited availability of a new treatment called dialysis. Nevertheless, dilemmas like these are continuing not only in the scenario of global health but also in the daily practice of medical care units.

Quoting George J. Annas "unless you give everybody everything or nobody anything, you're rationing, even if you don't call it rationing"[1] and therefore society needs more than basic rules or a public process on rationing to include the human rights dimension, since this dimension will be able to provide the qualitative counterpart of a problem that tends more and more to be dealt with by economists in a quantitative perspective.

During the two days of the Second Biennial Seminar in Health Law and Bioethics 10 speakers presented US and European views on the fundamental right to healthcare, patients rights, ethics of health costs rationing, citizen's health duties, healthcare delivery national systems and other related topics. The text that follows contains the majority of these presentations by alphabetical order.

It is also important to mention and thank the financial support of the *Calouste Gulbenkian Foundation*, the *Luso-American Foundation for the Development* and the Ministry of Health (Portugal) to the traveling of the Portuguese speakers.

We hope this book will spread the interest on the scientific developing in Health Law and Bioethics as a main contributor to a better distribution and delivery of healthcare in global and national levels, and to the understanding of the significance to humankind of the recognition of healthcare as a fundamental human right.

[1] In: Nicole Laskowski, Health Care as a Human Right-US. and Portuguese professors meet for seminar on health law and bioethics, BUToday, June 6, 2007.

Introduction

Wendy K. Mariner

Can basic legal and ethical principles assuring equitable access to care survive growing pressure to control costs? At a time of increasing global economic competition, European and North American countries face rising health care costs. These costs are driven in part by the proliferation of biomedical technologies, increased longevity, aging populations, and aspirations for better health in general for all people around the world. The pressure to control costs poses significant challenges to ensuring access to care. Can countries ensure universal access to care without unfair rationing? What role should insurance play in rationing access to care itself? Should individuals assume more responsibility for their own health or their own costs? What kinds of cost controls can be justified, and on what grounds? Should new technologies be subjected to more stringent rules than existing health services? Are some groups more likely than others to be disadvantaged by different market and regulatory regimes?

These questions were the subject of the 2nd Biennial Seminar in Health Law and Bioethics, held in Boston, Massachusetts, USA, on 30-31 May 2007. The papers presented at the Seminar and collected in this volume examine key legal and ethical principles that govern access to care and ask whether they can continue to do so in the future without significant modification. Because this question is common to so many countries, meaningful answers are most likely to be developed by sharing the scholarship, perspectives, and experience of different nations. This work offers a sample of current scholarship in Portugal and the United States,

and demonstrates both common and different (although sometimes complementary) perspectives on the concept of rationing care.

Choosing a legal and ethical framework for access to care

The first three chapters examine how the legal framework for a country's health care system is created, highlighting tensions between social solidarity and personal responsibility in organizing a national health system. Paula Lobato de Faria lays the groundwork with a comprehensive description of Portugal's health system, which illustrates several modern trends. Like other countries in the OECD, Portugal has been increasing the percentage of its gross domestic product spent on health. It has also begun to expand the role of the private sector in managing its National Health Service, in part, perhaps, to gain more control over rising costs. Portugal's political changes have also modified the legal framework for its health care system, although the reforms do not necessarily reflect a consistent political philosophy. Both political and structural reforms may affect the conception of patients' rights and whether patients have duties or whether the idea of patient duties are more properly characterized as inherent limits on the scope of patient rights.

Rising costs are testing conceptions of social solidarity elsewhere in Europe. Jorge Simões and Sofia Nogueira da Silva place the national experience in the context of the European Union, where most countries face similar cost pressures. They note a degree of convergence in the cost-containment measures adopted by EU member states, but there are conflicting trends in the harmonization of social institutions. On the one hand, as the number of EU member countries grows, national sovereignty is carefully guarded and consistency sometimes seems possible only

at the level of general principles. On the other hand, the jurisprudence of the Court of Justice of the European Communities has been developing "the foundations for the possibility of free choice of health care providers." They conclude that Europe must make better use of resources if it is to preserve its welfare state model.

The United States has yet to build a truly universal model of health care or social insurance. Yet, as Wendy Mariner writes, public opinion in the United States increasingly favors a more rational system of universal access to affordable care. Her chapter takes a fresh look at how the pressures of rising costs and public demands for access to care may pull reform in quite different directions, either toward more universal access or toward more personal responsibility for costs. Examining the role of insurance in financing care, she cautions that shifting responsibility for costs to patients — especially in the form of penalties or rewards for staying healthy — may lead reforms farther away from social solidarity and back to the idea that everyone should pay for her own care.

Access to biotechnology in a global economy

The chapters in this section consider discrepancies in access to care in and their justifications. Professor George Annas examines how new biotechnologies — especially experimental drugs for currently untreatable diseases — exacerbate the pressure on costs. He analyzes Americans' resistance to recognizing how health care is rationed, using as an example the case of *Abigail Alliance v. Von Eschenbach*, in which patients sought a constitutional right to obtain drugs that had not been approved by the Food and Drug Administration. Even without considering costs, he argues that patients are helped rather than harmed by a rational research process.

Professor Patricia Roche explores the dilemmas presented by the development of new drugs for specific races of people, analyzing the approval of BiDil to treat heart failure in African-Americans. Both the science and the controversy over approval raise important questions about the meaning of "race", particularly the relationship between race and genetic variation. Limiting drugs to a particular "race" of people has cost implications, but more importantly, it may encourage artificial divisions in the health system and violations of the fundamental human right of non-discrimination.

Perspectives on rights to health and health care

The final three chapters explore how fundamental legal principles relate to the broader principles of human rights and how they are codified and implemented in international covenants, constitutions and other laws. Dr. Michael Grodin provides a useful introduction to the concept of the human right to health, as embodied in the Universal Declaration of Human Rights (UDHR) and the International Covenant for Economic, Social and Cultural Rights (ICESCR). He argues that health and human rights are mutually reinforcing; population health depends upon respect for human rights, and human rights cannot be fully protected unless the population is healthy. Although he recognizes that the historical distinction between negative and positive rights is a false dichotomy, he argues for greater attention to the positive aspects of the human right to health in order to encourage governments to respect, protect and fulfill their obligations.

Professor Eleanor Kinney provides an overview of the legal implementation of the international human right to health, focusing on the provisions of national constitutions. It is troubling, if not surprising, that a country's explicit commitment,

in the text of its constitution, to protecting health does not necessarily mean that the country adequately addresses the health care needs of its population. Other laws, however, may carry out the obligations of states parties to the UDHR and ICESCR and other treaties and conventions. As she concludes, the "real work" of implementing the human right to health may come from policy makers and health care practitioners who create genuine access to high quality, affordable health care for all. To that we might add lawyers, who can develop the more specific legal framework and enforcement mechanisms to protect the right for all.

Helena Melo examines concepts of patient rights in European law, providing a comprehensive description of the sources of the rights of patients in the European Union. Her chapter emphasizes the importance of respecting these hard won rights, even in the face of cost pressures. Biomedical progress, such as that discussed in the chapters by Professors Annas and Roche, not only offers the potential for saving lives and increasing costs, but also the risk of ignoring human dimension in the physician-patient relationship. Professor Melo calls for preserving the right to respect and dignity as human being. It is possible that, by respecting this most fundamental right, legal systems can preserve both the dignity of their people and their scarce health care resources.

Common themes

Three themes emerge from these contributions. First, all the countries described in this volume face similar demographic and economic pressures, yet they continue the perennial search for better quality health care for all, in spite of the relentless rise in costs. European countries are trying to preserve social solidarity while introducing cost control measures that challenge traditional

conceptions of social insurance. The United States may be proceeding toward the same goal, albeit coming from a different direction. These common concerns and goals suggest that there is much to be gained from international cooperation and sharing both conceptual models and practical experiences.

Second, health system reform movements that respond to cost pressures may affect the legal structure governing the rights of patients and the obligations of providers, either deliberately or inadvertently. Despite differences in national health care systems, the United States and OECD countries are changing the financial incentives for both patients and providers in ways that are likely to influence the legal definitions of patient rights.

And finally, despite the focus on changes at the macro level, all the authors recognize the importance of respecting the rights of individuals within the health care system. This last is not simply a matter of tradition, but an essential element of any social structure that purports to benefit human beings. Here, both scholarship and experience urge renewed attention to the freedoms and entitlements contained within the human to health. As health care systems adapt to the challenges of the twenty-first century, legal systems must preserve and protect the human rights that form the foundation for health.

The health law and bioethics seminars

This volume celebrates an ongoing collaboration among health law and bioethics scholars in Portugal and the United States. The Biennial Health Law and Bioethics Seminar series is a joint venture of the Department of Health Law, Bioethics and Human Rights at the Boston University School of Public Health, and the Discipline of Health Law, Ethics and Biolaw at the National School of Public Health, New University of Lisbon. The

seminars are designed to build more solid scientific bridges between American and Portuguese institutions and to facilitate the exchange of knowledge among academics and researchers in the fields of health law, bioethics, and human rights. Participating faculty share ideas in an open forum to enhance teaching and scholarship and enrich the public conversation about health issues of common concern around the globe.

The Seminar series was inspired by Paula Lobato de Faria, Associate Professor of Health Law and Biolaw, National School of Public Health, New University of Lisbon, when she was a Visiting Scholar in the Department of Health Law, Bioethics & Human Rights, Boston University School of Public Health in 2004. Professor Lobato de Faria chaired the first Seminar in Health Law and Bioethics in Lisbon, Portugal, 2-3 June 2005, with generous support from the Luso-American Foundation. In keeping with the goal of sharing knowledge, the papers presented at the 1st Biennial Seminar in Health Law and Bioethics were published in *The Role of Health Law, Bioethics and Human Rights to Promote a Safer and Healthier World*, edited by Professor Lobato de Faria. We are pleased to continue the tradition with the publication of this second volume of papers from the 2nd Biennal Seminar in Health Law and Bioethics.

We are grateful to the Calouste Gulbenkian Foundation for its support of the publication of papers presented at the 2nd Biennial Seminar.

The Portuguese universal health system

Paula Lobato de Faria*

> "Human anatomy and physiology are the same worldwide, but the organization and delivery of health care reflect individual cultures."
>
> In Annas, J. G. et al. (1990), Preface — p. xxxi.

I. General data

Considering the last available data (2005) Portugal health expenditure in relation to GDP is currently 10.2%[1]. Portugal has been increasing the amount of gross domestic product (GDP)** spent on health, which has grown 24.4% percent in the period 1995-2001[2]. In 2005 the spending on health level was just right below the OECD average considering the health expenditure per capita notwithstanding spending almost 2000 euro per capita. In terms of GDP and income inequality Portugal GDP per capita is 20,030 USD PPP[3].

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The author would like to thank the most valuable collaboration in this article of João Pereira da Costa (Health Law jurist), Sara Vera Jardim (LL.M in Law) and Hilson Cunha Filho (Masters in Public Health).

** A list of the abbreviations used is presented in the end of this chapter.

Health care in Portugal is mainly financed by public funds (direct and indirect taxes). However, private expenditure (essentially out of pocket payments and private health insurance) in health has been around a quarter of the total expenditure on health (2.8% in a total of 10.0% of GDP spent on health care in 2004)[4].

Other relevant information may derive from the analysis of the OECD data on "health expenditure by functions of health care". At this level, in 2005, Portugal spent: 61% in curative and rehabilitation medicine; 1% in long-term care (OECD average is 11%); 25% in medical goods; 10% in ancillary services and 3% in public health and administration[5].

In Portugal the public health and prevention policies were never considered as a main priority by the State. Consequently, in 2005, and despite the fact that average OECD countries spend 3.1% of their public share in health expenditure, Portugal is only spending 1.4%. Pharmaceutical expenditure is a major health budget problem considering the most needed health sustainability. In the same year, Portugal spent 436 USD PPP in pharmaceuticals 60% of this value being assumed by the public sector. If we consider the period between 1995 and 2005 it is possible to determine the annual growth in pharmaceutical spending, which in Portugal is increasing in an annual average growth rate of 3.7%[5].

Also according to the last available data, in 2001 the employment rate in the health sector was 3.4 percent of the active population[6]. By the year 2004, there are 377 Health Centres in the country, with a further 1,940 extensions and 1,102 beds (primary health care), 75 general hospitals with a total of 22,634 beds and 95 psychiatric, alcoholics and drug abusers institutions with a capacity of 2,809 beds. In these institutions were working 24,697 physicians, 39,429 nurses and 7,475 paramedical professionals. Approximately 35,751 medical doctors, 4691 dentists, 9,395 pharmacists and 45,906 nurses were listed as members of their respective professional associations.[7]

In 2005 the main health indicators were: 4.6 nurses per 1,000 inhabitants; 3.4 physicians per 1000 inhabitants (1.7 general practitioners and 1.7 specialists per 1000 population[8]); 0.3 pharmacies per 1,000 inhabitants; 116.5 hospital admissions per 1000 inhabitants; 1,938.8 large or medium surgical procedures per day and 3.9 medical consultations per inhabitant.[9]

There are strong regional asymmetries in what concerns the health condition of the population showing that poverty is still associated with less quality of life and health care access.[10]

Portugal has 10,6 million of total population and has a population average annual growth rate of 0.5%.The mortality average age is getting higher every year. Life expectancy at birth in Portugal in 2006 was 75.2 years for men and 80.4 for women. This evolution brought the country from 7.7% of the population aged over 65 in 1960 to 17.0% in 2005 (over the OECD average)[11].

A dramatic and well known change in Portuguese health indicators can be found in the infant mortality rate which has decreased over the past 30 years from the concerning 10.9 per 1,000 in 1990 to 3.9 per 1000 in 2004. This positive evolution is due to the good policies and strategies that where set over the years[12].

A negative indicator is the AIDS incidence rate which puts Portugal in second place in the list of new cases year per million (79.5%). The USA is currently number one with 137 new cases; the OECD average is 18.8%.

A very concerning indicator is the mortality from road accidents putting Portugal in second place of all OECD countries with 17.4 dead per 100,000 population[13]. In 2005, the main causes of death for the Portuguese are cardiovascular diseases (211.7/ 100,000 individuals) and malignant tumors (156.1/100,000 individuals) of a total standardized mortality rate of 676.9/ 100,000 individuals[14].

The perceived health status gives us some concerning information because only 39% of the population aged 15 and over reported to be in good health. The OECD average is 69%[15].

II. The Portuguese health care system

Historical note on medical care[16]

Health services in Portugal have an historical Christian background, based in the charity spirit of helping the poor, the sick and the handicapped[17]. The embryo of the schools of medicine in Portugal may be found in an ancient (around the XII century) type of hostelry, built near pilgrims' roads that gave shelter to people in need. The existence and maintenance of these places were mainly due to the first Portuguese Queens, since Kings and other noble men were engaged in the war against the moors and other neighbour kingdoms. Those hostelries that started as regular shelter facilities were at a point divided into two different areas, in which one was only for the sick lodgers. These areas where the sick were treated by people with some kind of experience in the art of healing (normally monks), correspond to the first "hospitals"[18] in the country and hence to the very first schools of medicine.

Medicine was first taught in Portugal in a XII century monastery *(Mosteiro de Santa Cruz)* where it was part of a non systematized curricula among other subjects such as theology, mathematics and grammar. A man named Mendo Dias is the first person who is known to have studied medicine in Paris and to teach what he had learned back in Portugal in that monastery at that time. Frei Gil de Santarém (1185-1265) from whom there are numerous medical writings in the Évora Library and Pedro Hispano (1216-1276) who became Pope John XXI, where two of the first famous Portuguese who studied medicine in Paris[19].

The first University in the country was founded in Lisbon (General Study of Lisbon), in 1290 by the King D. Dinis. Since the very start it had medicine in its curricula but this subject was considered inferior to other courses, like law, letters or art. Medicine was taught by only one professor until 1493 when it begun to be taught by two professors. In 1537 the University moved to Coimbra.

In 1503-1504 under the King D. Manuel, the first reform of the medical course was made with the objective of improving education and efficiency amongst its students. The course begin to have the duration of five years and in the end of this one the graduated had to pass an examination done by the *físico-mor* ("major physician"), in order to get the "habilitation letter", prior condition to the practice of medicine.

The organization of the medical profession in Portugal dates from 1898, when the Association of the Portuguese Physicians was created. This Association changed its name to *Ordem dos Medicos* (Order of Physicians) in 1938.

The Order of Physicians was established by the decree-law 29 172 dated November 24th, of 1938 and succeeded the Association of the Portuguese Physicians. At the time it embraced only the physicians who practiced medicine as a liberal profession. This legal instrument was replaced by decree-law 40 651 dated June 21st, of 1956 and later amended three times by respectively, decree-law 48 587 of September 23rd, 1968, decree-law 48 879 of February 22nd, of 1969 and decree-law 333/70 of July 14th. With the democratic revolution the need for new rules increased.

In 1977, Decree-Law 282/77 of July 5th approved the present Statute of the Order of Physicians. The preamble of the statute recognizes disciplinary competence to the Order of Physicians and determines its jurisdiction over all the physicians.

The Order of Physicians is a public law professional association, consisted of all the physicians as single persons. As a

public law association it expresses the constitutional desideratum for the participation of the citizens in the general government. It allows an articulation between the public interest, concerning the manner in which certain activities — as the medical activity — should be exercised, and the private interests of its professionals.

The professional orders find, since 1982, a constitutional legitimation in article 267/4 of the Portuguese Constitution (before, their existence, and particularly the restricted access to the profession, were highly discussed and controversial). According to article 267/4 of the Portuguese Constitution, public associations can only be created to perform specific functions (principle of specification) and necessarily different from the ones of the Unions (non-competition principle). Additionally they must have an internal organisation based upon democratic principles and on the respect for its member's rights. As a public law association, the Order of Physicians was created by a legislative act (in the case, by Decree-law 282/77, of July 5th). The extent and scope of its powers is determined by this legislative act.

Its primary object is the representation of the interests of its members — physicians. Simultaneously they must regulate the profession and stipulate its disciplinary rules. In order to accomplish these last nominated functions, and because it is a public association, the Order of Physicians has received, by law, administrative powers and the necessary instruments from the state to exercise a truly public administration function, even if restricted to its members.

As it happens in general with other professional public associations, the Order of Physicians is based upon the principles of the obligation of inscription and quotas system. That also means that the organization of the physicians obeys the principle of the control of the access to the profession (as already stated above). Moreover the Order involves a whole particular deontological system and its inherent sanctions panel.

As part of the so-called "autonomic public administration", the Order of Physicians is granted a major degree of autonomy from the state. Despite this autonomy the Order is subjected to the State's guardianship in terms of the control of legality as any other public law entity.

The NHS — the National Health Service

Presently, the Portuguese Health Care System is based in the existence of a National Health Service (NHS)[20] composed of the healthcare institutions and units (hospitals and health centres) that belong to the Public sector, under the control of the Ministry of Health[21]. The NHS[22] is considered by Article 64 of the Portuguese Constitution as the main element to attain the fulfilment of the *right to health care protection*: "Everyone has the right to health protection and the duty to defend and promote it", and according to the same constitutional disposition, is oriented by the principles of universal access (accessible to all citizens), comprehensive health care services (offering all kinds of healthcare needed), pending to gratuity, "participated" (managed with the collaboration of all health care actors) and decentralized (organized with proximity to the populations served)[23].

The NHS is composed of the health care units that are under the supervision of the Ministry of Health, including two main entities: hospitals and health centres (Bases XXII/2 and XXXVI of Health Bases Law — Law 48/90, August 24th). It is important to note at this point that the current concept of hospitals had their legal existence recognized long ago, in the year 1946 (Law 2011), while the Health Centres model was only conceived after the health reform of 1971[24] (DL 413/71, of September 27th). In numbers from the National Health Plan, in 2001, 363 health centres equipped the Portuguese territory, with 1797 extensions,

employing 6,961 physicians, 6,850 nurses and 875 paramedics. A reform of the primary health care sector is currently under development.

Nevertheless, Portugal has a considerable private healthcare sector[25] the majority of which contracts with the State to provide health care services to NHS beneficiaries.

A very intensive trait of the Portuguese Health System legal history has been the constant changing of this reality in each different government or even sometimes during the same government. In fact, Portugal passed through different health policies phases that had a strong effect in the structure of the health care system and in the way that its components are conceived and managed. These phases were more clear in the past, depending on the ideology of the political party in power, but nowadays the scenario is more fuzzy, and the type of reforms do not correspond to any of the ideologies originally connected to a political party. Traditional leftist political parties can at present show liberal reforms and vice-versa. The constant changes, however, are a very strong characteristic of the health legislation field. Going back and forth in some of the reforms has happened very often as we will see in the description below.

The first phase, from 1976 to 1990, based in the original version of Article 64 of the CRP, was a post-revolutionary period where the prevalent idea was to subordinate the private sector to a *social medicine* concept[26], to make the NHS the only healthcare provider in the country. This was expressed in a paragraph of the original version of Article 64, where it was said that the State should "orient its actions to the socialization of medicine" (this principle was substituted *grosso modo* in the constitutional amendment of 1989 by the sentence "socialization of costs" which has prevailed up to the present days). In 1986, Portugal became member of the European Economic Community (now European Union) and became

eligible for European funding for social and economic infrastructure development which included the health sector. Since then the Portuguese NHS facilities were able to expand in better and more sustained way as the country's increasing wealth significantly benefited the health sector.

A second phase may be identified from 1990 to 2002. In 1990[27], with a liberal politics party in power, the Health Bases Law (Law 48/90, of August 24th) was enacted, giving to the health sector an entrepreneurial orientation legal framework for the first time. This legal reform had two crucial points:

i) *The integration of the NHS in a "Health System's" context*
The 1979 NHS legislation ignored the existence of an important private and social sector in the health framework. The above-mentioned 1990 Health Bases Law, created for the first time in Portuguese Health Law the concept of "Health System", inserting in this one, besides Ministry of Health dependent public hospitals and health centers, *i.e.* the NHS, also the private health care institutions, which had contracts with the latter (see Base XII, *ibid.*).

ii) *The birth of private management in the public health sector*
The 1990 new law aimed at stimulating the Portuguese private health sector and mainly the private management of NHS facilities. The starting point was the *Hospital Fernando da Fonseca*[28], a new 600 bed public hospital near Lisbon built by the State and opened in 1995, under a management contract with a private consortium. This modality is still unique but other forms of private management within the NHS started at this point. Besides the *Fernando da Fonseca Hospital*, and other few isolated experiences of private management in public hospitals, there were no more consequences of the 1990 law in what concerns the NHS main structure and organisation.

The beginning of a third phase is marked by the first and only amendment to the Health Bases Law in 2002 (Law 27/2002, of November 8th) and is still going on. In fact, the mentioned amendment allowed the transformation of 33 public hospitals in SA companies (*Sociedades Anónimas* — Joint Stock Companies), switching these institutions from the state administrative sector (public statute and management) to the state entrepreneurial sector (private statute and management). From January 1, 2003, approximately 30% of Portuguese public hospitals (corresponding to close to 50% of the public sector bed capacity) were managed under a private legal framework.

Nevertheless, the changing of Government in 2005 led to a new switch in the legal nature of hospitals. The DL 233/2005 of December 29th transformed the hospitals SA into hospitals "EPEs", *i.e.,* "Entrepreneurial Public Entities", meaning that the management of these hospitals was again integrated in the public sector rules.

This period, although punctuated by health policy divergences between the two main political parties, has been marked by a solidification of an entrepreneurial management scheme in public health units. This assertion may be seen in hospitals by the PPPs initiative and in health centers with the creation of the *USFs,* as described in the two following points:

i) *The PPPs*
Ten new public funded and owned hospitals are expected to be constructed over the next few years within a "PPPs — private investment, public financing and private management"[29] framework[30]. The PPPs are defined by Article 2/1 of DL 86/2003, of April 26th as a Union of Contracts under which private entities (named as "private partners") oblige themselves before a "public partner", to a lasting performance of a collective need. The financing,

investment and management of the specific developed activity belong, altogether or partly, to the "private partner". In the Health sector, the PPP's object is a lasting association of "private partners" to the provision of health care.

These partnerships consist of one or more of the following activities: conception, construction, financing, conservation and management of the health units. The main principles and tools of the Heath PPP's are defined by DL 185/2002, of August 20th, amended by DL 141/2006, of July 27th, while DR 14/2003, of June 30th has approved a standard specification contract. The development and implementation of the PPP's in the health sector is an assignment of an *"ad hoc" Mission Unit* nominated "Parcerias. Saúde", created by *Resolução do Conselho de Ministros* 1627/2001, of November 16th.

ii) *The USFs*

The *Unidades de Saúde Familiar* (Family General Practicioner's Units) or *USFs* constitute the main innovation of the ongoing national reform of the management of primary health care units[31], by using a range of market mechanisms within the public sector. Having a strong and close relation with the local Health Centers *(Centros de Saúde),* although they are technically and functionally autonomous, the *USFs* are primary health care units that use mainly contract based management tools to set a basic series of health services[32] that ought to be accessible by the populations.

Although the Health Bases Law[33] sets primary health care as a priority, the Portuguese Healthcare System has been up to now too Hospital centered. The *USFs* represent some of the new implemented policies with the aim of reducing Hospital over-utilization, rationing the use of resources and create incentives for people to have a *family doctor,* offering a range of basic health care services in close proximity to the patients.

The performance contracts celebrated by the *USFs* brought stronger incentives[34], which had repercussions in the implementation of the first *USFs,* as in just a few years the number of these units in the country has grown dramatically[35].

The *USFs* management model is considered a breakthrough[36] in the primary care public sector strategies, mainly because it introduces a new dynamic in the system by reinforcing the shared responsibility between different health care professionals, to comply with the performance agreements. This reality is different from traditional health centers which are mainly focused on the physicians' responsibility and which management is not based on performance levels.

USFs may assume three different models/forms. Each model (A, B or C) offers different levels of autonomy and goals. A team/group of health care professionals (led by a physician) must apply[37] to constitute an *USF*, providing the fulfillment of all legal requirements.

To conclude, it is pertinent to note that although the Primary Health Care sector is still undergoing the development of the still recent introduction of the *USFs*, a new reform has already been set. This occurred based on the norms approved by DL 28/2008, of February 22nd, which created the *Agrupamentos de Centros de Saúde* or *ACES* (Health Centers' Clusters).

Article 2/1 of this statute defines the *ACES* as "health services with administrative autonomy constituted by several functional units belonging to one or more health centers" (author's translation).

It is still early to conclude if the *USFs* are going to continue to be the basic model of a new management paradigm in Portuguese primary health care units or if they are going to be

diluted in the latest forms of health centers' organization prescribed in the 2008 *ACES* mentioned statute.

III. The National Health Plan

The Ministry of Health, by the auspices of the Portuguese Directorate-General for Health, has published a National Health Plan for the period 2004-2010[38], based on the fundamental values and principles of human dignity, solidarity, social justice, citizens' empowerment, equity, sustainability and continuity of care setting the necessary interventions and recommended strategies.

This Plan points out the strategic guidelines for the minimum range of activities that the institutions of the Ministry of Health should assure within the context of an agenda to improve health gains and efficiency. The Plan presents a state of the art in several areas of the health sector, both in a global view and in a healthcare system perspective. It aims to comprise all the fundamental health issues along the life cycle, mentioning in particular areas such as transmissible diseases, cancer, cardio-vascular diseases, chronic-degenerative diseases, mental health and psychiatric diseases, pain and traumatic lesions. Every section of the plan analyses the current figures on each issue, the existing regional interventions and national programs. The Regional Office of WHO supervised and assessed the conception and contents of the document.

IV. Main administrative structure of the Ministry of Health

A) Organic statute of the Ministry of Health

In 2006, the structure of the Ministry of Health (MH) central services and dependent bodies was the object of an important

administrative reform by a new statute (DL 212/2006, of October 27th, approving the Ministry of Health Organic Statute). This Ministry is the governmental department that has the responsibility to define and promote national health policies[39], using its normative functions while having the obligation to provide the assessment of its policies outcomes (Article 1, *ibid.*).

To achieve the aforementioned goals the MH must regulate all health care activities (public and private) as well as to plan, to audit, to inspect and to assess all the NHS related issues (Article 2 of the mentioned Organic Statute). This body is also responsible for the financing of the NHS (*ibid.*)

According to the Health Bases Law, the MH and the Regional Health Administration Departments (*ARSs*) may contract with private institutions in order to assure NHS beneficiaries the proper health care services, provided that the institutions demonstrate the economic benefit and the adequate quality-cost relation between the health care provided and its cost and assure equity in the access to care[40].

The organic structure of the Portuguese MH comprises a very complex and heavy system, which relies on the interaction of different juridical kinds of entities[41] (central services and departments; public agencies; enterprises and consulting bodies; healthcare units) with diverse functions, *e.g.* bureaucratic, management or healthcare delivery, towards which the MH exercise diverse types of powers[42].

The Minister of Health is the vertex of the administrative pyramid of the Portuguese Health System. Immediately underneath the Minister, there are five central bodies (Article 4 of the MH Organic Statute) all with special and diverse powers including regulation and evaluation powers. These entities, which are especially regulated by the mentioned organic statute are the following: the High Commissioner for Health (Article 11, *ibid.*), the IGAS — General-Inspectorate for Health Activities (Article

12, *ibid.*), the Authority for Blood and Transplantation Services (Article 15, *ibid.*), the DGS-Directorate-general for Health (Article 14, *ibid.*) and the General Secretariat of the Ministry of Health (Article 13, *ibid.*).

Working under the supervision of the Minister of Health, belonging as such to the "indirect" administration, there are several public agencies, which execute the objectives of the MH. These entities, according to Article 5/1 and 2 of the MH Organic Statute, are the following:

— The ACSS — Central Administration for the Health System (Article 16, *ibid.*);
— The INFARMED — National Authority of Medicine and Health Products (Article 17, *ibid.*);
— The INEM-National Medical Emergency Institute (Article 18, *ibid.*);
— The Portuguese Blood Institute (Article 19, *ibid.*);
— The IDT- Institute for Drugs and Drug-Addiction (Article 20, *ibid.*);
— The INSA-National Health Institute Ricardo Jorge (Article 21, *ibid.*), and
— The *ARSs* — Regional Health Departments[43] (Article 22, *ibid.*).

B) The General-Directorate for Health

In Chapter III, Section I, Article 14 of the DL 212/2006, of October 27th we find the basic structure and responsibilities of the Portuguese General-Directorate for Health. This body inherited the competences and attributions of the entity first established in 1899 with the controversial name *Direcção-Geral de Saúde e Beneficência Pública* (General-Directorate of Health and Public Beneficence)[44].

In 1911, the General-Directorate of Health and Public Beneficence was transformed into the General-Directorate of Health (DGS), splitting from the public beneficence services, which were then integrated in a different public institution. In the same year Ricardo Jorge, a distinguished physician who had a crucial role in the spread and promotion of the Public Health science and teaching in Portugal was nominated the first Portuguese General Surgeon (Director-General for Health).

According to the mentioned DL 212/2006, of October 27th and also in DR 66/2007, of May 29th (DGS Organic Statute) the DGS must regulate, orient and coordinate all the health promotion related issues, especially regarding disease prevention[45]. The definition of the desirable technical conditions for the health care services is also a crucial DGS responsibility. The DGS is directed by the General Surgeon *(Director-Geral de Saúde),* who is obligatorily a physician, being also the national Health Authority[46]. The General Surgeon may nominate up to three sub-directors to his office (Article 14/3 DL 212/2006, of October 27th).

The DGS has the responsibility to develop Public Health programs[47], as well as setting orientations for health programs in order to make them more efficient and with a higher quality standard (Article 14/2, of the MH Organic Statute). The national epidemiologic surveillance, health statistics[48] and technical health care related studies are all in the sphere of responsibility of the DGS.

Especially considering the quality promotion of all health care services the DGS shall determine and disseminate guidelines for the development of excellence at all levels of care (Article 2/2/c) of The DGS Organic Statute). In this last legal reform the DGS has also assumed the mission, the responsibilities and the powers of the extinguished Institute for Health Quality (Article 10, *ibid.*). In the same direction, the DGS has today the responsibility to define the standards of the best practices, having

the power to the licensing of healthcare units in articulation with the ACSS — Central Administration for the Health System (Article 2/2 d) *ibid.*).

To achieve all the goals mentioned above, the DGS may rely on the collaboration and support of all the Ministry of Health services and related institutes, as well as the cooperation of all healthcare providers (integrated or not in the NHS[49]).

C) Regional Health Departments (ARS, I.P.)

The already mentioned *ARS, I.P.* are mentioned in Chapter III, Section II, Article 22 of the DL 212/2006, of October 27th. Here we found the legal description of the *ARS's* main structure and powers. The *ARS's* are public agencies regulated by Public Law, integrated in the "indirect" administration, being a legal entity with administrative and financial autonomy (Article 1/1 of the *ARSs* Organic Statute — DL 222/2007, of May 29th).

The *ARSs* mission, if summarized in a basic and clear goal, would be to assure the access to health care services to all the population in their specific region. To achieve this goal the *ARSs* must guarantee a level of services adequate to their population needs, accomplishing along the way the objectives of the National Health Plan for their region (Article 22/1, of DL 212/2006, of October 27th). The organic statute of the *ARSs* determines that these bodies should be composed of three different organs: a Directive Board, a Supervising Official (*Fiscal Único*) and a Consultant Board (Article 22/3 and 4, *ibid.*). The Directive Board has a different structure design depending on the area of the specific *ARS*. In the more populated regions of the Lisbon and Tagus Valley *ARS* and the North *ARS* the Directive Boards are composed of one president, one vice-president and three other members; in the *Alentejo, Algarve* and *Center ARSs* the same board

is composed by a president, one vice-president but only two more members.

Within their specific regions, the *ARSs* must coordinate, evaluate and execute the health policies, accordingly with the global and sectorial policies with the main objective of using the resources adequately. In this sense the *ARSs* shall participate in the definition of the coordination measures in intersectorial grounds (see Article 22/2/a)/b) and c), *ibid.*).

The *ARSs* must also assure the human and material resources planning, including the execution of necessary investment projects for the healthcare units under its supervision. These units, technically supported by the *ARSs*, also have the crucial responsibility of evaluating the healthcare unit's performance, providing the national policies and technical demands. The *ARSs* are also the competent bodies to provide a technical opinion regarding the future licensing of new private health care institutions (Article 22/2/d)/e) and f), *ibid.*).

The aforementioned description of the *ARSs* structure and functions in the Ministry of Health Organic Statute is repeated and developed in the *ARSs* own organic statute, the DL 222/2007 of May 29th. In fact, accordingly to Article 3/2 of the latter, *ARSs* must assure the subsequent actions:

— To coordinate and execute the Ministry of Health policies in their own geographic area (*ibid.*/a) and b));
— To cooperate in the elaboration of the National Health Plan, as well as in the monitoring of its application (*ibid.*/c));
— To develop and enhance public health activities to promote their population's health (*ibid.*/d));
— To assure the adequate network contracts between health care providers (*ibid.*/e));
— To plan, coordinate and monitor the human resources management within their own area of influence (*ibid.*/i)).

— To give advice on the creation, modification and integration of health care services (*ibid.*/m));
— To license private health care units (*ibid.*/p)).

Finally, showing how broad the functions of the *ARSs* are in the management and administration of the Portuguese health system, these public agencies have also important responsibilities concerning the laboratory studies and tests for transplantation purposes. In fact, the *ARSs*, have the obligation of maintenance of the National Center of Bone Marrow, Stem Cells and Umbilical Cord Blood Donors[50] (CEDACE), and of the computerized waiting list for transplantation (*ibid.*/h)).

V. Legal Framework of the Private Health Sector

According to Article 64 of the CRP, the State must provide adequate conditions to assure the citizen's right to access quality health care services. In order to achieve this goal, the State may act at different levels in the health care chain (financing, contracting, or providing services itself), working alongside private institutions. Article 64/3/d) of the CRP, constitutionally defines the desirable interaction between the State and the private health care units. It determines as State priorities the supervision and the control of the entrepreneurial and private forms of the medical practice, which should operate in conjunction with the NHS, in order to assure, in public and private health care units, a high and adequate level of quality and efficiency.

The Health Bases Law (Law 48/90, of August 24th) also sheds some light on this matter. In Chapter IV, Base XXXVII, it especially mentions the State's duty of supporting the private health sector development. In this sense, one of the measures

prescribed by this law is the facilitation for NHS human resources (working in the public sector), to work in the private sector as well (Base XXXVII/2, *ibid.*). Additionally, the *ARSs* may celebrate contracts with private health care units to provide specific services to the NHS beneficiaries (*ibid.,* Base XXVII/3/e).

Moreover, private health care institutions have to meet the State's licensing requirements, and to cooperate with the State's supervising and surveillance in all the quality related issues to operate legally. In particular, private hospitalization must act in conjunction with the NHS (*ibid.,* Base XXXIX/1 and 2).

The legal definition of private healthcare units is found in Article 1/2 of DL 13/93, of January 15th which states that these units are not integrated into the NHS, even though they provide medical, nursing, inpatient or recovery services.

DL 13/93, of January 15th is the legal framework statute of the private health care units, comprising the major principles and requirements applicable to these units. According to this statute, private institutions need a Health Minister's Order authorizing the licensing of the private unit (Article 4/1, *ibid.*). The types of services provided and the specialties that the private institution may offer should all be stated in the *License Order,* as well as the maximum number of users/patients permitted (*ibid.*/2).

Two principles must be also assured: the adequacy[6] of the requiring entity and the quality of the services provided (*ibid.,* Articles 7 and 8).

A final requirement, public control, comprises the responsibility of two different bodies, the DGS and the IGAS. The first has to perform an audit/evaluation prior to the Minister's authorization, and the latter may collaborate (when requested) with the DGS in the supervising and control activities.

DR 63/94, of November 2nd prescribes the requirements for the installation, organization and functioning of private health

care units and sets the standards throughout its 46 articles and 11 annexes, as follows:

— Quality promotion system (amongst other norms, see Article 43, *ibid.*);
— Location (Section I, Articles 4 and 6, *ibid.*);
— The terrain (Section II, Articles 6 and 7, *ibid.*);
— The building (Section III, Articles 8 to 19, *ibid.*);
— The technical facilities and equipments (Article 35, *ibid.*);
— Confidentiality issues (Article 41, *ibid.*);
— Safety issues (amongst other norms, see Article 42, *ibid.*).

The licensing, functioning and supervision of several private medical activities have specific legal regulations. This is the case of drug abuse treatment clinics (regulated by DL 16/99, of January 25th), physical rehabilitation clinics (regulated by DL 500/99, of November 19th [52]), private dental care clinics (regulated by DL 233/2001, of August 25th [53]), social support private entities (by DL 64/2007, of March 14th).

VI. The National Health System and patient rights

During the Portuguese dictatorship that lasted 48 years (1926-1974) the country was politically ruled by authoritarian and "anti-liberal" policies based on a Constitution that deliberately excluded fundamental rights of the citizens. This dictatorial repression explains why the legislator was so reluctant to use the "language of rights", even in the health legislation, and the term "rights" never appeared during that period. An example of this is the Hospital Statutory Law of 1968 (Decree-Law 48,357, dated 27th of April 1968), in which we find, in Articles 80 to 82, some of the main patients rights of today (privacy, informed consent,

refusal of treatment, religious assistance) without ever using expressions such as "rights" or "patients rights".

The situation changed after the entering into force of the first democratic Constitution, in April 1976. In this new Constitution of the Portuguese Republic, the importance of the fundamental rights increased considerably compared with all former Portuguese constitutions. The chapters on rights, liberties and guaranties of the citizens are now wide and protected from any subsequent constitutional revisions by article 288/d) of the Constitution.

The demystification of the use of the word "right" after the revolution had immediate consequences in the first National Health Service Law (1979) where some "rights" are already given to the user of the system. Surprisingly, the Portuguese citizen had to wait until the Health Bases Law of 1990 (Law 48/90, dated 24th of August) to have a real legal statute of rights in the health sector.

In the Base XIV of this law, there are nine rights attributed to the users of the health system: a) the right to choose the deliverer of care within some restrictions; b) the right to decide to take or to refuse health care, unless exceptions exist in the law; c) the right to be treated by adequate means, with humanity, promptness, technical accuracy, privacy and respect; d) the right to confidentiality of the personal data disclosed; e) the right to be informed about their situation, the possible alternatives of treatment and the probable evolution of their condition; f) the right to receive, if desired, religious assistance; g) the right to complain and to sue regarding the way they were treated and, if it is the case, to receive compensation for damage; h) the right to constitute representative organisations that would defend their interests; i) the right to constitute organisations that will collaborate with the health system, like associations for the promotion and defence of health or health units friends groups.

Base XIV/2 continues with the list of the duties of the health system where we find among others, the duty to respect the rights of the other patients and the duty to collaborate with the health professionals in relation to their own health.

Patient's rights in the Portuguese legal framework also include the "Oviedo Convention" (Council of Europe Convention for the Protection of Human Rights and Biomedicine). This convention is now part of the internal juridical order after a Presidential Decree of the 3rd January 2001.

All the rights inscribed in the Health Bases Law and in the Oviedo Convention are fundamental rights and are the patrimony of any citizen in the position of being a user of a public or private Portuguese health care unit.

Although the laws and declarations exist, doubts persist whether patients' rights are truly observed in hospitals and other health care units of the country.

There are various reasons for the lack of implementation of the law, the first being the difficulties that come from the deficiencies of the Portuguese health law. As we saw above, the Law gives important rights to the citizens as users of the health services. Nevertheless, these norms are too vague and general to be of practical use. There are no specific regulations to guide the health provider on the detailed contents of the declared rights of a patient.

Another factor that creates obstacles to patient's rights protection is the dilution of responsibility in the present setting of healthcare units. The number of health professionals that deal with one single patient continues to increase. Consider the classical example of the medical secret that is no longer a "medical" but a "shared" secret among numerous different health professionals. How is it possible to protect the right to confidentiality in these circumstances?

Patient's rights are also affected by the crisis of the Portuguese justice system, which being particularly slow and

expensive, makes the citizen reluctant to bring to court actions to remedy violations of their rights law or even seek the advice of a lawyer. Civil liability regarding damage caused by health care malpractice in Portugal is still governed under the "Napoleonic" rule of the *culpa* (fault) that demands going to court in order to get compensation. The judicial difficulties together with this system, leads Portuguese patients to be very hesitant to bring attention to violation of their rights made by health professionals or health care institutions.

All the mentioned obstacles to a real implementation of patients' rights in Portuguese health care units lead to the conclusion that the patient is still the weakest link in the health care process. Even if the law undoubtedly declares his rights, the Portuguese patient is normally a fearful individual, unaware of his legal status and with no direct representative organizations in the civil society.

Several factors seem to point to a higher standard of protection of patients' rights in the future, as these rights become better known, discussed and respected by health professionals.

VII. Patients' duties in Portugal

A) The inheritance of European fundamental duties theory

The subject of "patients' duties" subject cannot be understood without being linked to the broader issue of "fundamental rights and duties" because these two issues share some basic conceptual problems. As we will explain more in detail, "patients' duties" have inherited some of the main juridical features of fundamental duties in European countries constitutional law and this fact can partially help to explain some

of the problems European laws have to define the concept of "patient duty" and its scope.

In fundamental rights and duties theory, there is no consensus on whether to consider fundamental duties as "autonomous counterparts" to fundamental rights or as a mere "manifestation of inherent limits" of the latter[54]. There is little express recognition of the existence of fundamental duties in the majority of European constitutions and where it does happen, the mentioned duties are seen as limits upon fundamental rights and freedoms or as a natural part of the "socially integrated individual", rather than as independent existing and enforceable duties[55].

One of the main reasons for the reluctance of European democratic constitutions to recognize and to mention fundamental duties may be historical, as citizens' duties lists are still a symbol of dictatorial political regimes, being a feature of communist constitutions or reminders of the dark effects of the "national duty" so cherished by the Third Reich[56].

Therefore, it seems that the absence of "patients' duties" in European health laws follows the general tendency of avoiding a written recognition of citizens' duties. Not even the crucial citizens' duties of paying taxes or to attend obligatory school have expression in most of European Constitutions. Fundamental duties are mainly considered as an implicit corollary of a unwritten rule of responsibility that all citizens should have regarding the use of their rights and freedoms. European case law treats fundamental duties as "constitutional values", used for a proper systematic interpretation of the constitutional principles rather than as an independent source of particular obligations of the individual[57].

In what concerns the European Union Law, we cannot find any fundamental duties nor in the Treaties or in the derivate law. These duties which are considered to be historically seen as

"republican obligations imposed on each citizen for the common well-being"[58] are deeply linked to the concept of citizenship which is it self not developed in the Community Law". Stefan Kadelbach, in his work on fundamental duties in the perspective of the European Court of Justice, concludes that these duties in Community Law "do not form autonomous counterparts to fundamental rights"[59].

Nevertheless, despite their rather "subsidiary" nature to rights and freedoms, citizens' fundamental duties cannot be considered as mere moral obligations. We may find some evidence of this assertion in some countries case law, *e.g.* Finland, where two 1997 judgments referred to the constitutional duty to defend the country regarding criminal guilt and sentencing[60] and also in the German constitutional parental duties which are enforceable by the law, being considered not as mere limits to parental rights but rather as one of the elements that defines parental law[61]. We also find European countries (*e.g.* Portugal) that have included a fundamental duty to defend and promote health in the Constitution (Art. 64/1), duty that is repeated in health ordinary laws, showing that this fundamental duty towards health is not seen as a mere moral obligation.

The importance of a balance between patients' duties and health professionals' rights and duties is not very often mentioned as a tool to the implementation of patients' rights, but it was the main concern of the European Forum of Medical Associations Statement on the "Declaration of Amsterdam" (Declaration on the Promotion of Patients' Rights in Europe)[62], issued during a meeting with WHO, held in Stockholm in February 1996. This statement, as we will show, is evidence that the medical professionals feel the gap between all the weight given to patients' rights and the lack of any importance given to correspondent patients' responsibilities, mainly in what concerns their duty to collaborate with health professionals.

In the mentioned document, the Forum "recalls" that "an essential element in the fulfillment of patients' rights to health care is mutual confidence between the health care professional and the patient (implying mutual recognition of the rights and obligations of both parties) and that the relationship between professional and patient should be one of partnership, with the object of achieving an appropriate improvement in the health of the patient" (§6 of the mentioned document). The Forum Statement also cherishes that the Declaration of Amsterdam, in the part entitled "purpose of the document" draws attention "in particular to patients' responsibilities both to themselves (for their own self care) and also to health professionals (for providing them with all necessary information for diagnosis and treatment, as well as for recognizing that they are entitled to the same rights as other citizens)" (*ibid.,* §8).

B) The duties of Portuguese patients

The already mentioned Portuguese Health Bases Law (Law 84/90, of the 24th of August) gives a general responsibility to the individuals in the accomplishment of the right to health protection (Bases I/1 and IV/3 of the Law), but it also attributes concrete duties to the patients. In Base XIV/2, the same Law has a list where we find that the users of the health system have the following duties:

1) To respect the rights of the other users;
2) To observe the rules of organisation and functioning of the services and institutions;
3) To collaborate with the health professionals in relation to their own health;

4) To use the services in accordance with the established rules;
5) To pay the charges that derived from healthcare deliverance when due.

Being unusual in contemporary European Health Law, we may find a reason for the list of Portuguese patients' duties if we consider that these duties where adapted from the Hospital Statute (Decree Law 48,357, of the 27th April, art. 81) that dates from 1968, when Portugal was still not a democracy. This gives force to the fundamental duties theory that these duties are connoted as juridical features of dictatorial regimes. The 1990 adaptation deleted the article of the 1968 law that mentioned as a legal obligation of the patients the duty to comply with the medical prescriptions and therapeutics prescribed to them. However the 1968 Law was never explicitly derogated, and this duty nowadays seems to be against the self-determination principle and informed consent rules.

Note of the author

Portugal is under a constantly changing legal framework, mainly in the social sectors of Health, Labor and Education. Reforms come in rapid succession, sometimes without enough time to be understood or implemented before being replaced by a newer reform. An article on the legal framework of the national healthcare system has an inherent risk of being (at least partially) already outdated at the time it is published.

Health politics is in constant movement these days in Portugal. Hence, health legislation in our country is constantly changing the juridical shape of the Portuguese Health System. The author recommends that readers check for amendments of the legislation mentioned in this chapter before quoting it.

List of used abbreviations

ACES	*Agrupamentos de Centros de Saúde* (Health Centers' Clusters)
ARSs	*Administrações Regionais de Saúde I.P.* (Regional Health Departments, Public Agencies)
CRP	*Constituição da República Portuguesa* (Constitution of the Portuguese Republic — Constitutional — Law 1/ 2005, of August 12th)
D.R.	*Diário da República* (Portuguese Official Journal)
DGS	*Direcção-Geral da Saúde* (Directorate-General for Health)
DL	*Decreto-Lei* (Decree-Law)
DN	*Despacho Normativo* (Order Implementing the law)
DR	*Decreto-Regulamentar* (Decree Implementing the law)
e.g.	*exempli gratia*
EEC	European Economic Community
EPEs	*Entidades Públicas Empresariais* (Entrepreneurial Public Entities)
EU	European Union
GDP	Gross Domestic Product
i.e.	*id est*
Ibid.	*ibidem*
LO	*Lei Orgânica* (Organic Statute)
MH	Ministry of Health
NHS	*Serviço Nacional de Saúde* (Portuguese National Health Care Service)
OECD	Organization for Economic Co-operation and Development
OPSS	*Observatório Português dos Sistemas de Saúde* (Portuguese Health System Observatory)
PORT	*Portaria* (Implementing Order)
PPPs	*Parcerias Público-Privadas* (Public-Private Partnerships)

SA	*Sociedade Anónima* (Joint Stock Company)
UNESCO	United Nations Educational, Scientific and Cultural Organization
USD PPP	Purchasing Power Parity in US Dollar
USF	*Unidades de Saúde Familiar* (Family General Practicioner's Units)
WHO	World Health Organization

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[2] *Ibid.* See also Campos, A. C. & Ramos, F., 2005. Contas e ganhos na saúde em Portugal : dez anos de percurso. In *Desafios para Portugal:Seminários da Presidência da República*. Lisboa: Casa das Letras. p.159-223. These authors mention that between 1990 and 2002 health expenses increased from 6.2% to 8.6% of the GDP.

[3] OECD, *ibid.*

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[11] INE, *ibid.*

[12] Directorate-General of Health, 2006.

[13] OECD, *ibid.*

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[15] OECD, *ibid.*

[16] See for this section Ferreira, F. A. Gonçalves, 1990. História da saúde e dos serviços de saúde em Portugal. Lisboa : Fundação Calouste Gulbenkian, p. 62 and 63.

[17] *Ibid.*, p. 65.

[18] The English word *hospital,* which is the same in Portuguese, has its origin in the Italian term *sprital* or *spital* that means "hostelry". Until the Discoveries period, the current word for hospital was still *sprital* (*Ibid.,* p. 62 and 63*).*

[19] *Ibid.,* p. 75 and 76.

[20] The NHS enshrined in Article 64 of the CRP (fundamental right to health care protection) was first created and regulated by Law 56/79 of September 15th. This law may be considered implicitly revoked in 1990 by the Health Bases Law — Law 48/90, August 24th. In fact, it is preconized by the doctrine (see for all Ferrara, F. (1987) p. 191-195) that when the legislator approves a new global legal framework for a certain matter, this is equivalent to a renovative *mens legislatoris*, which should lead the interpreter to a conclusion in the sense of an abrogation of the ancient ruling system. [Ferrara, F., 1987. Interpretação e aplicação das Leis. 4th ed. *Colecção Studium* : temas filosóficos, jurídicos e sociais. Coimbra : Arménio Amado]. Additionally, the subsequent approval of a new statute of the NHS in 1993 (DL 11/93, of January 15th, which implemented the Health Bases Law) is also a clear sign of the legislator's intention of breaking in block with the past legal regime.

[21] See Base XII/2 of Health Bases Law (Law 48/90, of August 24th).

[22] As a sociological note, we may cite here Barreto, A. , 2003. Social change in Portugal : 1960-2000. In Pinto, A. C., ed. 2003. Contemporary Portugal : politics, society and culture. New York : Columbia University Press. (Social Sciences Monographs). 159-182, stressing how the NHS represents an important milestone regarding the evolution of health care services in Portugal. The author states that "(...) after a slow evolution, already visible during the 1960s, the health system underwent a rapid expansion, covering all the territory, and is apparently within the reach of whole population regardless of region, locality, profession or social condition. In the late 1970s when the National Health Service was created, around two-thirds of the population were already covered by some other system of sickness support. The reduction in infant mortality, and death from contagious disease (including tuberculosis), as well as the increase in life expectancy,

attest the positive effects of the expansion of public health services". See *ibid*., p. 171.

[23] See Article 64/2/a), of the CRP. See for all Canotilho, J. J. G. & Moreira, V., 2007. Constituição da República Portuguesa Anotada. 4th ed. Vol. 1. Coimbra : Coimbra Editora, on the annotation to Article 64.

[24] For a description of the early history of health centers in Portugal see Sakellarides, C., 2005. De Alma a Harry : crónica da democratização da saúde. Coimbra : Almedina. p.65-75.

[25] Private Health expenditure is currently 2.8% of the GDP. Source UNDP (United Nations Development Programme), 2007. Human Development Reports 2007/2008 (Portugal) [monograph on the Internet]. [accessed June 2008]. Available at: http://hdrstats.undp.org/countries/data_sheets/cty_ds_PRT.html.

[26] See Canotilho, J. J. G. & Moreira, V., 1978. Constituição da República Portuguesa : anotada. Coimbra : Coimbra Editora, in annotation to the original version of Article 64/3/c) of the CRP.

[27] Based on data provided by the *Portuguese Observatory of Health Systems,* although there are small divergences in the interpretation and description of the legal reform of 1990.

[28] In 2008, a new Minister of Health (of the same Government) announced the end of the private management contracts in this Hospital. A new legal status reverting the management of *Fernando da Fonseca* Hospital to the Public sector has been announced, although not yet approved.

[29] For an insight on the historical evolution of the private intervention in the public provision of health care services, especially regarding PPPs, see Reis, V., 2004. A intervenção privada na prestação pública : da expansão do Estado às parcerias público-privadas. *Revista Portuguesa de Saúde Pública*. Volume temático : 4 (2004) 121-135.

[30] It is necessary to mention that the Minister of Health recently announced some changes to be applied to the PPPs in

the health sector. However, a legal expression of this intention was not yet approved.

[31] See DL 298/2007 of August 20, which created the legal framework of these units. It is though important to mention that the concept of the *USFs* has more than 10 years, since it was already previewed in DL 157/99 of May 10th.

[32] *PORT* 1368/2007, of October 18th establishes the basic level of services required.

[33] Law 48/90, of August 24th (Base XIII) determines primary healthcare care as the top priority of the Health Care System; however, this legal prescription does not reflect the real situation.

[34] *E,g.* pay-for-performance financing schemes; more autonomy in terms of management throughout an explicit agreement between the government and the professionals.

[35] Numbers available point to the existence of 105 *USFs* by January 2008, spread throughout the country. Available at: http://www.mcsp.min-saude.pt.

[36] Base XXXVI of Law 48/90, of August 24th, focus on the need of using and implementing some new management tools in the public health care management.

[37] DN 9/2006, of February 16th. This piece of legislation has the set of rules that health professionals must observe when applying for the constitution and management of an *USF*.

[38] Available at: http://www.dgs.pt and http://www.euro.who.int/observatory .

[39] The Health Ministry is specifically responsible to achieve the goals set by the Health Bases Law (see Base VI of Law 48/90, of August 24th).

[40] Base XII of the Law 48/90, of August 24th.

[41] See Article 3 of the Organic Statute.

[42] These powers belong to two categories: "direction" powers, which concern central services or other bodies that are directly

dependent from the Minister and "supervision" powers, concerning public agencies (organizations to which government has devolved power). The "supervision" powers (*tutela*) have a more or less intervention level, depending on the degree of autonomy given by statute to those "quasi" — independent public bodies (see Article 199/d) of the CRP, on the different administrative powers of the Government).

[43] The *ARSs* are five the North Regional Health Department; the Lisboa and Tagus Valley Regional Health Department; the Centre Regional Health Department; the Alentejo Regional Health Department and the Algarve Regional Health Department (see Article 5/2, *ibid.*).

[44] This body statute, published in 1901 was a long and exhaustive document with 374 Articles, each one with several paragraphs creating a difficult structure with too many entities with overlapping competences and powers.

[45] See Article 2 of DR 66/2007, of May 29th.

[46] According to DL 336/99 of September 29th and by the Article 4/1 of DL 212/2006, of October 27th.

[47] Article 2/3/c) *ibid.* determines that the DGS is responsible for the coordination of all necessary interventions in the Public Health ambit, especially considering the Public Health emergencies.

[48] The DR 66/2007, of May 29th in its Article 2/2/f) goes further on this responsibility, demanding form the DGS a "continuous enhancement of the health statistics provided by this Institution".

[49] See (Article 2/5 *ibid.*).

[50] More information about this Center is available at: http://www.chsul.pt/relatorio_cedace.htm.

[51] *Ibid.,* Base XXXIX/1 and 2.

[52] Article 8 of this statute was revoked by DL 222/2007, of May 29th

[53] Article 9 of this statute was revoked by DL 222/2007, of May 29th

[54] See Weber, A., ed., 2001, Fundamental rights in Europe and North America. Part A. The Hague : Kluwer Law International. p. 8.

[55] It seems to be the general opinion of the authors of 11 European countries that contributed to the chapter on fundamental duties *in* Weber, A., *op.cit.* See pages 95-96 in particular.

[56] Holznager, B., 2001, *in* Weber, A., *op. cit.,* p. 95.

[57] Garlick, L. & Wyrzikovski, M., 2001, *in* Weber, A., *op.cit.,* PL60.

[58] Kadelbach, S., 2001, *in* Weber, A., *op. cit.*, p. EC 81

[59] *Ibid.,* p. EC 82.

[60] Scheinin, M., 2001, *in* Weber, A., *op.cit.*, p. 69.

[61] Holznagel, B., *ibid.*, p.

[62] See "Declaration on the Promotion of Patients Rights in Europe", 1996. *International Digest of Health Legislation.* 47(3), p. 410-411.

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The Portuguese universal health system

Paula Lobato de Faria*

> "Human anatomy and physiology are the same worldwide, but the organization and delivery of health care reflect individual cultures."
>
> In Annas, J. G. et al. (1990), Preface — p. xxxi.

I. General data

Considering the last available data (2005) Portugal health expenditure in relation to GDP is currently 10.2%[1]. Portugal has been increasing the amount of gross domestic product (GDP)** spent on health, which has grown 24.4% percent in the period 1995-2001[2]. In 2005 the spending on health level was just right below the OECD average considering the health expenditure per capita notwithstanding spending almost 2000 euro per capita. In terms of GDP and income inequality Portugal GDP per capita is 20,030 USD PPP[3].

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** A list of the abbreviations used is presented in the end of this chapter.

Health care in Portugal is mainly financed by public funds (direct and indirect taxes). However, private expenditure (essentially out of pocket payments and private health insurance) in health has been around a quarter of the total expenditure on health (2.8% in a total of 10.0% of GDP spent on health care in 2004)[4].

Other relevant information may derive from the analysis of the OECD data on "health expenditure by functions of health care". At this level, in 2005, Portugal spent: 61% in curative and rehabilitation medicine; 1% in long-term care (OECD average is 11%); 25% in medical goods; 10% in ancillary services and 3% in public health and administration[5].

In Portugal the public health and prevention policies were never considered as a main priority by the State. Consequently, in 2005, and despite the fact that average OECD countries spend 3.1% of their public share in health expenditure, Portugal is only spending 1.4%. Pharmaceutical expenditure is a major health budget problem considering the most needed health sustainability. In the same year, Portugal spent 436 USD PPP in pharmaceuticals 60% of this value being assumed by the public sector. If we consider the period between 1995 and 2005 it is possible to determine the annual growth in pharmaceutical spending, which in Portugal is increasing in an annual average growth rate of 3.7%[5].

Also according to the last available data, in 2001 the employment rate in the health sector was 3.4 percent of the active population[6]. By the year 2004, there are 377 Health Centres in the country, with a further 1,940 extensions and 1,102 beds (primary health care), 75 general hospitals with a total of 22,634 beds and 95 psychiatric, alcoholics and drug abusers institutions with a capacity of 2,809 beds. In these institutions were working 24,697 physicians, 39,429 nurses and 7,475 paramedical professionals. Approximately 35,751 medical doctors, 4691 dentists, 9,395 pharmacists and 45,906 nurses were listed as members of their respective professional associations.[7]

In 2005 the main health indicators were: 4.6 nurses per 1,000 inhabitants; 3.4 physicians per 1000 inhabitants (1.7 general practitioners and 1.7 specialists per 1000 population[8]); 0.3 pharmacies per 1,000 inhabitants; 116.5 hospital admissions per 1000 inhabitants; 1,938.8 large or medium surgical procedures per day and 3.9 medical consultations per inhabitant.[9]

There are strong regional asymmetries in what concerns the health condition of the population showing that poverty is still associated with less quality of life and health care access.[10]

Portugal has 10,6 million of total population and has a population average annual growth rate of 0.5%.The mortality average age is getting higher every year. Life expectancy at birth in Portugal in 2006 was 75.2 years for men and 80.4 for women. This evolution brought the country from 7.7% of the population aged over 65 in 1960 to 17.0% in 2005 (over the OECD average)[11].

A dramatic and well known change in Portuguese health indicators can be found in the infant mortality rate which has decreased over the past 30 years from the concerning 10.9 per 1,000 in 1990 to 3.9 per 1000 in 2004. This positive evolution is due to the good policies and strategies that where set over the years[12].

A negative indicator is the AIDS incidence rate which puts Portugal in second place in the list of new cases year per million (79.5%). The USA is currently number one with 137 new cases; the OECD average is 18.8%.

A very concerning indicator is the mortality from road accidents putting Portugal in second place of all OECD countries with 17.4 dead per 100,000 population[13]. In 2005, the main causes of death for the Portuguese are cardiovascular diseases (211.7/ 100,000 individuals) and malignant tumors (156.1/100,000 individuals) of a total standardized mortality rate of 676.9/ 100,000 individuals[14].

The perceived health status gives us some concerning information because only 39% of the population aged 15 and over reported to be in good health. The OECD average is 69%[15].

II. The Portuguese health care system

Historical note on medical care[16]

Health services in Portugal have an historical Christian background, based in the charity spirit of helping the poor, the sick and the handicapped[17]. The embryo of the schools of medicine in Portugal may be found in an ancient (around the XII century) type of hostelry, built near pilgrims' roads that gave shelter to people in need. The existence and maintenance of these places were mainly due to the first Portuguese Queens, since Kings and other noble men were engaged in the war against the moors and other neighbour kingdoms. Those hostelries that started as regular shelter facilities were at a point divided into two different areas, in which one was only for the sick lodgers. These areas where the sick were treated by people with some kind of experience in the art of healing (normally monks), correspond to the first "hospitals"[18] in the country and hence to the very first schools of medicine.

Medicine was first taught in Portugal in a XII century monastery *(Mosteiro de Santa Cruz)* where it was part of a non systematized curricula among other subjects such as theology, mathematics and grammar. A man named Mendo Dias is the first person who is known to have studied medicine in Paris and to teach what he had learned back in Portugal in that monastery at that time. Frei Gil de Santarém (1185-1265) from whom there are numerous medical writings in the Évora Library and Pedro Hispano (1216-1276) who became Pope John XXI, where two of the first famous Portuguese who studied medicine in Paris[19].

The first University in the country was founded in Lisbon (General Study of Lisbon), in 1290 by the King D. Dinis. Since the very start it had medicine in its curricula but this subject was considered inferior to other courses, like law, letters or art. Medicine was taught by only one professor until 1493 when it begun to be taught by two professors. In 1537 the University moved to Coimbra.

In 1503-1504 under the King D. Manuel, the first reform of the medical course was made with the objective of improving education and efficiency amongst its students. The course begin to have the duration of five years and in the end of this one the graduated had to pass an examination done by the *físico-mor* ("major physician"), in order to get the "habilitation letter", prior condition to the practice of medicine.

The organization of the medical profession in Portugal dates from 1898, when the Association of the Portuguese Physicians was created. This Association changed its name to *Ordem dos Medicos* (Order of Physicians) in 1938.

The Order of Physicians was established by the decree-law 29 172 dated November 24th, of 1938 and succeeded the Association of the Portuguese Physicians. At the time it embraced only the physicians who practiced medicine as a liberal profession. This legal instrument was replaced by decree-law 40 651 dated June 21st, of 1956 and later amended three times by respectively, decree-law 48 587 of September 23rd, 1968, decree-law 48 879 of February 22nd, of 1969 and decree-law 333/70 of July 14th. With the democratic revolution the need for new rules increased.

In 1977, Decree-Law 282/77 of July 5th approved the present Statute of the Order of Physicians. The preamble of the statute recognizes disciplinary competence to the Order of Physicians and determines its jurisdiction over all the physicians.

The Order of Physicians is a public law professional association, consisted of all the physicians as single persons. As a

public law association it expresses the constitutional desideratum for the participation of the citizens in the general government. It allows an articulation between the public interest, concerning the manner in which certain activities — as the medical activity — should be exercised, and the private interests of its professionals.

The professional orders find, since 1982, a constitutional legitimation in article 267/4 of the Portuguese Constitution (before, their existence, and particularly the restricted access to the profession, were highly discussed and controversial). According to article 267/4 of the Portuguese Constitution, public associations can only be created to perform specific functions (principle of specification) and necessarily different from the ones of the Unions (non-competition principle). Additionally they must have an internal organisation based upon democratic principles and on the respect for its member's rights. As a public law association, the Order of Physicians was created by a legislative act (in the case, by Decree-law 282/77, of July 5th). The extent and scope of its powers is determined by this legislative act.

Its primary object is the representation of the interests of its members — physicians. Simultaneously they must regulate the profession and stipulate its disciplinary rules. In order to accomplish these last nominated functions, and because it is a public association, the Order of Physicians has received, by law, administrative powers and the necessary instruments from the state to exercise a truly public administration function, even if restricted to its members.

As it happens in general with other professional public associations, the Order of Physicians is based upon the principles of the obligation of inscription and quotas system. That also means that the organization of the physicians obeys the principle of the control of the access to the profession (as already stated above). Moreover the Order involves a whole particular deontological system and its inherent sanctions panel.

As part of the so-called "autonomic public administration", the Order of Physicians is granted a major degree of autonomy from the state. Despite this autonomy the Order is subjected to the State's guardianship in terms of the control of legality as any other public law entity.

The NHS — the National Health Service

Presently, the Portuguese Health Care System is based in the existence of a National Health Service (NHS)[20] composed of the healthcare institutions and units (hospitals and health centres) that belong to the Public sector, under the control of the Ministry of Health[21]. The NHS[22] is considered by Article 64 of the Portuguese Constitution as the main element to attain the fulfilment of the *right to health care protection*: "Everyone has the right to health protection and the duty to defend and promote it", and according to the same constitutional disposition, is oriented by the principles of universal access (accessible to all citizens), comprehensive health care services (offering all kinds of healthcare needed), pending to gratuity, "participated" (managed with the collaboration of all health care actors) and decentralized (organized with proximity to the populations served)[23].

The NHS is composed of the health care units that are under the supervision of the Ministry of Health, including two main entities: hospitals and health centres (Bases XXII/2 and XXXVI of Health Bases Law — Law 48/90, August 24th). It is important to note at this point that the current concept of hospitals had their legal existence recognized long ago, in the year 1946 (Law 2011), while the Health Centres model was only conceived after the health reform of 1971[24] (DL 413/71, of September 27th). In numbers from the National Health Plan, in 2001, 363 health centres equipped the Portuguese territory, with 1797 extensions,

employing 6,961 physicians, 6,850 nurses and 875 paramedics. A reform of the primary health care sector is currently under development.

Nevertheless, Portugal has a considerable private healthcare sector[25] the majority of which contracts with the State to provide health care services to NHS beneficiaries.

A very intensive trait of the Portuguese Health System legal history has been the constant changing of this reality in each different government or even sometimes during the same government. In fact, Portugal passed through different health policies phases that had a strong effect in the structure of the health care system and in the way that its components are conceived and managed. These phases were more clear in the past, depending on the ideology of the political party in power, but nowadays the scenario is more fuzzy, and the type of reforms do not correspond to any of the ideologies originally connected to a political party. Traditional leftist political parties can at present show liberal reforms and vice-versa. The constant changes, however, are a very strong characteristic of the health legislation field. Going back and forth in some of the reforms has happened very often as we will see in the description below.

The first phase, from 1976 to 1990, based in the original version of Article 64 of the CRP, was a post-revolutionary period where the prevalent idea was to subordinate the private sector to a *social medicine* concept[26], to make the NHS the only healthcare provider in the country. This was expressed in a paragraph of the original version of Article 64, where it was said that the State should "orient its actions to the socialization of medicine" (this principle was substituted *grosso modo* in the constitutional amendment of 1989 by the sentence "socialization of costs" which has prevailed up to the present days). In 1986, Portugal became member of the European Economic Community (now European Union) and became

eligible for European funding for social and economic infrastructure development which included the health sector. Since then the Portuguese NHS facilities were able to expand in better and more sustained way as the country's increasing wealth significantly benefited the health sector.

A second phase may be identified from 1990 to 2002. In 1990[27], with a liberal politics party in power, the Health Bases Law (Law 48/90, of August 24th) was enacted, giving to the health sector an entrepreneurial orientation legal framework for the first time. This legal reform had two crucial points:

i) *The integration of the NHS in a "Health System's" context*
The 1979 NHS legislation ignored the existence of an important private and social sector in the health framework. The above-mentioned 1990 Health Bases Law, created for the first time in Portuguese Health Law the concept of "Health System", inserting in this one, besides Ministry of Health dependent public hospitals and health centers, *i.e.* the NHS, also the private health care institutions, which had contracts with the latter (see Base XII, *ibid.*).

ii) *The birth of private management in the public health sector*
The 1990 new law aimed at stimulating the Portuguese private health sector and mainly the private management of NHS facilities. The starting point was the *Hospital Fernando da Fonseca*[28], a new 600 bed public hospital near Lisbon built by the State and opened in 1995, under a management contract with a private consortium. This modality is still unique but other forms of private management within the NHS started at this point. Besides the *Fernando da Fonseca Hospital*, and other few isolated experiences of private management in public hospitals, there were no more consequences of the 1990 law in what concerns the NHS main structure and organisation.

The beginning of a third phase is marked by the first and only amendment to the Health Bases Law in 2002 (Law 27/2002, of November 8th) and is still going on. In fact, the mentioned amendment allowed the transformation of 33 public hospitals in SA companies (*Sociedades Anónimas* — Joint Stock Companies), switching these institutions from the state administrative sector (public statute and management) to the state entrepreneurial sector (private statute and management). From January 1, 2003, approximately 30% of Portuguese public hospitals (corresponding to close to 50% of the public sector bed capacity) were managed under a private legal framework.

Nevertheless, the changing of Government in 2005 led to a new switch in the legal nature of hospitals. The DL 233/2005 of December 29th transformed the hospitals SA into hospitals "EPEs", *i.e.,* "Entrepreneurial Public Entities", meaning that the management of these hospitals was again integrated in the public sector rules.

This period, although punctuated by health policy divergences between the two main political parties, has been marked by a solidification of an entrepreneurial management scheme in public health units. This assertion may be seen in hospitals by the PPPs initiative and in health centers with the creation of the *USFs,* as described in the two following points:

i) *The PPPs*
Ten new public funded and owned hospitals are expected to be constructed over the next few years within a "PPPs — private investment, public financing and private management"[29] framework[30]. The PPPs are defined by Article 2/1 of DL 86/2003, of April 26th as a Union of Contracts under which private entities (named as "private partners") oblige themselves before a "public partner", to a lasting performance of a collective need. The financing,

investment and management of the specific developed activity belong, altogether or partly, to the "private partner". In the Health sector, the PPP's object is a lasting association of "private partners" to the provision of health care.

These partnerships consist of one or more of the following activities: conception, construction, financing, conservation and management of the health units. The main principles and tools of the Heath PPP's are defined by DL 185/2002, of August 20th, amended by DL 141/2006, of July 27th, while DR 14/2003, of June 30th has approved a standard specification contract. The development and implementation of the PPP's in the health sector is an assignment of an *"ad hoc" Mission Unit* nominated "Parcerias. Saúde", created by *Resolução do Conselho de Ministros* 1627/2001, of November 16th.

ii) *The USFs*

The *Unidades de Saúde Familiar* (Family General Practicioner's Units) or *USFs* constitute the main innovation of the ongoing national reform of the management of primary health care units[31], by using a range of market mechanisms within the public sector. Having a strong and close relation with the local Health Centers *(Centros de Saúde),* although they are technically and functionally autonomous, the *USFs* are primary health care units that use mainly contract based management tools to set a basic series of health services[32] that ought to be accessible by the populations.

Although the Health Bases Law[33] sets primary health care as a priority, the Portuguese Healthcare System has been up to now too Hospital centered. The *USFs* represent some of the new implemented policies with the aim of reducing Hospital over-utilization, rationing the use of resources and create incentives for people to have a *family doctor,* offering a range of basic health care services in close proximity to the patients.

The performance contracts celebrated by the *USFs* brought stronger incentives[34], which had repercussions in the implementation of the first *USFs,* as in just a few years the number of these units in the country has grown dramatically[35].

The *USFs* management model is considered a breakthrough[36] in the primary care public sector strategies, mainly because it introduces a new dynamic in the system by reinforcing the shared responsibility between different health care professionals, to comply with the performance agreements. This reality is different from traditional health centers which are mainly focused on the physicians' responsibility and which management is not based on performance levels.

USFs may assume three different models/forms. Each model (A, B or C) offers different levels of autonomy and goals. A team/group of health care professionals (led by a physician) must apply[37] to constitute an *USF*, providing the fulfillment of all legal requirements.

To conclude, it is pertinent to note that although the Primary Health Care sector is still undergoing the development of the still recent introduction of the *USFs*, a new reform has already been set. This occurred based on the norms approved by DL 28/2008, of February 22nd, which created the *Agrupamentos de Centros de Saúde* or *ACES* (Health Centers' Clusters).

Article 2/1 of this statute defines the *ACES* as "health services with administrative autonomy constituted by several functional units belonging to one or more health centers" (author's translation).

It is still early to conclude if the *USFs* are going to continue to be the basic model of a new management paradigm in Portuguese primary health care units or if they are going to be

diluted in the latest forms of health centers' organization prescribed in the 2008 *ACES* mentioned statute.

III. The National Health Plan

The Ministry of Health, by the auspices of the Portuguese Directorate-General for Health, has published a National Health Plan for the period 2004-2010[38], based on the fundamental values and principles of human dignity, solidarity, social justice, citizens' empowerment, equity, sustainability and continuity of care setting the necessary interventions and recommended strategies.

This Plan points out the strategic guidelines for the minimum range of activities that the institutions of the Ministry of Health should assure within the context of an agenda to improve health gains and efficiency. The Plan presents a state of the art in several areas of the health sector, both in a global view and in a healthcare system perspective. It aims to comprise all the fundamental health issues along the life cycle, mentioning in particular areas such as transmissible diseases, cancer, cardio-vascular diseases, chronic-degenerative diseases, mental health and psychiatric diseases, pain and traumatic lesions. Every section of the plan analyses the current figures on each issue, the existing regional interventions and national programs. The Regional Office of WHO supervised and assessed the conception and contents of the document.

IV. Main administrative structure of the Ministry of Health

A) Organic statute of the Ministry of Health

In 2006, the structure of the Ministry of Health (MH) central services and dependent bodies was the object of an important

administrative reform by a new statute (DL 212/2006, of October 27th, approving the Ministry of Health Organic Statute). This Ministry is the governmental department that has the responsibility to define and promote national health policies[39], using its normative functions while having the obligation to provide the assessment of its policies outcomes (Article 1, *ibid.*).

To achieve the aforementioned goals the MH must regulate all health care activities (public and private) as well as to plan, to audit, to inspect and to assess all the NHS related issues (Article 2 of the mentioned Organic Statute). This body is also responsible for the financing of the NHS (*ibid.*)

According to the Health Bases Law, the MH and the Regional Health Administration Departments (*ARSs*) may contract with private institutions in order to assure NHS beneficiaries the proper health care services, provided that the institutions demonstrate the economic benefit and the adequate quality-cost relation between the health care provided and its cost and assure equity in the access to care[40].

The organic structure of the Portuguese MH comprises a very complex and heavy system, which relies on the interaction of different juridical kinds of entities[41] (central services and departments; public agencies; enterprises and consulting bodies; healthcare units) with diverse functions, *e.g.* bureaucratic, management or healthcare delivery, towards which the MH exercise diverse types of powers[42].

The Minister of Health is the vertex of the administrative pyramid of the Portuguese Health System. Immediately underneath the Minister, there are five central bodies (Article 4 of the MH Organic Statute) all with special and diverse powers including regulation and evaluation powers. These entities, which are especially regulated by the mentioned organic statute are the following: the High Commissioner for Health (Article 11, *ibid.*), the IGAS — General-Inspectorate for Health Activities (Article

12, *ibid.*), the Authority for Blood and Transplantation Services (Article 15, *ibid.*), the DGS-Directorate-general for Health (Article 14, *ibid.*) and the General Secretariat of the Ministry of Health (Article 13, *ibid.*).

Working under the supervision of the Minister of Health, belonging as such to the "indirect" administration, there are several public agencies, which execute the objectives of the MH. These entities, according to Article 5/1 and 2 of the MH Organic Statute, are the following:

— The ACSS — Central Administration for the Health System (Article 16, *ibid.*);
— The INFARMED — National Authority of Medicine and Health Products (Article 17, *ibid.*);
— The INEM-National Medical Emergency Institute (Article 18, *ibid.*);
— The Portuguese Blood Institute (Article 19, *ibid.*);
— The IDT- Institute for Drugs and Drug-Addiction (Article 20, *ibid.*);
— The INSA-National Health Institute Ricardo Jorge (Article 21, *ibid.*), and
— The *ARSs* — Regional Health Departments[43] (Article 22, *ibid.*).

B) The General-Directorate for Health

In Chapter III, Section I, Article 14 of the DL 212/2006, of October 27th we find the basic structure and responsibilities of the Portuguese General-Directorate for Health. This body inherited the competences and attributions of the entity first established in 1899 with the controversial name *Direcção-Geral de Saúde e Beneficência Pública* (General-Directorate of Health and Public Beneficence)[44].

In 1911, the General-Directorate of Health and Public Beneficence was transformed into the General-Directorate of Health (DGS), splitting from the public beneficence services, which were then integrated in a different public institution. In the same year Ricardo Jorge, a distinguished physician who had a crucial role in the spread and promotion of the Public Health science and teaching in Portugal was nominated the first Portuguese General Surgeon (Director-General for Health).

According to the mentioned DL 212/2006, of October 27th and also in DR 66/2007, of May 29th (DGS Organic Statute) the DGS must regulate, orient and coordinate all the health promotion related issues, especially regarding disease prevention[45]. The definition of the desirable technical conditions for the health care services is also a crucial DGS responsibility. The DGS is directed by the General Surgeon *(Director-Geral de Saúde),* who is obligatorily a physician, being also the national Health Authority[46]. The General Surgeon may nominate up to three sub-directors to his office (Article 14/3 DL 212/2006, of October 27th).

The DGS has the responsibility to develop Public Health programs[47], as well as setting orientations for health programs in order to make them more efficient and with a higher quality standard (Article 14/2, of the MH Organic Statute). The national epidemiologic surveillance, health statistics[48] and technical health care related studies are all in the sphere of responsibility of the DGS.

Especially considering the quality promotion of all health care services the DGS shall determine and disseminate guidelines for the development of excellence at all levels of care (Article 2/2/c) of The DGS Organic Statute). In this last legal reform the DGS has also assumed the mission, the responsibilities and the powers of the extinguished Institute for Health Quality (Article 10, *ibid.*). In the same direction, the DGS has today the responsibility to define the standards of the best practices, having

the power to the licensing of healthcare units in articulation with the ACSS — Central Administration for the Health System (Article 2/2 d) *ibid.*).

To achieve all the goals mentioned above, the DGS may rely on the collaboration and support of all the Ministry of Health services and related institutes, as well as the cooperation of all healthcare providers (integrated or not in the NHS[49]).

C) Regional Health Departments (ARS, I.P.)

The already mentioned *ARS, I.P.* are mentioned in Chapter III, Section II, Article 22 of the DL 212/2006, of October 27th. Here we found the legal description of the *ARS's* main structure and powers. The *ARS's* are public agencies regulated by Public Law, integrated in the "indirect" administration, being a legal entity with administrative and financial autonomy (Article 1/1 of the *ARSs* Organic Statute — DL 222/2007, of May 29th).

The *ARSs* mission, if summarized in a basic and clear goal, would be to assure the access to health care services to all the population in their specific region. To achieve this goal the *ARSs* must guarantee a level of services adequate to their population needs, accomplishing along the way the objectives of the National Health Plan for their region (Article 22/1, of DL 212/2006, of October 27th). The organic statute of the *ARSs* determines that these bodies should be composed of three different organs: a Directive Board, a Supervising Official (*Fiscal Único*) and a Consultant Board (Article 22/3 and 4, *ibid.*). The Directive Board has a different structure design depending on the area of the specific *ARS*. In the more populated regions of the Lisbon and Tagus Valley *ARS* and the North *ARS* the Directive Boards are composed of one president, one vice-president and three other members; in the *Alentejo, Algarve* and *Center ARSs* the same board

is composed by a president, one vice-president but only two more members.

Within their specific regions, the *ARSs* must coordinate, evaluate and execute the health policies, accordingly with the global and sectorial policies with the main objective of using the resources adequately. In this sense the *ARSs* shall participate in the definition of the coordination measures in intersectorial grounds (see Article 22/2/a)/b) and c), *ibid.*).

The *ARSs* must also assure the human and material resources planning, including the execution of necessary investment projects for the healthcare units under its supervision. These units, technically supported by the *ARSs*, also have the crucial responsibility of evaluating the healthcare unit's performance, providing the national policies and technical demands. The *ARSs* are also the competent bodies to provide a technical opinion regarding the future licensing of new private health care institutions (Article 22/2/d)/e) and f), *ibid.*).

The aforementioned description of the *ARSs* structure and functions in the Ministry of Health Organic Statute is repeated and developed in the *ARSs* own organic statute, the DL 222/2007 of May 29th. In fact, accordingly to Article 3/2 of the latter, *ARSs* must assure the subsequent actions:

— To coordinate and execute the Ministry of Health policies in their own geographic area (*ibid.*/a) and b));
— To cooperate in the elaboration of the National Health Plan, as well as in the monitoring of its application (*ibid.*/c));
— To develop and enhance public health activities to promote their population's health (*ibid.*/d));
— To assure the adequate network contracts between health care providers (*ibid.*/e));
— To plan, coordinate and monitor the human resources management within their own area of influence (*ibid.*/i)).

— To give advice on the creation, modification and integration of health care services (*ibid.*/m));
— To license private health care units (*ibid.*/p)).

Finally, showing how broad the functions of the *ARSs* are in the management and administration of the Portuguese health system, these public agencies have also important responsibilities concerning the laboratory studies and tests for transplantation purposes. In fact, the *ARSs*, have the obligation of maintenance of the National Center of Bone Marrow, Stem Cells and Umbilical Cord Blood Donors[50] (CEDACE), and of the computerized waiting list for transplantation (*ibid.*/h)).

V. Legal Framework of the Private Health Sector

According to Article 64 of the CRP, the State must provide adequate conditions to assure the citizen's right to access quality health care services. In order to achieve this goal, the State may act at different levels in the health care chain (financing, contracting, or providing services itself), working alongside private institutions. Article 64/3/d) of the CRP, constitutionally defines the desirable interaction between the State and the private health care units. It determines as State priorities the supervision and the control of the entrepreneurial and private forms of the medical practice, which should operate in conjunction with the NHS, in order to assure, in public and private health care units, a high and adequate level of quality and efficiency.

The Health Bases Law (Law 48/90, of August 24th) also sheds some light on this matter. In Chapter IV, Base XXXVII, it especially mentions the State's duty of supporting the private health sector development. In this sense, one of the measures

prescribed by this law is the facilitation for NHS human resources (working in the public sector), to work in the private sector as well (Base XXXVII/2, *ibid.*). Additionally, the *ARSs* may celebrate contracts with private health care units to provide specific services to the NHS beneficiaries (*ibid.,* Base XXVII/3/e).

Moreover, private health care institutions have to meet the State's licensing requirements, and to cooperate with the State's supervising and surveillance in all the quality related issues to operate legally. In particular, private hospitalization must act in conjunction with the NHS (*ibid.,* Base XXXIX/1 and 2).

The legal definition of private healthcare units is found in Article 1/2 of DL 13/93, of January 15th which states that these units are not integrated into the NHS, even though they provide medical, nursing, inpatient or recovery services.

DL 13/93, of January 15th is the legal framework statute of the private health care units, comprising the major principles and requirements applicable to these units. According to this statute, private institutions need a Health Minister's Order authorizing the licensing of the private unit (Article 4/1, *ibid.*). The types of services provided and the specialties that the private institution may offer should all be stated in the *License Order,* as well as the maximum number of users/patients permitted (*ibid.*/2).

Two principles must be also assured: the adequacy[6] of the requiring entity and the quality of the services provided (*ibid.,* Articles 7 and 8).

A final requirement, public control, comprises the responsibility of two different bodies, the DGS and the IGAS. The first has to perform an audit/evaluation prior to the Minister's authorization, and the latter may collaborate (when requested) with the DGS in the supervising and control activities.

DR 63/94, of November 2nd prescribes the requirements for the installation, organization and functioning of private health

care units and sets the standards throughout its 46 articles and 11 annexes, as follows:

— Quality promotion system (amongst other norms, see Article 43, *ibid.*);
— Location (Section I, Articles 4 and 6, *ibid.*);
— The terrain (Section II, Articles 6 and 7, *ibid.*);
— The building (Section III, Articles 8 to 19, *ibid.*);
— The technical facilities and equipments (Article 35, *ibid.*);
— Confidentiality issues (Article 41, *ibid.*);
— Safety issues (amongst other norms, see Article 42, *ibid.*).

The licensing, functioning and supervision of several private medical activities have specific legal regulations. This is the case of drug abuse treatment clinics (regulated by DL 16/99, of January 25th), physical rehabilitation clinics (regulated by DL 500/99, of November 19th [52]), private dental care clinics (regulated by DL 233/2001, of August 25th [53]), social support private entities (by DL 64/2007, of March 14th).

VI. The National Health System and patient rights

During the Portuguese dictatorship that lasted 48 years (1926-1974) the country was politically ruled by authoritarian and "anti-liberal" policies based on a Constitution that deliberately excluded fundamental rights of the citizens. This dictatorial repression explains why the legislator was so reluctant to use the "language of rights", even in the health legislation, and the term "rights" never appeared during that period. An example of this is the Hospital Statutory Law of 1968 (Decree-Law 48,357, dated 27th of April 1968), in which we find, in Articles 80 to 82, some of the main patients rights of today (privacy, informed consent,

refusal of treatment, religious assistance) without ever using expressions such as "rights" or "patients rights".

The situation changed after the entering into force of the first democratic Constitution, in April 1976. In this new Constitution of the Portuguese Republic, the importance of the fundamental rights increased considerably compared with all former Portuguese constitutions. The chapters on rights, liberties and guaranties of the citizens are now wide and protected from any subsequent constitutional revisions by article 288/d) of the Constitution.

The demystification of the use of the word "right" after the revolution had immediate consequences in the first National Health Service Law (1979) where some "rights" are already given to the user of the system. Surprisingly, the Portuguese citizen had to wait until the Health Bases Law of 1990 (Law 48/90, dated 24th of August) to have a real legal statute of rights in the health sector.

In the Base XIV of this law, there are nine rights attributed to the users of the health system: a) the right to choose the deliverer of care within some restrictions; b) the right to decide to take or to refuse health care, unless exceptions exist in the law; c) the right to be treated by adequate means, with humanity, promptness, technical accuracy, privacy and respect; d) the right to confidentiality of the personal data disclosed; e) the right to be informed about their situation, the possible alternatives of treatment and the probable evolution of their condition; f) the right to receive, if desired, religious assistance; g) the right to complain and to sue regarding the way they were treated and, if it is the case, to receive compensation for damage; h) the right to constitute representative organisations that would defend their interests; i) the right to constitute organisations that will collaborate with the health system, like associations for the promotion and defence of health or health units friends groups.

Base XIV/2 continues with the list of the duties of the health system where we find among others, the duty to respect the rights of the other patients and the duty to collaborate with the health professionals in relation to their own health.

Patient's rights in the Portuguese legal framework also include the "Oviedo Convention" (Council of Europe Convention for the Protection of Human Rights and Biomedicine). This convention is now part of the internal juridical order after a Presidential Decree of the 3rd January 2001.

All the rights inscribed in the Health Bases Law and in the Oviedo Convention are fundamental rights and are the patrimony of any citizen in the position of being a user of a public or private Portuguese health care unit.

Although the laws and declarations exist, doubts persist whether patients' rights are truly observed in hospitals and other health care units of the country.

There are various reasons for the lack of implementation of the law, the first being the difficulties that come from the deficiencies of the Portuguese health law. As we saw above, the Law gives important rights to the citizens as users of the health services. Nevertheless, these norms are too vague and general to be of practical use. There are no specific regulations to guide the health provider on the detailed contents of the declared rights of a patient.

Another factor that creates obstacles to patient's rights protection is the dilution of responsibility in the present setting of healthcare units. The number of health professionals that deal with one single patient continues to increase. Consider the classical example of the medical secret that is no longer a "medical" but a "shared" secret among numerous different health professionals. How is it possible to protect the right to confidentiality in these circumstances?

Patient's rights are also affected by the crisis of the Portuguese justice system, which being particularly slow and

expensive, makes the citizen reluctant to bring to court actions to remedy violations of their rights law or even seek the advice of a lawyer. Civil liability regarding damage caused by health care malpractice in Portugal is still governed under the "Napoleonic" rule of the *culpa* (fault) that demands going to court in order to get compensation. The judicial difficulties together with this system, leads Portuguese patients to be very hesitant to bring attention to violation of their rights made by health professionals or health care institutions.

All the mentioned obstacles to a real implementation of patients' rights in Portuguese health care units lead to the conclusion that the patient is still the weakest link in the health care process. Even if the law undoubtedly declares his rights, the Portuguese patient is normally a fearful individual, unaware of his legal status and with no direct representative organizations in the civil society.

Several factors seem to point to a higher standard of protection of patients' rights in the future, as these rights become better known, discussed and respected by health professionals.

VII. Patients' duties in Portugal

A) The inheritance of European fundamental duties theory

The subject of "patients' duties" subject cannot be understood without being linked to the broader issue of "fundamental rights and duties" because these two issues share some basic conceptual problems. As we will explain more in detail, "patients' duties" have inherited some of the main juridical features of fundamental duties in European countries constitutional law and this fact can partially help to explain some

of the problems European laws have to define the concept of "patient duty" and its scope.

In fundamental rights and duties theory, there is no consensus on whether to consider fundamental duties as "autonomous counterparts" to fundamental rights or as a mere "manifestation of inherent limits" of the latter[54]. There is little express recognition of the existence of fundamental duties in the majority of European constitutions and where it does happen, the mentioned duties are seen as limits upon fundamental rights and freedoms or as a natural part of the "socially integrated individual", rather than as independent existing and enforceable duties[55].

One of the main reasons for the reluctance of European democratic constitutions to recognize and to mention fundamental duties may be historical, as citizens' duties lists are still a symbol of dictatorial political regimes, being a feature of communist constitutions or reminders of the dark effects of the "national duty" so cherished by the Third Reich[56].

Therefore, it seems that the absence of "patients' duties" in European health laws follows the general tendency of avoiding a written recognition of citizens' duties. Not even the crucial citizens' duties of paying taxes or to attend obligatory school have expression in most of European Constitutions. Fundamental duties are mainly considered as an implicit corollary of a unwritten rule of responsibility that all citizens should have regarding the use of their rights and freedoms. European case law treats fundamental duties as "constitutional values", used for a proper systematic interpretation of the constitutional principles rather than as an independent source of particular obligations of the individual[57].

In what concerns the European Union Law, we cannot find any fundamental duties nor in the Treaties or in the derivate law. These duties which are considered to be historically seen as

"republican obligations imposed on each citizen for the common well-being"[58] are deeply linked to the concept of citizenship which is it self not developed in the Community Law". Stefan Kadelbach, in his work on fundamental duties in the perspective of the European Court of Justice, concludes that these duties in Community Law "do not form autonomous counterparts to fundamental rights"[59].

Nevertheless, despite their rather "subsidiary" nature to rights and freedoms, citizens' fundamental duties cannot be considered as mere moral obligations. We may find some evidence of this assertion in some countries case law, *e.g.* Finland, where two 1997 judgments referred to the constitutional duty to defend the country regarding criminal guilt and sentencing[60] and also in the German constitutional parental duties which are enforceable by the law, being considered not as mere limits to parental rights but rather as one of the elements that defines parental law[61]. We also find European countries (*e.g.* Portugal) that have included a fundamental duty to defend and promote health in the Constitution (Art. 64/1), duty that is repeated in health ordinary laws, showing that this fundamental duty towards health is not seen as a mere moral obligation.

The importance of a balance between patients' duties and health professionals' rights and duties is not very often mentioned as a tool to the implementation of patients' rights, but it was the main concern of the European Forum of Medical Associations Statement on the "Declaration of Amsterdam" (Declaration on the Promotion of Patients' Rights in Europe)[62], issued during a meeting with WHO, held in Stockholm in February 1996. This statement, as we will show, is evidence that the medical professionals feel the gap between all the weight given to patients' rights and the lack of any importance given to correspondent patients' responsibilities, mainly in what concerns their duty to collaborate with health professionals.

In the mentioned document, the Forum "recalls" that "an essential element in the fulfillment of patients' rights to health care is mutual confidence between the health care professional and the patient (implying mutual recognition of the rights and obligations of both parties) and that the relationship between professional and patient should be one of partnership, with the object of achieving an appropriate improvement in the health of the patient" (§6 of the mentioned document). The Forum Statement also cherishes that the Declaration of Amsterdam, in the part entitled "purpose of the document" draws attention "in particular to patients' responsibilities both to themselves (for their own self care) and also to health professionals (for providing them with all necessary information for diagnosis and treatment, as well as for recognizing that they are entitled to the same rights as other citizens)" (*ibid.,* §8).

B) The duties of Portuguese patients

The already mentioned Portuguese Health Bases Law (Law 84/90, of the 24th of August) gives a general responsibility to the individuals in the accomplishment of the right to health protection (Bases I/1 and IV/3 of the Law), but it also attributes concrete duties to the patients. In Base XIV/2, the same Law has a list where we find that the users of the health system have the following duties:

1) To respect the rights of the other users;
2) To observe the rules of organisation and functioning of the services and institutions;
3) To collaborate with the health professionals in relation to their own health;

4) To use the services in accordance with the established rules;
5) To pay the charges that derived from healthcare deliverance when due.

Being unusual in contemporary European Health Law, we may find a reason for the list of Portuguese patients' duties if we consider that these duties where adapted from the Hospital Statute (Decree Law 48,357, of the 27th April, art. 81) that dates from 1968, when Portugal was still not a democracy. This gives force to the fundamental duties theory that these duties are connoted as juridical features of dictatorial regimes. The 1990 adaptation deleted the article of the 1968 law that mentioned as a legal obligation of the patients the duty to comply with the medical prescriptions and therapeutics prescribed to them. However the 1968 Law was never explicitly derogated, and this duty nowadays seems to be against the self-determination principle and informed consent rules.

Note of the author

Portugal is under a constantly changing legal framework, mainly in the social sectors of Health, Labor and Education. Reforms come in rapid succession, sometimes without enough time to be understood or implemented before being replaced by a newer reform. An article on the legal framework of the national healthcare system has an inherent risk of being (at least partially) already outdated at the time it is published.

Health politics is in constant movement these days in Portugal. Hence, health legislation in our country is constantly changing the juridical shape of the Portuguese Health System. The author recommends that readers check for amendments of the legislation mentioned in this chapter before quoting it.

List of used abbreviations

ACES	*Agrupamentos de Centros de Saúde* (Health Centers' Clusters)
ARSs	*Administrações Regionais de Saúde I.P.* (Regional Health Departments, Public Agencies)
CRP	*Constituição da República Portuguesa* (Constitution of the Portuguese Republic — Constitutional — Law 1/ 2005, of August 12th)
D.R.	*Diário da República* (Portuguese Official Journal)
DGS	*Direcção-Geral da Saúde* (Directorate-General for Health)
DL	*Decreto-Lei* (Decree-Law)
DN	*Despacho Normativo* (Order Implementing the law)
DR	*Decreto-Regulamentar* (Decree Implementing the law)
e.g.	*exempli gratia*
EEC	European Economic Community
EPEs	*Entidades Públicas Empresariais* (Entrepreneurial Public Entities)
EU	European Union
GDP	Gross Domestic Product
i.e.	*id est*
Ibid.	*ibidem*
LO	*Lei Orgânica* (Organic Statute)
MH	Ministry of Health
NHS	*Serviço Nacional de Saúde* (Portuguese National Health Care Service)
OECD	Organization for Economic Co-operation and Development
OPSS	*Observatório Português dos Sistemas de Saúde* (Portuguese Health System Observatory)
PORT	*Portaria* (Implementing Order)
PPPs	*Parcerias Público-Privadas* (Public-Private Partnerships)

SA	*Sociedade Anónima* (Joint Stock Company)
UNESCO	United Nations Educational, Scientific and Cultural Organization
USD PPP	Purchasing Power Parity in US Dollar
USF	*Unidades de Saúde Familiar* (Family General Practicioner's Units)
WHO	World Health Organization

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[2] *Ibid.* See also Campos, A. C. & Ramos, F., 2005. Contas e ganhos na saúde em Portugal : dez anos de percurso. In *Desafios para Portugal:Seminários da Presidência da República*. Lisboa: Casa das Letras. p.159-223. These authors mention that between 1990 and 2002 health expenses increased from 6.2% to 8.6% of the GDP.

[3] OECD, *ibid.*

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[11] INE, *ibid.*

[12] Directorate-General of Health, 2006.

[13] OECD, *ibid.*

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[15] OECD, *ibid.*

[16] See for this section Ferreira, F. A. Gonçalves, 1990. História da saúde e dos serviços de saúde em Portugal. Lisboa : Fundação Calouste Gulbenkian, p. 62 and 63.

[17] *Ibid.*, p. 65.

[18] The English word *hospital,* which is the same in Portuguese, has its origin in the Italian term *sprital* or *spital* that means "hostelry". Until the Discoveries period, the current word for hospital was still *sprital* (*Ibid.,* p. 62 and 63*).*

[19] *Ibid.,* p. 75 and 76.

[20] The NHS enshrined in Article 64 of the CRP (fundamental right to health care protection) was first created and regulated by Law 56/79 of September 15th. This law may be considered implicitly revoked in 1990 by the Health Bases Law — Law 48/90, August 24th. In fact, it is preconized by the doctrine (see for all Ferrara, F. (1987) p. 191-195) that when the legislator approves a new global legal framework for a certain matter, this is equivalent to a renovative *mens legislatoris*, which should lead the interpreter to a conclusion in the sense of an abrogation of the ancient ruling system. [Ferrara, F., 1987. Interpretação e aplicação das Leis. 4th ed. *Colecção Studium* : temas filosóficos, jurídicos e sociais. Coimbra : Arménio Amado]. Additionally, the subsequent approval of a new statute of the NHS in 1993 (DL 11/93, of January 15th, which implemented the Health Bases Law) is also a clear sign of the legislator's intention of breaking in block with the past legal regime.

[21] See Base XII/2 of Health Bases Law (Law 48/90, of August 24th).

[22] As a sociological note, we may cite here Barreto, A. , 2003. Social change in Portugal : 1960-2000. In Pinto, A. C., ed. 2003. Contemporary Portugal : politics, society and culture. New York : Columbia University Press. (Social Sciences Monographs). 159-182, stressing how the NHS represents an important milestone regarding the evolution of health care services in Portugal. The author states that "(...) after a slow evolution, already visible during the 1960s, the health system underwent a rapid expansion, covering all the territory, and is apparently within the reach of whole population regardless of region, locality, profession or social condition. In the late 1970s when the National Health Service was created, around two-thirds of the population were already covered by some other system of sickness support. The reduction in infant mortality, and death from contagious disease (including tuberculosis), as well as the increase in life expectancy,

attest the positive effects of the expansion of public health services". See *ibid*., p. 171.

[23] See Article 64/2/a), of the CRP. See for all Canotilho, J. J. G. & Moreira, V., 2007. Constituição da República Portuguesa Anotada. 4th ed. Vol. 1. Coimbra : Coimbra Editora, on the annotation to Article 64.

[24] For a description of the early history of health centers in Portugal see Sakellarides, C., 2005. De Alma a Harry : crónica da democratização da saúde. Coimbra : Almedina. p.65-75.

[25] Private Health expenditure is currently 2.8% of the GDP. Source UNDP (United Nations Development Programme), 2007. Human Development Reports 2007/2008 (Portugal) [monograph on the Internet]. [accessed June 2008]. Available at: http://hdrstats.undp.org/countries/data_sheets/cty_ds_PRT.html.

[26] See Canotilho, J. J. G. & Moreira, V., 1978. Constituição da República Portuguesa : anotada. Coimbra : Coimbra Editora, in annotation to the original version of Article 64/3/c) of the CRP.

[27] Based on data provided by the *Portuguese Observatory of Health Systems,* although there are small divergences in the interpretation and description of the legal reform of 1990.

[28] In 2008, a new Minister of Health (of the same Government) announced the end of the private management contracts in this Hospital. A new legal status reverting the management of *Fernando da Fonseca* Hospital to the Public sector has been announced, although not yet approved.

[29] For an insight on the historical evolution of the private intervention in the public provision of health care services, especially regarding PPPs, see Reis, V., 2004. A intervenção privada na prestação pública : da expansão do Estado às parcerias público-privadas. *Revista Portuguesa de Saúde Pública*. Volume temático : 4 (2004) 121-135.

[30] It is necessary to mention that the Minister of Health recently announced some changes to be applied to the PPPs in

the health sector. However, a legal expression of this intention was not yet approved.

[31] See DL 298/2007 of August 20, which created the legal framework of these units. It is though important to mention that the concept of the *USFs* has more than 10 years, since it was already previewed in DL 157/99 of May 10th.

[32] *PORT* 1368/2007, of October 18th establishes the basic level of services required.

[33] Law 48/90, of August 24th (Base XIII) determines primary healthcare care as the top priority of the Health Care System; however, this legal prescription does not reflect the real situation.

[34] *E,g.* pay-for-performance financing schemes; more autonomy in terms of management throughout an explicit agreement between the government and the professionals.

[35] Numbers available point to the existence of 105 *USFs* by January 2008, spread throughout the country. Available at: http://www.mcsp.min-saude.pt.

[36] Base XXXVI of Law 48/90, of August 24th, focus on the need of using and implementing some new management tools in the public health care management.

[37] DN 9/2006, of February 16th. This piece of legislation has the set of rules that health professionals must observe when applying for the constitution and management of an *USF*.

[38] Available at: http://www.dgs.pt and http://www.euro.who.int/observatory .

[39] The Health Ministry is specifically responsible to achieve the goals set by the Health Bases Law (see Base VI of Law 48/90, of August 24th).

[40] Base XII of the Law 48/90, of August 24th.

[41] See Article 3 of the Organic Statute.

[42] These powers belong to two categories: "direction" powers, which concern central services or other bodies that are directly

dependent from the Minister and "supervision" powers, concerning public agencies (organizations to which government has devolved power). The "supervision" powers (*tutela*) have a more or less intervention level, depending on the degree of autonomy given by statute to those "quasi" — independent public bodies (see Article 199/d) of the CRP, on the different administrative powers of the Government).

[43] The *ARSs* are five the North Regional Health Department; the Lisboa and Tagus Valley Regional Health Department; the Centre Regional Health Department; the Alentejo Regional Health Department and the Algarve Regional Health Department (see Article 5/2, *ibid.*).

[44] This body statute, published in 1901 was a long and exhaustive document with 374 Articles, each one with several paragraphs creating a difficult structure with too many entities with overlapping competences and powers.

[45] See Article 2 of DR 66/2007, of May 29th.

[46] According to DL 336/99 of September 29th and by the Article 4/1 of DL 212/2006, of October 27th.

[47] Article 2/3/c) *ibid.* determines that the DGS is responsible for the coordination of all necessary interventions in the Public Health ambit, especially considering the Public Health emergencies.

[48] The DR 66/2007, of May 29th in its Article 2/2/f) goes further on this responsibility, demanding form the DGS a "continuous enhancement of the health statistics provided by this Institution".

[49] See (Article 2/5 *ibid.*).

[50] More information about this Center is available at: http://www.chsul.pt/relatorio_cedace.htm.

[51] *Ibid.,* Base XXXIX/1 and 2.

[52] Article 8 of this statute was revoked by DL 222/2007, of May 29th

[53] Article 9 of this statute was revoked by DL 222/2007, of May 29th

[54] See Weber, A., ed., 2001, Fundamental rights in Europe and North America. Part A. The Hague : Kluwer Law International. p. 8.

[55] It seems to be the general opinion of the authors of 11 European countries that contributed to the chapter on fundamental duties *in* Weber, A., *op.cit.* See pages 95-96 in particular.

[56] Holznager, B., 2001, *in* Weber, A., *op. cit.,* p. 95.

[57] Garlick, L. & Wyrzikovski, M., 2001, *in* Weber, A., *op.cit.,* PL60.

[58] Kadelbach, S., 2001, *in* Weber, A., *op. cit.*, p. EC 81

[59] *Ibid.,* p. EC 82.

[60] Scheinin, M., 2001, *in* Weber, A., *op.cit.*, p. 69.

[61] Holznagel, B., *ibid.*, p.

[62] See "Declaration on the Promotion of Patients Rights in Europe", 1996. *International Digest of Health Legislation.* 47(3), p. 410-411.

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Are Cost Controls Legal and Ethical? A European Perspective

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1. European integration on health

The 1957 Treaty of Rome created the European Economic Community (EEC), and defined a common market, characterized by the abolition, as between Member States, of obstacles to the free movement of goods, persons, services and capital.

In practice, however, technical norms, health and safety standards, national regulations on the right to practise certain professions and exchange controls all restricted the free movement of people, goods and capital.

Progressively, most of such barriers were abolished and the Treaty of Maastricht, signed in February 1992, created the European Union (EU), and effectively established a single market. It also introduced new forms of co-operation between member states, namely on defence and in the area of justice and home affairs. By adding this inter-governmental co-operation, the Maastricht Treaty created a new structure, based on three pillars — the European Council, the European Parliament and the European Commission.

Since its foundation, the EU has been a magnet, attracting a constant stream of new members, culminating in its historic expansion from 15 to 25 in 2004, and from 25 to 27 in 2007.

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Presently the EU embraces 27 countries — Belgium, France, Germany, Italy, Luxembourg, Netherlands, Denmark, Ireland, United Kingdom, Greece, Portugal, Spain, Austria, Finland, Sweden, Cyprus, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovakia, Slovenia, Bulgaria and Romania — and over 490 million people.

Firms are prevented from fixing prices or carving up markets among them by the European Union's anti-trust policy. People can move around more freely for work because member states recognise many of each other's academic and professional qualifications. Governments have also agreed to take decisions affecting the single market by a system of majority voting rather than by unanimous agreement — which is much harder to achieve.

Following the rejection of the European Constitution by France and the Netherlands in 2005, and a two years period of reflection, *the EU leaders agreed* on a detailed mandate for a new Intergovernmental Conference, whose task will be to draw up a Reform Treaty by the end of 2007.

The EU evolved, expanded and revised the original Treaty, but its member states' social systems never obeyed a common policy, contrary to what occurred in vast areas of economic and financial policy, of which the creation of a single currency for the set of countries that adhered to it — the Euro — is an example.

Several attempts have been made, in particular by the European Commission, to homogenise the social policy in the various countries, but they have encountered strong opposition, both from national governments and public opinion, concerned with the potential loss of the specificities of their national social systems.

Some progress has been made, however. The 2005-2010 Agenda covers policies designed to provide jobs, fight poverty and promote equal opportunities for all, including mobile workers, so that they can enjoy the same social security and pension rights

throughout the EU. These policies are designed in partnership with public authorities at every level — from local to national - , employer and worker representatives, and non-governmental organisations. It is also a framework for supporting member states in reforming pensions and health care, tackling poverty and the employment and social issues resulting from ageing populations, as well as fostering equal opportunities, and eradicating inequality and discrimination.

Consumer policy is part of the EU strategic objective of improving the quality of life for all its citizens. In addition to direct action to protect their rights, the EU ensures that consumer interests are built into its legislation in all relevant policy areas.

Some effort has been made to coordinate actions among state members in terms of public health, which explicitly appeared as a European matter in the Treaty of Rome. For instance, when a pandemic threatens to spread, the EU draws up a co-ordinated response plan as it did, for example, for avian influenza. The European Centre for Disease Prevention and Control, headquartered in Stockholm, identifies, assesses and communicates information on current and emerging threats. It works with national health protection bodies to develop Europe-wide disease surveillance and early warning systems. By having a central agency rather than relying on informal networking arrangements, the EU can react faster, which can make the difference between a minor outbreak and a serious epidemic.

For other areas of the health care sector, however, policies have been mainly developed on a national level, without particular concern for homogenisation across the EU.

As for the future, there have been contradictory signs. On the one hand, people tend to refuse any loss of national sovereignty, and the progressive enlargement of the EU makes it even harder to achieve common agreements. On the other hand, the Court of

Justice of the European Communities has been building — mainly through jurisprudence — the foundations for the possibility of free choice of health care providers in the EU territory for all citizens of its member states.

In the late 1990s, the Court ruled that patients could seek medical treatment in another EU country and be reimbursed when they returned home. The EU judges declared that patients did not need prior authorisation from their own health authority or health insurer before seeking treatment elsewhere, as it was understood that such a requirement would run counter to EU rules, designed to break down national barriers between member states.

Naturally, the extent to which patients will look for health care abroad will depend on a range of factors, such as the availability of suitable services, the distances to be travelled, the languages spoken in the chosen country, and the amount of the reimbursement at home. The latter variable is of considerable importance, as the judges deliberately established that patients going abroad for treatment would be reimbursed in line with the rates which apply in their home country — a proviso designed to reduce the impact on national social security systems. Therefore, if receiving health care abroad turns out to be more expensive, it will be the patient's responsibility to pay the difference.

National health systems will have to deal with a more fluid population as an increasing number of patients in their catchment area seek treatment in another EU country and other EU citizens come to use their own services. Pressure will rise on the most efficient systems to deal with a growing demand, and on the least desirable systems to cope with underused capacity.

In order to limit this problem, the European Court specifically determined that non-emergency treatment can be refused to patients from other countries in the EU if it can be shown that

the extra demand would jeopardise access to proper health care for the country's own residents.

Two cases were brought to the Court by citizens from Luxembourg. In the first case, Nicolas Decker complained that his insurance company had refused to reimburse him for a pair of spectacles he had bought across the border in Belgium. The judges decided that this refusal violated the EU rules on the free movement of goods.

In the second case, Raymond Kohll sued his insurance company after it turned down his request for his daughter to be treated by an orthodontist in Germany. The European Court ruled that the treatment was to be considered a service and that the company's refusal was illegal since it amounted to an unfair barrier to the orthodontist's right to provide services. (Busse, Wismar and Berman, 2002)

To bring some light into the matter, the European Commission launched, in 2006, a consultation paper to clarify the terms and conditions under which citizens of the European Union can get health care in other member states.

Although currently only around 1% of citizens seek care outside their own countries, numbers are likely to increase, for various reasons. For instance, demand has risen as more people from northern Europe retire to sunnier parts of Europe and as more people commute to work across borders. The creation of budget airlines have also boosted travel.

The aim of the EU health services initiative — which will inform forthcoming draft legislation — is to define which medical services entitle patients to cross EU borders and what quality of care they should expect, and to clarify who will pay for it. It is to be expected, however, that the Council will try to limit the exercise of this right by patients, as it would cause a significant increase in expenditure, especially in countries with large waiting lists and waiting times for elective care.

The European Commission, on the other hand, has been influencing, as a regulator, health-related areas such as the environment, scientific research, the requirements for one to become a care provider, and the harmonisation of the qualifications required for an individual to practice as a health care professional.

2. Health care systems across the European Union

One of the main reasons for the absence of common health policy derives from the fact that each national health care system developed, through decades (or even centuries), its own economic, political, social and cultural specificities. Even so, it is possible to identify two main public insurance models in Europe — one of them initially proposed by Bismarck in the late nineteenth century Germany, and the other by Lord Beveridge, in the aftermath of the Second World War, in the United Kingdom.

In 1883, Germany adopted a new law, innovative world-wide, which forced employers to contribute to an insurance scheme for their employees. At first, this was exclusively directed at low-income employees, and later expanded to cover higher-income groups as well. It was, in a word, the first ever social State-imposed security system.

This movement subsequently evolved into a compulsory insurance system, financed through shared contributions from employers and employees, which covered temporary illnesses, permanent disability and premature death. Insurance was therefore associated with employment and not citizenship or residency, and coverage was obtained through regular contributions, leading to immediate or future benefits.

In 1911, in the United Kingdom a health care financing model was created that was based on workers' contributions towards

mutual insurance companies which were then responsible for the payment to providers. Later, in the mid-20th century, a new model emerged based on a higher responsibility from the State and a larger range of services included. This was possible at the time due to very specific circumstances resulting from a strong feeling of solidarity among the British people at the end of the Second World War, an increasing concern with equitable policies, and the acceptance of a stronger State.

The 1942 the Beveridge Report, entitled "Social Insurance and Allied Services", defined health care provision as a pillar for the creation of a viable social security system in Britain. The Report was based on the assumption of an intervening State. It was a more complete model than the one proposed by Bismarck, in the sense that it intended to cover a wide range of risks, "from birth to the grave", including the situation of social exclusion.

The National Health Service (NHS) was created in 1948, following the 1946 NHS Act, which was a cornerstone for many health care systems around the globe, based on five nuclear characteristics: (1) the public responsibility for the provision of free access to health care; (2) the comprehensiveness of coverage, as the Department of Health was expected to "promote a comprehensive health service for the improvement of the physical and mental health of the people of England and Wales for the prevention, diagnosis and treatment of illness"; (3) the universality principle, meaning that the system covered the whole population; (4) the equality principle, as all citizens in need should have access to the same quality of services, without any economic, social or geographic discrimination; and (5) the autonomy of health care professionals, and in particular clinical independence, which allowed the most appropriate use of modern technology towards the population welfare, without any administrative interference.

Despite being an essentially British phenomenon, the rise of the welfare state provided a demonstration effect that impelled other countries towards similar movements. In Europe, we can find three main health care system models, two of which are based on the principle of public insurance:

1) Social health insurance, with compulsory income-related contributions, shared between the employer and the employee. Contributions are collected by health insurance funds (which are normally not-for-profit organisations), independent from government and which are also responsible for health care provision — either directly, or by contracting with private providers. Public authorities assume a role of regulation and supervision in this context. For instance, they may intervene in case of risk coverage disparities between different insurance funds. Traditionally, access to different funds depended on the individual's profession, religion or area of residence. In several countries, social health insurance covers most of the population, even though universality is not necessarily an objective.
2) National health service (NHS), financed from taxes. Payment is compulsory, and determined by income. The State is responsible for the management of the NHS, and generally (but not necessarily) for the direct provision of care.
3) Private health insurance, covering individuals or groups, with contributions based on the level of risk. In the various EU members, this type of insurance exists as well, but tends to complement public coverage. Top-up private insurance may cover public sector co-payments, better hospitalisation conditions, private care provision, and/or services excluded from the statutory health care system.

As we can see from Table 1, in eight EU15 Member States taxation is the main source of funding for health care. Taxes may be national (as in Portugal, Ireland and the UK), mainly regional (Denmark and Sweden), a combination of both (Spain and Finland), or related to the payment of insurance premiums (Italy). In the Netherlands, health care is financed from a combination of social and private insurance; in Greece and Belgium it is financed from a mixture of taxes and social insurance; and in Germany, France, Luxembourg and Austria a mandatory social insurance system is in place.

Table 1
Sources of financing in the EU, in the 1990s (%)

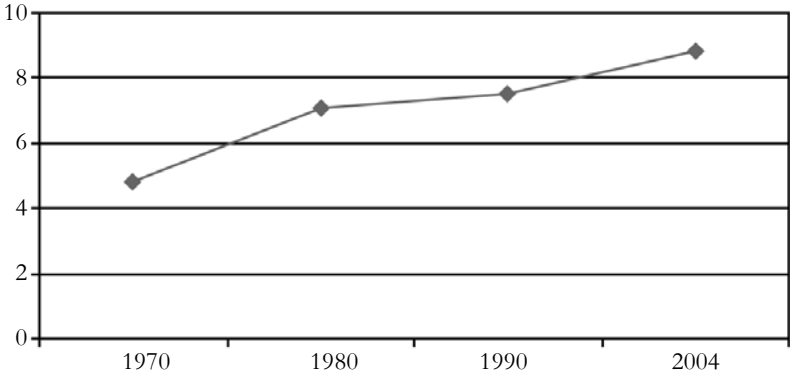
MEMBER STATE	TAXATION	SOCIAL INSURANCE	VOLUNTARY INSURANCE	OUT-OF-POCKET PAYMENTS	OTHER
Austria	24	54	7.5	14	–
Belgium	38	36	–	17	9
Denmark	80.7	–	1.9	17.4	–
Finland	62.2	13	2.2	20.8	1.8
France	3.6	71.6	7	16.5	1.3
Germany	11	64.8	7.1	7.3	9.8
Greece	33.3	24.1	2.1	40.4	–
Ireland	68.1	7.3	8.6	13.9	2.1
Italy	64.6	–	2.6	31.2	2.4
Luxembourg	30	49.8	2	7.9	2.8
Netherlands	10	68	15	7.1	–
Portugal	55.2	6	1.4	37.4	–
Spain	59.3	15.3	7	16.3	1.7
Sweden	69.7	13.4	–	16.9	–
United Kingdom	78.8	12.3	5.6	3.2	–

Source: Mossialos & Le Grand, 1999 (adapted).

3. Health expenditure

Total health care expenditure in EU member states has risen steadily from as little as 4.8% in 1970 to 8.8 % of GDP in 2004, as we can see from Figure 1.

Figure 1
Total health expenditure — Average % GDP, in EU15 (1970-2004)



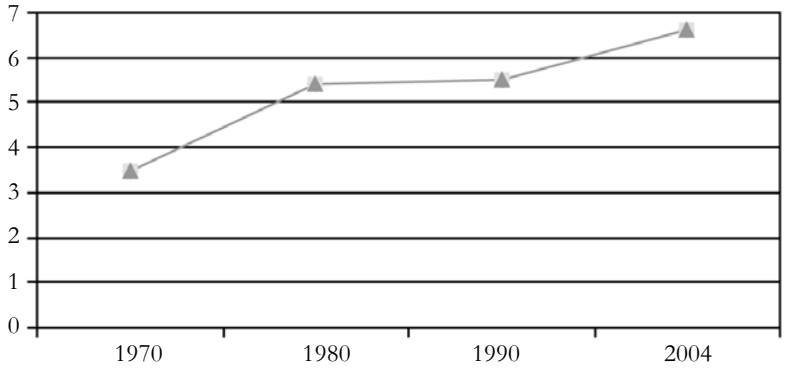
Source: OECD Health Data, 2006.

This growth is more pronounced in public expenditure, which increased from 3.5% in 1970 to 6.6% of GDP in 2004 (Figure 2).

Private health expenditure also grew during this period, although at a smaller rate, having gone up from 1.7% in 1970 to 2.7 % of GDP in 2004 (Figure 3).

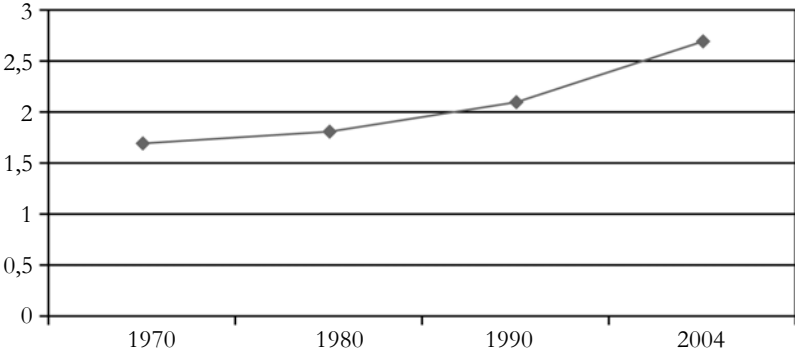
As for the future, the OECD (2006) presents projections for the public expenditure on health care and long-term care (and its increase in terms of % of GDP) for 2050, based on two different scenarios: one in which no policy action is assumed, the "cost pressures" and a "cost containment" scenario that embodies the assumed effects of policies curbing expenditure growth.

Figure 2
Public health expenditure — Average % GDP in EU15 (1970-2004)



Source: OECD Health Data, 2006.

Figure 3
Private health expenditure — Average % GDP in UE-15 (1970-2004)



Source: OECD Health Data, 2006.

As we can see from Table 2, in the "cost-pressure" scenario average health and long-term care spending across OECD countries is projected to almost double from 6.7% of GDP in 2005 to 12.8% by 2050. In the "cost-containment" scenario, average expenditures would sill reach around 10.1% of GDP by 2050 (OECD, 2006).

Table 2
Public Health and long-term care spending in % of GDP

HEALTH CARE			LONG TERM CARE			TOTAL		
2005	2050		2005	2050		2005	2050	
	COST-PRESSURE	COST-CONTAINMENT		COST-PRESSURE	COST-CONTAINMENT		COST-PRESSURE	COST-CONTAINMENT
5.7	9.6	7.7	1.1	3.3	2.4	6.7	12.8	10.1

Source: OECD, 2006.

The European Commission (2006) estimates the impact of ageing populations, between 2004 and 2050, for the EU25 member states. Table 3 presents the estimated demographic impact on public expenditure on health care and long-term care

Table 3
Demographic impact on public expenditure on health care and long-term care, as %GDP, between 2004 and 2050 (European Commission)

	PUBLIC EXPENDITURE ON HEALTH CARE		PUBLIC EXPENDITURE ON LONG-TERM CARE	
	2004	VARIATION BY 2050 DUE TO DEMOGRAPHIC EFFECT	2004	VARIATION BY 2050 DUE TO DEMOGRAPHIC EFFECT
EU 25	6.4	1.6	0.9	0.6

Source: European Commission, 2006.

(European Commission, 2006). Public spending on health care is projected to increase 1.6 percentage points of GDP and public spending on long term case 0.6 percentage points between 2004 and 2050.

4. Determinants of health care expenditures

There is a wide range of factors that contribute to the increase of health expenditures. On the demand side, we can identify three main reasons:

1) Ageing populations. The consequences of demographic projections must be carefully interpreted, as they will depend on the actual use of health care, on services made available to older people, and on technological change. In fact, many countries have been trying to alleviate the use of hospital beds by promoting the availability of long-term care facilities and home care for elderly people.
2) Increasing levels of income. As income increases, so do individual expectations regarding the quality of care and the level of services consumption, regardless of their insurers' changes in terms of coverage characteristics. There is significant literature on this topic — for instance, the OECD estimates an income elasticity of demand of around 0.2, while a number of other studies also point at low elasticities, suggesting demand for health care to be relatively inelastic (Folland, Goodman and Stano, 2003). For the United States, Newhouse (1992) also supports a coefficient of elasticity that is positive but lower than one.
3) The widening access to health care and insurance coverage. Nearly all OECD countries — with the relevant exceptions

of the US and Switzerland — have State-supported health insurance systems in place. Coverage steadily increased and, in the late 1970s, it was already close to 100% in many countries. On the other hand, out-of-pocket expenses decreased during the 1960s and 1970s, followed by a slight increase in the 1980s. If we combine the average public share in total health expenditure with the increasing coverage level, it is possible to estimate the public financial effort with health care.

On the supply side, we can also add the following reasons for a health care expenditure rise:

1) Technological change, including new methodologies, new drugs, new equipments and new medical interventions (Newhouse, 1992): it is not easy, however, to evaluate its impact on expenditure, as some of it may actually allow for higher efficiency, thus resulting in savings, especially if we take indirect costs into consideration. For instance, new medicines may, in some cases, reduce the need for surgery, others may reduce the need for the hospitalisation of mental patients, and vaccines may prevent the spread of contagious diseases (OECD, 1995). Economic evaluation, important as it is, still has a long way to go in terms of determining the cost-effectiveness of new technology.
2) An increasing health care provision, accompanied by some degree of supplier-induced demand. For instance, the number of hospital beds increased considerably in the 1960s and 1970s, due to better coverage, an optimistic perspective on demographic growth, propensity to favour hospital care as opposed to preventive and primary care, and a financing system that, in some countries, effectively

promoted hospitalisation. By the end of the 1970s, however, many countries had to face a surplus of hospital beds, due to decreasing natality rates, a reduction on average lengths of stay for inpatient care, and the growing use of ambulatory care. Taking advantage of the asymmetry of information present in this sector, a possible solution for this excessive supply was to artificially induce additional demand.

The OECD (2006) estimated the impact on the public health expenditure increase of its main determinants, for the period 1970-2002. The most important results are presented in Table 4. The income effect is very significant, while the effect of ageing populations is much smaller.

Table 4
Impact of the main determinants on public health expenditure increase (1970-2002)

	INCREASE RATE IN PER CAPITA PUBLIC HEALTH EXPENDITURE	DECOMPOSITION OF THE EXPENDITURE INCREASE		
		AGEING-POPULATION EFFECT	INCOME-EFFECT	RESIDUAL EFFECT
Average OECD	4.3 0.4	2.5	1.5	

Source: OECD, 2006.

5. Cost containment measures in EU member states, in the early twenty-first century

Given the clear imbalance between the growth rate of expenditure and available resources, governments have been forced to implement cost-containment measures. Such measures, which were sometimes integrated in wider reform strategies, can

be divided into two groups, depending on whether they intend to influence the demand or the supply side of health care. The most commonly used measures are presented in Table 5.

Table 5
Cost-containment measures adopted
by EU member states since the late 1990s

Limits to public resources:
• Increasing co-payments or user charges;
• Tightening of co-payment exemptions;
• Explicit rationing decisions;
• Escalating role of voluntary health insurance;
New budgetary techniques:
• Introduction of fixed budgets;
• Combination of fixed budgets and production-related payments;
• Budgets for individual providers as opposed to sector-related budgets.
Controlling methods:
• Control on wages and fees;
• Control on inputs;
• Control on the number of hospital beds;
• Introduction of clinical guidelines;
• Reference pricing system;
• Limits on average hospital length of stay and development of alternative care methods.

Source: Mossialos & Le Grand, 1999 (adapted).

1) Limits to public resources

Most EU members adopted co-payment systems in order to control the expenditure on drugs, dental care and, in some cases,

inpatient and ambulatory care. However, and despite increases in the use of co-payments, these have never been the most important mechanism for cost containment.

The development of positive and negative lists for prescription drugs, to determine which are entitled to public reimbursement was also a wide-spread measure, integrated in an effort to establish priorities in the health care provision. Apart from the pharmaceutical and dental care areas, most countries do not use treatment restrictions as a way of shifting spending onto patients.

However, there have been some moves towards establishing priority-setting frameworks or guidelines for decision making, to help explicit rationing decisions.

2) New budgetary techniques

Most EU governments, especially since the 1980s, have tightened the control over hospitals, given the share of hospital care on total health expenditure. However, the growth of expenditure on ambulatory care and medicines forced them to widen their intervention to these areas as well.

Cost control measures seem to be most efficient when a single financing source for health care is in place, and when measures such as the imposition of financial ceilings, restrictions to the construction of new hospitals and to the acquisition of expensive equipments, the reduction of the number of acute-care beds, and the control of staff numbers and payments to professionals are implemented.

In ambulatory care, payments to professionals are now negotiated centrally in some countries, while others opted for the imposition of ceilings to global payments to doctors, in order to compensate for increases in the volume of care. The same measure was also adopted for the payment of self-employed

nurses and diagnostic exams. Prices for medical interventions inside and outside hospitals were also adjusted and limits were defined.

3) Controlling methods

- Control on fees — in Belgium, for instance, the government reduced fees by 3% in 1996, for doctors working for insurance funds.
- Control on inputs — some countries control wages, staff numbers and capital expenditures, and most member-states impose *numerus clausus* limits in medical schools and in hiring doctors;
- Control on the number of hospital beds — most countries have actually reduced the number of acute-care beds in recent years;
- Development of clinical guidelines — in 1993, a new system for therapeutic consensus was introduced in France for a set of diseases, techniques and treatments, intended to evaluate medical practice outside hospitals and, later, to be extended to all clinical activities. But the guidelines do not apply if the annual contract between government and doctors has not been agreed. These guidelines, also adopted by other EU members, specify when and how certain procedures, diagnostic exams and medicines related to a given health problem should be used.
- Implementation of reference pricing – under this payment system, similar prescription medicines included in the same list are reimbursed by the State based on the price of the reference drug (which is normally either the cheapest or the second cheapest in the group, depending on the country). If a more expensive medicine is prescribed, patients must

pay the excess. This method intends to increase both patient and doctor's sensitivity to actual costs.

- Control over hospital lengths of stay and promotion of alternative care — evolution in medical knowledge and technology allows continuous reductions in the average length of stay for a given inpatient treatment. Similarly, new alternative care — such as ambulatory care — may reduce costs, avoid hospital-related infections, hospitalisation-related stress and anguish, and allow for a quicker recovery and return to work.
- In the EU there have been attempts to control the acquisition of expensive medical equipment, by creating the so-called health maps, which determine how such equipment should be distributed in a country's territory, therefore avoiding waste and over-capacity. In addition, several countries have established independent bodies to assess new technology, namely in terms of its cost-effectiveness.

6. Conclusions

Even today, health policy remains largely a responsibility of individual member states within the European Union, even though some common efforts have been made concerning efficiency and the rational use of limited resources.

Most countries — if not all — are under constant pressure because health care expenditures show no signs of declining, and available resources remain scarce.

The concern in controlling health care costs has been a key stimulus for the health care reforms in Europe since the 1980s. Cost-control measures are left to national decision makers, but will certainly remain on the EU agenda, if for nothing else

because national budget deficits must remain below 3% of GDP.

Naturally, there has been a degree of convergence in the chosen measures to contain the cost of health care. However, methods employed by different countries differ according to the way in which their heath care systems are organized and financed.

If Europe intends to preserve its welfare state model and to continuously improve equity, access and quality of care, efforts must be made to make a better use of available resources.

Even so, health care expenditures will continue to rise, due to ageing populations, technological change, and increasing income and expectations. If, having achieved maximum efficiency, resources continue to be insufficient to guarantee a comprehensive coverage to the whole population, difficult choices will have to be made, and member state governments will need to either increase resources (namely by increasing taxes or health care-related contributions), reduce the set of services included in public insurance, or even question its universality.

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Social Solidarity and Personal Responsibility in Health Reform*

Wendy K. Mariner**

In the United States, calls to expand access to health *care*, when not simply ignored, typically result in bills or legislation to reform health *insurance*. We are in the midst of just such a transformation today. Several states have adopted reform laws to make insurance available to most of their residents.[1] Presidential candidates are offering their own proposals for the nation's health care system.[2] Former Treasury Secretary Paul O'Neill even declared that health care should be a right, adding that wealthier people should help pay for those who will never be able to afford their own care.[3] Most Americans cannot afford to pay for more than minor medical procedures out of their own pockets. Insurance is the vehicle that finances the rest.[4] Thus, insurance has come to stand for health care.[5]

Yet buying insurance is not the same thing as buying health care. Conflating the two can exacerbate disagreements about the responsibilities of government, business, and individuals for health and health care.[6] Health reform proposals reflect different philosophies about who should be responsible for certain health conditions — society at large or the individual herself. Current health insurance reform proposals borrow from both camps, combining provisions

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based on actuarial fairness with provisions promoting social solidarity by prohibiting certain forms of risk rating and underwriting.

This essay argues that amalgamating reforms that serve inconsistent goals can perpetuate, rather than resolve, conflict. Part I suggests that combining commercial indemnity insurance and social insurance forges a contract for traditional indemnity insurance plus discretionary personal services — an "insurance + services" contract — which pulls the system in opposite directions. Part II examines a recent example of the service side of this insurance + services contract — coverage of so-called "wellness programs," which base premiums, discounts or rewards on meeting specific standards of behavior. Often justified on grounds of actuarial fairness, they foster the idea that certain health conditions are matters of personal responsibility. Yet, there has been virtually no discussion of what principles ought to govern the choice of conditions targeted by wellness programs. Experience to date, however, suggests that such programs are likely to disadvantage those most in need of social assistance. In the context of rising health care costs, such personal responsibility provisions may unravel the social solidarity that prompted reform in the first place.[7]

I conclude that using commercial insurance to provide access to care encourages reforms based on actuarial fairness promote the view that health is each person's personal responsibility. These reforms may return to us to the days before health insurance, and have the potential to undermine social solidarity beyond the insurance sphere.

I. Social solidarity and personal responsibility in health insurance

There are many explanations why the United States has never adopted a system for universal access to health care, much less national health insurance.[8]

Underlying much of the political disagreement are very different views about the nature of health care. At one end of a wide spectrum is the view a person is (or ought to be) responsible for her own health and pay for her own medical care like other ordinary consumer goods.[9] At the other end are those who find health is somehow special so that society should be responsible for ensuring everyone access to care, regardless of ability to pay.[10] Health reform proposals reflect these opposing views, and the difficulty of reconciling them undoubtedly has stymied agreement on reform. Without greater clarity about whether insurance should reflect social solidarity or personal responsibility, or which health conditions deserve social insurance coverage and which do not, gridlock is likely to continue.

Recent trends in health insurance in the United States reflect both these competing values.[11] On one hand, there are signs that the country is moving toward universal health insurance coverage for reasons of social solidarity. Public opinion polls report that a large majority of Americans favor universal access to care.[12] Health care is no longer affordable for most Americans without insurance.[13] Employment-based health insurance covers a declining proportion of nonelderly Americans.[14] This decline, however, has been offset by expansions in public (state) Medicaid and SCHIP programs.[15] Several states have adopted or are considering legislation to increase insurance coverage.[16] But state level reforms are limited by ERISA preemption,[17] and recent proposals for national reform at the federal level suggest that momentum for universal coverage is building.[18] Even employers may support reforms that include universal coverage.[19]

At the same time, a competing trend has emerged favoring increased personal responsibility for health and health insurance. The beginning of the twenty-first century saw a return to more traditional indemnity health insurance following the late 1990's backlash against managed care.[20] Although most health insurance plans still include

procedures for managing care, most private insurance companies see their plans as commercial insurance products covering specified losses, and not as a mechanism for financing universal access to care.[21] Continuing health care cost increases also put pressure on insurers, government, and employers to reduce the need for care, tie premiums to claims experience, and shift more costs onto insureds.[22] Health savings accounts are popular among some employers, because they make employees responsible for a portion of their health care expenses.[23] A recent innovation, wellness coverage, offers discounted premiums or rewards for employees who participate in programs to prevent health risks, such as smoking cessation programs, exercise programs, and blood pressure and cholesterol screening programs.[24] These programs, however, expand the concept of personal responsibility from financial liability to responsibility for one's own health status.

Social solidarity

Given the complexity of medicine and disease, there may be good reason to create health insurance structures that aim for both universality and some degree of personal responsibility in coverage. Nonetheless, those two goals pull insurance in opposite directions. This tension affects both private commercial insurance and public benefit programs, like Medicare, Medicaid or Veterans and military health benefits that are not formal insurance plans.

The concept of social solidarity embodies goals of mutual aid and support.[25] The idea is that we are all in this together, and no one should be abandoned. Such aspirations inspired early mutual aid societies to spread and share financial risks.[26] Where people are considered to be equally and randomly at risk for medical problems, it makes sense for everyone to chip in and make sure that, when injury or illness occurs, help is available to anyone who needs it.[27] To

fulfill their responsibilities to their populations, governments often adopt social insurance systems to finance health care.[28] The principle of mutual aid and support is evident in rules for universality of coverage and uniform premium rates. Most systems bar medical underwriting to exclude people from coverage and prohibit or limit segmented markets and risk classification. The defining feature is that people are not excluded or asked to pay more because of their own health status, health risks or medical claims experience.

Even in the absence of universal social insurance in the United States, state and federal laws move commercial insurance toward social solidarity goals. For example, laws requiring guaranteed issue preclude insurers from excluding certain people from the pool.[29] State laws requiring coverage of specific services (mandated benefits) embody social policies about what coverage must be available to all (except self-insured employee group plans exempted under ERISA). Most state laws forbid charging higher premiums to women, even if women are more likely than men to use medical care on average.[30] Many states also prohibit premium discrimination on the basis of genetic information.[31]

The federal Health Insurance Portability and Accountability Act (HIPAA)[32] prohibits certain group of health plans from discriminating in eligibility or premiums on the basis of health status factors, such as medical condition or claims experience.[33] More general anti-discrimination laws also foster social solidarity. For example, the federal Americans with Disabilities Act prohibits discrimination in employee health insurance coverage solely on the basis of disability.[34] Title VII of the Civil Rights Act of 1964 prohibits discrimination in employee benefits on the basis of race, color, religion, sex, or national origin.[35] Employee group health plans generally offer the same premium rate to all employees, regardless of age, health status, or claims experience. Offering the same coverage for the same premium regardless of age is a significant example of solidarity, since health costs tend to increase with age.[36]

Personal responsibility

Commercial insurance captures the concept of personal responsibility in efforts to achieve actuarial fairness. Here, the idea is that each person should pay for his own risks and no others. In contrast to social solidarity, the personal responsibility principle is that people are different and we should not be responsible for those who are different from us. Actuarially fair insurance policies classify and segregate insureds into groups according to the type and amount of risk they represent, with different coverage, exclusions, and premiums.[37] In health insurance, this means that the market for insurance is segmented into multiple categories with multiple products.

Commercial insurers use medical underwriting and risk rating to classify people. Medical underwriting, used primarily in individual policies in the United States, avoids insuring specific individuals for predictable (non-fortuitous) risks.[38] For coverage of other risks, actuarial fairness aligns premium rates with the individual's level of risk. Other payments, like the cost-sharing devices of deductibles and co-payments, serve both to discourage unnecessary medical care (and claims) and to engage the insured in effectively "insuring" her own losses to some degree. Coverage limits, although strictly a matter of covered losses, can also serve to discourage unnecessary care and claims.[39] For example, limits on services restrict the number of inpatient hospital days or physician office visits covered. Caps on paid claims, such as annual or lifetime limits on the dollar amount of health care expenditures covered, provide a ceiling on the insurer's risk.

The complicated terms of commercial health insurance policies may be an inevitable consequence of the difficulty of determining what should count as a loss. While a broken limb or heart attack presents an unmistakable claim on the need for medical care, many health conditions are more ambiguous. What,

if any, care is needed can often be debated, making the insurer's risk more difficult to calculate.[40] Moreover, the cost of care varies significantly around the country, yet continues to rise everywhere.[41] Such concerns may not be unique to health insurance, but are undoubtedly more intense in assessing health insurance claims. Indeed, health insurance may push the boundaries of insurable risks.

Insurance policies and service contracts

Fundamental to the concept of insurance is the premise that covered risks should be fortuitous — that is, unplanned and unanticipated.[42] State laws and market demand, however, have crafted exceptions to the principle in many health insurance policies. The consequence may be confusion about what counts as an insurable risk.

The best known exception is coverage of preventive services, such as immunizations, disease screening (e.g., mammograms), dental cleaning, prenatal care, well baby visits, and annual physical examinations. There are undisputed social policy reasons for these exceptions; such services can prevent disease and keep people healthy.[43] Requirements for insurance coverage are generally based on concerns that many people, especially low-income groups, would not obtain such services if they had to pay for them out of pocket. Insurance coverage encourages prevention by paying for it. Moreover, preventive services typically cost less than treatment for the disease. These are sound rationales for encouraging prevention, but they do not fit insurance well.

The use of insurance to achieve desirable public policy goals challenges the nature of commercial insurance. Preventive care is not a typical insurable risk, because it is predictable and under

the control of the insured. The specific services are explicitly paid for whenever the insured chooses to obtain them. Insurers can predict the cost of such coverage, but assume no risk, removing the agreement from of the realm of insurance. Instead, the insurance payments to health providers function like assets of the insured to pay for a defined set of services. The result looks more like a service contract than an insurance policy.

Health reimbursement accounts (HRAs) expand the service contract concept beyond preventive care.[44] A particular type of HRA, the health savings account (HSA), has become more attractive to individuals and employee group health plans since receiving favorable tax treatment.[45] Although not yet widespread, HRAs are the current paradigm for so-called "consumer-directed" care, described as giving consumers more choice than they had with regular health insurance, primarily managed care plans.[46] Both supporters and critics agree that such accounts are designed to make consumers more cost-conscious by forcing them to pay for a portion of their care.[47] Although there is as yet little data about how most individuals spend their account funds, it is likely that most are spent in preventive care, as described above, as well as less expensive, acute medical services, such as treatment for a sprained ankle, which are more discretionary or less costly than hospitalizations.[48] Shifting this kind of care out of the defined benefit package trims health plans of their coverage of some non-fortuitous risks. While there are limits on the type of care for which the funds can be used, HRA accounts move responsibility for seeking and paying for care back onto the individual.

Health reimbursement accounts embody the view of some health economists and policy analysts that health insurance is a personal financial asset that can be used to buy medical care at the consumer's discretion, a view at odds with that of insurance

purists. In these commentators' view, insurance distorts the market for health care by enabling, even encouraging, individuals to buy more care than they need, or at least more care than is economically efficient for the country.[49] Their focus of analysis is the purchase of health care; insurance is merely a source of funds for payment.

In contrast, the traditional insurance industry view is that its product is a promise to pay only for specified losses. In this view, an insurance policy is not a cash equivalent to pay for whatever the insured chooses to buy. Therefore, HRAs, like coverage of preventive services, distort insurance. While health economists argue that consumers should be deliberate, rational purchasers of care, insurers expect to pay only for fortuitous losses. Pairing HRAs with defined benefit insurance policies couples very different conceptions of the function of insurance.

Economists concerned about national health expenditures object to generous insurance policies on the ground that they buy too much care.[50] But, the reason we have insurance is to pay for losses that we could not otherwise afford. If health care is a consumer good, freely bought and sold in the marketplace, then it should not matter what resources consumers use to buy it. Wages, daddy's trust fund, and health insurance are all cash equivalents. Moreover, if health care is a consumer good, who cares what people buy? Why not let the market determine what services people value? Of course, the main reason for objecting to unrestrained spending is that it raises the price of care so that not everyone can afford it.[51] Yet unaffordability matters only if health care is something more than an ordinary consumer good, something that should be available to everyone regardless of ability to pay. Thus, the economic argument against buying too much care supports the idea of social solidarity in ensuring access to care for everyone. Paradoxically, however, the solution offered to rising health

care costs — making people responsible for more of their care — weakens social solidarity.

Summary

The exceptions to traditional indemnity insurance for insurable risks are usually justified on two grounds: cost (to society at large, government or private insurers, or employers who contribute to premiums); or social policy (to improve health, encourage "good" behavior or discourage "bad" behavior). In many cases, both reasons are intertwined, so that is difficult to disentangle one from another, as may be seen in the example of wellness programs discussed below. Adding exceptions for these reasons may make some sense in a universal social insurance system, where everyone is in the pool, to remove financial barriers to important services. Adding them to private insurance sold in the commercial market outside the context of a universal social insurance system, however, may simply widen the sphere of personal responsibility.

Neither social solidarity nor personal responsibility principles, by themselves, can explain or justify the package of health insurance reforms put forward today. Coverage of some conditions and services reflect social solidarity, while other provisions encourage personal responsibility and treat health care as a consumer good. Implicit in this division of reform provisions is the idea that some conditions are socially acceptable, such that all society ought to share (at least financial) responsibility for their prevention or consequences, while other conditions are socially unacceptable, so that individuals should shoulder the burden themselves.[52] Yet there has been no significant debate about what principles ought to govern classifying particular health conditions as either an individual responsibility or a social responsibility.

II. The peculiar case of wellness programs

The most recent examples of allocating health conditions to the personal responsibility side of the equation are wellness programs.[53] Although often offered as part of a health insurance plan, such programs function like service contracts, with the individual earning rewards for performing specific tasks (or incurring a loss for failing to do so). For example, those who get screened for hypertension or high cholesterol might receive a discount on their health plan premium. Those who attend regular exercise programs might avoid paying the plan's deductible. Those who take medication as prescribed might have their drug co-payment waived. Those who fill out a personal health history and agree to be monitored by a disease management group may get cash prizes. Some employees welcome the programs, while others object that they are intrusive and unrelated to job performance or consider them a mechanism to get rid of the employees most likely to incur expensive medical claims.[54] Even the *Wall Street Journal* worried in print that employers may be overreaching by monitoring employees' health.[55]

A wellness program uses risk data to selectively modify rates for individuals who are already in an insurance pool. In theory, it is the insured, instead of the insurer, who changes the rate—by complying with the program's requirements. Generally, however, everyone in the group who does not have a particular risk factor, like smoking or diabetes, receives a discount or reward. The effect is to charge higher rates to individuals with specific health risks or behaviors. The specific conditions for which financial differences are allowed offer some insight into what we hold people personally responsible for.

A well-publicized example was the plan adopted by Clarian Health, an Indiana hospital system, to charge employees bi-weekly fees if they failed to meet target health standards, beginning in

2009:[56] US$10 if BMI ≥ 30; $5 for blood pressure > 140/90; $5 for glucose levels > 120; $5 for low density lipoprotein Cholesterol > 130; $5 for smoking; and $5 for not completing a health assessment. After public opposition to its plan, Clarion made the plan voluntary and withdrew the penalties on those who fail to meet the targets. Instead, it will offer the same amounts as bonuses to those who voluntarily meet the targets.[57] The effect, however, may be the same.

Laws forbidding medical underwriting and basing premium rates on individual health risks would seem to prohibit this result. Nevertheless, wellness programs have joined preventive services as an exception to the fortuity principle in many health insurance plans. The tension between rewarding wellness and banning discrimination based on health risks, however, may be reflected in the fact that it took the federal government more than a decade to issue final regulations under the federal Health Insurance Portability and Accountability Act.[58] Like several health insurance reform proposals, the Act prohibits discrimination on the basis of health factors while simultaneously allowing group health plans to offer financial rewards for "adherence to programs of health promotion and disease prevention."[59] The regulations attempt to reconcile the exception for wellness programs with the general prohibition against discrimination on the basis of any health factor.

The difficulty of reconciling the two can be seen in examples of acceptable programs described in the regulations. Even programs that base rewards on an individual satisfying a health-related standard can qualify for the exception if they meet four criteria, which, judging from the examples, appears to be relatively easy to do.[60] The regulations approve a hypothetical wellness program that waives the $250 annual deductible for participants who have a body mass index (BMI) between 19 and 26. Those who are unable to lose enough weight for medical reasons can earn the reward by walking 20 minutes a day 3 days a week. A

medical condition prevents individual E from meeting either standard. The regulations approve a result in which the "plan agrees to make the discount available to E if E follows the physician's [unspecified] recommendations."[61]

It is hard to argue that this program does not discriminate on the basis of a health factor. The conclusion that it is not discriminatory relies on the idea that, if all else fails, health plans can force participants to follow a physician's recommendations. Although it is doubtful that employers could require employees to obey their physicians as a general condition of employment, some employers are refusing to hire smokers because smokers in general have higher health insurance claims than non-smokers.[62] The same reasoning could be applied to similarly costly conditions, such as obesity.[63]

One might argue that wellness programs simply offer rewards that would not otherwise be available. However, some programs do impose penalties. More important, the distinction between rewards and penalties is often in the eye of the beholder.[64] All these programs create incentives to conform to specific standards as a condition of employment or as a condition of obtaining insurance coverage. In principle, it is only the price of coverage, not coverage itself, that is conditional on compliance. Yet, if the costs of coverage depend on satisfying specific health standards, then costs are based on health factors. They are the same risk factors that insurers would ordinarily take into account in determining premium rates, absent a legal prohibition against discrimination. In effect, therefore, wellness programs reintroduce the very risk rating that legislation aimed at social solidarity initially forbade.

Wellness program goals

First adopted by a small (now growing) number of employee group health plans,[65] wellness programs are intended either to

keep employees healthy and productive or to reduce premiums (or both). State Medicaid and commercial insurance reform laws that allow financial incentives for wellness programs may have been adopted for either health or financial goals.[66] Private employers who support health goals, however, may need to see a financial return (or reduced costs) in order to sustain wellness programs.[67]

Whether wellness programs can achieve better health or cost savings remains to be seen. Their promise may not be realized without a long-term investment. Set up costs are concentrated in the early years, with savings beginning years later when (and if) participants avoid expensive services.[68] Full benefits to the insurer or employer depend on long-term enrollment by individual participants. In the United States, about 17 percent of participants in private health plans change plans every year.[69] This weakens the financial incentive for any single plan to offer wellness programs, unless competing plans have similar programs.

One probably ought not to expect financial miracles from wellness programs. Unless such programs stave off illnesses that are more expensive than other diseases not targeted, they may simply shift the causes, not the costs, of illness.[70] Preventive measures cannot guarantee good health or immortality.[71] Nor do they affect the cost of care, including preventive care, that is provided, which continues to rise.[72] Perhaps the best that may be hoped for is disease compression — postponing debilitating illness to very short period before death at a ripe old age.[73]

Implications for social solidarity

In addition to introducing personal responsibility into insurance pools, wellness programs depart from social solidarity in at least two other ways. First, to the extent that they succeed in improving health and reducing costs, they may benefit the federal

government more than the private sector, further dividing the country along lines of coverage. Current wellness programs target risk factors for chronic diseases, which account for about three-quarters of the costs of medical care in the U.S.[74] In general, chronic diseases and disabilities are more prevalent among populations who are low income, uninsured or covered by Medicaid or Medicare (including the elderly), than among those with commercial insurance.[75] This suggests that government has a larger financial stake in reducing the cost of chronic conditions than the private sector.[76] The Centers for Medicare and Medicaid and presidential candidates are already emphasizing disease prevention over expanding insurance coverage.[77] If these efforts do not reduce costs, government may consider more direct measures to ensure compliance with health standards.[78]

Another way in which wellness programs depart from social solidarity is by targeting risk factors that are more prevalent among disadvantaged populations than among those of higher socio-economic status. Health status is strongly correlated with income.[79] Chronic conditions are more common among lower income populations.[80] Diabetes disproportionately affects African Americans, Hispanics, Native Americans, and Alaska Natives.[81] Smoking is more prevalent among lower income groups.[82] Thus, the people most likely to be subject to wellness program requirements may be those who need insurance the most and can least afford higher costs. While such groups may benefit from the improved health promised by such programs, their circumstances raise questions about whether their participation is truly voluntary.

Risk factors that wellness programs target can be seen as conditions for which society holds individuals personally responsible. Such conditions change as science identifies new sources of risk and society alters its norms of behavior.[83] For example, smoking moved from a relatively common habit to pariah status in a few decades.[84] The fact that obesity is now called

an epidemic suggests little public tolerance for the overweight.[85] Diabetes, once considered out of anyone's control, also appears to be moving into the realm of personal responsibility. Significantly, however, wellness programs have not yet targeted other health risk factors, such as job stress and shift work.[86]

It is instructive to examine the conditions that are not (yet) considered suitable for personal responsibility. Among the health factors on which HIPAA prohibits discrimination are "participation in activities such as motorcycling, snowmobiling, all-terrain vehicle riding, horseback riding, skiing, and other similar activities."[87] It is possible that sports enthusiasts use less medical care or less costly care than people with chronic diseases.[88] Nonetheless, one might suspect that their exclusion from risk rating is based more on social preference than on financial considerations. Making sure that victims of injuries are covered for medical care seems like simple justice, even when they assume the physical risk of injury. But, then, why single out other conditions, especially those that are less likely to be voluntarily assumed? The only plausible reason would be the comparative cost of coverage. Yet, if cost is the real reason, then any comparably expensive condition, regardless of how acquired, should be treated in the same manner. [89] Of course that would return the entire enterprise to classifications based on individual health risks.

The absence of empirical support for distinguishing among conditions on the basis of costs and savings suggests that wellness programs may rely on unstated, perhaps unrecognized, bias against disadvantaged groups of people.

III. Conclusion

The peculiarly American mix of entitlement and personable responsibility in today's health reform proposals may be evidence

of our ambivalence about social solidarity and personal responsibility for health. It may also mask deep divisions in beliefs about whether society or the individual ought to be responsible for health. Trying to have it both ways may make it impossible to agree on sustainable reform.

What is missing from current health reform debates is any serious discussion of the role of insurance in defining responsibility for health. The use of market-based, private insurance to provide universal access to care has encouraged reforms based on actuarial fairness, which make everyone responsible for his own risks. A focus on medical care costs confuses the use of insurance with the purchase of consumer goods. Attempts to cabin the cost of medical services by selectively inserting elements of risk-based cost-sharing into insurance policies chip away at the general goal of universal coverage. Increased cost sharing encourages the belief that health is the personal responsibility of individuals, and not the responsibility of all society.

So far, increased cost sharing has been applied selectively. People are slotted into the actuarial fairness side of the equation ostensibly for reasons of public health or social costs. But, an underlying motivation may be prejudice against historically disenfranchised groups. Combining wellness programs with insurance tends to disadvantage those most in need of assistance, undermining social solidarity. In the long run, people may be excluded not only from affordable premiums, but also from jobs or eligibility for government services. In the absence of any explicit standard for selecting the conditions subject to higher payments, there is no principled limit to the scope of personal responsibility for one's health. If the standard is cost, however, then efforts to insert personal responsibility for health into social insurance reforms may presage a return to an era in which everyone was responsible for his own costs. After all, the

original argument for coverage based on cost was actuarial fairness.

Alternatively, if services to prevent illness and promote health and fitness become an accepted part of health insurance coverage, insurance may be transformed from its indemnity function into the role of financing personal services. In such circumstances, it will be difficult to place any boundaries on the demand for services or their costs. If preventive measures push expensive illness to later ages, then the federal government will have even more incentive to bring younger, healthier people into its risk pool in to spread the costs of the population it finances. In that case, the initial effort to achieve actuarial fairness may ultimately yield a form of government-sponsored social insurance.

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[6] *See, e.g.,* Enthoven, A. C., 1980. Health plan: the only practical solution to the soaring cost of medical care. Reading, MA: Addison-Wesley Publishing Company (proposing competing health maintenance organizations); Herzlinger, R. 2007. Who killed health care? New York: McGraw-Hill (arguing for a consumer-oriented system, with mandatory health insurance for

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[7] Stone, *supra* note 5 at 46 ("Insurance is a social institution that helps define norms and values in political culture, and ultimately shapes how citizens think about issues of membership, community, responsibility, and moral obligation.").

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[24] *See* Part II *infra*.

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[31] *See* National Conference of State Legislatures, 2005. Genetics & health insurance state anti-discrimination laws. Denver, CO. Washington, DC: National Conference of State Legislatures. Available at http://www.ncsl.org/programs/health/genetics/ndishlth.htm.

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[33] 29 U.S.C. § 1182.

[34] Americans with Disabilities Act of 1990, 104 Stat. 328, 42 U.S.C. § 12101 et seq.

[35] Civil Rights Act of 1964, as amended, 42 U.S.C. § 2000e.

[36] *See* Centers for Disease Control and Prevention. The Merck Company Foundation, 2007. State of aging and health in America 2007. Whitehouse Station, NJ: The Merck Company Foundation. Available at http://www.cdc.gov/aging/saha.htm (reporting that the "cost of providing health care for one person aged 65 or older is three to five times greater than the cost for someone younger than 65"); Borger, C. et al., 2006. Health spending projections through 2015: changes on the horizon. *Health Affairs,* 25 (2), p. W61-W73. *But see* Reinhardt, U.E., 2003. Does the aging of the population really drive the demand for health care?, *Health Affairs.* 22(6), p. 27-39. p. 34-35. (arguing that research shows that a gradually increasing elderly population is not likely to cause disproportionate national cost increases, and that labor and administrative costs may play more important roles in raising costs).

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[51] *See, e.g.,* Rice, T., 2003. The economics of health reconsidered. 2nd ed. Chicago, IL: Health Administration Press; Hall, M. A., 1997. Making medical spending decisions: the law, ethics, and economics of rationing mechanisms. New York: Oxford University Press. *See also* Collins, S. R., 2007. Consumer-drive health care: why it won't solve what ails the United States health system. *Journal of Legal Medicine*. 28 (1) 53-77 (summarizing studies finding that higher cost sharing discourages people from getting care, with people with incomes lower than $50,000 twice as likely to avoid or delay care as those in other plans); Havighurst, C. C. & Richman, B. D., 2006. Distributive injustice(s) in American health care. *Law & Contemporary Problems*. 69 (4), p. 1-77, p. 38-39 (arguing that the goal of reducing consumer demand for health services might have been better met by capping the "tax subsidy" or issuing government vouchers).

[52] It brings to mind the concept of the "deserving poor," used to distinguish those who deserved charity or government benefits from those who did not. *See* Handler, J. F. & Hollingsworth, E. J., 1971. The deserving poor: a study of welfare administration. Chicago: Markham; Rosenberg, C. E.,

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[56] McGregor, J., 2007. Being unhealthy could cost you: money. *Business Week,* Aug. 5. Available at www.businessweek.com/bwdaily/dnflash/content/aug2007/db2007081_804238.htm?chan=search.

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[58] Department of the Treasury. Department of Labor. Department of Health and Human Services, 2006. Nondiscrimination and wellness programs in health coverage in the group market: final rules. *Federal Register.* 71 (239) Dec. 13, p. 75013-75055. The final rules add parallel provisions to regulations implementing the Internal Revenue Code, the Employee Retirement Income Security Act, 29 U.S.C. § 1001 et seq., and HIPAA requirements for certain small group and individual plans added to the Public Health Service Act. *Id.*

[59] 29 U.S.C. § 1182 (a) (prohibiting group health plans from conditioning eligibility on a health factor); 29 U.S.C. § 1182 (b)(1) (forbidding group health plans from requiring "any individual (as a condition of enrollment or continued enrollment under the plan) to pay a premium or contribution which is greater than such premium or contribution for a similarly situated individual enrolled in the plan on the basis of any health status-related factor"); and 29 U.S.C. § 1182 (b)(2)(B) (providing that paragraph (1) shall not be

construed "to prevent a group health plan, and a health insurance issuer offering group health insurance coverage, from establishing premium discounts or rebates or modifying otherwise applicable copayments or deductibles in return for adherence to programs of health promotion and disease prevention.").

[60] The criteria are: (1) the value of the reward is not more than 20 percent of the premium for the participant (including both employer and employee contributions); (2) the program must be "reasonably designed to promote health or prevent disease"; (3) eligible individuals must be able to qualify for the reward at least once a year; and (4) the program must be available to all similarly situated individuals. 29 C.F.R. § 2590.702 (f)(2).

[61] 29 C.F.R. § 2590.702 (f) Example 4.

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[63] *See* Ostbye, T., 2007. Obesity and workers' compensation: results from the Duke Health and Safety Surveillance System. *Archives of Internal Medicine,* 167 (8), p. 766-773 (finding that obese workers had higher medical costs and worker compensation claims than non-obese employees).

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[66] *See, e.g.*, 2006 Mass. Acts 58, §54 (authorizing the Massachusetts Medicaid program to create wellness programs and to reduce MassHealth premiums or co-payments for "enrollees who comply with the goals of the wellness program"); §§ 76-79 (requiring community rating for commercial insurance without regard to health status but permitting premiums to vary based on wellness program usage, tobacco usage age, group size, industry, participation rate, geographic area, and benefit levels).

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[68] Leatherman, S. et al., 2003. The business case for quality: case studies and an analysis. *Health Affairs.* 22(2), p. 17-30. p. 17, 21 (reporting total expenditures of $330 per patient and $405 in savings over a 9-year period).

[69] Cunningham, P. J. & Kohn, L., 2000. Health plan switching: choice or circumstance? *Health Affairs,* 19(3), p. 158-164, p. 158, 159 (also finding that more that 2/3 changed plans because they changed employment or their employer changed the plans offered; 16% switched to a less expensive plan and about 8% moved to a plan they liked better).

[70] Leonhardt, D., 2007. Free lunch on health?: think again. *The New York Times,* Aug. 8. Available at www.nytimes.com/2007/08/08/business/08leonhardt.html?_r=1&oref=slogin; Targeting particular conditions may have unintended consequences. *See, e.g.*, Nissen, S. E. & Wolski, K., 2007. Effect of rosiglitazone on the risk of mycardial infarction and death from cardiovascular causes. *The New England Journal of Medicine,* 356(24), p. 2457-2471 (meta-analysis of studies, concluding that a drug widely used to treat type 2 diabetes may slightly increase the risk of risk of myocardial infarction and death from cardiovascular disease).

[71] *See* Allin, S. et al., 2004. Making decisions on public health: a review of eight countries. Copenhagen: European Observatory on Health Care (finding little empirical evidence on the effectiveness and costs of prevention programs); U.S. Congress. Congressional Budget Office, 2004. An analysis of the literature on disease management programs. Washington, DC: Congressional Budget Office; Russell, L. B.,1986. Is prevention better than cure?. Washington, DC: Brookings Institution (questioning broad prevention claims); *See also* Fronstin, P. 2002. Can "consumerism" slow the rate of health benefit cost increases?, *EBRI Issue Brief*, 247, July 2002 (reporting that 10% of the population accounted for 58% of health expenditures).

[72] *See* Aaron, H. J. & Schwartz, W. B., 1984. The painful prescription: rationing hospital care. Washington, DC: Brookings Institution Press (describing the role of technology in increasing costs and the need for rationing care).

[73] *See* Callahan, D., 1993. The troubled dream of life: in search of a peaceful death. New York: Simon & Schuster. p. 123.

[74] *See* Hoffman, C., Rice, D. & Sung, H-Y, 1996. Persons with chronic conditions: their prevalence and costs. *JAMA.* 276 (18) 1473-1479 (reporting that 76% of direct medical care costs in the U.S. are for chronic conditions); Sipkoff, M., 2003. Health plans

begin to address chronic care management. *Managed Care*. 12(12) 24-25, 29-31 (reporting approximately 78% of health care spending is on behalf of individuals with chronic conditions); Collins, S. et al., 2006. Health coverage for ailing baby boomers: findings from the Commonwealth Fund survey of older adults. Washington, DC: The Commonwealth Fund. (Publication No. 884) Available at www.commonwealthfund.org/usr_doc/884_Collins_hlt_coverage_aging_baby_boomers.pdf?section=4039.

[75] Centers for Disease Control and Prevention, 2006. Hyattsville, Maryland: National Center for Health Statistics. Available at www.cdc.gov/nchs/data/hus/hus06.pdf#088. Services for people with disabilities account for a disproportionately large share of Medicaid spending. Sommers, A. & Cohen, M., 2006. Medicaid's high cost enrollees: how much do they drive spending?: Washington, DC: Kaiser Commission on Medicaid and the Uninsured. The Kaiser Family Foundation. (Issue Paper 7490) p. 6, 8. Available at www.kff.org/medicaid/upload/7490.pdf (3.4% of all Medicaid enrollees were institutionalized and accounted for 31.6% of expenditures; non-institutionalized enrollees with disabilities represented 14.2% of enrollees and 30.6% of expenditures).

[76] *See* Blumberg, L. & Holahan, J., 2004. Government as reinsurer: potential impacts on public and private spending. *Inquiry*. 41(2), p. 130-143. *See also* Goetzel, R Z. et al., 2007. Can health promotions programs save medicare money? *Clinical Interventions in Aging*, 2(1), p. 117-122 (concluding that well-designed health promotion programs for older people could save Medicare money). *But see* (J. E. Wennberg & E. S. Fisher, eds., 2006. The care of patients with severe chronic illness: an online report on the Medicare program by the Dartmouth Atlas Project. Lebanon, NH: Center for the Evaluative Clinical Sciences (finding that Medicare could reduce chronic care costs by up to 30% by reducing the variability and inconsistency of services provided).

Available at www.dartmouthatlas.org/atlases/2006_Chronic_Care_Atlas.pdf.

[77] The CMS is to begin Senior Risk Reduction Demonstration, an experimental program of health promotion services for Medicare beneficiaries. *See also* Broder, D. S., 2007. A route to better care, *Washington Post,* June 3, B7 (describing the candidates' statements). *See also* Department of Health and Human Services. Centers for Medicare & Medicaid Services, 2006. West Virginia Medicaid Member Agreement. Baltimore, Maryland: Centers for Medicaid and State Operations. Available at www.wvdhhr.org/bms/oAdministration/bms_admin_WV_SPA06-02_20060503.pdf (tiered benefit packages based on compliance with health goals).

[78] *See* Tesh, S. N., 1988. Hidden arguments: political ideology and disease prevention policy. New Brunswick, NJ: Rutgers University Press. p. 46 (arguing that state laws targeting individual conduct were prompted by a need to reduce health care costs or to lower mortality rates); Lupton, D., 1995. The imperative of health: public health and the regulated body. London : Sage.

[79] *See* Institute of Medicine. Committee on the Consequences of Uninsurance, 2003. A shared destiny: community effects of uninsurance. Washington, DC: The National Academies Press; M. Marmot & R. G. Wilkinson, eds., 1998. Social determinants of health: the solid facts. Copenhagen: World Health Organization; Wilkinson, R. 1996. Unhealthy societies: the afflictions of inequality. New York: Routledge; Centers for Disease Control and Prevention, 2006. Hyattsville, Maryland: National Center for Health Statistics. p. 32-41.

[80] Centers for Disease Control and Prevention, 2006. Hyattsville, Maryland: National Center for Health Statistics. p. 42; Islam, M. K. et al., 2006. Social capital and health: does egalitarianism matter?: a literature review. *International Journal for Equity in Health,* 5 (3), p. 1-28.

[81] Gold, M. et al., 2007. Study of Federal spending on diabetes: an opportunity for change: executive summary. Princeton, NJ. Washington, DC: National Changing Diabetes Program. Mathematica Policy Research. p.1 (finding that federal government expenditures accounted for "12 percent of the $645 billion in total federal health spending" in 2005), available at www.mathematica-mpr.com/publications/PDFs/FederalSpending.pdf.

[82] *See* Barbeau, E. M., Krieger, N. & Soobader, M-J., 2004. Working class matters: socioeconomic disadvantage, race/ethnicity, gender & smoking in NHIS 2000. *American Journal of Public Health*. 94 (2), p. 269-278 (reporting smoking is associated with working class jobs, low educational levels, and low income).

[83] *See generally* Barsky, A. J., 1988. Worried sick: our troubled quest for wellness. Boston: Little Brown (arguing that as population health improves, Americans focus on lesser risks).

[84] *See* R. L. Rabin & S. D. Sugarman, eds., 1993. Smoking policy: law, policy & culture. New York, Oxford University Press. p 3-21 (describing how public perceptions of personal responsibility for risk creation affect policy choices).

[85] *See* Hedley, A. A. et al., 2004. Prevalence of overweight and obesity among US children, adolescents, and adults, 1999-2002. *JAMA,* 291 (23), p. 2847-2850. *But see* Flegal, K. M. et al., 2005. Excess deaths associated with underweight, overweight, and obesity. *JAMA*, 293 (15), p. 1861-1867 (finding obesity, but not overweight, associated with excess mortality).

[86] *See* Kawachi, I., 2006. Injustice at work and health: causation or correlation? *Occupational and Environmental Medicine,* 63(9), p. 578-579 (analyzing the literature); McEwen, B. S., 1998. Protective and damaging effects of stress mediators. *New England Journal of Medicine,* 338 (3), p. 171-179 (explaining the physiologic response to stress and its links to obesity and hypertension).

[87] 26 C.F.R. § 54.9802-1(f)(ii); 29 C.F.R. § 2590.702(f)(ii); 45 C.F.R. § 146.121(f)(ii).

[88] *See, e.g.*, List of Top 10 Summer Sports with most injuries provides warning for Olympic enthusiasts, 2000. *Medscape Medical News*, Sept. 1. Available at http://www.medscape.com/viewarticle/412143.

(listing the top 10 summer recreational activities, with number of injuries, and total costs of injury, including medical, legal and other costs: Basketball (1,633,905; $19.7 billion); Bicycles (1,498,252; $28.6 billion); Baseball (492,832; $6.6 billion); Soccer (477,647; $6.7 billion); Softball (406,381; $5.1 billion); Trampolines (246,875; $4.1 billion); Inline Skating (233,806; $4.2 billion); Horseback riding (196,260; $4.9 billion); Weightlifting (189,942; $2.7 billion); Volleyball (187,391; $2.1 billion).

[89] *See* Olin, G. L. & Rhoades, J. A., 2005. The five most costly medical conditions 1997 and 2002: estimates for the U.S. civilian noninstitutionalized population. Rockville, MD: Agency for Healthcare Research and Quality. (Medical Care Expenditure Panel Survey. Statistical Brief No. 80).

Rationing American Style*

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The great myth of American health care is that "Americans don't ration health care." The truth is that Americans ration medical care all the time: by price, by insurance coverage, by geography, and even by race and ethnicity. But because as a culture we want to believe that we put such a high value on health and autonomy, we cannot admit that we ration even to ourselves. Even those who know how the system works call it "quiet" or "silent" rationing.[1] So when Americans talk about rationing, we almost always complain about how the government is preventing people from getting needed medical care by its arbitrary rules. And the most consistently savaged government agency is the Food and Drug Administration, the agency whose job it is to make sure that drugs and medical devices are "safe and effective" before they are allowed on the market.

The thesis of this chapter is that Americans will never be able to face explicit medical rationing until we can face our mortality, and, as illustrated by the all-too-common case of cancer, we are nowhere near being able to come to grips with our mortality today. Thus, rationing American style, that is, "quiet" rationing, will remain the rule in the United States for the foreseeable future.

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The inability of Americans to accept their mortality, and our concurrent belief that simply spending more money on medical care will somehow prevent death, is no secret. J. M. Coetzee's violent, anti-apartheid *Age of Iron,* for example, is written as a letter by a retired classics professor, Mrs. Curren, to her daughter who lives in the United States. Mrs. Curren is dying of cancer, and her daughter advises her to come to the United States for treatment. She replies, "I can't afford to die in America. No one can, except Americans." Dying of cancer has been considered a "hard death" for at least a century, and there have been national efforts in the United States to cure cancer that date from the establishment of the National Cancer Institute (NCI) in 1937, later intensified by the declaration of a "war on cancer" with the National Cancer Act of 1971.[2] More recently, calls for more cancer research have followed the announcement by Elizabeth Edwards, wife of presidential candidate John Edwards, that her cancer is no longer considered curable.

Frustration with the methods and slow progress of mainstream medical research has helped fuel a resistance movement that distrusts both conventional medicine and government, and that has called for the recognition of a right for terminally ill cancer patients to have access to any drugs they want to take. Prominent examples include the popularity of Krebiozen in the 1950s and of laetrile in the 1970s. As an NCI spokesperson put it more than 20 years ago when thousands of people were calling the NCI hotline pleading for access to interleukin-2, "What the callers are saying is, 'Our mother, our brother, our sister is dying at this very moment. We have nothing to lose.'"[2] Since then, more novel drugs have become available, and some have demonstrated evidence of at least months of prolongation of progression free survival in clinical trials. Families search the Internet for clinical trials, new drugs, and even untested chemicals, such as dichloracetate, that seem to offer them some hope. In

addition, basing advocacy on their personal experiences with cancer, many families have taken out their frustrations on the Food and Drug Administration (FDA), which they see as a government agency denying them access to potentially life-saving treatments.

In May 2006 some of these families won an apparent major legal victory when the U.S. Court of Appeals for the District of Columbia, in the case of *Abigail Alliance v. Von Eschenbach,*[3] agreed with their argument that patients with cancer have a constitutional right of access to investigational drugs. This opinion occasioned heated controversy, including new FDA proposals to make experimental drugs more easily available to patients not enrolled in research protocols.[4] Ultimately however, the opinion was vacated, reargued, and reversed by the full bench of the U.S. Court of Appeals for the District of Columbia in July 2007.[5] The debate fostered by the opinion nonetheless opened a recurring question at the heart of our anti-rationing medical system: do cancer patients for whom there are no effective treatments have a right to take experimental drugs their physicians think might be beneficial, even in the absence of evidence of effectiveness?

The constitutional controversy

A lobbying group named the Abigail Alliance for Better Access to Developmental Drugs (the Alliance) sued the FDA to prevent it from enforcing its policy of prohibiting the sale of drugs that had not been proven effective to competent adult patients who are terminally ill and have no alternative treatment options. The Abigail Alliance is named after Abigail Burroughs, who was diagnosed with squamous cell carcinoma of the head and neck when she was only 19 years old. Two years after the diagnosis, in 2001, she died. Before her death she had tried unsuccessfully to

obtain experimental drugs on a compassionate use basis from ImClone and AstraZeneca, and was accepted for a clinical trial only shortly before her death. Her father founded the Abigail Alliance in her memory.[6]

In 2003 the Alliance had asked the FDA to promulgate new regulations that made post-Phase I new drugs available to terminally ill patients who were not in clinical trials. The FDA rejected this suggestion, which led to the lawsuit which alleged, among other things, that the FDA's policy was resulting in deaths and that terminally ill patients should have the right "to assume the risks if their physicians advise them that a treatment may save or prolong their lives and if they have no other viable options."[3]

The trial court dismissed the Alliance's lawsuit for failure to state a proper legal claim. The appeals court, in a two-to-one opinion written by Judge Judith Rogers who was joined by Judge Douglas Ginsburg, reversed. They concluded that competent, terminally ill adult patients have a "right to access to potentially life-saving post-Phase I investigational new drugs, upon a doctor's advice, even where that medicine carries risks for the patient" and remanded the case to the trial court to determine if the FDA's current policy violated that right.[3]

The right to life

The appeals court thought that the relevant constitutional issue was spelled out in the due process clause of the Fifth Amendment, which provides that "no person shall be...deprived of life, liberty, or property without due process of law." The question, as the court put it, was whether the due process clause "protects the right of terminally ill patients to make an informed decision that may prolong life, specifically by use of potentially life-saving new drugs that the FDA has yet to approve for

commercial marketing but that the FDA has determined, after Phase I clinical human trials, are safe enough for further testing on a substantial number of human beings."[3] The court understood that new fundamental constitutional rights are not easily found, and must be capable of "careful description," but thought that Abigail Alliance's proposed right qualified because, "the Alliance asks only that the decision to assume these known or unknown risks [of a post-phase 1 drug] be left to the terminally ill patient [and his or her physician] and not to the FDA."[3]

The court supported its conclusion by finding that this right has deep legal roots, citing old British cases for the proposition that there is a right to self-defense and a right to self-preservation, and concluding that "Barring a terminally ill patient from the use of a potentially *life-saving treatment* impinges on this right of self-preservation."[3] (emphasis supplied) In a footnote, the court restated this proposition: "The fundamental right to take action, even risky action, free from government interference, in order to save one's own life undergirds the court's decision."[3] Ultimately, the court relied almost exclusively on the *Cruzan* case[7] which recognized the right of a competent adult to refuse life-sustaining treatment, including a feeding tube, saying:

The logical corollary is that an individual must also be free to decide for herself whether to assume any known or unknown risks of taking a medication that might prolong her life. Like the right claimed in *Cruzan,* the right claimed by the Alliance to be free of FDA imposition does not involve treatment by the government or a government subsidy. Rather, much as the guardians of the comatose patient in *Cruzan* did, *the Alliance seeks to have the government step aside* by changing its policy so the individual right of self-determination is not violated.[3] (emphasis supplied)

The court concluded that another opinion, the 1979 unanimous laetrile decision, *Rutherford,* in which the U.S.

Supreme Court held that Congress had made no exceptions for terminally ill cancer patients in the FDA law governing drug safety regulation, was not relevant.[8] It decided this because the Supreme Court never reached the question of whether terminally ill cancer patients had a constitutional right to take whatever drugs their physicians prescribed, and ruled that even if it had, laetrile was not a similar drug because it had never had a Phase I human trial.

The dissent

Judge Thomas Griffith, the dissenting judge, argued that the constitutional right the majority found simply does not exist. He noted, for example, that to be recognized as a fundamental right, there must be "evidence that the 'asserted right has any place in our Nation's traditions.' Quite simply, the majority has provided no evidence of a right, deeply rooted in our Nation's history and traditions, to procure and use experimental drugs."[3] He further noted that the British cases are examples of "abstract concepts of personal autonomy" that provide insufficient evidence of the existence of a fundamental right. Moreover, "The history of drug regulation in this country does not evidence a tradition of protecting a right of access to drugs; instead, it evidences government responding to new risks as they are presented."[3]

As to *Cruzan,* Judge Griffith argued that "A tradition of protecting individual *freedom* from life-saving, but forced, medical treatment [based on battery] does not evidence a constitutional tradition of providing affirmative *access* to a potentially harmful, even fatal, commercial good."[3] As to the laetrile case, he noted simply that the legislation governing the FDA has "no implicit exemption for drugs used by the terminally ill." He quoted the Court: "the FDA generally considers a drug safe when the

expected therapeutic gain justifies the risk entailed by its use. For the terminally ill, as for anyone else, a drug is unsafe if its potential for inflicting death or physical injury is not offset by the possibility of therapeutic benefit."[3,8]

Finally the dissenting judge argued that if the new constitutional right is accepted, it is unlikely to be limited to only terminally ill patients seeking post-Phase I drugs. Specifically, the judge asked if the right must also apply to patients with "serious medical conditions," to patients who "cannot afford potentially life-saving treatment," or to patients whose physicians believe "marijuana for medicinal purposes... is potentially life saving?" The judge continued, "Perhaps most significantly, what potential must a treatment have in order for the Constitution to mandate access?"[3]

Discussion

The stories of dying patients trying unsuccessfully to enroll in clinical trials are compelling, and the current U.S. system of ad hoc exceptions to safety and efficacy requirements is deeply flawed. Nonetheless, the central constitutional question raised in this case is more abstract and rests on determining whether this case is or is not like the right-to-refuse-treatment case of Nancy Cruzan, a woman in a permanent vegetative state whose family wanted tube feeding discontinued because they believed that is what Nancy herself would have wanted. I do not think *Abigail Alliance* is like *Cruzan*. It is instead almost identical to the physician-assisted suicide cases in which a terminally ill patient is seeking to end his or her life using physician-prescribed drugs because life has become intolerably burdensome.

The U.S. Supreme Court has decided unanimously that no such right exists.[9, 10] First, there is no history of support for this right.

And second, although the right seems narrowly defined, it is very unclear to whom it should apply. Why only terminally ill patients? Don't patients in extreme pain that cannot be alleviated have even a stronger interest in suicide? And why is the physician necessary, or why are physician-prescribed drugs the only acceptable method? None of these questions can be answered by examining the Constitution.[11]

Similarly in *Abigail Alliance,* as the dissenting judge suggests, the new constitutional right proposed is much more like a policy statement than a constitutional right. Again, why just terminally ill patients? And why involve a physician at all? If it is the patient's right to autonomy, why isn't the requirement of a government-licensed physician's recommendation at least as burdensome as the requirement of the FDA's approval of the experimental drug? And why would this new constitutional right only apply to access to post-Phase I drugs? Why not access to medical devices, like the artificial heart, or even to schedule I controlled substances, like marijuana or LSD? If it is a constitutional right, these should be available too, at least unless the state can demonstrate a "compelling interest" in regulating them.

This reasoning explains why the full Circuit Court reversed this opinion (with the 2 judges previously in the majority becoming the two dissenting judges in the new 8 to 2 opinion of the full bench).[5] The Circuit Court upheld the FDA's position and rejected the creation of a new constitutional right for terminally ill patients, for the same reasons that the U.S. Supreme Court had rejected the "right" of terminally ill patients to have access to physician-prescribed drugs they could use to end their lives.[9-11] The U.S. Supreme Court then ended *Abigail Alliance* case in January 2008, when it refused to consider an appeal of the Circuit Court decision.

This is not, however, the end of the matter. Attempts to change the law will continue in other forums, similar to the

physician-assisted suicide cases, in which the fight just shifted to the states (although only one so far, Oregon, has provided physicians with immunity for prescribing life-ending drugs to their competent, terminally ill patients).[12] In this case, the debate will continue in the forum in which it began — the FDA — and in Congress, which created the FDA in the first place.

Congress

Congressional action also had its birth with the story of one cancer patient, and was also heavily influenced by a controversy over the removal of a feeding tube. "Terri's Law" was enacted in Florida in 2003 to try to prevent the removal of a feeding tube from Terri Schiavo, in a case substantially identical to *Cruzan*, which is the case primarily relied on by the majority in *Abigail Alliance*. Terri's "case" went national two years later.[13] In the midst of it, in March 2005, the *Wall Street Journal* asserted editorially, "If Terri Schiavo deserves emergency federal intervention to save her life, people like Kianna Karnes deserve it even more."[14] The title of the editorial was, "How About a 'Kianna's Law?" Kianna Karnes was at the time a 44 year old mother of four who was dying of kidney cancer. Her only hope of survival, according to the editorial, was to gain access to one of two experimental drugs in clinical trials, but neither company running the trials (Bayer and Pfizer) would make the drugs available to her on a compassionate use basis. This was because, according to the *Journal,* the FDA "makes it all but impossible" for the manufacturers "to provide them to terminal patients on a 'compassionate use' basis."[14]

Almost immediately after the editorial appeared both drug manufacturers contacted Kianna's physicians to discuss the appropriateness of releasing the drugs to her. But within two days

of the editorial, she was dead. The *Wall Street Journal* editorialized, "isn't it a national scandal that cancer sufferers should have to be written about in The Wall Street Journal to be offered legal access to emerging therapies once they've run out of other options?"[15] It noted that Mrs. Karnes' father, John Rowe, himself a leukemia survivor, was now working with the Abigail Alliance on a "Kianna's Law." That law, formally entitled the "Access, Compassion, Care, and Ethics for Seriously Ill Patients Act" or the "ACCESS Act," was introduced in November 2005 and is an attempt to make it much easier for seriously ill patients to gain access to experimental drugs.[16,17]

The proposed Act began with a series of congressional "findings" — statements that Congress asserts as facts – including most centrally that "Seriously ill patients have a right to access to available investigational drugs, biological products, and devices." The Act does not define "seriously ill patients," but one of its findings suggests that they include "patients who face morbidity or death from their disease," which would seem to cover just about every person with a "serious" disease. The Act permits the sponsor of an investigational drug, biological product or device to apply for Tier I approval based on (i) data from a completed Phase I trial, (ii) "preliminary evidence that the product may be effective against a serious or life-threatening condition or disease...", and (iii) an assurance that the clinical trial will continue. The standard to be used in approving the application is that "the potential risk to a patient of the condition or disease outweighs the potential risk of the product, and the product may possibly provide benefit to the patient..."[17]

The labeling of the product shall state that it is for use by a patient whose physician has documented in writing that the patient has exhausted all approved treatment options and has been unsuccessful in obtaining treatment with an investigational drug for which the patient is a reasonable candidate. The patient

must provide written informed consent, but must also sign "a written waiver of the right to sue the manufacturer or sponsor of the drug, biological product, or device, or the physicians who prescribed the product or the institution where it was administered, for an adverse event caused by the product, which shall be binding in every State and Federal court."[17]

Although Congress is the proper forum to address this issue, this initial attempt has some of the same problems as the *Abigail Alliance* decision: first, the patients it applies to are not well identified, although the group is much broader than terminally ill and seems to encompass virtually any sick person without a conventional treatment that works; and second, treatment is confused with research, and clinical research is equated with clinical care. Most troubling, however, is that patient-subjects are asked to take on all of the risks of the uncontrolled experiments; current research rules — which prohibit mandatory waivers of rights by research subjects — are to be amended to require such waivers as a price of obtaining the investigational agent. This is ethically wrong, and an attempt to convert the FDA from a patient-protection agency into a pharmaceutical and biotech industry promotion agency.

FDA proposal

After the FDA lost the May 2006 decision in *Abigail Alliance,* it began to consider amending its rules to encourage more drug manufacturers to offer their experimental agents through compassionate use programs.[4] These programs had first come into prominence during the early days of HIV/AIDS when there were no effective treatments and AIDS activists demanded that they have early access to investigational drugs because, in the words of their inaccurate slogan, "A Research Trial is Treatment

Too."[18] In early December 2006 the FDA issued a set of proposed regulations with a press release entitled "FDA Proposes Rules Overhaul to Expand Availability of Experimental Drugs." The title of the proposed regulations could have been taken from an ACT-UP agenda: "Expanded Access to Investigational Drugs for Treatment Use."[19]

The FDA's Expanded Access proposal adopts the expansive language later used by Congress in terms of covered patients, defining them as "seriously ill patients when there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the patient's disease or condition."[4] Manufacturers are required to file an "expanded access submission," and the product must be administered or dispensed by a licensed physician who will be considered an "investigator," with all the reporting requirements that role has.[3]

Of course, the major problem with expanded access or compassionate use programs has never been the FDA; rather, it has been the manufacturers who have no incentives to make their products available outside of clinical trials, because this may make it more difficult to recruit research subjects, could subject the manufacturer to liability for serious adverse reactions, and cost recovery has been uncertain. [4, 16, 20] The drug companies are right to worry that the approaches of the judiciary, Congress, and FDA will probably make clinical trials more difficult to conduct, because few seriously ill patients who have exhausted conventional treatments would rather be randomly assigned to an investigational drug than have a guarantee that they will receive the investigational drug their physician recommends for them. This could result in significant delays in the approval and overall availability of drugs that demonstrate effectiveness — a result no one favors. Even if patients with cancer are willing buyers, drug manufacturers are not willing sellers in this context.

Physicians and patients

The cover story for all of the proposed changes is patient choice. But without scientific evidence choice cannot be informed, and fear of death will predictably overwhelm fear of unknown risks. This is understandable. As Jay Katz, the leading scholar on informed consent has noted, when medical science seems impotent to fight nature, "all kinds of senseless interventions are tried in an unconscious effort to cure the incurable magically through a 'wonder drug,' a novel surgical procedure, or a penetrating psychological interpretation."[21]

Another *Wall Street Journal* article, entitled "Saying No to Penelope," illustrates the impossibility of limiting access to unproven cancer drugs to competent adults. The article tells the story of 4-year-old Penelope, who is dying from neuroblastoma that has proved resistant to all conventional treatments. Her parents seek "anything that has a prayer of saving her." In her father's words, "The chance of anything bringing her back from the abyss now is very low. But the only thing I know for sure is if we don't treat her she will die." With Penelope hospitalized and in pain, her parents continue "searching Penelope's big brown eyes for clues as to how long she wants to continue to battle for life."

It has been suggested that a physician's supervision can safeguard against "magical thinking" and help make informed consent real.[22] But as Katz has noted, although physicians (and he could have added, drug companies) often justify such last-ditch interventions as simply being responsive to patient needs, they "may turn out to be a projection of their own needs onto patients."[21] This certainly seems to be the case in the provision of Kianna's Law that requires the patient to waive all of his or her rights to sue the physician and manufacturer for injury.

Government and the market

There is another recurrent theme: the belief that government is hurting its citizens by preventing them from getting access to medicines that can help them, and that the market if left alone would be a better solution. The last time the U.S. Supreme Court dealt with the rights of terminally ill cancer patients to obtain unapproved drugs was in the context of laetrile. The *Abigail Alliance* court was correct to note that laetrile had never had a phase l trial, but every indication was that the drug, known as vitamin B17, was harmless, albeit also ineffective against cancer.

Laetrile itself became a legal *cause celebre* in 1972 when the Alameda County California district attorney arrested physician John A. Richardson and charged him with multiple violations of the state's cancer quackery laws. Richardson was a member of the John Birch Society, and this organization quickly formed the Committee for Freedom of Choice in Cancer Therapy, ultimately setting up 127 committees nation wide.[23] It took another seven years before the FDA prevailed in its case before the Supreme Court.[8] The basic arguments against FDA regulation remain the same today, i.e., the FDA follows a "paternalistic public policy that prevents individuals from exercising their own judgment about risks and benefits. If the FDA must err, it should be on the side of patients' freedom to choose."[24]

Public policy

The FDA will prevail before the U.S. Supreme Court again, should any future case like this get reviewed there. This is not only because there is (and can be) no constitutional right to access to whatever substance a patient, and/or a patient's physician thinks

might be helpful in the absence of evidence. And even if there were, the state has the same compelling interest in approving drugs as it has in licensing physicians, i.e. protecting the health of the public. From a public policy viewpoint, the original *Abigail Alliance* court, Congress, and the FDA all seem to be suffering from the "therapeutic illusion" in which research, designed to test a hypothesis for society, is confused with treatment, done for the best interests of individual patients.[21,25,26] Of course there is a continuum, and it is understandable that many patients with cancer, told that there is nothing conventional medicine can do for them, will want access to whatever is available in or outside the context of a clinical trial. But this is a problem for patients, physicians, the FDA, and drug manufacturers. First because terminally ill patients can be harmed and exploited; there really are better and worse ways to die. Second, it is only through research, not "treatment," that cancer may become a chronic illness that is treated with a complex array of drugs, given either together or in a progression.[27,28] The right to choose in medicine is a central patient right: but the choices can and should be limited to reasonable medical alternatives, which themselves are based on evidence.

This is good public policy, but it is much easier said than done.[29] Death is feared, and even dreaded in our society, and few of us are likely to be able to die at home, at peace, with our loved ones in attendance, without seeking the "latest new treatment." There is always something new to try, and there is almost always anecdotal evidence that it could help. This is one reason that even extremely high prices do not affect demand for cancer drugs, even ones that add little or no survival time. And of course, as long as Americans, and their health insurers, are willing, even eager, to pay almost any price for even a low probability of a brief extension of life, rationing any more beneficial forms of health care will not even be considered, at least not openly and honestly.

When does caring for the patient demand primary attention to palliation rather than to long-shot, high-risk, investigational interventions? Coetzee's Mrs. Curren, who rejected novel medical treatment for her cancer and insisted on dying at home, told her physician, whom she saw as "withdrawing" from her after giving her a terminal prognosis — "His allegiance is to the living, not the dying." — "I have no illusions about my condition, doctor. It is not [experimental] care I need, just help with the pain."

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The Role of Race in Drug Development

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Introduction

Racial classifications are increasingly being used in the development and marketing of drugs by pharmaceutical companies that portray their products as necessary tools for reducing health disparities among racial and ethnic groups in the United States. Significant gaps in the health status of such groups in the United States have persisted over the last several decades, despite indications of overall improvement in the health of white Americans. It is generally recognized that such disparities exist and reducing disparities is a national priority.[1] Whether race based drugs are a solution to the problem is highly debated by scientists, clinicians and policy analysts. In 2005 the Food and Drug Administration (FDA) added to the controversy when it approved the drug BiDil specifically for use in treating African-Americans with heart failure. This essay uses the example of BiDil to illustrate the dilemmas presented by the development of race based medicines and to examine the meaning of race, particularly the relationship between race and genetic variation. It concludes that the evidence weighs against using race as a proxy for individual genetic variation.

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The BiDil controversy

BiDil is the trade name for an anti-hypertensive drug that combines two older generic drugs (hydralazine and isosorbide dinitrate) into one pill.[2] Federal approval of the drug in 2005 was newsworthy primarily because the FDA identified BiDil as an adjunct therapy for treating severe heart failure in self-identified Black patients.[3] The FDA had never approved a drug for use by a specific racial group before, and reactions to the decision ranged from celebration to outrage. Not surprisingly, the celebratory camp included NitroMed, Inc., the company in control of the patent rights for the drug at the time of the FDA announcement, and others who had been involved in bringing the drug to market. NitroMed had estimated that annual sales from BiDil could reach $350 million within a few years.[4] With a patent that would run until 2020, the company had reason to cheer its investment in the drug. Given the long history of the drug's development (discussed below), others involved in bringing the drug to market were undoubtedly also relieved to finally reach this positive endpoint. But those who were financially invested in developing BiDil were not alone in reacting positively to the FDA's approval of the combination drug. Many clinicians and health care analysts hailed the drug as an important advance in efforts to improve outcomes for African Americans suffering from heart failure and applauded the FDA's decision as the only responsible action it could have taken.[5, 6]

Despite such favorable responses, the FDA's evaluation of the drug has also been the target of significant criticism. Some analysts faulted the FDA for making a decision based on questionable science.[7] Others viewed the agency as succumbing too readily to pressures from a company intent on capturing a niche market and a society in need of interventions to reduce racial disparities.[8] Another group of critics focused on the

harmful effects that the message implicit in identifying a drug as race specific — that race is biological — would likely have on efforts to reduce the health disparities experienced by racial and ethnic minorities it the United States.[9] A review of the history that preceded the approval of BiDil is helpful in understanding the bases for these criticisms.

BiDil's complex history

The story of BiDil began 30 years ago when Jay Cohn, a cardiologist from the University of Minnesota, pursued his idea of using a combination of two vasodilators (hydralazine and isosorbide dinitrate) to develop a more effective treatment for heart failure than the standard therapies.[10] Throughout the 1980's Cohn studied the effects of adding this "H-I" combination to standard treatment regimens in the Veterans Administration Cooperative Vasodilator Heart Failure Trials (V-HeFT I and V-HeFT II). At the conclusion of V-HeFT I, Cohn, along with other researchers, reported a reduction in mortality in the group receiving the H-I combination, but admitted that the difference in mortality between that group and the placebo arm of the study was of only "borderline statistical significance".[11] In the V-HeFT II trial, the H-I combination as an adjunct to standard therapies was compared to another adjunct, enalapril, an angiotensin-converting enzyme (ACE) inhibitor. At this trial's conclusion, the ACE inhibitor seemed to exceed the effects of Cohn's combination drugs for some patients.[12] But those who do not respond to or are unable to tolerate enalapril were still in need of effective therapies, and Cohn stuck with his investment in the H-I combination and faith in the drug's potential to help those patients.

While the V-HeFT trials were underway Cohn had obtained a patent for a method of combining two blood pressure medications

to treat heart failure in the general population and subsequently licensed that patent to Medco, a pharmaceutical company that developed a pill (under the trade name BiDil) that combined the two drugs in a fixed dose. Medco then sought FDA approval to market BiDil as a treatment for heart failure. Their new drug application (NDA) was based on the data from the V-HeFT trials showing that the combination drug had benefited some patients. However, the FDA concluded that the data was not sufficient to satisfy its approval criteria and in 1997 rejected the company's application. Medco subsequently abandoned its efforts to commercialize the drug and the property rights reverted to Cohn.

Still clinging to his belief in BiDil, Cohn revisited data from the V-HeFT trials to compare the response of Black subjects to White subjects in those prior studies. This retrospective analysis led him to conclude that ACE inhibitors seemed to provide benefit for White subjects and that the H-I combination might have a similar advantage for Black patients.[13] Although responses to the drugs were not uniform within either racial group, he concluded that prospective trials conducted with a significant number of African American patients were warranted to determine if his observation about the combo drug had real merit. Such trials became possible after Cohn licensed rights to the drug to a different company, NitroMed, Inc.

Once NitroMed obtained a property interest in BiDil, the company consulted with the FDA about seeking approval of BiDil as a race-specific drug.[14] The agency confirmed that its approval would be contingent upon a clinical trial demonstrating efficacy for African American patients. However, the agency didn't think that a study comparing Black and White patients would be necessary given the results of the V-HeFT studies and encouraged NitroMed to conduct a single population trial instead.[1515] Temple, R., Stockbridge, N., BiDil for Heart Failure in Black Patients: The U.S. Food and Drug

In the meantime, Cohn and another cardiologist, Peter Carson, obtained a revised patent for the same drug combination but as a method to treat heart failure in African American patients. Since that patent runs to 2020, (whereas the original patent would expire in 2007), it provided the economic incentive for NitroMed and its investors to sponsor the clinical trials necessary for its NDA to be submitted to the FDA.

The African-American Heart Failure Trial (A-HeFT) was started in 2001 and conducted at 161 centers across the United States to see if BiDil (as an adjunct to standard therapies) would reduce mortality and hospitalization rates for self-identified Black patients who had moderate or severe heart failure.[16] Designed to run until 2005, the study included 1050 subjects who were randomly assigned to receive either BiDil or a placebo in addition to standard therapy. In July of 2004, the study's Data Safety Monitoring Board identified such a lower mortality rate in the subjects receiving BiDil that the study was terminated earlier than planned.[17] As reported by the study's investigators, the data generated up to that point showed a 43% improvement in survival in the BiDil group based on 32 deaths (out of 518 subjects) compared to 54 deaths (out of 532 subjects) in the group receiving placebo.[18] Additionally, rates of first hospitalization for heart failure differed significantly between the two groups: 16.4% in the BiDil group compared to 24.4% in the placebo group.[19] Based on this new data, NitroMed submitted its application for approval of BiDil to the FDA.

In June 2005 NitroMed's application was reviewed by the FDA's Cardiovascular and Renal Drugs Advisory Committee. When the review was completed, all nine members of the expert panel voted in favor of the FDA approving BiDil for treatment of heart failure.[20] However, two panel members voted against labeling the drug as indicated for Black patients out of concern that the restriction would be over interpreted to mean that the

drug's effects were due to racial identification rather than biology and because it could impede use by other patients who might also benefit from the drug.[21] Since the FDA is not bound by the conclusions of its advisory panels, it had the option of approving the drug for treatment of heart failure in the general population and rejecting the racial indication in labeling. However, on June 23 the FDA accepted the panel's recommendations and approved the drug as "indicated for the treatment of heart failure as an adjunct to standard therapy in self-identified black patients to improve survival, to prolong time to hospitalization for heart failure, and to improve patient-reported functional status."[22]

The wisdom of this decision quickly became the topic of debate in the popular press, national news shows and various science, law and public policy journals. The heart of the controversy was over what relationship, if any, race has to biology, and in the context of drug development, what relationship race has to variation in drug responses.[23] Given its stature as an agency that is obligated to make decisions based on science, by approving BiDil as indicated for Black patients, the FDA can be seen as sending a message to the public that it supports the view that race is biological. This is particularly problematic as it is at odds with the predominant views of modern anthropologists, evolutionary biologists and geneticists on the meaning of race.

Race and biology

The idea that there are varieties of humans distinguishable one from the other on the basis of physical characteristics originated with 18th century naturalists, but it was 19th century anthropologists who introduced the term "races" for subdivisions within the human race and posited that the races were not of equal rank or value.[24] Although different labels have been used for

racial groups over time, the notion of natural, hierarchical categories of humans persisted in anthropology for well over a century and was used beyond that discipline not only to explain differences among humans but as a justification for the injustices of colonization and the atrocities of slavery and the Holocaust. Over the course of the 20th century this institutionalized idea of races as discrete and unchanging populations was increasingly challenged by biologists' explanations of human evolution, so that eventually the social scientists who had in effect invented the concept of race as biology were compelled to disown the idea.[25] This is reflected in a statement issued by the American Anthropological Association in 1998 declaring that "inequalities between so called 'racial' groups are not consequences of their biological inheritance but products of historical and contemporary social, economic, educational, and political circumstances."[26]

The acknowledgement by anthropologists that race is a social construct contributed to what Troy Duster has characterized as the "do away with race bandwagon".[27] This refers to recent trends in the humanities, medicine, science and even politics to either redefine the concept of race or banish it from established discourse. The bandwagon gained some momentum with the completion of the Human Genome Project and the explosion in genetic variation research that has followed. With these developments the public's attention and hopes have shifted from the social sciences to genetics to provide insights on what it means to be human and to "rescue us from race and ... racism".[28] When directly asked about the biological basis of race the leading experts on genetics have been quick to respond with the conclusion reached by Craig Venter, former researcher at the National Institutes of Health and president of Celera Genomics, who said: "Race is a social concept, not a scientific one. We all evolved from the same small number of tribes that migrated out

of Africa and colonized the world."[29] Other geneticists put it more bluntly and dismiss the idea that humans can be divided into racial subgroups with unique, biological differences as "bogus"[30] and therefore not seriously entertained by credible scientists.

It is tempting to accept such pronouncements on their face, especially when they fit with one's own understanding of race and come from individuals highly respected in the field. Moreover non-scientists may feel ill equipped to challenge their assessments on scientific grounds. But blindly accepting these conclusions is unsatisfactory, because it leaves some questions about race and genetic variation unexamined and unresolved. Most importantly, if racial classifications are not scientifically valid, why do we continue to see references to race and racial groups in genetic studies published in established medical and scientific journals, particularly studies that purport to demonstrate variability in drug response based on race or ethnicity?[31] It would seem that either race correlates with biological differences related to health or it doesn't. Probing the scientific evidence behind the pronouncement that race is not biological is important for answering that question and resolving the public policy issues raised by the experience with BiDil.

"Race" and genetic variation studies

One way to test the notion of race as biologically determined (hence genetic) would be to take DNA from many individuals across the globe and have molecular geneticists analyze the samples and sort them into clusters according to genetic similarity without regard to how the sources of those samples might identify with any racial or ethnic classification. Then re-link the racial identifiers to the samples and have the analysts re-group them according to racial classification and compare the results of

each data set. If the samples in part one fell into neat discrete groups and/or those groups were highly correlated to the racial groups in part two of the exercise, it would seem to indicate that there is a biological basis for racial classifications. And if they did not, it would refute the notion. As it turns out, studies with a design similar to this hypothetical exercise have been done with interesting but complex results.

For example, Lynn Jorde and Stephen Wooding examined DNA samples from populations in Europe, Asia and Africa[32] to explore the relationship between genetic variation and race.[33] When the population identifiers of the samples were over laid onto the clusters arranged by genetic similarity (based on distribution of over a hundred alleles) they observed that "all Europeans, East Asians and Africans were correctly placed according to their respective continents of origin."[34] Nevertheless, they cautioned against concluding that this verified traditional concepts about race. They pointed out that when samples from individuals who occupy geographic regions intermediate from the geographically discontinuous regions of Europe, East Asia and sub-Saharan Africa were added to the data, those samples did not fall neatly into any of the prior categories and instead considerably overlapped more than one category. The researchers noted that while an individual might have a 90% probability of sharing ancestry with other members of one cluster, he or she will also have a 5% probability of assignment into each of the other clusters. As they explained:

[H]uman genetic variation... tends to be geographically structured, such that most individuals from the same geographic region will be more similar to one another than to individuals from a distant region. Because of a history of extensive migration and gene flow, however, human genetic variation tends to be distributed in a continuous fashion and seldom has marked geographic discontinuities.[35]

Consequently, they concluded that geographic ancestry, rather than race provides "a more subtle and complex description of an individual's genetic makeup".[36] When David Goldstein and Joel Hirshorn analyzed published studies to see if gene variants have different effects among racial or ethnic groups, they reached a similar conclusion about the genetic similarity of humans overall: there are no sharp genetic boundaries in the human population and when gene variants are present, they have similar effects in different groups.[37]

As demonstrated by Jorde and others[38] genetic variants can be present with different frequencies in different groups and genetic clusters can generally correspond to regional affiliation or geographic ancestry. On that basis, it may seem reasonable to use ancestry when needing a tool for inferring genetic variation. Geographic ancestry has the advantage of being easily discerned by simply asking an individual what his or her ancestry is. Thus it would appear to be a somewhat robust proxy for genetic variation and as such could have a legitimate and useful role in research and clinical decisions. There is, however, disagreement among scientists as to when it should be used to infer genetic variation and when it should not. There is also a lack of consistency among scientists on what they mean by ancestry in this context and that makes it difficult to know when their recommendations for using ancestry should be adopted or rejected.

There are variation experts who think that genetic ancestry as represented by racial or ethnic identity is frequently a suitable proxy for genetic variation in medicine and research.[39] Although these experts recognize that indiscriminate linkage of racial and ethnic categories with genetics has potential social costs, they endorse such categories as starting points for understanding disease prevalence and responses to treatment.[40] Other experts recognize that self reported identifiers such as race or ethnicity

might in some cases have a correlation with ancestral origins but don't subscribe to general use of such identifiers as proxies for genetic variation. They are careful to emphasize that the connection between ancestry and genetics can be "quite blurry" particularly when an individual's ancestors originated from many different parts of the world.[41] Because using population affiliation as an indication of the presence or absence of a genetic variant related to diagnosis of disease or to predict drug response would often result in faulty conclusions where analyzing the gene of interest might not, they warn against using such proxies.[42]

The gene CYP2D6 illustrates this hazard. The gene encodes for enzymes used by the body to break down toxins and metabolize many drugs, including codeine. Individuals with certain alleles (null CYP2D6 alleles) are unable to convert codeine to its active form, morphine, which means they get little or no pain relief from taking the drug. While there is substantial variation between populations (the median frequencies of these alleles is 26% in European populations, 7% in African populations and 6% in Asian populations[43]), Jorde and Wooding emphasize that the variants are in all populations and reliance on population affiliation alone is "at best, a crude and potentially inaccurate indicator of response to codeine and other CYP2D6 — metabolized drugs."[44]

A similar problem results from relying on population averages for predicting responses to ACE inhibitors as Cohn did when he reanalyzed the V-HeFt studies described above. Data from several studies demonstrates that many African Americans would respond better to ACE inhibitors than many European Americans would.[45] For this reason, labeling a drug, whether it is an ACE inhibitor or BiDil, as indicated for use by one racial group may create more problems than it solves.

If the results of an open label extension study announced by NitroMed a year after BiDil went on the market are substantiated,

genotyping may replace racial profiling in prescribing the drug.[46] A common polymorphism (C825T) on the gene for the G protein beta 3 subunit may account for the positive results reported in subjects of the A-Heft trial which was the basis for the FDA approval of the drug. While this polymorphism appears to be more prevalent in subjects who self identify as African Americans, it is not exclusively present in African Americans.

Of course there will be times when it is not feasible to do an individual genetic assessment prior to making clinical recommendations or decisions. The gene variants associated with susceptibility to a disease or response to a drug may not yet be identified. When the technique exists, it may be too time consuming for the decision at hand or not affordable for the individual. In those circumstances, relying on self reported identifiers such as race, ethnicity or geographic ancestry may seem to be the best that physicians can do. But such use will have to be informed by careful, critical assessments of studies that purport to demonstrate links between affiliation with a racial or ethnic group and the relevant susceptibility or treatment response. "The general public, including policy makers, are easily seduced by topological thinking, and so must be made aware of the genetic data that help to prove it wrong."[47] It is up to physicians as well as other scientists to provide that awareness.

Conclusion

So should the FDA have rejected the submission of an NDA that was supported with studies on one racial group or at least not have agreed to label a drug for use in one racial group? Either action would seem to be more consistent with the understanding of race endorsed by modern anthropologists and many prominent scientists, particularly those involved in studying genetic variation

in humans, that race is a social construct, and not a biological one. Those who object to the FDA taking such a stance, at least in regard to BiDil, are quick to point to the implications this would have had for those patients who would have been denied the benefits that BiDil has to offer if it had not been approved. The choice is presented as this: either endorse race in this way or deprive patients (in this case African Americans) who need treatment of a drug that could benefit them. The problem is that at least in regard to this drug, there were other ways for the H-I combination to reach patients who might benefit from it. The results of V-HeFT trials had been published, and physicians could prescribe the two generics for patients who might have benefited from them at that point. Most importantly, the FDA could have approved BiDil for use in the general population, but avoided the race label. Data from the A-HeFT trial would still have been made available via the prescription labeling information. That information clearly suggests to physicians that it might be of benefit to some self-identified African American patients not responding to standard therapy but it doesn't suggest it should not be considered for non-African American patients not responding to other therapies. On a practical level, that would also mean that prescribing for non-African American patients would not be considered "off label" use. Depending upon the terms of their prescription benefits some patients might encounter problems getting coverage for such "off label" use. Approval by the FDA for use by the general population would avoid those obstacles.

If the goal is developing more effective interventions it would be better to focus efforts on discovering the genetic variations underlying development of disease and variation in drug responses rather than racial differences. At the same time it is important to recognize that although a better understanding of the biological differences among individuals may be a necessary step in developing effective treatments, developing new drugs will

not be sufficient to reduce disparities in health. Understanding the social and economic policies and environmental factors that affect health and access to health care and instituting strategies that address these factors will be equally important and necessary.

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FDA News, June 23. Available at www.fda.gov/bbs/topics/NEWS/2005/NEW01190.html. Although both of these generic drugs were already on the market, neither hydralazine nor

isosorbide dinitrate had previously been approved for treatment of heart failure.

[3] Since the 1960's ethno-racial classification has been recognized as a matter of self-identification and not something that can be assigned by an observer. This is demonstrated by changes in the protocol used by the federal Census Bureau. Individuals select from a list as many racial or ethnic identifiers they think or feel applicable to them. In regard to the package insert for BiDil, it refers to use in "black patients". (Available at www.fda.gov/cder/foi/label/2005/020727lbl.pdf.) The FDA, the researchers and drug sponsors consider Black and African American as synonymous and use the terms interchangeably. (See notes 12, 15 *infra*).

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The Human Right to Health

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Introduction

Let me start with the conclusions of this exploration into the human right to health. I will argue in this paper that health is inextricably linked to human rights status. One cannot have a healthy population without due consideration of the human rights status of individuals within the state, and human rights cannot be protected and upheld unless the population is healthy. I will also argue that there exists a human right to the highest attainable standard of health as a moral obligation, legal duty, and as an international human right.

Historically, rights were often described in two categories: negative or civil and political rights, and positive or economic, social, and cultural rights.[1] Negative rights are the civil and political rights to noninterference that protect the individual from the state, while positive rights are the economic, social, and cultural rights that obligate the state to progressively provide for its population. Many states have distinguished between these two types of rights, though the distinction is in fact a false dichotomy, as most scholars recognize. Positive rights and negative rights are interdependent and indivisible. For example, the negative civil and political rights to freedom,

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liberty, protection, and due process cannot exist without positive investment by the state in building institutions like law enforcement and a judicial system to enforce these rights.

In the history of human rights discourse, debate primarily has focused on whether and how rights can be prioritized and balanced. The issue of prioritization of rights has played out as a debate between developed nations, which often emphasize civil and political rights over economic, social, and cultural rights, and developing nations, which tend to stress economic, social, and cultural rights over civil and political rights. Again, these two types of rights truly work together, and emphasizing one type at the expense of the other is detrimental to the cause of advancing human rights and the benefits that accompany them. This paper will focus on both the positive and negative right to health, in addition to describing what the concept of health entails. It will also focus on how moving beyond the right to health care toward the right to healthy conditions is necessary for respecting a right to health.

What characteristics of health make it of special concern to us? Why is health so important? Health is a universal and primary human good, as fundamental to the satisfaction of our needs as food and shelter. Health is a precondition to pursuing and achieving whatever life goals one might have, and it increases the range of available opportunities in much the same way that education does. The highest attainable standard of physical and mental health is a fundamental human right, yet health is unpredictable and unevenly distributed across the population. While some need little health care, others may have overwhelming needs. But the human right to health is universal, and all are entitled to the highest attainable standard, as has been articulated in international human rights for nearly sixty years.

History of the righr to health

Since the end of World War II and the establishment of the United Nations, a new era of international human rights has begun, grounded in the notion of human dignity. This new era was ushered in with the ratification of the International Bill of Human Rights, which includes the United Nations Universal Declaration of Human Rights (UDHR), the International Covenant of Civil and Political Rights, as well as the International Covenant on Economic, Social, and Cultural Rights. The Universal Declaration of Human Rights expresses both positive and negative rights in the same document, and both the International Covenant on Economic, Social, and Cultural Rights and International Covenant on Civil and Political Rights recognize a right to the highest attainable standard of health. The rights outlined by these documents are integral to what it is to be human, and as such, they ought to compel universal respect regardless of whether such respect is demanded.

The first explicit mention of the right to health is in the Universal Declaration of Human Rights of 1948. [2] This seminal document asserts that "everyone has a right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing, and medical care and necessary social services." A series of major international human rights instruments followed the UDHR in further enumerating a right to health.

The International Covenant on the Elimination of All Forms of Racial Discrimination of 1965 states that parties must undertake to prohibit and eliminate racial discrimination in all forms and to guarantee the rights of everyone without discrimination as to race, color, national or ethnic origin. Importantly, it also enumerates the rights to public health and medical care.[3]

Article 12 of the International Covenant on Economic, Social, and Cultural Rights of 1966 "recognizes the right of everyone to the enjoyment of the highest attainable standard of physical and mental health".[4] In an important step to achieving that end, the covenant outlines specific items necessary for realizing the right to health, mandating state parties to take steps to 1) reduce still birth rates, infant mortality, and provide healthy development for children; 2) improve the environment and industrial hygiene; 3) prevent, treat, and control epidemics, endemics, and occupational and other diseases; and 4) create conditions to assure medical service and attention for illness.

The International Covenant on Civil and Political Rights of 1966 defines the role of the state in protecting life and obligates states to undertake measures to eliminate epidemics.[5]

The Convention on the Elimination of All Forms of Discrimination Against Women in 1979 directs state parties to take all measures to eliminate discrimination against women in health care.[6] Parties must ensure a policy of access to health services, including family planning during both the pregnancy and the postnatal period.

The Convention on the Rights of the Child in 1989 extends to children the provisions of the right to health articulated in the International Covenant on Economic, Social, and Cultural Rights.[7] It asserts the state's obligation to diminish infant and child mortality, with an emphasis on primary care, combating disease and malnutrition, providing clean drinking water, and combating environmental pollution.

General comment 14 to Article 12 of the International Covenant on Economic, Social, and Cultural Rights in 2000 is perhaps the most important document in establishing the right to health in that it explains what is meant by a right to the "highest attainable standard of health".[8] A special United Nations rapporteur on the right to health works to establish benchmarks and monitor states' observance of the treaty.

The right to health is also expressed in several national and regional human rights instruments, such as the rulings of the European Court of Justice and the South African constitution, which has permitted successful lawsuits that have forced the state to provide certain medical services.

The World Health Organization (WHO) has also recognized a right to health. In the preamble to its constitution it declares, "The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition."[9]

The right to health

The concept of a right to health or health care is of recent origin. It is estimated that it was not until 1910 that one had a more than 50% chance of getting better after going to a random US health care facility, as opposed to not going at all. Initially, in the United States health care was not considered to be a government concern and was provided by laypeople, family, and clergy. Few options existed for safe and effective health care. When the US government began to take direct action to protect the health of the populace, it was not due to a concern for individual welfare, but rather for national defense. Thus, the US first took steps to provide care for the armed services and national defense forces to protect the interests of state security. Later programs for the working class were implemented to achieve a more productive labor force.

As set forth in the International Bill of Human Rights, the right to health contains both freedoms and entitlements. Freedoms include the right to have control over one's health and body, as well as a right to be free from nonconsensual medical

treatments and experimentation. Entitlements, on the other hand, include a right of access to an equitable health care system. Moreover, the right to health is indivisible, interdependent, and interrelated with other basic human rights, such as the rights to food and education. In the public health perspective, the right to the highest attainable standard of health also includes the rights to property and to primary health care, appropriate and equitable health services, basic immunizations, adequate nutrition, adequate housing, and freedom from violence. Also included are sexual and reproductive health information and services, such as family planning. Rights that provide the preconditions for health are also crucial, like the right to safe water and adequate sanitation, and generally, the right to a clean and safe environment, as well as to information about health care.

Audrey Chapman, a researcher at the American Association for the Advancement of Science in Washington D.C., raised three important questions about the right to health.[10] The first question is whether the concept of highest attainable level of health is an average or a basic minimum, and whether it refer to the individual or the entire population. The right to health cannot simply mean the right to be healthy, as this may not always be possible. Health depends not only on state responsibility, but also on the actions of individual factors in society, such as behavior or heredity. A second question is who ought to determine the content and scope of the highest attainable level of health. Certainly views vary across societies and among different groups. Opinions also differ on what constitutes health and what type of healthcare appropriately reflects a given set of social, cultural, political, and economic circumstances. Third, how is the highest attainable level of health is to be evaluated and measured? Should it be correlated to levels of development and available resources? Is there a minimum or, for that matter, a maximum level of investment in the health sector required by all state parties? With innovations in technology and treatments, to

what extent are countries, particularly affluent ones, obliged to make these high tech inventions widely available? Although increasing attention has been paid to these questions, they have not been definitively resolved.

Medical and public health approaches for a right to health

The health status of a population is related to its human rights status. The language of rights is powerful. Rights entail the obligation of the state to respect, monitor, promote, and ensure that the rights of individuals are protected. How does the state carry out its obligation to respect, protect, and fulfill the right to health? The two fields most directly involved with health take different approaches to answering this question. Medicine's therapeutic focus translates to an approach to the right to health that expands access to health care, whereas public health's focus on prevention leads to a right to health approach that protects health and provides preventive services. Let us assume that health care, whether therapeutic or preventative, leads to some improvement in health, so that access and availability of health services becomes important to health status. Health status may also be a function of medical care, but it is estimated that this accounts for less than 10% of the population's overall health. Additionally, it is estimated that only one sixth of the years gained in life expectancy in this century is attributable to improvements in medicine and medical care and only ten percent of preventable premature deaths are a result of lack of medical care. Health status is a function of a number of things, but particularly of public health measures that protect basic human rights like the rights to primary health care, appropriate and equitable health services, basic immunizations, adequate nutrition, adequate housing, and freedom from violence.

Health status is strongly associated with socioeconomic status, educational background, and discrimination, especially racial and gender discrimination.[11,12] This holds particularly true for women. Women comprise 50% of the world's population, yet they are responsible for over two thirds of the world's working hours, earn less than 10% of the world's income, and own less than 1% of the world's property.[13] Public health interventions cannot be very effective when they are laid onto a foundation of socioeconomic inequalities and rights violations. Only after attention is given to these structural factors influencing health should the focus turn to basic public health interventions, such as providing adequate food, clean water, appropriate sanitation measures, and shelter. Public health measures such as immunizations, followed by antibiotics and high-tech medicine should be the last measures taken to improve the health of a population. The public health model deals with population problems upstream, promoting prevention, while medicine is more narrowly concerned with individuals, using downstream approaches focusing on treating disease. Health promotion and disease prevention are more important and more cost effective than treating disease after it has already taken hold. Whether for a geographic area, a community, or an individual, health status is heavily dependent upon inputs and factors seemingly unrelated to health services. Poor countries can more effectively and efficiently raise health standards by first providing clean water, sanitation, vaccinations, and other simple public health measures, rather than providing curative medical care to only a small fraction of the population. Even industrialized countries can gain much more from health promotion and disease prevention than from downstream, "rescue medicine".

Though commitment to free and equal health care is an important step for human rights and social justice, it is unlikely to single-handedly overcome marked health inequalities in society. In Britain, inequalities of health status in lower occupational groups

persisted some 30 years after the introduction of universal health care, and these inequalities applied to all stages of life.[14] Access to curative health care is not enough. The focus must be on social, economic, and cultural rights by putting an emphasis on prevention, primary care, and community health. As such, the right to the highest attainable level of health is interrelated with other rights such as the rights to food, housing, education, safe working conditions, good nutrition (particularly in childhood), and the women's right to education — one of the most successful ways to improve the health of women and children.

The cost of a right to health

In 1978, the WHO established a campaign of health care for all by the 21st century.[15] The WHO recognizes translating the right to health to specific core provisions of human rights instruments as necessary for the campaign's success. In the World Development Report of 1993, the World Bank outlined a package of essential public health and medical services.[16] This minimum care package would expand immunizations, cover HIV prevention, and guarantee prenatal care, delivery care, and family planning services. If implemented, it is estimated that this package would eliminate 32% of the disease burden in low-income countries and 15% in middle-income countries. The package outline for low-income countries costs $12 per capita per year and in middle-income countries costs $22 per capita per year.

Is the provision of this health care package possible? This depends on the commitment of nations and individuals to social justice and respecting the right to health. The amount of money needed to fund the health care package proposed by the World Bank pales in comparison to the immense wealth circulating in the hands of the world's most developed nations and wealthiest

individuals. According to the United Nations Human Development Report of 2005, the 500 richest individuals in the world have a combined income exceeding that of the poorest 416 million. The poorest 2.5 billion people, comprising 40% of the world's population, live off less than $2 a day and earn only 5% of the world's income. Combining these data with those from the World Bank proposal for an essential health package we can see that providing an essential package of medical and public health services to this poorest 40% of the world's population would cost approximately $30 billion per year, or less than 0.2% of the income of the richest 10% of the world's population.

As of 2005, the United States was spending nearly $2 trillion or approximately $6,700 per capita on health per year, accounting for 16.0% of the gross domestic product.[17] Yet, of the industrialized countries, the US has the lowest percentage of population and government assured health insurance. Some 47 million Americans, or one sixth of the total US population, lack access to health insurance.[18] Moreover, despite high levels of health spending, the US generally compares poorly with other industrialized countries on health outcome indicators and even worse than some developing countries.[19] Mozambique, one of the poorest countries in the world, in 1999 vaccinated more than 3.6 million children against a wide range of diseases, covering virtually the entire eligible age group.[20] In contrast, only approximately 80% of infants and toddlers in the United States receive the full course of recommended vaccinations for diphtheria, tetanus, polio, and measles.[21] The example of healthcare in the United States reveals a disconnect between health resources and basic health outcomes. Funding must be translated to the most effective and just forms of health care if a right to health is to be realized. But despite the various enumerations of a right to health included in the UDHR and other instruments, explicitly defining a right to health remains a challenge.

Moving forward: the human rights approach to health

A human rights approach to health emphasizes that effective and sustainable provision of health-related services can only be achieved if the state is willing to participate in designing policies and programs that implement the right to health. Human rights and health can be improved by paying special attention to the process through which health care policy decisions are made. For the protection and benefit of the public, health policies and programs must also include the input and participation of the community. Participation and empowerment go hand in hand. Necessary tools include enabling the public to have a legitimate voice in the public realm, participation in decision-making, and raising legitimate demands based on human rights claims. The main effect of the human rights approach to health is the framing of basic health needs as health rights, in other words, establishing that health is a social justice issue which involves concrete governmental obligations. Furthermore, a human rights approach to health also recognizes that every human being is endowed with a set of human rights, a worthy end in itself.

Increasing governmental accountability for the health of the populace is a crucial component of the human rights approach to health. A central advocacy principle used by nongovernmental organizations employing a human rights approach to health is holding governments accountable for their obligations under international law, regional law, national constitutions and legislation. By ratifying human rights treaties that affirm the right to health, the state agrees to be accountable to the international community as well as to the people living within its jurisdiction for the fulfillment of these obligations. Failure to fulfill these obligations can be challenged in national and international forums.

Certain international obligations apply uniformly to all states and require immediate compliance, while others can be realized

progressively, depending on conditions in the country concerned. Progressive realization must be understood as an obligation of states to move as expeditiously and effectively as possible towards the full realization of the right in question. An example of an obligation that a state must immediately observe is the duty to ensure freedom from discrimination in health related matters and to allow participation in decision-making processes that affect the public's health and well-being. States agree to take deliberate, concrete, and targeted steps towards the full realization of the right to health. Also included in many states' immediate obligations is the duty to ensure that people can enjoy the right to health at an essential level, as through the provision of essential primary health care. These immediate obligations are known as a minimum.

Increased attention must be immediately paid to the health needs of the poor and otherwise vulnerable, and attempts must be made to rectify unacceptable imbalances in the health statuses of different population groups. Under General Comment 14, states have obligations concerning maternal, child, and reproductive health, healthy and natural workplace environments, prevention, treatment and control of diseases, and health facilities goods and services.[22]

Monitoring is key to realizing the right to health, and requires assessing the numbers, policy, and distribution of functional public health and health care facilities. Monitoring of nondiscrimination, monitoring of economic accessibility, and monitoring of physical accessibility and quality are paramount.

Conclusion

In conclusion, our primary goal should be to focus on the positive right to health. This means not just medical care, but

health care, and also the rights to the highest attainable level of health. A health Bill of Rights is required that is not just a series of negative rights, but also includes positive social, cultural, and economic rights. A human rights perspective calls for governments to respect, protect, and fulfill their obligations. The current agenda should focus on the improvement of maternal and child health, particularly reproductive health. Placing priorities on public health measures such as preventing, treating, and controlling epidemic, endemic, and occupational diseases is essential, as well as providing basic primary care for all, and curative medical services for those who are ill.

Health must be seen as a global issue. Our world is interdependent. The movement of toxic waste, greenhouse gases, radiation, and infectious disease knows no boundaries. An international bill of health and human rights that includes not just civil and political rights, but economic, social, and cultural rights is needed if a right to health is truly to be realized.

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The International Human Right to Health in Domestic Constitutional and Statutory Law

ELEANOR D. KINNEY*

I. Introduction

The predominant and probably most effective method of recognizing, implementing and enforcing international human rights has been through the legal architecture and culture of the legal infrastructure of nation states. Most international human rights treaties — which are generally international treaties between nation states — place the responsibility of recognition, implementation and enforcement of treaties on the states parties that sign and ratify the treaties.

This chapter first provides an overview of the legal implementation of the international human right to health, of which constitution making is a potentially important part. The chapter concludes with observations about the role of constitutions and law in the realization of the international human right to health.

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II. The legal infrastructure

The elements of an optimal legal infrastructure for the recognition of the international human right to health are:

- International and Regional Treaties
- National (and Provincial) Constitutions
- National Legislation and Regulation
- Provincial (State) and Legislation and Regulation

A. International and regional treaties

Since the 1940s and the close of World War II, the United Nations and regional international organizations have adopted treaties and other instruments which have, over the years, developed and articulated the contours of an international human right to health and health care.

As a matter of international jurisprudence, the fundamental statement of the international human right to health and health care is stated in the Universal Declaration of Human Rights adopted in 1948. The relevant provision is article 25.1 which provides:

> Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.[1]

As the Universal Declaration does not have the force of international law, there are two international covenants to implement it: the International Covenant for Civil and Political

Rights (ICCPR),[2] and the International Covenant for Economic, Social and Cultural Rights (ICESCR).[3]

The later treaty, ICESCR, states the fundamental legal norm establishing the international right to health and health care. According to Article 12 of ICESCR, the right to health includes "the enjoyment of the highest attainable standard of physical and mental health."[4] Article 12 of ICESCR specifically provides that states parties "recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health."[5]. Article 12 then enumerates several steps to be taken for "full realization" of this right.[6] These steps include:

- The provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child.
- The improvement of all aspects of environmental and industrial hygiene.
- The prevention, treatment and control of epidemic, endemic, occupational and other diseases.
- The creation of conditions which would assure to all medical service and medical attention in the event of sickness.

A human right to health is also recognized in numerous other UN international human rights treaties that address the needs of historically vulnerable populations that have often been the subject of discrimination. Such treaties include the International Convention on the Elimination of All Forms of Racial Discrimination of 1965,[7] the Convention on the Elimination of All Forms of Discrimination against Women of 1979,[8] and the Convention on the Rights of the Child of 1989.[9] All of these treaties specify rights to health for the relevant populations in two respects. First, they all prohibit discrimination in the provision of health care services and, second, they often state affirmative rights

to particular types of health care services of special importance to the relevant population, such as obstetrical and gynecological services in the case of women. At Figure 1 is a list of exemplary regional treaties recognizing an international human right to health and health care.

B. National (and provincial) constitutions

There is wide variation in constitutional provisions regarding health and health care and lack thereof in the constitutions of the

Figure 1
Exemplary Regional Public International Organizations and their Regional Treaties Recognizing an International Human Right to Health

COUNCIL OF EUROPE
EUROPEAN UNION AN ORGANIZATION FOR SECURITY AND COOPERATION IN EUROPE

European Social Charter of 1961 as revised (art. 11).
European Convention on Human Rights (1950)

ORGANIZATION OF AMERICAN STATES (OAS)

American Declaration of the Rights and Duties of Man (1948)
American Convention on Human Rights ("Pact of San Jose, Costa Rica") (1969)
Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights ("Protocol of San Salvador") (art. 10) (1988)

ORGANIZATION OF AFRICAN UNITY

African Charter on Human and Peoples' Rights (1981)

countries of the world.[10] This phenomenon is mostly likely due to the fact that national constitutions have been adopted at different times and under different historic situations. Specifically, only 21 national constitutions that were in effect before World War II are in effect today and, of those, only nine have provisions regarding health and health care in their constitutions.[11] Currently, about 68 percent of countries have constitutional provisions regarding health and health care. Further, 54 percent of countries have ratified ICESCR and 30 percent have ratified a relevant regional treaty. [12]

There does not seem to be much correlation between an explicit commitment regarding health and health care in a national constitution and the performance of individual countries on addressing the health care needs of their populations. Some countries have detailed provisions while other countries, which may have the highest annual expenditures for health care services (a proxy for support of health care) have no provision regarding health and health.[13] Also, according to our study, countries that expressed the greatest constitutional commitment to health — evidenced by inclusion of both a statement of entitlement and duty — had an average government per capita expenditure for health care of $308 in 2000.[14] The same average for countries that had no provision regarding health or health care was $716.95. [15] Such findings suggest that there is no correlation between the intensity of constitutional commitments and average per capita government expenditures for health and health care.

Nevertheless, a constitution can be extremely useful in institutionalizing the international human right to health and health care within a nation state. A constitution can establish and define legal rights to health and health care. In our study, nearly 40 percent of nations specifically created a right to health and health care within the constitution.[16] Also, about 38 percent of nation states established an affirmative and sometimes

enforceable duty on the part of the state to provide health care to the population.[17]

As a practical matter, the constitution must address some issues if the nation state is authorized to proceed to enact legislation. Specifically, the constitution must provide some authority for health legislation. In the United States Constitution, for example, the constitutional authority for federal laws pertaining to all health related legislation and regulation is Congress' authority to enact legislation to spend money to "promote the general welfare"[18] and regulate commerce among the states.[19]

Constitutions can also establish and specify in considerable detail the nature of government obligations to provide, promote and protect health and health care as policy imperatives. The constitutions of several countries are quite prescriptive in actually designing the health sector legal infrastructure for their nation state.[20]

C. National legislation and regulation

Across the world, the allocation of responsibility for health and health care within specific nation statutes varies. In some countries, the national government has predominant responsibility. However, in much of the world, the locus of governmental responsibility for the health and health care of the population lodges with regional or even local government.

Historically public health protections are the first focus of government activity regarding health care.[21] Indeed, governments had relatively limited responsibilities for health and health care until the Twentieth Century. National governments became more actively involved after World War II when national and regional governments in more developed countries took on the

responsibilities for regulating private health insurance and providing health coverage through public programs.

1. Contents of national legislation

Ideally and regardless of where the locus of authority over the health care sector resides, national legislation should at least articulate the goals and objectives for a national health care sector and address the following issues:

- Public health protection and promotion.
- Prohibitions against discrimination on the basis of race, religion, ethnic origin, gender, sexual orientation and disability regarding access to public and private health care services and health insurance.
- Regulation of providers to ensure safety and quality of care.
- Regulation of health insurance to address solvency and other issues.
- Direct provision of health care services or public health insurance for vulnerable groups.

First and foremost, legislation at the national level should provide for public health protection and promotion. The issue should be addressed at the national level as the national government will often be called upon by international and regional international organizations such as the World Health Organization to address international epidemics and other public health crises. Also national governments increasingly are called up to address public health emergencies such as a flu pandemic.

A second body of national legislation should include prohibitions against discrimination on the basis of race, religion, ethnic origin, disability, gender and sexual orientation in both the

public and private provision of health care services. Discrimination on any basis can impose a serious barrier to care and often in circumstances where health care services of good quality and highly affordable are otherwise available.

A third body of requisite law important for the national realization of the international human right to health and health care is the regulation of insurance and risk-bearing health care providers is regulation of insurance. In most developed countries, regulation of insurance is performed at the national level. In the United States, for fairly idiosyncratic historic reasons, regulation of insurance has been lodged with states. This arrangement has made it difficult to regulate health insurance in the United States uniformly.

Finally, the international human right to health generally implicates a government obligation to assure access to affordable and high quality health care. Given the high cost of health care in most of the world, government at some level will be pressed to finance at least or at best provide health care services to some or all of the population. The allocation of this obligation among levels of governments in nation states is obviously varied and inevitably spread across local, regional and national levels.

2. UN Economic, Social and Cultural Committee's General Comment 14

The UN Economic, Social and Cultural Committee published a General Comment 14 to ICESCR that outlines the content of the international right to health and its implementation and enforcement.[22] Building on the typology of the content of social human rights developed by Asbjørn Eide in 1987,[23] General Comment 14 imposes three types or levels of obligations: the obligations to *respect*, *protect* and *fulfill*. The obligation to *respect*

requires states parties to refrain from interfering directly or indirectly with the enjoyment of the right to health. The obligation to *protect* requires states parties to take measures that prevent third parties from interfering with article 12 guarantees. The obligation to *fulfill* requires states parties to adopt appropriate legislative, administrative, budgetary, judicial, promotional and other measures towards the full realization of the right to health.[24]

General Comment 14 clearly addresses implementation. It imposes a duty on each of the states party "to take whatever steps are necessary to ensure that everyone has access to health facilities, goods and services so that they can enjoy, as soon as possible, the highest attainable standard of physical and mental health." Implementation also requires adoption of "a national strategy to ensure to all the enjoyment of the right to health based on human rights principles which define the objectives of that strategy, and the formulation of policies and corresponding right to health indicators and benchmarks." The national health strategy should also "identify the resources available to attain defined objectives, as well as the most cost-effective way of using those resources." The national health strategy and plan of action should "be based on the principles of accountability, transparency and independence of the judiciary, since good governance is essential to the effective implementation of all human rights, including the realization of the right to health."[25]

There are also remedies if states parties do not fulfill the international human right to health. The comment explicitly provides that a state party which "is unwilling to use the maximum of its available resources for the realization of the right to health is in violation of its obligations under Article 12" and places the burden on the state party to justify that it has that it has made use of "all available resources at its disposal" to satisfy its obligations regarding the right to health. General Comment 14 also specifies violations of the Article 12 including "state actions, policies or laws

that contravene the standards set out in Article 12 of the Covenant and are likely to result in bodily harm, unnecessary morbidity and preventable mortality." Violations of the obligation to protect include "failure of a State to take all necessary measures to safeguard persons within their jurisdiction from infringements of the right to health by third parties." Violations of the obligation to fulfill include "failure of States parties to take all necessary steps to ensure the realization of the right to health."[26]

General Comment 14 accords remedies to individual parties. Specifically, any person or group victim of a violation of the right to health should have access to effective judicial or other appropriate remedies at both national and international levels. All victims of such violations should be entitled to adequate reparation, which may take the form of restitution, compensation, satisfaction or guarantees of non-repetition. National ombudsmen, human rights commissions, consumer forums, patients' rights associations or similar institutions should address violations of the right to health.[27]

D. Provincial (state) and local legislation and regulation

Provincial and/or component states within a nation state will have obligations regarding realization of the international human right to health. Historically, comparable local health authorities have been engaged in public health protection and even promotion before the rise of the nation state in the 18th and 19th centuries.[28]

The legal authority for state and local health authorities vary across the globe. In the federal system of the United States, the states have primary responsibility for the regulation and promotion of the public's health. States' authority for public health regulation comes from the police power and the *parens*

patriae power (to protect children and incompetent adults).[29] The state police power is the foundational power of sovereign states irrespective of authorizing constitutional provisions.[30] Basically, the police power supports government authority to protect and promote public health in many dimensions. The police power includes protecting public safety, regulation of risks to health and safety in the environment, work place and other public venues.

Local governments basically function as "boots on the ground" in the implementation of public health measures such as safety inspections. They also work in conjunction with a vast private health care sector including a variety of health care institutions and professionals in the provision of health care services particularly to the poor and vulnerable groups. Indeed, a critical local institution is the local public hospital that has responsibilities to care for the poor and uninsured in communities throughout the world.

One very important role for states and, in particular, localities is to establish networks of personnel and resources to support private providers that serve more vulnerable populations. Specific local networks of resources and personnel should include all the relevant services needed for preventive case such as vaccinations, acute care in hospitals in the event of serious illness or injury, and even long-term care. In the United States, the community health center movement has done much to assure these networks for the poor and uninsured.[31] It is not surprising that the creation of these networks has been an important component of many of the proposals for health reform at the state and local level.[32]

IV. Conclusion

For full recognition and ultimate realization of the human right to health, the nation state (which has the primary duties to

respect and protect the right) must sign and ratify the treaties. It is also the nation state that sponsors a process for making the constitution of the nation state. In constitutional theory, citizens of a state can – in an established process – come together and write and legalize a constitution. A constitution can establish the nation states core values for the present and future. Legislation at the national, state (provincial) and local levels is needed for implementation of these constitutional principles. However, the real work of realization comes from the work of policy makers, administrators and health sector workers to establish the kinds of networks and resources to assure accessible to high quality, affordable health care for all – the ultimate criterion for realization of the international human right to health and health care.

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[2] United Nations, 1966. International Covenant on Civil and Political Rights, General Assembly Resolution 2200A (XXI), U.N. GAOR, 21st Sess., Supp. No. 16, at 49, U.N. Doc. A/6316.

[3] United Nations, 1966. International Covenant on Economic, Social and Cultural Rights, General Assembly Resolution 22001 (XXI), U.N. GAOR, 21st Sess., Supp. No. 16, U.N. Doc. A/6316, 993 U.N.T.S. 3.

[4] *Id.* at Art. 12.

[5] *Id.*

[6] *Id.*

[7] United Nations, 1965. Convention on the Elimination of All Forms of Racial Discrimination, Dec. 21, 1965, art. 5(d)(vii), General Assembly Resolution 2106 (XX), U.N. GAOR, 20th Sess.,

Supp. No. 14, at 47, U.N. Doc. A/6014 (1965), 660 U.N.T.S. 195, 222 (*entered into force* Jan. 4, 1969).

[8] United Nations, 1979. Convention on the Elimination of All Forms of Discrimination against Women, Dec. 18, 1979, art. 12, General Assembly Resolution 34/180, U.N. GAOR, 34th Sess., Supp. No. 46, U.N. Doc. A/34/36 (1980) (*entered into force* Sept. 3, 1981).

[9] United Nations, 1989. Convention on the Rights of the Child of 1989, Nov. 20, 1989, art. 24, General Assembly Resolution 44/25, U.N. GAOR, 44th Sess., Supp. No. 49, U.N. Doc A/44/49 (1989) (*entered into force* Jan. 4, 1969).

[10] Kinney, E. D. & Clark, B. A., 2005. Provisions for health and health care in the constitutions of the countries of the world. *Cornell International Law Journal.* 37 (2) , p. 285.

[11] *Id.* at 293.

[12] *Id.* at 298 & Table 2.

[13] *Id.*

[14] *Id.* at 295.

[15] *Id.*

[16] U.S. CONSTITUTION art I, § 1.

[17] U.S. CONSTITUTION art. 1, § 8, cl. 3.

[18] *See* Kinney, E. D. & Clark, B. A., *supra* note 10, at 290.

[19] See Kinney, E. D., 2002. Administrative law and the public's health. *The Journal of Law, Medicine & Ethics*, 30 (2), p. 212-223.

[20] United Nations. Committee on Economic, Social and Cultural Rights, 2000. The right to the highest attainable standard of health: U.N. ESCOR, 22d Session U.N. Doc. E/C, Dec. 4, 2000, ICESR General Comment 14 (2000) [Hereinafter cited "ICESCR General Comment 14"].

[21] Eide, A., 1995. The new international economic order and the promotion of human rights. In A. Eide, C. Krause & A. Rosas, eds., 1995. Economic, social and cultural rights: a textbook. Dordrecht: Martinus Nijhoff Publishers. p. 21. See Hendriks, *supra* note 20.

[22] The material quoted and/or referred to in this paragraph is from ICESCR General Comment 14.

[23] The material quoted and/or referred to in this paragraph is from ICESCR General Comment 14.

[24] The material quoted and/or referred to in this paragraph is from ICESCR General Comment 14.

[25] The material referred to in this paragraph is from ICESCR General Comment 14.

[26] *See* Rosen, G., 1993. A history of public health. Expanded edition. New York: W. W. Norton; Fee, E., 1994. Public health and the state: the United States. In D. Porter, ed., 1994. The history of public health and the modern state. Amsterdam: Rodopi. p. 224, 227-28.

[27] *See generally* Gostin, L. O., 2000. Public health law: power, duty, restraint. Berkeley: University of California Press. p. 25-59.

[28] *See generally* Novak, W. J., 2002. The legal origins of the modern American state. In A. Sarat, B. Garth & R. A. Kagan, eds., 2002. Looking back at law's century. Ithaca: Cornell University Press. p. 249-283.

[29] *See* Lefkowitz, B., 2007. Community health centers: a movement and the people who made it happen. New Brunswick: Rutgers University Press.

[30] *See* Commonwealth Fund. Alliance for Health Reform, 2007. State coverage initiatives: will moving toward universal coverage make the system work better for everyone? Washington, D.C.: Alliance for Health Reform. Available at http://www.allhealth.org/briefing_detail.asp?bi=115. [Accessed January 24 2008).

Patients' Rights in Europe

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The first question we can ask when we speak about "patients' rights in Europe" is to know what is meant by "patient". A "patient" is a person, *i.e.,* a human being. We have been discussing in European Philosophy, for the last XXI centuries, what being a person means, and there is still no consensus in this field[1]. Nevertheless, we can consider that a "patient" is a person who is receiving medical treatment or that is registered with a particular physician — a person who suffers or may suffer from a disease or health problem.

The concept of "health" generally used by European Law is the one that was given by the World Health Organization's Constitution (WHO) on 7 April 1948: health is "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity"[2]. As Karl Jaspers stated, that kind of health does not exist, because according to the given definition, "everyone is always diseased"[3].

As a matter of fact, each epoch has defined its own concept of health in accordance with its own scientific knowledge, and therefore each concept can only be understood within the context of a certain period of medical knowledge. Each concept has, as well, reflections in the social and juridical understandings of health and disease. "Disease" does not exist by itself, but is

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constructed by Medicine after analyzing a set of symptoms shown by people, and can lead to the stigmatization of the ill person[4].

Having this in mind the Legislator at the European Union and the Council of Europe usually considers that the patient is a person who is in a vulnerable situation — because she or he is diseased — but that does not lose her/his status as bearer of rights.

If we analyze the existing legislation in the field of patients' rights we conclude that a distinction can be drawn between the rights of the patient as a "person", and the rights of the patient as a "diseased person".

As a "person" the patient is a full citizen that has the rights that are recognized in the main texts of international law, such as Universal Declaration of Human Rights[5], Universal Declaration on the Human Genome and Human Rights[6], Universal Declaration on Bioethics and Human Rights[7], International Covenant on Civil and Political Rights[8], International Covenant on Economic, Social and Cultural Rights[9], Convention on the Rights of the Child[10], Convention for the Protection of Human Rights and Fundamental Freedoms[11], European Social Charter (revised)[12], and Charter of Fundamental Rights of the European Union[13].

According to these juridical texts every patient has the specific rights to life[14], to physical and mental integrity[15], to liberty[16], to personal identity[17], to respect of her/his privacy[18], to work[19], to social security[20], and to protection of health[21].

Having in mind the general texts on human rights, the international organizations have adopted specific documents that recognize more detailed rights of persons who are in a particular situation — who have a disease and therefore belong to a group that is vulnerable and frail because of the suffering it causes and of the fear of not recovering. Examples of these texts are:

— Resolution 37/194 on Principles of Medical Ethics[22];
— Convention on Human Rights and Biomedicine[23];

— Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research[24];
— International Declaration on Human Genetic Data[25];
— Recommendation n.º R (81) 1 on Regulations for Automated Medical Data Banks[26];
— Recommendation Rec(2006) 18 of the Committee of Ministers to Member States on Health Services in a Multicultural Society[27];
— Recommendation Rec(2007) 7 of the Committee of Ministers to Member States on Management of Patient Safety and Prevention of Adverse Events in Health Care[28];

Within this group of people who suffer from a disease, the European Legislator considers that particular protection should be given to certain groups of patients. These specific rights are, for instance, recognized in:

— Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin[29];
— Recommendation 779 (1976) on the Rights of the Sick and the Dying[30];
— Recommendation 818 (1977) on the Situation of the Mentally Ill[31];
— Recommendation n.º R (90) 13 on Prenatal Genetic Screening, Prenatal Genetic Diagnosis and Associated Genetic Counseling[32];
— Recommendation n.º R (92) 3 on Genetic Testing and Screening for Health Care Purposes[33].
— Recommendation 1418 (1999) 1 on the Protection of the Human Rights and Dignity of the Terminally Ill and the Dying[34];
— Recommendation Rec(2003) 10 on Xenotransplantation[35];

— Recommendation n.º Rec(2003)24 on the Organization of Palliative Care[36];
— Recommendation n.º Rec(2004)10 concerning the Protection of the Human Rights and Dignity of Persons with Mental Disorder[37].

In the European Union patients' rights are also recognized in ethical texts approved by the World Medical Association (WMA) and by the Council for International Organizations of Medical Sciences (CIOMS). Examples of these are:

— Helsinki's Declaration[38];
— Lisbon's Declaration[39];
— Venice's Declaration[40];
— Ottawa's Declaration[41];
— Inuyama's Declaration[42];
— Tokyo's Declaration[43];
— International Ethical Guidelines for Biomedical Research Involving Human Subjects[44].

The referenced documents address terminal illness, on biomedical research involving human subjects or persons suffering from mental disorder, or on the general rights of the patient.

Other ethical documents that recognize rights of diseased people with rights are the European Charter of Patients' Rights[45], the Declaration on the Promotion of Patient's Rights in Europe[46], the European Association for Children in Hospital's Charter of Children admitted to Hospital[47] and the Vienna Recommendations on Health Promoting Hospitals[48].

This recognition of patient's rights which seems so natural to us today is a consequence of the shift in European Law from a paternalistic approach to medicine to an approach that favors the

primacy of patient autonomy, from an approach according to which the patient only did what the physician told him was best for her/his health to an approach that defends as a general rule that no intervention in the health field can be carried out unless and until the patient has given informed and free consent to it[49]. The application of the principle of beneficence by the physician, as stated in the Hippocratic oath ("I will use treatment to help the sick according to my ability and judgment but never with a view to injury and wrongdoing"), now also must consider the patient's preferences about whether to undergo medical treatment.

If we study the above legal and ethical documents we will be able to enumerate several rights of the patient. The patient is, according to European Law, entitled to:

— the right to respect of her or his person as a human being;
— the right to receive health care appropriate to her or his needs;
— the right to information about health services and how to use them;
— the right to a quality of care marked by technical and human standards;
— the right to be informed about her/his health status and about the diagnosis, prognosis and progress of treatment;
— the right not to be informed about the medical facts about her/his condition;
— the right to choose who should be informed on her/his behalf;
— the right to obtain a second opinion;
— the right to self-determination;
— the right to refuse or halt a medical intervention;
— the right to participate or not in scientific research;
— the right to confidentiality about all information of a personal kind revelead;

— the right of access to her/his medical files;
— the right to require the correction, completion, deletion, clarification and updating of personal and medical data;
— the right to have her/his privacy respected when medical interventions are carried out;
— the right to continuity of care;
— the right to have her or his moral and cultural values and religious and philosophical convictions respected;
— the right to enjoy support from family, relatives and friends during the course of care and treatment;
— the right to receive spiritual support and guidance;
— the right to access to safe health care;
— the right to complain when she/he feels her/his rights have not been respected;
— the right to form associations with other patients to defend their common interests;
— the right not to be discriminated against in the enjoyment of the referenced rights on any ground such as sex, race, color, genetic features, language, religion, political or other opinion, national or social origin, birth or other status;
— the right to humane terminal care and to die in dignity.

If we consider this list of rights, the most important, in our point of view, are the first and the last one: the right of every patient to respect of her or his person as a human being and the right to humane terminal care and to die in dignity. The respect for this last right is essential, because, although Medicine has added several years to life expectancy at birth, it has not yet assured life quality to those added years. Special protection by the law is required for the very elderly who frail and vulnerable and have diminished capacity to exercise their own autonomy.

If these rights are respected in the provision of care, all the other referred rights are, as well, observed.

According to the World Medical Association's International Code of Medical Ethics[50], the physician "shall in all types of medical practice, be dedicated to providing competent medical service in full technical and moral independence, with compassion and respect for human dignity". The doctor-patient relationship, therefore, has to be a "fully human" relationship.

Biomedical progress sometimes poses a risk to the humanity of the doctor-patient relationship. The multiplication of diagnostic tests may reduce the physician to a mere technician and the patient to the sum of the results of the tests. The very progress that can save lives can also make the human being simultaneously invisible and transparent, since her/his genetic constitution may be well known through genetic testing and disease foreseen before any symptoms appear. In such circumstances, the results of the predictive genetic tests may be used to unfairly discriminate against a person on grounds of his/her genetic constitution.

These situations may violate human dignity, which is the most important value of European Union's law[51]. Its respect and protection requires that the patient can never be seen as a research object or a biological ruin.

The patient may be in a state of weakness and dependency because she or he is ill. Nevertheless she or he is entitled to protection and support according to European Union's law, since there is a duty of solidarity among the members of the welfare states in order to protect the fundamental rights of each of its citizens.

Good clinical practice means not only a good diagnosis of the problem and skillfully carried out treatment, but also a humanistic knowledge and practice — it means that the doctor-patient relationship is fully human until the last moment of the patient's life. Thus being, the "last" right of each and every patient is the right to terminal care and to die in dignity.

The respect for this right is particularly important since medical progress has made it possible to cure many previously incurable or fatal diseases and to prolong a person's survival, by deferring the moment of death. As a result, the "quality of living" of the terminally ill and of the dying is often neglected. In order to enable a human being to die in dignity the physician shall not — according to Council of Europe's recommendations and jurisprudence[52] on this issue — aim exclusively at the prolongation of life, hastening or postponing death. He shall, otherwise, provide palliative care that aims to achieve and maintain the best possible quality of life for patients.

"Palliative care" is generally understood in European Law as "an approach that improves the quality of life of patients and their families facing the problem associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual"[53].

The right to die in peace and with dignity that must be respected by whomever provides this kind of care is recognized, for instance, in:

— Recommendation 779 (1976) on the Rights of the Sick and Dying;
— Recommendation 1418 (1999)1 on the Protection of the Human Rights and Dignity of the Terminally Ill and the Dying;
— Recommendation n. Rec. (2003)24 on the Organization of Palliative Care.

The obligation to respect the dignity of the terminally ill and of the dying implies good pain management and taking into account psychological, social and spiritual needs. It also implies

not using disproportionate medical measures and ensuring that relatives and friends are encouraged to accompany the person who is dying. The fulfillment of these needs will allow the dying patient to give a personal meaning to the time that she/he still has to live — will enable each person to "live" her or his own death. Even if no one asked us what we wanted before we were born, there is no reason for doing the same in what concerns our own death, and not to fulfill our needs before we disappear along the road curve[54].

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[1] Different definitions can be found in European Culture: from the mask used in Greek theatre, to Boethius idea that *persona est rationalis naturae individua substantia*, to Descartes' concept of *cogito ergo sum*, to the personalists idea that a person is "what can not be repeated twice"...

[2] See: WHO, 2008. About WHO. Geneva: World Health Organization. Available at http://www.who.int/about/en/.

[3] Jaspers, K., 1986. Der Arzt in technischen Zeitalter. München: R. Piper GMBh & Co. KG, p. 52.

[4] Stigmatization caused by a disease is clear in the little dwarfs' words in *The Birthday of the Infanta:* "When the truth drawned upon him, he gave a wild cry of despair, and fell sobbing to the ground. So it was he who was misshapen and hunchbacked, foul to look and grotesque. He himself was the monster and it was at him that the children had been laughing (...)". Wilde, O., 1997. The collected works of Oscar Wilde, Hertfordshire: Worsworth Editions, p. 271.

[5] All European Union's member States are also members of the United Nations and of Council of Europe. The Universal Declaration of Human Rights (UDHR) was adopted and

proclaimed by General Assembly Resolution 217 A (III) of 10 December 1948.

[6] Adopted by the UNESCO's General Conference on 11 November 1997 (UDHG).

[7] Adopted by UNESCO's General Conference on 19 October 2005.

[8] Adopted and opened for signature, ratification and accession by Assembly Resolution 2200A (XXI) of 16 December 1966 (ICCPR).

[9] Adopted and opened for signature, ratification and accession by the General Assembly resolution 2200A (XXI) of 16 December 1966 (ICESCR).

[10] Adopted and opened for signature, ratification and accession by General Assembly resolution 44/25 of 20 November 1989 (CRC). The protection of the child on medical care is also given by Recommendation 874 (1979) on a European Charter on the Rights of the Child, adopted by the Parliamentary Assembly on 4 October 1979.

[11] Treaty opened for signature by the member States of the Council of Europe on 4 November 1950 (CPHR).

[12] Treaty opened for signature on 3 May 1996 (ESCREV).

[13] The European Parliament, the Council and the Commission solemnly proclaimed the Charter on 7 December 2000 (ECFR).

[14] Art. 3 of UDHR, art. 6 of ICCPR, art. 6 of CRC, art. 2 of CPHR and art. 2 of ECFR.

[15] Art. 5 of UDHR, art. 7 of ICCPR, art. 3 of CPHR and art. 3 of ECFR. About the concept of torture in International Law see Grodin, M. A., 2006. Caring for survivors of torture and refugee trauma in the United States and Portugal. In P. L. de Faria, ed., 2006. The role of health law, bioethics and human rights to promote a safer and healthier world. Lisbon: Fundação Luso-Americana para o Desenvolvimento, p. 64-65.

[16] Art. 9 of ICCPR and art. 5 of CPHR and art. 6 of ECFR.

[17] Art. 2 of UDHG.

[18] Art. 12 of UDHR, art. 16 of CRC, art. 8 of CPHR and art. 7 of ECFR.

[19] Art. 23 of UDHR, art. 1 of Part II of ESCREV, art. 6 of ICESCR and art. 15 of ECFR.

[20] Art. 22 of UDHR, art. 9 of ICESCR, art. 12 of Part II of ESCREV and art. 34 of ECFR.

[21] Art. 12 of ICESCR, art. 24 of CRC, art. 11 of Part II of ESCREV and art. 35 of ECFR.

[22] Adopted by the United Nations' General Assembly on 18 December 1982.

[23] Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, opened for signature on 4 April 1997. See about patients' rights in International Law, MÉJICA, J. & Díez, J. R., 2006, El estatuto del paciente, Navarra: Editorial Aranzadi, p. 17-20.

[24] Opened for signature on 25 January 2005. Rights of persons who undergo medical research are also laid down in Recommendation n.º R (90) 3 of the Committee of Ministers to Member States concerning Medical Research on Human Beings, adopted on 6 February 1990.

[25] Adopted on 16 October 2003 by the 32nd session of the General Conference of UNESCO.

[26] Adopted by Council of Europe's Committee of Ministers on 23 January 1981. The respect of rights in the collection and processing of medical data is also guaranteed by Recommendation n.º R (97) 5 of the Committee of Ministers to Member States on the Protection of Medical Data adopted on 13 February 1997.

[27] Adopted by the Committee of Ministers on 8 November 2006.

[28] Adopted by the Committee of Ministers on 24 May 2006.

[29] Opened for signature on 24 January 2002.

[30] Adopted by the Parliamentary Assembly of the Council of Europe on 29 January 1976. On the same day was adopted by the same assembly Resolution 613 (1976) on the rights of the sick and dying.

[31] Adopted by the Parliamentary Assembly of the Council of Europe on 8 October 1977. Council of Europe's Committee of Ministers adopted on 22 February 1983, as well, in the field of the rights of persons suffering from mental disorder, Recommendation n.º R(83) 2 concerning the Legal Protection of Persons Suffering from Mental Disorder Placed as Involuntary Patients.

[32] Adopted by the Committee of Ministers on 21 June 1990. About the rights of people who undergo genetic testing see Nunes, Rui & Melo, H. P. de, 2000. Genetic testing in the workplace: medical, ethical and legal issues. *Law and the Human Genome Review,* 13, July-December, p. 119-142.

[33] Adopted by Council of Europe's Committee of Ministers on 10 February 1992. The rights of the participants in screening programs recognized in Recommendation n.º R (94) 11 of the Committee of Ministers to Member States on Screening as a Tool of Preventive Medicine, adopted by the Committee of Minster on 10 October 1994.

[34] Adopted by the Parliamentary Assembly of the Council of Europe on 25 June 1999.

[35] Adopted by the Committee of Ministers on 19 June 2003. The protection of xenograft recipients is, as well, guaranteed by Recommendation 1399 (1999) on Xenotransplantation, adopted by the Parliamentary Assembly on 29 Jannuary 1999, and by Recommendation n.º R (97) 15 of the Committee of Ministers to Member States on Xenotransplantation adopted on 30 September 1997.

[36] Adopted by the Committee of Ministers of the Council of Europe on 12 November 2003.

[37] Adopted by the Committee of Ministers on 22 September 2004. Legal protection of adults who, by reason of an impairment or insufficiency of their personal faculties, are unable to make autonomous decisions, is also provided by Recommendation n.º R(99) 4 on Principles Concerning the Legal Protection of Incapable Adults, adopted by the Committee of Ministers on 23 February 1999.

[38] The WMA Declaration of Helsinki on the Ethical Principles for Medical Research Involving Human Subjects was adopted by the 18th WMA General Assembly, in Helsinki, on June 1964, and amended by the 29th WMA General Assembly, in Tokyo, on October 1975, by the 35th WMA General Assembly, in Venice, on October 1983, by the 41st WMA General Assembly, in Hong Kong, on September 1989, by the 48th WMA General Assembly, in Somerset West, on October 1996 and by the 52nd WMA General Assembly, in Edinburgh, on October 2000.

[39] The WMA Declaration on the Rights of the Patient was adopted by the thirty-forth World Medical Assembly, in Lisbon, on September/October 1981 and amended by the forty-seventh WMA General Assembly, in Bali, on September 1995.

[40] The WMA Declaration on Terminal Illness was adopted by the thirty-fifth World Medical Assembly, in Venice, on October 1983 and revised by the WMA General Assembly, in Pilanesberg, on October 2006.

[41] The WMA Declaration of Ottawa on the Rights of the Child to Health Care was adopted by the 50th World Medical Assembly, in Ottawa, on October 1998.

[42] This Declaration on Human Genome Mapping, Genetic Screening and Gene Therapy was adopted in the XXIVth Round Table Conference of the CIOMS, in Inuyama City, on July 1990.

[43] This Declaration that lays down guidelines for Physicians concerning Torture and other Cruel, Degrading Treatment or Punishment in Relation to Detention and Imprisonment, were adopted by the 29th World Medical Assembly, in Tokyo, on

October 1975, and editorially revised at the 170th Council Session, in Divonne-les-Bains, on May 2005, and at the 173rd Council Session, in Divonne-les-Bains, on May 2006.

[44] Issued by CIOMS in Geneva on 2002.

[45] This Charter, based on the current situation in the European countries, was presented in November 2002 in Brussels by the Active Citizenship Network.

[46] A WHO European Consultation on the Rights of Patients, meeting in Amsterdam, from 28 to 30 March 1994, endorsed the Declaration as a set of principles for the promotion and implementation of patients' rights in WHO's European Member States.

[47] Adopted by the European Association for Children in Hospital in Leiden, in 1988.

[48] These Recommendations were adopted at the third Workshop of National/Regional Health Promoting Hospitals Network Coordinators, in Vienna, on 16 April 1997.

[49] About paternalism v. autonomy see Stauch, M., Wheat, K. & Tingle, J., 2006. Text, cases and materials on medical law. 3th edition. New York: Routledge-Cavendish, p. 28-40; Jonsen, A. R., Siegler, M. & Winslade, W. J., 2006. Clinical ethics. 6th edition. New York: McGraw-Hill, p. 54. and Bilancetti, M., 2006. La responsabilità penale e civile del medico. 3rd edition. Padova: CEDAM, p. 368-378.

[50] Adopted by the third General Assembly of the WMA in London on October 1949 and amended by the 22nd World Medical Assembly in Sydney on August 1968, by the 35th World Medical Assembly in Venice, on October 1983, and by the WMA General Assembly in Pilanesberg, on October 2006.

[51] Art. 1 of Convention on Human Rights and Biomedicine and art. 1 of ECFR.

[52] See the following cases of the European Court of Human Rights: Case of Glass v. The United Kingdom (Application

n.º 61827/00), and Case of Pretty v. The United Kingdom (Application n.º 2346/02). These cases are available at: http://cmiskp.echr.coe.int/.

[53] WHO, 2008. WHO definition of palliative care. Geneva: World Health Organzation. Available at: http://www.who.int/cancer/palliative/definition/en/print.html.

[54] As a Portuguese Poet (Fernando Pessoa) wrote, "Death is the road curve. To die is only not to be seen anymore".