17 OCT. 1994

INTERNATIONAL ENCYCLOPAEDIA OF LAWS

MEDICAL LAW
SPAIN

by

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Kluwer, Deventer
1993

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04.01.3 – 19018

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The present work is the partial result of a Research Project supported by the Government of the Canary Islands (Departament of Education, Culture and Sport). The authors are indebted to Karl McLaughlin for translating the bulk of the original Spanish version of this work and supervising the remainder, and to Fátima Flores-Mendoza, Research Assistant in Criminal Law at the University of La Laguna, for compiling the list of contents (index).

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LIST OF ABBREVIATIONS

Art.	Article
ATS	Ayudante Técnico Sanitario (a type of nurse)
CC	Código Civil (Civil Code)
CP	Código Penal (Penal Code)
EC	European Community
GP	General Practitioner
INSALUD	National Institute of Health
LGS	Ley General de Sanidad (General Health Law)
MO	Ministerial Order
OMC	Organisation of Colleges of Physicians
RD	Royal Decree

General Introduction

I. The General Background of the Country

§ 1. Geography and Climate

1. Lying at the southwestern end of the European continent, and with a total area of 504,782 square kilometres, which includes the Balearic and Canarian archipelagos, Spain occupies the bulk of the Iberian Peninsula. Of its 5,849 km of peninsular perimeter, 3,904 correspond to the Cantabrian Sea, the Atlantic and the Mediterranean, with the remainder taken up by the country's borders with Portugal (to the East) and France and the principality of Andorra (to the North). Spain is the second most mountainous country in Europe after Switzerland and is characterised by a combination of mountain ranges and river basins. The country enjoys one of the most benign climates in Europe, with a marked contrast between the predominantly mild climate and even temperatures of the coastal areas and archipelagos, and the more continental climate inland, although even here but temperatures rarely fall to very low levels.

2. Spain's population in 1991 was 39,159,000, with a density of 78 inhabitants/km2.

§ 2. Cultural Make-Up

3. Although the country's national language is Spanish, the official status granted to the Catalan, Basque and "Gallego" languages in their respective Autonomous Communities has led to a strengthening of the corresponding regional cultures.

4. Spain has no established church of the state, although the majority of the population is Catholic; an estimated 37% of taxpayers expressly requested that part of their taxes be used to maintain the Catholic Church in 1988.

§ 3. Political and Judicial System

5. The Spanish Constitution of 1978 is the body of legislation which underpins the country's political system. Article 1 stipulates that Spain is a social and democratic state based on the rule of law and also describes the political system as a parliamentary monarchy.

6. The King is the head of state, without legislative powers, and is also commander in chief of the armed forces.

7. The government, or executive branch, is responsible for the country's international and national policies, as well as the state administration. It consists of the president, vice-presidents, ministers and other members stipulated by law. The King proposes a candidate for the presidency of the government after consultation with the leaders of the political groups which gain parliamentary representation in a general election. The candidate put forward must obtain the approval of the Congress of Deputies.

8. Legislative power lies with the Cortes Generales, which comprise two Chambers: the 350-member Congress of Deputies, which represents the Spanish people as a whole, and the 225-member Senate, which represents territories and provinces. Both chambers are elected by universal suffrage in elections at which all Spaniards over the age of 18 are entitled to vote. Voters choose between candidates in each of the country's 51 constituencies (49 provinces, together with Ceuta and Melilla). Exceptionally, however, some senators are appointed directly by the Autonomous Communities.

The 17 Autonomous Communities (Andalusia, Aragon, Asturias, the Balearics, Basque

Country, Canary Islands, Cantabria, Castilla-La Mancha, Castilla-Leon, Catalonia, Extremadura, Galicia, La Rioja, Madrid, Murcia, Navarra and Valencia) have their own governments and regional parliaments. The extent to which each Community is competent to handle its own affairs depends on the processes provided for in the Constitution and the corresponding Statutes of Autonomy.

State and Autonomous Community elections are held every four years.

9. The judicial system is tailored to the State's political structure, in accordance with the provisions of the Constitution of 1978 and the subsequent Organic Law on Judicial Power of 1985. The system consists of a Supreme Court, National High Court, Central Magistrates' Courts and Central Criminal Courts, which have jurisdiction over the entire nation; High Courts of the Autonomous Communities; Provincial High Courts, Petty Courts with criminal jurisdiction, as well as courts for administrative litigation, labour disputes, prison matters, and juvenile courts, all of which have provincial jurisdiction; courts of first instance and magistrates' courts, corresponding to juridical districts, and justices' courts in municipalities where none of the above exist.

10. The Constitutional Court is supreme in matters relating to the interpretation of the country's Constitution. Its competences and workings are laid down in the Constitution itself and in the Constitutional Court Law of 1979. A single body, whose jurisdiction extends over the entire country, the Court deals with appeals and questions of constitutionality concerning laws, normative provisions or enactments which have the force of law. It also handles appeals for constitutional protection in cases involving the violation of rights and public freedoms and conflicts of jurisdiction which arise between the State and Autonomous Communities or between the Autonomous Communities themselves.

11. Spain's Constitution of 1978 was drawn up with Europe in mind. Title III of Chapter III concerning international treaties provides for a flexible system for the conclusion of treaties under which competences derived from the Constitution may be transferred to international organisations or institutions (article 93). It also provides for the incorporation of such treaties into national legislation (art. 96). Spain acceeded to the European Community in 1986, although it was not until 1992, following the Maastricht agreements which marked a substantial step forward in the process of European integration, that modifications had to be made to the Constitution to adapt it to new Community legislation. Article 13 was amended to extend voting rights in local elections to foreign residents.

§ 4. Population and Vital Statistics

12. Of Spain's population of 39,159,000 in 1991, 19,125,000 were male and 20,034,000 female (51%). 24.4% were aged under 18 and 11.7% over 65.

The country's birth and death rates stood at 13/1000 and 9/1000 respectively, with infant mortality (children aged under 1) standing at 11/1000. The population growth rate for the period 1973-1986 was 0.9%. The fertility rate in 1986 was 1.8 children per woman, while the life expectancy for those born in the same year was 76 years. Spain's fertility rate is one of the lowest in the world, below that of France, the United Kingdom, Sweden, Holland, Switzerland and Belgium, and only slightly higher than Italy's. The fall in the rate has given cause for concern in recent years and is a marked contrast to the situation up to the mid-70s, when Spain enjoyed one of the highest rates in Europe.

13. 77% of the population is urban based.

§ 5. Social and Cultural Values Regarding Health

14. Spain´s health statistics are similar to those of its European partners. The number of cases of notifiable disesases or illnesses has fallen considerably over recent years and can now

be considered as being normal and a reflection of the significant improvement of the health care system. In 1991, for example, 3.755.221 cases of flu were notified, along with 15.938 cases of hepatitis and barely 36.000 cases of food poisoning.

Nutritional habits have gradually declined and the traditional healthy mediterranean diet is suffering as a result.

The recent fall in the number of smokers has levelled off over the last few years and the figure now stands at approximately 34% of the adult population, For its part, alcohol consumption is amongst the lowest in Europe.

The World Health Organisation recorded 9.112 cases of AIDS in Spain in 1991, of which 233 resulted in death .

Under the ambitious National Transplant Programme, 232 heart transplants, 3 lung transplants, 16 heart and lung transplants, 21 liver and 1.371 kidney transplants were carried out.

II. General Description of the Health Care System

§ 1. General Review of the Spanish Health Care System

15. The precursors of the National Health System put in place by the General Health Law (Ley General de Sanidad —LGS—) were the Institution of Public Welfare, the National Health and the Social Security.[1] During the last century, and up to the early years of the present one, the Public Welfare was a state scheme which catered for the needs of the destitute and the poor. In addition to providing health cover, the scheme also covered other areas of need such as food, education and employment;[2] the advent of epidemiological diseases led to a strengthening of action in the field of public health.[3]

There was, however, a large sector of society which, although not destitute, did not have sufficient means to meet its health needs. Demands were growing for a type of protection to ensure that such people would not be forced into poverty, which was a requirement for Public Welfare eligibility. Particularly vulnerable were workers who although they found it difficult to make ends meet, were not entitled to Public Welfare given that they were not "poor". Others, meanwhile, were better off and could afford to take out private social insurance cover. In this way independent social insurance gradually became established as a means of providing cover for old age, subsistence, accidents at work, family responsibilities, common illnesses, invalidity, illnesses derived from the exercise of one's profession, etc). Eventually, the State responded to working class demands and created a Compulsory Insurance scheme under a Law passed on 14 December 1942. The scheme provided protection for the least well-off sectors of the population and afforded health assistance for general medical care as well as a variety of outpatient surgery specialities and medicines. National health-care centres[4] were set up to deal with certain illnesses, whereas other levels of (hospital) health care were provided by local corporations and non-profitmaking institutions such as the Catholic Church and the Red Cross. Subsequent endeavours were made to develop a Social Security system. A first step was the promulgation of Law 193/1963 of 28 December which established the bases of the Social Security system. This law attempted to bring together all existing forms of social insurance and was followed by the Social Security Law of 21 April 1966, which aimed to provide health assistance for a specific sector of society, ie workers. Workers were brought under the system because as paid employees they (together with their employers) helped finance the cost of Social Security services (Revised Text approved by Decree 2065/1974 of 30 May). The scheme forms part of the current National Health System, which covers a wide range of beneficiaries.[5]

The health care system underwent gradual transformation until the State decided to include the Social Security system as yet another of its functions. The system was granted its own normative provisions and it began to move away from the "labour" criterion on which entitlement to health assistance was previously gounded.[6]

16. A new stage was reached with the passing of the Spanish Constitution of 1978, which recognises the right to health protection in article 43.1. Entitlement covers all Spaniards as well as foreigners resident in Spain;[7] however, article 41 of the Constitution stipulates also that "the public authorities shall maintain a public Social Security system for all citizens, to guarantee sufficient social assistance and services..." One can deduce from this that the Social Security system has become totally "decoupled" from worker status, given that it has to cater for all Spaniards, which has obvious repercussions on the manner in which the system is financed. Under this constitutional principle, the authorities are obliged to implement and safeguard health protection; health thus is given the status of a *public service* in accordance with the provisions of article 43.2 of the Constitution.[8] A reflection of this can be seen in the universalisation of Social Security assistance which resulted from the creation of a system of non-contributory pensions.

The basic principles on which the National Health System is grounded are those set out in the General Health Law, which was drawn up to enforce the mandate of article 43.2 of the Constitution.[9] The public bodies responsible for health protection are the State Administration, Autonomous Communities and local corporations. The National Health System comprises all the Health Services of the State Administration and those of the Autonomous Communities. Decentralisation, which is a requirement set out in the Constitution and in the respective Statutes of the Autonomous Communities, is a fundamental principle which determines to a large degree the way in which health services are provided. These services are brought under the wing of the Autonomous Communities, while the State is essentially charged with powers of management and coordination. The State is competent as regards basic concepts of care, general coordination and top-level inspection, aspects which aim to maintain unity in the field of health and to achieve basic equality among citizens as regards their health. Executive-type services are the responsibility of the Autonomous Communities, which also exercise normative powers where the State has not reserved these for itself in relation to health. Local corporations participate in the management and control of Health Areas.

§ 2. Regulation of the Health Care System

17. A new legal framework to govern health was needed in view of the fact that the 1944 Law which established the bases of the National Health Service had become obsolete and out of touch with society's needs and health requirements. The General Health Law (LGS) under which the current National Health System was created, gave specific form to the health-care principles and objectives which had been mapped out previously in the Constitution. In doing so, it did away with the models of public health-care action which had prevailed in the nineteenth and early twentieth centuries and which concentrated on collective as opposed to individual assistance. Today's priorities include health promotion, prevention of illnesses and diseases and health education. The system, which covers mental health also, caters for the entire population, including those not covered by Social Security and persons without means of subsistence (article 3 of the LGS).

18. The protection of *public health*, particularly aspects of prevention, is a primary concern of the Spanish State, as reflected in the passing of Organic Law 3/1986 of 14 April on Special Public Health Measures, which empowers the health authorities to adopt certain measures in cases or situations of emergency or need. The measures cover examinations, treatment, hospitalisation or control when there exists reasonable grounds to assume that the health of the population may be at risk (article 2). It also enables the Administration to temporarily centralise supplies of medicines or health products where problems of supply exist, in order to ensure efficient distribution. Furthermore, in addition to authorising preventive action —with the corresponding curtailment of citizens' freedoms—, the law also empowers the Administration to control the sick or persons who have been in contact with them and their environment in cases where public health has already been affected, especially in the case of an epidemic (article 3). The legal system for the protection of collective is present also in the Criminal Law,

which penalises a series of conducts deemed to be dangerous to the health of the public;[10] in addition to all the above, there exists a wide range of administrative regulations governing aspects relating to health protection.

19. The *individual health* of citizens is a public health priority of the State, both in terms of prevention and assistance. State care is a constitutional obligation and an area in which significant progress has been achieved, particularly as regards the care provided by the Social Security system. The universalisation of individual protection, which has entailed partial abandonment of the former mode of financing the system through contributions, means that public health care is now available to all citizens as the result of the universalisation of individual protection, which has entailed partial abandonment of the former mode of financing the system through contributions.

The General Health Law allows citizens to choose their primary care G.P. in their Health Area; it provides for the creation of an integrated network of public hospitals and the association of private general hospitals to the National Health System when required. It also provides for the right to freely practice a health-care profession and for freedom of enterprise in the health sector, in accordance with the provisions laid down in the Constitution.[11]

20. The structure of the model of assistance is thus conceived as a whole, which comprises activities to enhance and promote health, prevention, curative assistance and rehabilitation. Health services are *structured* in such a way as to facilitate user proximity and a form of decentralised management which allows for public participation. Each Autonomous Community has its own Health Service, which includes all the centres, services and establishments in the Community in question. The cornerstones of these Services are the Health Areas, which are generally designed to cater for populations of between 200,000 and 250,000 and which provide all the services available under the health system. For smoother running, Health Areas are divided into Basic Health Zones for primary health care. The Zones' Health Centres and General Hospitals, in addition to providing assistance, also play a role in promoting health, preventing illness and disease and in teaching and research, all in accordance with the programmes which each Health Area draws up as complementary activities to those undertaken by the primary care network. To this end, the basic organisation of the system centres on the National Institute of Health (which is managed by the Social Security system), with health services reorganised as follows:

I) On the territorial level, the health system comprises essentially Health Areas, divided in turn into Basic Health Zones.

II) As regards assistance, the following levels exist:

A) *Primary Care.*[12] This is provided to individuals and families in Health Centres by medical teams, which in addition to curing in the strict sense also undertake promotion, prevention and rehabilitation activities. The Health Centres are staffed by general practitioners, paediatricians, nursing staff, social workers and administrative personnel. The staff carry out their work in the Centre itself and in the patient's home, and may be called to deal with emergencies. Health education is also undertaken by Centres.

B) *Specialist care.*[13] Hospitals, which are better equipped both in terms of staff and facilities, are the cornerstones of specialist care. They also act as centres for teaching and research and carry out their own health promotion and prevention activities, in accordance with Health Area programmes.

Medical assistance comprises General Medicine, as well as Specialist and Emergency Medicine services which are provided in health centres, on an in-patient basis or in the patient's home. Users covered by Social Security receive such services free of charge, and do not have to pay anything in addition to their normal contributions.

Pharmaceutical assistance covers pharmaceutical specialities, items and accessories as well as prescriptions issued by doctors under the Social Security system. These are completely

free of charge in certain cases (OAPs and their dependants, the handicapped, persons who have sustained accidents at work, etc). In other cases, users pay 40% of the retail price of the drug or medicine, except for some of a special nature. The fee is paid directly to the dispensing chemist.[14]

In addition, promotion and prevention work is carried out in the field of primary health care via the Health Centres. In some cases such action is targeted specifically on, for example, family planning, mental health and maternity care (Family Planning Units and Centres, Mental Health and Psychoprophylaxis Units).

21. *General Health Care Coordination* is the means by which minimum common goals for prevention, protection, promotion and assistance are determined. To this end, a number of competences are granted for coordination purposes and support is available from the Inter-Territorial Council of the National Health System, a body chaired by the Minister for Health and Consumer Affairs and consisting of a representative appointed by each Autonomous Community and an equal number of State Administration representatives. Coordination is also achieved by means of the Integrated Health Programme which is of paramount importance in ensuring that health services function efficiently. This integrated programme brings together State and Autonomous Community programmes as well as any joint plans drawn up to enable both sides to carry out their respective health care functions. Coordination at State level is also achieved through agreements concluded by the State and the Autonomous Communities, and any joint action which they may agree to undertake.

22. In general, health services are organised on the basis of direct public management, that is, through publicly-owned centres staffed by personnel who are subject to Public Law statutes.[15] However, provision is also made for the use of private forms of management of health services; this means that privately-owned centres may provide assistance on behalf of the health-care system. The public network is thus complemented through association agreements reached with private centres or through the linking up of private hospitals to the public system.

In order to exercise its functions,[16] the State relies on the administrative machinery of the Ministry of Health. All health-care centres and services come under the Autonomous Communities,[17] with the exception of the Instituto de Salud Carlos III, an independent institution belonging to the state administration, set up to provide technical and scientific support to State and Autonomous Communities Health Services.

The State health administration is charged with assessing the suitability of medicines and other health products and articles and is also responsible for authorising their use and controlling the quality of such products.

The General Health Law lays down certain minimum principles to be followed by the Autonomous Communities in the organisation of their Health Services, although it does not interfere with their competences granted to them under their respective statutes. Each Community delimits its Health Areas, which, in addition to an Area Board and Manager, must also include an Area Health Council, a collegiate body for consultation and montitoring of public health management in which the public participate (citizens, trade unions). In exercising their competences the Autonomous Communities must allow for democratic participation by all interested parties, including representatives of unions and employers' organisations. Each Community draws up its own Health Plan which contains all the actions necessary to help accomplish the goals set for its health-care centres. The plan also regulates the organisation, functions and allocation of material and staff.

§ 3. Financing of the Health Care

23. The General Health Law advocates a tightened belt approach to solve the problem of the large health service deficit caused by increased expenditure and squandering of resources.[18] Obviously, if the goals of the new health system were to be attained, an increase in spending was necessary to enable care to be extended to the entire population. The planning and fixing of the major principles of the system was crucially important, as were the search for sources of

financing and the distribution and management of financial resources.[19] Prior to 1986, restrictive health budgets were the order of the day; however, the gradual widening of the system of social security assistance to cover the entire population required more spending on public health and, therefore, increased funding for the sector.[20]

Chapter V of Title III of the General Health Law deals with the financing of the National Health System. The chief mechanism is the inclusion in the Budgets of the State, Autonomous Communities, local corporations and the Social Security of budget lines to cover the health care requirements of all the bodies and institutions which are dependent on the public administration (article 78 of the General Health Law).

The system is financed by social security contributions paid by employees and employers, transfers of State funds, fees charged for certain services and contributions made by the Autonomous Communities and local corporations.

In view of the increased expenditure during previous years, the financing of the National Health System was reformed by the Budget Law of 1989. The reform's major aim was to consolidate the system as a public service for all citizens, and to distribute existing resources rationally and enable social security health cover to be extended to the entire population.[21]

Financial functions in the field of health care are exercised by the State. The funds which it transfers to the Autonomous Communities depend on the size of the population to be covered. In addition, the Communities receive financing for their health-care centres from the Social Security budget, although they also contribute their own funds and raise money by charging for health services provided to third parties.

Apart from this basic funding mechanism, the State may at its discretion use other complementary forms to correct imbalances between regions. It may draw up its own action plans, including those for investment, and may provide partial or total financing of Autonomous Communities health programmes, or contribute to the financing of joint programmes drawn up between the State and one or all of the Communities.

III. Medical law

§ 1. Definitions and functions of Medical Law

24. Medical law is not clearly circumscribed in the Spanish legal system and is often confused with Health Law and Legal Medicine. Strictly-speaking, Health Law embraces the legal system of health in its entirety, particularly the public health system, public health actions and citizens' relations with the health-care system. Legal Medicine is the part of medicine which is used as an auxiliary instrument in the administration of justice.

Medical Law can thus be defined initially as *the parts of the legal order which concern themselves with Medicine, that is, the medical profession and, by extension, other health or health-related professions*. Medical law refers to the professional relations of physicians (and other similar professionals) with the system of health care, with (public and private) health-care users and patients, and other health professionals. However, in view of the constant widening of the scope of actions affecting health, nowadays Medical Law includes also *the legal implications of the application to human beings of the so-called Biomedical Sciences*, that is, not just medicine but also biology (e.g. genetics), biochemistry, biophysics, etc. To a certain degree also it takes in the specific legal aspects of the use by health professionals of certain technologies, such as computers. A problem currently exists with regard to the delimitation of Bioethics, due in particular to the influence exerted on the concept by the Americans, who understand Bioethics as comprising not just the ethical aspects (applied ethics) of the biomedical sciences but also philosophical, sociological and legal considerations also. Both Bioethics and (Bio)Medical Law study the biomedical sciences and how they affect human beings, although they do so from different perspectives: the former from the ethical viewpoint and the latter from the legal standpoint. However, it is now accepted that Bioethics, in the broad sense of the term, may constitute a focal point for the multi-disciplinary study of the implications of the biomedical sciences for human beings. It should be stressed nonetheless

that these sciences are independent and autonomous disciplines.
Medical law as such is not taught officially in Spanish universities, although it does figure occasionally in postgraduate courses. It is likely that under the proposed new curriculum for Universities the subject will be offered as an option, particularly with law and medical students in mind, although in the case of Schools of Medicine only Bioethics has tended to be included in the proposals, due partly to the confusion referred to just now and partly because it is probably considered that teachers of Bioethics will not necessarily require previous training in the subject (an opinion which, if that is indeed the case, would be misguided).
In any case, it has to be accepted that (Bio-)Medical Law today is an autonomous discipline which is of crucial theoretical and practical importance given its potential effects on society.

§ 2. Sources of Medical Law

25. Specific medical law sources in Spain have developed considerably over the years. As will become clear in the following pages, a number of Laws in Spain address medical issues: the 1979 Law on the Removal and Transplantation of Organs, the General Health Law of 1986; the 1988 Law on Techniques of Assisted Reproduction; the 1988 Law on the use of human gametes, embryos and foetuses; the Drugs and Medicines Law of 1990, and others. These issues are taken up further in Royal Decrees, which cover other aspects also such as blood donation, and in Ministerial Orders. Although rather scarce so far in this field, court rulings also can constitute sources of Medical Law and provide important (although not always legally binding) points of reference.

26. As regards non-specific cources, mention should be made first and foremeost of the Spanish Constitution of 1978, which sets out fundamental rights which may be affected by medical practice: the right to life and to physical and moral integrity (art. 15), the right to ideological freedom (art. 16), the right to freedom (art. 17), the right to privacy (art. 18), etc. The Constitution also enshrines the principle of non-discrimination (art. 14) and refers to the dignity of the human person and the free development of personhood (art. 10). In addition to the above, there are numerous provisions in both criminal and civil law which are applicable to the practice of medicine, particularly as regards liability in respect of malpractice and circumstances such as abortion. On the international level, special reference should be made to the human rights Conventions subscribed and ratified by Spain and which, as result, now form part of domestic law (art. 96 of the Constitution) and are of help in the interpretation of the fundamental rights laid down in the Constitution. Of particular interest in this regard is the Universal Declaration of Human Rights, which is mentioned expressly in the Constitution (art. 10.2). Other examples include the European Convention for the Protection of Human Rights and Fundamental Freedoms (1950) and the International Covenant on Civil and Political Rights (1966).

IV. Selected Bibliography

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NOTES

1. See M. BEATO ESPEJO, 'El sistema sanitario español: su configuración en la Ley General de Sanidad', in *Revista de Administración Pública*, n. 119, May-August 1989, p. 385.

2. The first law on Health was passed in 1855. On the basis of physicians' freedom to practise their profession, the law aimed to provide assistance for the poor; the health care it included covered collective - as opposed to individual- health only. 1925 saw the passing of Municipal and Provincial Regulations which once again focused on collective health and assistance for the poor. See P.P. MANSILLA IZQUIERDO, *Reforma Sanitaria. Fundamentos para un análisis*, (Ministerio de Sanidad y Consumo, Madrid 1986), pp. 5-7.

3. The General Public Health Instructions issued in 1904 created a system for the control of epidemiological diseases; similarly, the Regulations of 26 July 1945 governing the fight against infectious diseases, disinfection and protection against insect pests, and the Regulations of 4 February 1958 on the fight against trachoma, venereal diseases and dermatosis. See J. PEMAN GAVIN, *Derecho a la salud y Administración sanitaria*, (Publicaciones del Real Colegio de España, Bologna 1989), p. 119.

4. The 1944 law which established the foundations of the National Health system marked the first attempt to coordinate existing health-care networks (those of municipalities and provincial governments organised under the welfare system) and to cater for individual and not just collective health. See MANSILLA IZQUIERDO, *Reforma Sanitaria,* cit., p. 9.

5. The extension of Social Security cover since 1983 has been based on the labour status of the beneficiary. Cover was thus extended to the unemployed and unemployed members of their families (Law 31/1984 of 2 August), self-employed persons and their families (Royal Decree 43/1984 of 4 January), dependants under the age of 26 (Royal Decree 1377/1977 of 4 July), emigrants and their children (Royal Decree 916/1986) and persons over 26 who are unemployed and live with the direct beneficiary (Royal Decree 1682/1987 of 30 December). At 31 December 1989 38,433,425 people —96.14% of the total population of Spain— were entitled to health-care cover, according to a report on health-care institutions by the Ministry of Health and Consumer Affairs. Cover was further extended under Royal Decree 1088/1989 of 8 September to those with insufficient incomes, which brought many elderly persons and those on the edges of society into the system. The "health cover for all" process was completed by Social Security Law 26/1990 of 20 December, which partly reformed the Revised Text and created non-contributory pensions for retired people and invalids. Under this system pension entitlement is extended to persons over 65 resident in Spain, who have not paid social security contributions and do not have sufficient income.

6. See A. PALOMAR OLMEDA, 'Las normas jurídicas de Seguridad Social y las normas jurídico-administrativas', in *Revista de Administración Pública*, no. 126, September-December 1991, p. 412.

7. For an analysis of proposals for the reform of the health care system made during the period 1977-1982, see F.J. ELOLA SOMOZA, *Crisis y reforma de la asistencia sanitaria pública en España (1983-1990)*, (Fondo de Investigaciones Sanitarias de la Seguridad Social, Madrid

1991), pp. 71 ff.

8. Article 43.2 of the Constitution states that "the authorities shall organise and safeguard public health through the taking of preventive measures and the provision of the necessary facilities and services. In this respect, the law shall determine the rights and duties of all concerned". In the opinion of J.M. RODRIGUEZ PASTRANA, *El servicio público de la Sanidad: el marco constitucional*, (Civitas, Madrid 1984), pp. 31 f, "what is inferred from the Constitution is, therefore, a *Public Health Service*, which should not be confused with a monopolised National Health Service... The basic idea of the National Health Service is, to a certain extent, the socialisation of health management, which is placed in public hands... However, in a Public Health Service, although the State is certainly ultimately responsible for all public and private health-care activities, it does not reserve for itself the exclusive management of said activities...". Elsewhere, article 3.2 of the General Health Law states that public health-care assistance shall extend to the entire population.

9. Article 7 of the General Health Law states that health-care services shall be organised and shall function in accordance with the principles of efficiency, promptness, economy and flexibility.

10. Section Two of Title V of the Penal Code (articles 341-348 bis b) is devoted to public health and environmental offences. Among conducts deemed to constitute an offence are the unauthorised manufacture and selling of substances which are dangerous to health, breaches of regulations governing trade in such substances, the illegal dispensing of drugs and medicines, the alteration of medicinal substances, the malicious spreading of disease, fraud concerning food products and illegal drug trafficking.

11. See Chapter I, Part I.

12. See Royal Decree 137/1984 of 11 January, on Basic Health Structures.

13. See Royal Decree 521/1987 of 15 April on the structure, organisation and functioning of hospitals managed by the National Institute of Health.

14. Users may also be entitled to other services, such as payment for drugs or medicines not available in Spain, for fixed and orthopedic surgical appliances of a permanent or temporary nature, invalid vehicles, use of ordinary means of transportation (ambulances) for patients who require them frequently to follow treatment such as dialysis, radiotherapy, rehabilitation, etc.

15. Prior to 1978, the Social Security system was managed by the National Providence Institute (Instituto Nacional de Previsión), which was dissolved under Royal Decree 36/1978 of 16 November. Its functions were taken over by, among other bodies, the management institutions of the Social Security system: the National Institute of the Social Security (INSS), which handles payments of benefits under the system; the National Social Services Institute (INSERSO) which manages complementary social services (for the elderly and handicapped), and the National Institute of Health (INSALUD), which manages and administers the system's health-care services.

16. Under article 149.1.17 of the Constitution, the State is exclusively competent to draw up "the basic legislation and establish the economic regime of the Social Security system, although services may be provided by the Autonomous Communities". Under article 149.1.16 it is solely responsible for "external health. The bases and overall coordination of health. Legislation governing pharmaceutical products".

17. Under numbers 20 and 21 of article 148.1 of the Spanish Constitution, and in accordance with the terms laid down in their respective Statutes, Autonomous Communities may take on

competences in relation to social assistance and health and hygiene.

18. See ELOLA SOMOZA, *Crisis y reforma de asistencia sanitaria pública en España*, cit., p. 109.

19. Article 81 of the General Health Law (LGS) states that "the generalisation of the right to health protection and assistance, which entails bringing public health assistance and services into line, shall be accomplished by allocating financial resources which take into account both the size of the population in need of assistance in each Autonomous Community and also investments in health which need to be undertaken to correct health-care inequalities between territories, in accordance with article 12".

20. Increased expenditure was caused not merely by the extension of health care to the entire population, but also by the need to cater for mental health, the organisation and structure of the National Health system, research and the Instituto de Salud Carlos III. See ELOLA SOMOZA, *Crisis y reforma de la asistencia sanitaria pública en España*, cit., p. 113. Somoza argues that "*the increase in health expenditure produced by the LGS was clearly underestimated.* This, combined with the aforementioned ambiguity and the absence of specific commitments in the Law, lends support to the theory that *the LGS lacked sufficient policy backing to enable it to carry out its proposals. To a certain extent, it served rather to lay out a final scenario which successive reforms should aim towards,* insofar as sufficient resources could be allocated in future to implement them.

21. ELOLA SOMOZA, *Crisis y reforma de la asistencia sanitaria pública en España,* cit., pp. 113-120.

Part I. The Medical Profession

Chapter I. Access to the Medical Profession

§ 1.Medical Education

27. Regulation of the medical profession in Spain is currently in line with the guidelines laid down by European Community Law, particularly the Directives designed to harmonize conditions and requirements for entry to and specialisation in medical studies throughout a Community which is highly sensitive to the importance that the profession holds for society.[1]

28. Would-be students of medicine at university must pass compulsory aptitude tests designed to examine whether they are properly prepared for such studies. The tests, which are taken after the one-year pre-university course (C.O.U.), focus on the mainstream and optional subjects of the degree syllabus and are similar for all Spanish universities. They are held annually in universities and may be taken by Spaniards resident abroad and foreigners who attest to having followed a suitable course of study abroad. Once they have successfully taken these tests, candidates cannot then be asked to take further entrance exams, although faculties may limit the number of places on offer, in which case those who obtain the highest marks in the university entrance exam will be admitted.[2]

29. The official university Degree in Medicine was established by RD 1417/1990 of 26 October, which lays down guidelines for syllabuses leading to the awarding of the degree. The degree itself is valid throughout the country, although each faculty is at liberty to organise and plan its own syllabus leading to the award. Syllabuses are designed primarily to ensure that doctors trained in faculties of medicine gradually acquire sufficient clinical experience and expertise. The aforementioned Royal Decree[3] stipulates that training must provide students with:

a) an adequate knowledge of the sciences which form the basis of medicine and a sound understanding of scientific principles, including the measurement of biological functions, evaluation of scientifically-proven facts and data analysis.
b) an adequate knowledge of the structure, functions and behaviour of human beings, healthy and otherwise, as well as of the relationships between states of health and man's physical and social environment.
c) an adequate knowledge of clinical subjects and practice, in order to provide students with a coherent view of mental and physical illnesses, of the preventive aspects of medicine, of diagnosis and therapeutics, and of human reproduction.
d) adequate and appropriately-supervised clinical experience in hospitals.

Training focuses on the preventive, diagnostic and therapeutic aspects of medicine, with the help of clinical experience acquired in hospitals. Agreements reached between the public administrations and universities and health institutions in which university training is provided guarantee the practical teaching of medicine (universities have at least one teaching and research hospital).[4]

The Royal Decree guidelines state that medical studies shall be split into two cycles, each lasting three years.[5] Each cycle must offer a minimum of 250 course credits (a credit is the equivalent of 10 hours of theory or practical instruction), with a weekly teaching load of between 20 and 30 hours, including practicals. The amount of theoretical content shall not exceed 15 hours per week.

Although each faculty can plan its own courses leading to the degree in medicine, there are certain compulsory core subjects which must be included in medical studies in all Spanish universities to ensure that the qualifications awarded are consistent and uniform.[6]

RD 185/1985 of 23 January regulates the third cycle of university studies and the awarding of Ph.Ds in medicine. Postgraduate students wishing to obtain this degree must follow and pass the doctorate programme courses and seminars offered by the relevant department and successfully submit a doctoral thesis giving evidence of original research work.

30. Dentistry has been part and parcel of medical studies since the beginning of the century. It was made a specialist subject (Stomatology) by a Decree of 7 July 1944. However, the scarcity of dental health specialists, the criteria in force in neighbouring countries and in particular Community directives,[7] and also the need to avoid possible discrimination between specialists trained in Spain and the rest of the EC, made it necessary to create the specific profession of Dentistry. This came about through Law 10/1986 of 17 March, governing dentists and other dental health professionals, and Royal Decree 970/1986 of 11 April (subsequently modified by RD 1418/1990 of 26 October) which develops this law and creates the official qualification of Degree in Dentistry, which entitles the holder to practise the profession and thus firmly establishes dentistry as a separate academic discipline.

Thus, dentistry is granted its own syllabus, which is broken down into theoretical, practical and clinical teaching provided in two cycles of two and three years respectively. Training aims to provide dentists with the necessary competence to prevent, diagnose and treat abnormalities and diseases of the teeth, mouth, jaws and tissues. However, in this field of health the highest level of specialisation continues to be stomatology and maxillo-facial surgery.[8]

§ 2. Licensing of Physicians

I. General Practitioners

31. GPs perform their duties in the field of primary health care and diagnose and treat their patients' illnesses. In order to practise as a GP, it is sufficient to hold a degree in medicine, although registration with the local College of Physicians is compulsory.[9]

The functions of GPs who work for the Social Security are regulated by the Legal Statutes of Social Security Medical Personnel.[10] GPs' duties consist of providing medical assistance in health-care centres or in the patient's home to persons aged over seven who are covered by social security. They are obliged to remain in the centre during their surgery hours, and to attend emergency calls and take samples in patient's homes for clinical analysis where no local analyst is available or where this task canot be performed by a nurse. Requests for home visits may be made by telephone and must be met the same day. As regards surgery commitments, GPs must set aside two and a half hours every day, except holidays, to attend patients. Surgery times are designed in such a way as to take account of coordination between medical teams, local employment factors and public transport.[11]

Although GPs are not specialists, they play such an important role in the community that they are forced to constantly up-date their scientific knowledge and therapeutic techniques. RD 3303/1978 of 29 December regulates Family and Community Medicine as a specialist form of medicine. This specialist branch was available in hospitals only and outside the hospital context it had failed to match the advances made by General Medicine and by primary care in general, in spite of the fact that continuous training of this type was crucial in terms of helping meet the health-care needs of individuals in their family and community environment.[12] Moreover, concern for the continuous training of physicians was evident at EC level, as reflected in the adoption of Council Directive 86/547/EEC of 15 September 1986, which provided for specific and essentially practical training in general medicine lasting two years on a full or part-time basis. GP training has not been overlooked in Spain, although to date no statutory provisions have been enacted to incorporate the Directive into national law. A number of pilot schemes were implemented in 1989 and 1990, and these have led to agreements being signed between the Ministry of Health and the Organisation of Colleges of Physicians.[13]

II. Medical specialists

32. Specialist medical training was not regulated in Spain initially. Previously, the degree in medicine and surgery authorised the holder to engage in any medical activity, specialist or otherwise, and status as a specialist was obtained through constant practice by qualified physicians who performed specialist activities in health institutions, or physicians who had followed a specialist training course at postgraduate level and also those who were actually practising as specialists.[14] This rather chaotic situation came to an end with the promulgation on 20 July 1955 of a Law governing the teaching and practice of, and qualifications needed for, specialist branches of medicine (the law was developed further by the Decree of 23 December 1957). This law created the official degree of Specialist Physician, awarded by the State to graduates in medicine on completion of the appropriate specialist studies and prescribed periods of practical work. These courses were offered in university departments with chairs in the relevant subject or in Ministry of Education-approved specialist institutes or schools and clinics managed by university professors. In all cases, an examination had to be taken at the end of the specialist training.

At the same time, alongside the system created by the 1955 law, and in response to the ever-growing need for specialist doctors, a special system was being put in place in Social Security institutions.[15] This training system was no longer tied directly to universities, and candidates (interns and resident doctors) were linked to the Social Security by virtue of an employer-employee relationship, as opposed to the teacher-student relationship which operated in universities. Access to this type of training was limited by a numerus clausus mechanism and candidates were chosen on the basis of merit and their performance in an examination. On completion of the training, successful candidates were not awarded a degree (Specialist Physician) but rather a certificate attesting the type of specialist training received.

Subsequently, it was decided to adopt a single specialist training system, which was taken out of university hands. The first step in this direction was the passing of Royal Decree 2015/1978 of 15 July, which regulated the awarding of qualifications in specialist branches of medicine,[16] although this was later derogated by RD 127/1984 of 11 January,[17] which regulated specialist training and the awarding of the degree of Specialist Physician. Here again access is limited by a numerus clausus mechanism. A maximum quota of candidates for each speciality is established by the MIR system (the Spanish acronym for interns and resident physicians), although exceptional forms of access are permitted for academic staff of Faculties of Medicine.[18]

Controversy still exists today as to whether or not the system of access to specialist training set out in the law of 1955 (the status of which was subsequently reduced to an administrative regulation by the General Education Law of 4 August 1970) is still in force, or whether it has been derogated by the aforementioned Royal Decree of 1984. A rather contradictory piece of case law was established by the Supreme Court, which understood that the 1955 law, and therefore the two systems of access to specialist training programmes prior to the entry into force of RD 127/1984, were still in force. Thus, physicians who had completed their specialist training in accordance with the provisions of that law prior to the entry into force of the RD of 1984, were eligible for the award of the degree of Specialist Physician. This interpretation is supported by the argument that even the RD of 1984 itself may be viewed as being unconstitutional in that it runs contrary to Article 36 of Spain's Constitution which stipulates that professions which require an academic qualification shall be regulated by a law (as opposed to a Decree).[19]

33. The medical training system established by RD 127/1984 is considered unsatisfactory by most in medical circles, on the grounds that it prevents free access to the study of specialist subjects, which are limited in number and nature to those offered each year by the State in approved centres. Access to specialist training necessarily involves sitting a nationwide test, which is used to select the candidates who will follow specialist programmes in the various Teaching Centres.[20] Demand for places usually outstrips the number on offer (in recent years

25,000 candidates have been contesting the 3,500-4,000 places). The number of places available is made public every year by the Ministry of Education and the Ministry of Health and Consumer Affairs, after consultation with the competent authorities in the Autonomous Communities and with the National Committees of each specialist field.

Physicians following specialist medical training programmes do so as Resident Doctors in approved Teaching Units and Centres. Depending on the field chosen, they undertake supervised practical work designed to provide them with the professional know-how and responsibility required for efficient practice of their specialist field. Students must perform consistently well on the course, which may be taken on a full-time or part-time basis (in accordance with Directive 75/363/EEC of 16 June 1975). Some of those available in Spain require hospital-based training, while others do not.[21] Candidates are assessed at the end of each year and, on completion of the programme, results are forwarded by the Centre's Teaching Board to the appropriate National Committee for each specialist field, which then decides whether or not to propose the awarding of the specialist degree by the Ministry of Education and Science.

Lastly, it should be stressed that any physician who wishes to call himself a specialist and engage in specialist practic must hold the degree of Specialist Physician. Furthermore, the degree is a compulsory requirement for positions in public and private specialist units and institutions (article 1 of RD 127/84).

§ 3. Manpower Planning-Freedom of Establishment

34. As was stated earlier, the National Health System devised by the Spanish Constitution is based on the setting up of a public health service. In the words of RODRIGUEZ PASTRANA,[22] this merely means that "thenceforth the State possesses a legal instrument which allows it to intervene to regulate and control activities. However, in no way is it prejudged that management of the system will be the exclusive prerogative of the state or will be achieved through a state monopoly, directly or indirectly, or that it will coexist alongside private intitiative, albeit one which would come under the system's specific regime." Article 36 of the Constitution provides that "the law shall regulate specific aspects of the legal regime of Professional Associations and the exercise of professions requiring qualifications...", although it also acknowledges the freedom to choose one's profession (article 35.1) and freedom of enterprise in the health sector (article 38). Moreover, articles 88 and 89 and ff of the General Health Law (LGS) recognise both the right to freely practise a health profession and freedom of enterprise, in accordance with constitutional provisions. In short, freedom to engage in professional practice must be guaranteed, although room is made for limitations imposed by constitutional requirements, which aim to protect users of medical services by ensuring that the providers of such services are properly trained. Furthermore, Law 2/1974 of 13 February (subsequently modified by Law 74/1978 of 26 December) which deals with the rules governing professional associations, whose chief task is to regulate the exercise of the professions and defend the profesional interests of members (art. 1.3), states that the State shall guarantee the exercise of professions requiring qualifications, in accordance with statutory provisions (article 2.1).

35. It was stated above that the medical profession is one which requires a professional qualification and is regulated by law. A person may call himself a physician only if he has obtained a Degree in Medicine, on completion of a university course. However, the holding of the degree in itself is not enough to commence practice. Article 35 of the Statutes of the OMC makes registration a compulsory requirement for anyone wishing to practise medicine of any form, in both public and private centres. The OMC, which comprises all physicians in professional practice of any kind, either as independent doctors or in the employment of central or local administration, an Autonomous communities, all public or private entities,[23] requires members to comply with a series of obligations (membership fees, national health insurance, etc) and to adhere to certain rules of discipline.[24] Specialists must hold the appropriate specialist qualification, regardless of whether they work in the public or private sector.[25]

36. Freedom of enterprise must also be assured in the health sector, and this enables public and private health care to coexist in the sector. The acceptance of the premise that health, under the Spanish Constitution, is a public service necessarily implies that the public administrations are empowered to regulate and control private sector health activities also. However, this cannot be taken to mean that the Administration is the sole body entrusted with health care management. The General Health Law — which provides for private health services also — presupposes direct management of public health services, although at the same time it contemplates two basic avenues of indirect management, namely, agreements concluded with approved hospitals and other forms of association.

Agreements of this type enable the public administrations to harness outside resources to provide health services. In doing so, they can guarantee assistance and at the same time ensure that the approved centres do not themselves put in place complementary services which would undermine the optimal use of public resources. In concluding agreements with private centres, public administrations must give priority to non-profit making entities, as long as they are competitive with other centres in terms of efficiency, quality and cost (article 90.2 of the LGS). In all cases, the Administration will carry out the role of inspectorate with regard to health, administrative and economic aspects in relation to each patient (article 94.2 of the LGS).

Private hospitals which are linked to the public sector are virtually placed on an equal footing with their publicly-owned counterparts. As PEMAN GAVIN[26] has pointed out, linking "brings them under the wing of the public system and helps make their activities better known". The centres and establishments in question, as well as their services, remain in private hands, although the public administration is responsible for inspections and for all health, administrative and financial controls, just as for any public hospital (articles 66.3 and 94.1 of the LGS).

37. The exercise of non-nationals' freedom of establishment and freedom to provide services in Spain is regulated by Royal Decree 1691/1989 of 29 December, which also regulates the recognition of diplomas, certificates and other medical and specialist qualifications issued in other EC Member States. The provisions were drawn up in response to the need to incorporate various EC directives on the subject into Spanish legislation.[27] As regards the right of establishment of nationals of a member state, Article 7 of the Decree lays down the same rules as those which apply to Spanish practitioners, and stipulates that professionals must register with the College of Physicians and submit a certificate from their country of origin attesting that they have not been barred temporarily or permanently from practice. The Decree establishes a procedure enabling non-nationals to exercise legitimately their right of establishment. This procedure is applicable equally to physicians who set up their own practices as well as to those who enter the employment of others, and as a general rule it should not take longer than three months (article 13).

Practitioners form Member States who wish to provide their services on a temporary basis are exempted from compulsory registration with the College of Physicians, although they must submit to the local college a certificate stating that they hold the appropriate qualifications, together with an explanatory memorandum giving their address and outlining their motives for wishing to practise in the country. In all other respects they are bound by the entitlements and obligations of their Spanish counterparts, and are subject to the professional disciplinary or administrative regulations contained in Spanish law.

NOTES

1. A good reflection of this is Council Decision 75/364/EEC of 16 June 1975 to set up an Advisory Committee entrusted with the principal task of assuring a comparatively high level of training of physicians (including specialists) within the European Community (article 1).

2. Under article 26.1 of the University Reform Law (Organic Law 11/1983 of 25 August) it is up to the government to establish selection procedures for admittance to University centres. RD 1005/1991 of 14 June was drawn up to fulfil this aim; article 5.1 endorses the observations made in the text.

3. See also article 1.1 of Directive 75/363/EEC of 16 June 1975.

4. Article 104 of the General Health Law (Law 14/1986 of 25 April) states that all care structures of the health system must be made available for the continuous postgraduate teaching of professionals. RD 1558/1986 of 28 June sets out the general bases of the system of agreements between universities and health care institutions. Among other things, such agreements aim to assure clinical training for undergraduate and postgraduate medical students.

5. See also article 1.2 of Directive 75/363/EEC, which envisages that such studies shall last six years.

6. See Annex to RD 1417/1990 of 26 October.

7. See Directives 78/686/EEC, 78/687/EEC and 78/688/EEC of 25 July 1978 and 81/1057/EEC of 14 December 1981.

8. The Order of 9 September 1988 regulates access to specialist training in Stomatology and defines training and the awarding of the qualification following completion of the curriculum, in accordance with Community Directive 75/363.

9. See article 35 of the Statutes of the OMC, RD 1018/1980 of May. Professional practice by a physician who has not registered beforehand with the College of Physicians may constitute illegal practice and be punishable via article 572 of the Penal Code (see next chapter on the illegal practice of medicine).

10. The Legal Statutes were drawn up to comply with article 16.1 of the Social Security Law and were adopted by Decree 3160/1966 of 23 December. They have undergone several modifications since then; article 84.1.2 of the General Health Law confers the status of law on the Statutes.

11. See Circular 1/1982 of 9 December issued by the Under- Secretary of State for Health and Consumer Affairs.

12. Ministerial Order of 19 December 1983 sets out provisions for the postgraduate training in Family and Community Medicine.

13. Agreement of 8 March 1991 on continuous medical training, which is designed to update primary care GPs' knowledge and approaches, harmonise criteria for the diagnosis and prevention of the most common illnesses, promote team work and enhance relations between health-care professionals. The Agreement also creates a Continuous Training Committee in each College of Physicians.

14. See RODRIGUEZ PASTRANA, 'Régimen Jurídico de las especialidades médicas', in *Revista de Administración Pública*, n. 116, 1988, pp. 158 f.

15. See Ministerial Order of 28 July 1971 on Internists and Resident Physicians and Ministerial Order of 9 December 1977, which regulates postgraduate training in Social Security institutions.

16. The Ministerial Order of 11 February 1981 establishes equivalences for specialist branches already in existence prior to the passing of RD 2015/1978 of 15 July and, in order to respect acquired rights, sets up a transitory system for the awarding of specialist qualifications to cater for those who had commenced their training before 1 January 1980.

17. Derogatory Provision Number 1 also derogates the Law of 20 July 1955.

18. The Ministerial Order of 4 June 1987, which develops article 18 of RD 127/84, regulates access to the Specialist Physician qualification by physicians who are teaching assistants and tenured medical faculty staff.

19. See First Transitory Provision of RD 127/1984 of 11 January, which establishes access to the Specialist Physician qualification for professionals who had commenced their specialist training prior to 1 January 1980 and who could furnish proof of having at least two years' training. For a study of the issue and case law criteria, see RODRIGUEZ PASTRANA, 'Régimen jurídico de las especialidades médicas', in *Revista de Administración Pública*, n. 123, 1990; see also commentary on Supreme Court Ruling of 10 July 1991 by V. ESCUIN PALOP, 'Titulaciones médicas', in *La Ley*, 27 December 1991.

20. The Minsterial Order of 30 November 1984 (subsequently extended by the Order of 2 November 1987) sets out the rules governing selective tests for residents.

21. Under the Annex to RD 127/1984 of 11 January, the following branches require basic hospital training: Allergiology, Clinical Analysis, Pathological Anatomy, Anaesthesiology and Reanimation, Angiology and Vascular Surgery, Digestive Apparatus, Clinical Biochemistry, Cardiovascular surgery, General Surgery and Digestive Apparatus, Maxillofacial Surgery, Paediatric Surgery, Thoracic Surgery, Plastic and Reparatory Surgery, Medico-Surgical Dermatology and Venereology, Endocrinology and Nutrition, Clinical Endocrinology, Geriatrics, Haematology and Haemotherapy, Immunology, Intensive Medicine, Internal Medicine, Nuclear Medicine, Microbiology and Parasitology, Nephrology, Pneumology, Clinical Neurophysiology, Neurology, Obstetrics and Gynaecology, Ophthalmology, Medical Oncology, Radiotherapeutic Oncology, Otorhinolaryngology, Paediatrics and associated specific branches, Psychiatry, X-ray diagnosis, Rehabilitation, Rheumatology, Traumatology and Orthopaedic Surgery, and Urology. The following specialist branches do not require essentially hospital training: Family and Community Medicine, Preventive Medicine and Public Health. Branches which do not require hospital training: Stomatology, Hydrology, Space Medicine, Physical Education and Sports Medicine, Legal and Forensic Medicine and Occupational Medicine.

22. *El servicio público de la sanidad: el marco constitucional*, cit., p. 31.

23. Constitutional Court doctrine (particularly ruling 89/1989) endorses the view that compulsory registration with the College is constitutional, even for physicians employed by the Administration. It is not incompatible with freedom of association since, according to ruling 131/1989 of 19 July, which deals specifically with the issue, "although the professional services are provided under the public service regime or are dependent on a public organisation, the profession of physician is still being exercised, albeit with a compulsory registration requirement imposed by the legislature and the corresponding statutory provisions ... at the end of the day, this circumstance does not modify in any way whatsoever the nature of the activity, which continues to serve the same users. Although it is true that the requirement does involve a restriction on freedom of association, in that a physician is not free <u>not</u> to register, it is justified in the light of the general interest at stake in the professional practice of medicine: professional discipline, ethical rules, the good faith of third persons, all of which must be protected in conjunction with the constitutional values and rights of health, health care and the lives and physical integrity of the population".

24. The Statutes of the Organisation of Colleges of Physicians (OMC) and of the General Council of Colleges were passed by RD 1018/1980 of 19 May. Professional practice denotes the provision of medical services of all types, even where the physician does not practise privately or where he does not have his own facilities (article 35.2 of the Statutes).

25. Article 13 of the General Health Law empowers the government to adopt regulations to prevent illegal practice and malpractice, even though both are covered by Penal Code provisions (articles 321, 565, 572 and 586 bis) and administrative sanctions govern professional practice by unregistered physicians and aiding and abetting malpractice (article 40.1 and article 44 sections b) and m) respectively of the OMC Statutes).

26. *Derecho a la salud y Administración Sanitaria*, cit., p. 213.

27. See Directive 75/362/EEC, completed by Directive 81/1057/EEC; Directive 75/363/EEC, which was subsequently modified by Directive 82/76/EEC (which modifies Directive 75/362/EEC also).

Chapter II. Illegal Practice of Medicine

38. In the previous chapter we described the procedure for access to the medical profession. To recap briefly, it is necessary first to have completed university studies leading to the Degree in Medicine and Surgery which is awarded by Faculties of Medicine; it is also compulsory to register with the College of Physicians (Colegio Oficial de Médicos) in the intended area of practice:[1] furthermore, specialists must hold the appropriate diplomas accrediting that they have completed the relevant studies and practical work enabling them to call themselves specialists and seek employment as such in all private or public centres;[2] this means that although all graduates in medicine may practice any branch of medicine, no-one may use the title of specialist (or take up such a position) unless he holds the appropriate qualification. However, as we shall see below, the courts have reached a different conclusion with regard to this question. The profession may be practised only when the above-mentioned legal requirements have been met. All the above make up the exclusive rights of professional practice which is conferred on physicians in view of the high degree of qualification required and the subsequent penal protection afforded to the profession to prevent practice by non-members or non-qualified practitioners.
Illegal practice can indeed constitute an offence of encroachment and is punished by Spain's Penal Code (article 321, governing the offence of usurpation of functions): "Any person who practises a profession without holding the corresponding official qualification, or a qualification recognised by a legal provision or international convention, shall be liable to a prison sentence of between six months and one day and six years. Furthermore, where the offender passes himself off in public as a qualified professional he shall be liable to a fine of between 100,000 and 1,000,000 pesetas." It is generally held[3] that persons who commit such an offence harm various interests which have repercussions on society as a whole. The most important of these is the requirement concerning academic qualifications as a means of ensuring correct professional practice; the State endorses the validity of these qualifications in that it, and it alone, is empowered to award them. On a second level lies the collective interest of the profession concerned, which must ensure that professional practice is limited exclusively to those who can provide the necessary guarantees in the form of the recognised qualification. This exclusive right of practice means also that users (in this case, patients) will receive the services of a qualified professional, although it should be said that an unauthorised person who has provided satisfactory services and has cured the patient's illness will still nevertheless have committed an offence.

39. For an offence to exist the following requirements must be fulfilled:

a) An offence is committed only where the profession —such as medicine— which is practised illegally requires an academic qualification (notwithstanding the fact that the Penal Code refers to an "official" qualification, which is a much broader term).[4] Alternatively, the qualification may be one which is recognised by a legal provision (where authorisation is given to the awarding of the qualification by centres which do not belong to the State) or international convention, which affects in particular physicians or specialists (both Spanish and non-Spanish) who have obtained their professional qualification abroad.
b) The offender must perform actions proper to the profession of physician as stipulated in the regulations governing medical practice (see Chapter I of this part). No encroachment takes place where a patient treats himself or is aided by a relative, under the guidance of a physician. This is an important point given the increasing frequency with which patients, particularly the chronically-ill, treat themselves at home (diabetics who administer their own insulin injections, patients with terminal renal insufficiency who receive dialysis in their own home, patients with respiratory problems who give themselves oxygen, etc). The offence does not exist either in the case of charlatans (quacks) as long as they do not undertake operations or administer products (e.g. prescribe drugs) which may only be given by physicians.[5] This does not mean, however, that such persons are exonerated from liability in respect of possible injuries they

might cause to their patients or where the latter's condition seriously worsens as a result of being prevented from seeking the assistance of a qualified practitioner. The charging of a fee is not an indispensable requirement of illegal practice,[6] although exceptionally any such charge may mean that the impersonator is guilty of fraud (for example, if he deceives the patient by leading him to believe in the treatment, when in fact it will not cure him at all or has little bearing on the nature of the problem being treated).

c) There is debate as to whether one single action of the type mentioned above is in itself sufficient to constitute an offence or whether several are required. Although it is widely held that one single action suffices (except where the very nature of the profession or its regulations require something more habitual),[7] we are of the opinion that professional practice in general is characterised by repetition with various persons, and thus the activity deemed to constitute illegal practice must comprise several acts, at least in the case of medicine. Habitualness or repeated actions of the type mentioned above shall give rise to one offence only.

d) Encroachment may only be committed intentionally and thus it cannot stem from negligence, although this does not rule out a juridico-penal appraisal of the conduct of someone who mistakenly believes that he can carry out professional acts without the appropriate qualifications.

40. Any person who practices illegally in this way and, in addition, passes himself off in public as a professional shall be guilty of a more serious offence (article 321, paragraph 2 of the Penal Code).[8] For this aggravated offence to exist it is not sufficient for the offender to pass himself off as a qualified practitioner in the presence of one or more patients, but rather —and in addition to actions of encroachment— he must also make others believe that he holds the status in question.

41. The offence of encroachment may be concurrent with other offences: if, during the course of unlawful practice, harm is caused to a patient's health or life, because the treatment is inadequate due to the offender's lack of professional training, the person may be liable also for an offence of recklessness leading to homicide or bodily injury;[9] or of forgery of documents (academic or degree certificates);[10] and also, as has been mentioned above, in exceptional circumstances fraud.

42. A physician who fails to register with the College of Physicians, that is, a qualified practitioner who practises without first having registered with the appropriate association or body, where such a requirement is mandatory, shall be guilty of a misconduct (minor criminal offence) and liable to a fine (of between 10,000 and 100,000 pesetas, article 572 of the Penal Code).

43. Spanish courts have had to deal frequently with cases of illegal medical practice and have used the full weight of this criminal offence to punish such acts, whether by professionals of lower rank (nurses, for example)[11] who have impersonated physicians, or by persons who have no connections whatsoever with the health-care professions.[12] Dentistry has traditionally been the field to suffer most from encroachment. Although case law includes clear examples which constitute illegal practice of dentistry, such as when a dental technician undertakes implants or other activities proper to a qualified dentist,[13] or where such practices are undertaken by members of the nursing profession,[14] we would question the conviction of a graduate in medicine who does not hold the appropriate qualification required for dental practice, merely because he has habitually practised the speciality although without passing himself off as, or attributing to himself the status of, a qualified dentist, which is the only offence that is expressly prohibited, as was stated above.[15] The Supreme Court (2nd Chamber) ruled that an offence is committed by a medical graduate who, although not holding a qualification in dentistry, engages in habitual practice, but *not* when he does so occasionally and in special circumstances which justify his action, depending on the specific case.[16]

Other health-care professions, such as nursing,[17] have fallen foul of illegal practice by persons

who do not have the necessary training or qualifications.
To sum up, illegal practice (called literally impersonation or encroachment in Spanish) is an offence which may be committed by laypersons, by persons with no connections whatsoever with the profession, but also by health professionals whose qualifications are insufficient to entitle them to perform such activities. It may even be committed by physicians who do not hold the relevant specialist qualification.[18]

NOTES

1. Royal Decree 1018/1980 of 19 May, governing the Statutes of the Organisation of Colleges of Physicians and the General Council of Colleges of Physicians, stipulates in article 35 that it is compulsory for physicians to register with the College in order to practice any form of medicine, including where the physician does not practise privately or does not have his own surgery.

2. Royal Decree 127/1984 of 11 January, article 1.

3. G. RODRIGUEZ MOURULLO, 'El delito de intrusismo', in *Revista General de Legislación y Jurisprudencia*, 1969, pp. 235 ff.; D.M. LUZON PEÑA, "Problemas del intrusismo en el Derecho penal", in *La Ley*, 1985, pp. 1257 ff.; A. SERRANO GOMEZ, 'El intrusismo en la Odontología', in *Actualidad Penal*, 1988, p. 1067.

4. D.M. LUZON PEÑA, 'El título académico oficial en el delito de intrusismo', in *La Ley*, 1989, pp. 497 ff. Ruling of Supreme Court (2nd Chamber), 6 June 1989 (for a ruling in the opposite sense, ie not putting official qualification on an equal footing with an academic one, see Ruling of Supreme Court (2nd Chamber), 13 May 1989).

5. The Supreme Court has on occasions punished such acts (where medicines have been prescribed: Ruling (2nd Chamber) of 18 October 1978; and also in the case of a person who ran a Natural Medicine Surgery using the professional title of Dr in Naturopathy and Diet Counsellor: Ruling (2nd Chamber) of 23 January 1984).

6. See Ruling of Supreme Court (2nd Chamber) of 1 December 1970.

7. RODRIGUEZ MOURULLO, 'El delito de intrusismo', cit., pp. 259 ff.; Supreme Court Rulings (2nd Chamber) of 1 December 1970 and 19 June 1990.

8. Supreme Court Ruling of 2 October 1990.

9. Ruling of the Barcelona Provincial Court of 6 February 1990, by which a nurse was found guilty of professional recklessness, although she was cleared of charges of illegal practice.

10. Supreme Court Ruling of 2 October 1990 (forgery of official document, article 303 of the Penal Code).

11. Ruling of Supreme Court (2nd Chamber) of 8 March 1968.

12. The aforementioned rulings of the Supreme Court of 18 October 1978 and 23 January 1984.

13. Rulings of Supreme Court (2nd Chamber) of 26 February 1981, 11 April 1989, 29 June 1991; Lérida Provincial Court Ruling of 3 February 1990. Law of 17 March 1986, which regulates dental health professions, lists the competences of dental technicians as the design, elaboration, making and repair of dental apparatus using products, materials and techniques as indicated and prescribed by dentists. (article 1.2).

14. Rulings of Supreme Court (2nd Chamber) of 8 March 1968, 18 October 1969; (3rd Chamber) 11 October 1991 (competence to hire a nurse to take blood and carry out analytical tests on council premises).

15. The view is shared by SERRANO GOMEZ, 'El intrusismo en la Odontología', cit., p. 1068.

16. Ruling of Supreme Court (2nd Chamber) of 13 June 1990 (although the verdict was that an offence had been committed, the accused was cleared becuase in the court's opinion he had unwittingly committed an unavoidable error due to the incorrect legal guidance given by the College of Physicians on a somewhat "grey" issue (to use the Court's expression); Ruling of 12 March 1990 (dismissing possible error on the part of the physician), 21 June 1991. A previous ruling, using different arguments, had been given by the Supreme Court (2nd Chamber) on 18 October 1969.

17. For example, in Ruling of Supreme Court (2nd Chamber) of 28 March 1980.

18. C.M. ROMEO CASABONA, *El Médico ante el Derecho*, (Serv. Public. del Ministerio de Sanidad y Consumo, Madrid 1985, 3d. repr. 1990), p. 5.

Chapter III. Control over the Practice of Medicine

§ 1. The Order of Physicians

I. Legal Framework and general competences

44. In view of the importance of medicine in the community and the complex nature of medical services, the Administration has sought to reserve medical professional activity for those who are highly qualified both technically and scientifically.[1] Elsewhere we have discussed the fact that the position of physician or specialist can only be attained on completion of the relevant degree course in General Medicine or in the specialist field. The State has the exclusive right to issue such degree certificates, thus providing a guarantee that holders are qualified to provide medical services. However, the medical profession makes a further demand: it is not enough to simply guarantee that those who are admitted to the profession are properly qualified, it is also essential to ensure that medical practitioners perform their duties in accordance with the shared interests of the profession, thus establishing a kind of self-imposed control of the medical profession. The Spanish Constitution reflects this in its recognition of the value of professional associations for such purposes, stating in art. 36 that "the law shall regulate the specific legal attributes of Professional Colleges. The internal structure and procedures of the Colleges must be democratic".[2] The Professional Colleges Law of 1974 ('Ley General de Colegios Profesionales'), which is the basic corpus of regulations in this respect, had to be revised to bring it into line with constitutional provisions, particularly with regard to the democratic processes required of Colleges.[3] Legal exercise of the medical profession is subject to prior membership of a College.[4] Membership is compulsory,[5] as it is in other professional fields, and although this is the subject of no small amount of controversy in a wide range of professions, it provides a guarantee for the public and relieves them of the responsibility of establishing whether or not the person performing a medical act does indeed hold the appropriate qualifications for professional practice. Furthermore it provides an efficient means for members to defend their professional interests against inappropriate, unethical and illegal practice.

45. From the organisational point of view, aside from the above-mentioned law on professional bodies, medical practice is regulated by the Statutes governing the Organisation of Colleges of Physician and the General Council of Colleges of Physicians, as passed by RD 1018/1980 of 19 March, which repealed the previous Regulations dating back to 1 April 1967. The system is made up of the provincial Colleges of Physicians, Associations of Colleges of Physicians and the General Council of Colleges of Physicians, which constitute the organs of representation and the governing body of the Organisation of Colleges of Physicians (known by its acronym in Spanish, OMC). With the exception of the Associations of Colleges of Physicians, these bodies are corporations which are governed by public law and endowed with their own legal personality and full capacity to achieve their aims.[6]

46. The *Organisation of Colleges of Physicians* brings together all physicians who carry out professional activity of any type, whether independently or in the service of the Public Administration or private institutions. It is the sole representative body of the medical profession, with exclusive responsibility for the regulation of medical practice within its area of jurisdiction and the defence of professional interests (art. 1. 4 of the OMC). The fundamental aims of the OMC, according to art. 3, are as follows:

> a)The regulation, within its jurisdiction, of medical practice; exclusive representation of physicians and the defence of the professional interests of its members, without prejudice to the powers and responsibilities of the Public Administration in respect of physicians who are public servants.
> b)The safeguarding and observance of the deontological and ethical principles of the

medical profession, as well as its dignity and prestige, through the drawing up and application of the relevant codes of practice.
c)The promotion, by all available means, of the continuing scientific, educational, economic and social development of members through the organisation and maintenance of all kinds of educational institutions and the taking of all appropriate measures to ensure adequate social protection for members.
d)Cooperation with the public authorities in the provision of health care services, to which all Spanish citizens are entitled, and of the most efficient, just and equitable regulation of health care services and medical practice, as stipulated by the Professional Colleges Law.

47. The provincial *Colleges of Physicians* are the key element in the organisation of medical practice.[7] Art. 4.3 of the Professional Colleges Law prohibits the creation of any other college for the same profession within the limits of the territory concerned. Even so, each College may divide its provincial territories into districts, headed by a district council elected by the members in the area to perform the executive functions delegated by the College Board (art. 29 of the OMC). Among the powers and duties of the Colleges of Physicians, apart from those specifically stipulated in their individual statutes, are the following (art. 34 of the statutes of the OMC):

a)Responsibility for the representation of physicians before provincial authorities and institutions.
b)The defence of the rights and prestige of the members they represent, or any other member, if they are subjected to harassment, injury, lack of consideration or disregard in professional matters, so long as any such situations occur within the province. The College is also responsible for reporting instances of illegal practice piracy.
c)The keeping of a list of members, a register of professional qualifications and a list of medical districts in the province. They are also responsible for the gathering of statistics necessary for the carrying out of studies, projects and proposals concerning medical practice.
d)The application of the rules of ethics governing medical practice.
f)The taking of disciplinary action in cases of unfair competition, breaches of ethics and abuse of professional status as a physician. Colleges are also responsible for the implementation of disciplinary measures.
g)The study of the financial relationship between physicians and their clients and, where appropriate, the power to discipline members whose actions might undermine the dignity of the profession in this respect.
h)Regulation of the minimum fees for private practice. Colleges shall also express an opinion in fee-setting procedures and shall defend the interests of the medical profession before the Administration, Institutions, Courts, Organisations and private individuals in accordance with the current provisions.
i)Responsibility for the collection of professional fees and charges.
j)Cooperation with the public authorities in the formulation of health care policy and planning and implementation thereof, as well as participation in all matters relating to health promotion and health care.
k)The development and implementation of general and scientific educational programmes to complement those envisaged under the Plan drawn up by the General Council.
l)The development and administration of services and institutions to ensure adequate social security cover and other forms of professional cover for members.[8]

Each college must have an Ethics, Medical Law and Authorisations Committee. Furthermore, professional interests are most efficiently served by the setting up within the Colleges of specific Sections that bring together members working in the same professional area and with the same professional concerns. These Sections are responsible for matters

relating to the specialist field concerned and for presenting studies and proposals to the college bodies. A certain number of sections are obligatory,[9] although others may be created in the interests of the college concerned and in accordance with its statutes.

The governing bodies of the Colleges are the Board and the General Assembly of Members. The Board consists of a Plenary and a Standing Committee. Among other powers and responsibilities, it can take disciplinary action within its area of jurisdiction. For its part, the General Assembly is the College's highest representative body at provincial level[10] and comprises the total membership of the college. The Board is accountable to the General Assembly.

The financial running of the Colleges is independent of the General Council. They are autonomous in terms of the management and administration of their financial affairs. Each provincial college draws up an annual budget that has to be approved by the Assembly. College funds come from initial registration fees, the ordinary and extraordinary membership fees paid by members,[11] and a percentage of fees charged for the issuing of certificates, official stamps, official forms, medical assessments, etc.

48. *Associations of Colleges of Physicians,* which occupy a middle ground between the Colleges themselves and the General Council, are designed to coordinate and represent the Provincial Colleges and are governed by their own statutes. Responsibility for representation falls obligatorily on one of the presidents of the Colleges making up the Association. The Associations carry out whatever functions the General Council delegates to them.[12]

49. *The General Council of Colleges of Physicians* is the body that brings together, coordinates and represents all the provincial Colleges of Physicians in Spain. It is composed of the General Assembly,[13] a Plenary and a Standing Committee, as well as advisory bodies.[14] The Council is charged with the representation and defence of the legitimate aspirations of the medical profession, ethical guidance and control of professional practice, social, cultural and professional development and the promotion of the right to health. Among its most important functions are the drafting of the General Statutes of the Colleges, the passing of internal college regulations, the taking of disciplinary action against members of College Boards and of the Council itself, the drawing up of binding ethical rules to govern the medical profession and which are binding and the application and interpretation of such rules with a view to full and consistent complaince. The Council also handles and resolves appeals against Colleges presented by members, and sets minimum charges for private practice, etc.[15]

50. The democratic structure and workings of professional bodies imposed by the Constitution is reflected in the extensive regulations governing voting procedures for the election of office bearers, length of period of office and the causes of dismissal, conditions of eligibility and candidacies. The OMC also has disciplinary regulations applicable to members who commit any of the offencesset out in the statutes, be they minor, serious or highly serious, as well as the corresponding penalties, which may take the form of a private reprimand, an official warning, temporary suspension from practice or expulsion from the College (arts. 63-68 of the statutes of the OMC). Notwithstanding art. 63. 3 of the OMC statutes, which states that disciplinary responsibility is not to be understood as exempting members from liability of any other type that they might incur, the doctrine of the Constitutional Court with regard to breaches of the *non bis in idem* principle should be taken into account.

51. The fact that all practising physicians must register with a College does not preclude freedom of association in the context of a trade union organisation. Although the trade union movement is not normally associated with this kind of profession (or rather it has not been associated with it historically), recently doctors have become extremely active in industrial relations as a result, chiefly becuase more and more are gradually moving from what was traditionally independent practice towards salaried or civil service positions. Physicians' demands are therefore falling more within the realm of labour relations than the general framework of medical practice. We will not go into a detailed discussion of the ideological

principles of each association, but will merely make passing reference to the trade unions which currently cater for physicians: CESM (Confederación Estatal Sindicatos Médicos), CCOO (Comisiones Obreras), UGT (Unión General de Trabajadores) and FESIME-CSIF (Federación Estatal de Sindicatos Médicos).

II. Professional Duties towards Colleagues

52. The notions of 'fraternity' and 'loyalty' describe well the way in which members should conduct themselves towards colleagues, both in the exercise of the profession and in other areas. This involves not only the expectation that they will bring prestige and dignity to the profession, but that they will treat with respect those who receive medical treatment, ie patients. Patients should not be subjected to doctors casting aspersions on the morals or scientific abilities of a colleague in order to (for example) to attract the latter's clients. A special ethical principle prevents a doctor from suffering moral, professional or economic harm as a result of the activities of a colleague. Legal and ethical endorsement for the manner in which physicians should behave towards one another can be found in the Professional Colleges Law, the OMC Statutes and also in the new Code of Medical Ethics.[16]

53. Among the functions atributed to them under the Professional Colleges Law, colleges must "achieve harmony and cooperation among members and prevent unfair competition" (art. 5 k). This is undoubtedly the physician's chief duty towards colleagues, since unfair competition, for example, does not only imply unfairly taking a patient from a colleague or depriving him of the resultant earnings or prestige, but also poses a threat to the patients' dignity and health. The statutes of the OMC oblige members to "maintain the utmost *loyalty* in relations with the College and fellow members by notifying the College of knowledge of any ill-treatment or abuse suffered by a colleague in the exercise of his profession."[17] What underlies this precept is the notion of *solidarity* and mutual support that must govern the actions of physicians with regard to their peers.[18]

Duties are also laid down in connection with self-protection of the profession and of medical ethics in relation to activities of members that might encourage illegal practice by third parties. Therefore, one of the functions of professional colleges is to 'adopt whatever measures are necessary to prevent illegal practice" (art. 51 of the Professional Colleges Law). Similarly, the OMC statutes, for the same reasons, prohibit members from "tolerating or abetting a person who does not hold a degree in medicine and who attempts to practice the profession" (art. 44 b), and also "allowing their surgeries to be used by persons who, while they may be graduates in medicine, have not registered with the appropriate College of Physicians" (art. 44 m).

Other ethical duties apply to medical care and scientific matters. The Code of Ethics restrains a physician from interfering in the treatment of another physician's patient, except in emergencies or at the specific request of the patient (art. 34. 1). It also states that scientific, professional or deontological disputes between doctors should be resolved through the appropriate channels and should not become a focus of public controversy. In this regard, Colleges of Physicians may also "intervene to achieve agreement or arbitration on questions of a professional nature that may arise between members."[19]

III. Disciplinary Competences

54. Once again we must begin by turning to the Constitution and in particular article 36 which states that "the Law shall regulate specific aspects of the legal regime of professional bodies and the practice of professions for which a qualification is required. The internal structure and the functioning of such bodies must be democratic."

55. This constitutional formula led to the drafting of the Code of Medical Ethics, endorsed by the Ministry of Health and Social Security in the Ministerial Order of 23 April 1979, which put an end to the vacuum created by the reorganisation of professional bodies in 1967, when the ethical rules governing the medical profession in Spain contained in the annex to the 1945

Statute were derogated.[20]

In 1990, 11 years after the Ministerial Order, the new Code of Medical Ethics and Deontology was unveiled. The new Code, tailored to take account of the reports submitted by the Ethics Committee of the Organisation of Colleges of Physicians and the European Medical Guide, consists of 44 articles and one further concluding article. Divided into thirteen Chapters, it lays down, among other aspects, the general principles which should guide professional practice (Chapter II), physician-patient relations (Chapter III), professional secrecy (Chapter IV), health care quality (Chapter V), the role of physicians in reproduction and respect for the life and dignity of individuals (Chapter VI), relations between physicians (Chapter VII) and relations with the other health professions (Chapter VIII).

56. Mention should also be made of the General Statutes of the Organisation of Colleges of Physicians and the General Council of Colleges of Physicians respectively, which were approved by Royal Decree 1018/80 of 19 May 1980.

Article 3 of the Statutes of the former states that the Organisation's fundamental goal is to

> 2. Safeguard and observe the ethical and social principles of the medical profession, as well as its dignity and prestige. To that end it shall draw up and apply the appropriate Codes.
> 4. Collaborate with the authorities in giving effect to the right of all Spaniards to protection of their health and to the most efficient, just and fair regulation possible of health care and the practice of medicine, as well as to all the rights contained in the Law governing Professional Asociations.

Article 31 lists among the General Council's general powers the exercise of the functions set out in the Council's own rules and regulations in relation to the aims attributed to it under Article 3 of the Statutes and the Professional Colleges Law. Specific competences are outlined in article 32:

> 1. Ethics:
>
> Supervision of professional practice. Control over professional publicity of media information with reference to the profession, which might prove harmful to public health or to the legitimate interests, traditional prestige and dignity of the medical profession.

The Statutes also provide for the setting up within the General Council of a Central Committee on Ethics, Medical Law and Authorisations to advise the Council on all matters relating to its sphere of competence, to report on appeals lodged with the Council against decisions of Colleges on such matters and to handle all correspondence with the Administration on the above issues.

Articles 33 and 34 set out the competences of the provincial Colleges, which are charged with the application of ethical rules governing medical practice (article 34 d); it is their job also to ensure that registered member comply with their professional ethical and legal obligations (article 34 e); to take disciplinary action against members who engage in unfair competition, or who breach ethical rules or abuse their position as practitioners (article 34 f); to study the financial relationship between physicians and their clients and, where appropriate, take disciplinary action against members whose actions may undermine the prestige of the profession in this respect (article 34 h).

Title VIII of the Statutes deals specifically with Rules of Discipline, the general principles of which are given in article 63:

> 1. Members shall be liable to disciplinary action in the cases and circumstances set forth in the present Statutes.
> 2. The rules of discipline contained in the present Statutes do not exempt members from liability of any other type which they may incur.
> 3. Disciplinary measures may only be taken after the setting up of an enquiry to examine the case in question and in accordance with the procedure laid down in the

present chapter. However, in cases involving minor infringements and following a hearing of the member concerned, action may be taken without a specific enquiry.
4. The power to impose disciplinary measures lies with the Boards of the Colleges of Physicians. However, the appraisal and punishment of breaches of discipline committed by Board members shall be entrusted to the Assembly of College Presidents.
5. Any disciplinary action agreed upon shall be enforced with immediate effect, although decisions may be appealed. However, where enforcement might lead to irreparable or virtually irreparable harm, the body concerned may of its own initiative or at the request of the party concerned suspend the action against which the appeal has been lodged.
6. Colleges shall notify immediately the General Council of all disciplinary action taken in respect of serious or highly serious offences, and shall forward an extract of the file of enquiry. The General Council shall keep a register of action taken.

Breaches of discipline are described in article 64 and are classified as minor, less serious, serious and highly serious :

1. Minor misdemeanours:
a) Non-compliance with regulations governing College documentation or documents which must be processed by the College.
b) Failure to inform the College of changes affecting professional status etc, which must be recorded in the member's personal record.
c) Failure to heed College requirements or to submit reports when so requested by the College.
2. Less serious offences:
a) Failure to provide a certificate or information where provision does not entail risk to the patient.
b) Passing oneself off as having a qualification or competence when this is not the case.
c) Failure to submit contracts for College approval.
d) Manifest abuse in billing for services or charging a fee below the minimum stipulated fee.
e) Persisting in the commission of minor misdemeanours during a period of one year after being disciplined for such offences.
3. Serious offences:
a) Deliberate and rebellious lack of discipline towards College governing bodies and, in general, serious disrespect towards the latter.
b) Acts and omissions which undermine the morals, decorum, dignity, prestige and honour of the profession or which entail disrespect towards members.
c) Serious intentional or negligent breaches of professional secrecy resulting in harm to third persons.
d) Non-compliance with rules governing the restricted use of drugs and the exploitation of drug addiction for personal gain.
e) The issuing of reports or certificates known to be false.
f) Persisting in the commission of less serious offences during a period of one year after being disciplined for such offences.
4. Highly serious offences:
a) All conducts constituting offences of intent, within the field of the profession.
b) Intentional violation of professional secrecy.
c) Attacks on the dignity of persons in the course of professional practice.
d) Malicious or intentional neglect of patients.
e) Persisting in the commission of serious offences during a period of one year after being disciplined for such offences.

The article adds also that "failure to comply with the duties set out in article 43 of the present Statutes, violation of any of the prohibitions laid down in article 44 or non-compliance with the rules contained in the Code of Ethics, which are not covered by numbers 1, 2, 3 and 4

above, shall be adjudged in the light of the similarity of the offence with those listed above. In all cases, the Ethics Committee shall be heard before any disciplinary action is taken".

Still on matters of discipline, article 65 states as follows:

1. The following measures may be taken in respect of disciplinary offences covered by the previous article:
a) Private caution
b) Official caution
c) Temporary suspension from professional practice
d) Expulsion from the College of Physicians
2. Minor misdemeanours shall give rise to a private caution by agreement of the Board.
3. Official warnings shall be given in respect of less serious offences.
4. Serious offences shall be punishable by temporary suspension from practice for a period not exceeding one year.
5. Highly serious offences shall be punishable by temporary suspension from practice for a period of between one and two years.
6. Any member who is expelled from a College shall be barred from registering with another unless expressly authorised by the General Council. This punishment is applicable only where a member persists in the commission of highly serious offences. The decision to expel a member shall be taken by the Plenary Meeting of the Board, at which at least two thirds of Board members must be in attendance. At least half of those in attendance must vote in favour of expulsion.
7. In taking disciplinary action Colleges shall assess the responsibility of the accused in relation to the nature of the offence committed, as well as the importance of the offence and any other factors which might alter said responsibility. Where more than one punishment is laid down for each offence, the College is empowered to take the action it feels to be most appropriate.
8. Highly serious offences which affect the general interest may be reported in College publications.

Article 66 governing the expiry of disciplinary liability reads as follows:

1. Disciplinary liability shall expire:
a) On the death of the accused.
b) When the member complies with the disciplinary action taken.
c) On prescription of the offence(s).
d) On prescription of the disciplinary action or by agreement of the College concerned, which shall be ratified by the General Council.
2. Details of disciplinary action which are placed on the member's record shall be deleted provided that, once the member has complied with the action taken, he conducts himself properly for a period of three months (minor misdemeanours), six months (less serious offences), two years (serious offences) or five years (highly serious offences).
3. Offences shall prescribe one year after they are committed if no enquiry has been opened, except for offences which constitute a felony, in which case prescription shall be the same as that laid down for the felony, if greater than one year.

Authority to handle matters of discipline is regulated by article 67, which states that "minor misdemeanours shall be dealt with by the President of the College of Physicians, by agreement of the Board and in accordance with the provisions of article 63.3.

Other offences shall be dealt with by the Board, following the holding of a disciplinary enquiry and in accordance with the procedure described in the next article.

Where the disciplinary matter relates to an offence committed by a member of another Provincial College, the enquiry shall be undertaken in full by the College in whose territory the alleged offence took place. Any action taken shall be notified to the member's College through the General Council.

Disciplinary matters involving Board and General Council members shall be handled by the latter.

Lastly, article 68 regulates disciplinary procedure as follows:

1. The procedure shall be initiated automatically or at the request of a party, by agreement of the competent body, either of its own intitiative or following denunciation.
2. On learning of an alleged offence, the Board of the College is empowered to conduct a confidential investigation prior to taking the decision to undertake an official enquiry. Alternatively, on the basis of the information available to it, it may choose to take no further action and order that no disciplinary measures be taken or impose one of the punishments applicable to minor misdemeanours.
3. Once it has chosen to proceed, the body may take any interim measures it deems appropriate to assure the proper implementation of its eventual decision. No interim measures may be taken which might cause irreparable harm to those concerned or which involve a violation of rights protected by law.
4. On ordering an enquiry, the Board shall appoint a person to act as the "instructing judge" from among its members or from among the College's ordinary members. The person appointed must have more years of service than the person facing the disciplinary action or, alternatively, must have at least ten years professional practice. Acceptance of the appointment is compulsory, unless the appointee has good reason not to do so or his appointment is challenged before the Board by the member facing the action. The Board may appoint a Secretary or authorise the instructing udge to designate one from among the members of the College.
5. The only reasons which may justify non-acceptance of or challenge to an appointment are consanguinity up to the fourth degree or affinity to the second, close friendship, clear enmity or personal interest in the matter.
6. In order that they may be challenged, the appointments of the instructing judge and secretary shall be notified to the person against whom the proceedings have been instigated. The latter may exercise his right to contest the appointments within a period of eight days following receipt of notification.
7. The person against whom proceedings have been instigated may appoint a member to defend him or to serve as arbiter. He shall be notified of this possibility and shall be given ten days in which to notify the Board of the name of the person he chooses to appoint and also that said person is willing to act in such a capacity. The appointee shall be present in all the enquiries undertaken by the instructing judge and may propose that other lines of investigation be explored on behalf of the defendant.

The person facing the disciplinary action may also have his counsel accompany him during all proceedings.

8. The instructing judge is empowered to request any background information deemed necessary and to order any enquiries and other actions which might help clarify the circumstances under examination or which might help determine whether or not these merit disciplinary measures.
9. In addition to taking the appropriate statements, the instructing judge shall provide the accused with a written list of accusations, indicating clearly the alleged offences with which he is being charged. The accused shall be given a non-extendable period of eight days following receipt of the notification in which to answer the charges and furnish any proof he may wish. On receipt of this answer, or on expiry of the eight-day limit, the instructing judge shall admit or reject the proof offered and order any action which he considers to be of help in clarifying the circumstances.
10. On completion of his enquiries, and no later than four months after the opening of proceedings, the instructing judge shall propose a solution to the case. A copy of this proposal shall be provided to the accused, who shall have eight days following the date of receipt in which to study the contents and adduce further arguments in writing.
11. All the above proceedings shall be notified to the College Board, which, on receipt

of the arguments presented by the accused or once the time-limit for the presentation of any such argumants has lapsed, shall take a decision on the case during the first session held thereafter. The Board shall hear the opinion of the College's legal adviser (if one exists) or the Ethics, Medical Law and Authorisations Committee and shall notify the accused of the full text of its final decision.
12. The Board may choose to send the file back to the instructing judge and request further enquiries not pursued at the time but which are crucial to the final decision. In such cases, prior to sending the file back for further enquiries, the Board shall inform the accused of its decision so that he may, within eight days, present any arguments he considers appropriate. This period is not to be counted as the period for the presentation of further arguments referred to above.
13. Any decision marking the end of the disciplinary enquiry shall be grounded on specific motives. No circumstances other than those which served to draw up the list of accusations or the proposed solution shall be admitted, although said circumstances may well be appraised differently.
14. The accused may lodge an appeal to the General Council against the final decision within fifteen days. All appeals shall be submitted to the College, which shall forward the disciplinary file and its own report within three days to the Council.
15. The defendant may appeal against the decision of the General Council to the Court for Administrative Disputes.[21]

57. As was seen in Chapter I § 3.1, the problem may arise that more than one disciplinary body becomes involved. A case of this nature was dealt with by the Supreme Court (4th Chamber) with its ruling of 24 January 1989 (rapporteur magistrate Bruguera Manté). On 27 January 1983, following a disciplinary case concerning a physician charged with a serious offence, the Standing Committee of the General Council of Physicians suspended the accused from practice for a period of nine months. The decision was confirmed by the (as it was then) Territorial Court on 14 May, following an appeal by the accused. However, the Supreme Court allowed the appeal on the following grounds: "(...) It is inadmissible that, while a criminal procedure is being followed with regard to the very same events which gave rise to the disciplinary action, the case should have been proceeded with and resolved without first waiting for the ruling of the Criminal Court (...) However, it is true that in cases such as this, which involve a relationship of subjection or a special kind of supremacy between the physician and his professional association, the power to handle disciplinary matters may be different to and independent of criminal responsibility (...), although this does not mean that the principle of "non bis in idem" or no two punishments for the same offence should be violated". However, the ruling also states that "the necessary subordination of disciplinary powers to the jurisdiction of the criminal courts when a criminal procedure is being followed with regard to the same event means that the disciplinary proceedings may not be proceeded with, opened or concluded while the criminal enquiry continues."

58. Separate mention should be made of the disciplinary powers of the Administration with regard to medical staff of the Social Security system. Until such times as the new Framework Statute provided for in article 84 of the General Health Law comes into existence, the basic regulations are still those contained in the Legal Statute of Medical Staff of the Social Security system, under Decree 3160/66 of 23 December 1966. Given that the new Framework Statute should see the light of day shortly, we will include a brief outline of the system which is to be applied in future. The Statute is complemented by, among other provisions, Circular 15/85 of the Directorate General of INSALUD of 9 October 1985 and Circular 8/78 of the INP of 10 March.

It goes without saying that these rules and regulations apply only to medical employees of the Social Security system, in accordance with statutory provisions.[22]

Disciplinary offences and action are dealt with in Chapter VII. Article 65.1 should be understood as attributing disciplinary powers in relation to medical staff of the Social Security system to the Ministry of Health and Consumer Affairs, independently of any other jurisdiction

to which the members of staff may be subject in respect of activities which have no connection with their status as employees of the system. Consequently, and under article 65.2, the Ministry is competent to deal with disciplinary proceedings arising out of staff members' failure to fulfill their obligations towards the Social Security system.[23] Offences are classified as follows in article 66:

2. Minor misdemeanours:
a) Peristent lack of punctuality.
b) Negligence or inexcusable lack of care in the performance of one's specific duties, where this does not represent major harm to the service.
c) Discourtesy towards superiors, colleagues, subordinates and members of the public.
d) Improper or wrongful referral to specialists.
3. Serious offences:
a) Persistent commission of minor misdemeanours.
b) Absence from place of work without good cause.
c) Non-performance of specific duties where this causes major harm to the service.
d) The inclusion of false information in Social Security documents or certificates.
e) The issuing of unsigned prescriptions or improper use of prescriptions by the physician.
f) Taking of fees or similar reward from persons covered by Social Security or affiliated to it under the terms laid down in the regulations governing access to Social Security health care; to knowingly certify incapacity where such is not the case or to pursue personal financial gain by encouraging Social Security patients to seek private medical care.
g) Disrespect towards one's superiors, colleagues, subordinates and members of the public.
h) Non-compliance with regulations or instructions received where such non-compliance upsets the service or is detrimental to the care provided.
i) Breaches of professional secrecy.
j) The performance of acts which clash with the interests of the Social Security system.
k) Acts of insubordination in centres belonging to the Social Security system.
l) Generally, any inexcusably negligent action which is damaging to the care provided and any other action which is unbecoming of the dignity of the author.
4. Highly serious offences:
a) Persistent commission of serious offences.
b) Continuous and wilful lowering of professional standards.
c) Abandoning one's place of work, that is, failure to turn up for work for more than seventy-two hours without permission or good cause.
d) Individual or collective insubordination in the course of one's work in the Social Security system.
e) The causing of wilful caused to the Social Security system or persons covered by it.
f) Lack of integrity or morals and any other conduct which constitutes a Penal Code offence or felony.

The next article (67) sets out the punishments applicable to the above offences:

1. The following action may be taken in respect of the offences listed in the previous article:
a) Written caution, which may or may not be placed on the employee's record.
b) Loss of earnings for a period of between five and twenty days.
c) Suspension from duties without pay for a period of between one month and one year.
d) Permanent suspension from service.
2. The disciplinary action described in section b) above shall not entail loss of bonuses payable in respect of family circumstances.

Cautions are given for minor misdemeanours and may be issued by the provincial head office of INSALUD without a formal enquiry. Measures b) and c) apply to serious and highly serious offences, depending on the circumstances of the case; permanent suspension from duties shall apply only to highly serious offences (article 68). It should be noted that the measures contained in sections b) and c) of article 67 may well be contrary to article 31.3 of the Spanish Constitution, which stipulates that only a law (as opposed to a decree) can regulate such matters.[24]

§ 2. Professional Liability

I. General Aspects

59. The medical profession has become increasingly regulated in recent years;[25] as was seen in Chapters I and II above, this process of regulation stemmed from the need to define the scope of medical activity in the light of legal provisions governing professions which require academic qualifications, as stipulated in article 36 of the Spanish Constitution. It can be explained also by the importance which medical activity holds for society, which demands thorough regulation not merely to ensure that users may be defended against malpractice and physicians held liable for their actions, but also as a way of providing points of reference for professionals in situations in which they may have doubts as to their role,[26] and to help them take decisions when faced with difficult situations (organ transplants, euthanasia, abortion, etc.).[27] Regulation must keep in mind at all times the ultimate objective of the process, which is to confer on what is rapidly becoming increasingly complex medical activity a clear legal framework to enable the physician to perform his duties in a context of security.

Some have viewed this increased regulation of medical practice as being tantamount to a recourse on the part of the patient or his next-of-kin against the provider of treatment should conflict arise if the treatment does not achieve the expected curative results; conversely, it has also been seen as affording legal backing to physicians in such circumstances, protecting their diligent and responsible actions even though the patient's state of health has not been restored as well as could have been hoped.

There is certainly an element of truth to the above, which is why it would be rather one-sided to consider that regulating medical practice aimed essentially to persecute physicians; fears of this type gave rise to the threat of *defensive medicine*, that is, the physician would endeavour to confirm his diagnosis through numerous repetitive examinations which would serve to delay commencement of treatment, push costs up and undermine efficiency.[28] Practitioners themselves have long advocated that the conditions governing physicians' liability should be spelled out as clearly as possible, and their demands in this respect have been met by Spain's legal order in a way which shall be examined later.

60. The manifestations of professional medical practice the professional activities, and consequently any liability derived therefrom, may be studied from the standpoint of the legal nature of the provisions which regulate all such manifestations. A distinction is drawn between criminal and civil liability.

II. Criminal liability

61. The body of legislation governing the matter is the Spanish Penal Code, which distinguishes between liability stemming from conducts involving intent and those of a negligent nature.

A. Liability in respect of intentional conduct

62. Intentional conducts covered in the Penal Code presuppose that a conscious and wilful attack has been made on the legally-protected interest. The author of such conducts shall be liable for them if, in addition, another series of requirements are fulfilled, although he will be

exonerated from liability in certain cases if, for example, a justifying cause is involved, such as circumstances which render lawful the conduct that represents an attack on the legally-protected interest, given that the harm caused is permissible by law (for instance, a person who acts in legitimate self-defence or out of necessity).

63. Clearly this type of criminal liability covers physicians in the same way and under the same conditions as any other citizen. It would be extremely difficult —although not impossible— to imagine that a physician, in the course of professional practice and when performing a curative action, would intentionally commit homicide (article 407) or cause injury (articles 418-423). In such cases, there are no criteria which might differentiate the physician's scope of liability nor different rules of incrimination based exclusively on his status as a professional. Given that there is nothing to distinguish the intentional conduct of a physician from that of any ordinary person, and also that such offences are not commonplace in medical practice, the argument advanced by some that physicians should be held criminally liable only for any intentional offences they commit should be rejected. A different situation occurs when a physician uses his special knowledge to facilitate or secure the commission of an offence or to ensure that it goes unpunished. However, here again this situation is by no means limited to physicians but rather is equally applicable to pharmacists, chemists, biologists, gunsmiths, police officers, etc.

64. Nevertheless, consideration must also be given to the hypothesis that a physician deliberately and consciously *fails to assist* not just any sick person or the victim of an accident,[29] such as in the cases mentioned in a previous chapter, but his own patient, and as a result of this failure to act the patient dies or sustains irreparable consequences to his health. In these cases, jurists consider that an intentional or wilful offence does exist, the so-called offence committed by omission, which is the equivalent of an act committed through active (as opposed to passive) conduct. Depending on the circumstances and the specific case, an offence of homicide or wilful injury shall exist. Besides other requirements which need not be gone into here, the legal grounds for this criminal liability on the part of the physician are derived from the close relationship which exists between patient and physician as a result of the contract or other form of de facto connection (an example being the hospital doctor on duty who treats a casualty department patient). In these cases, in view of the privileged position enjoyed by the physician in relation to the life and health of the patient, he has a special duty to guarantee "his" patient's legally-protected interests and this obliges him to provide his services in such a way as to ensure that no harm comes to these interests, provided, of course, that he is able to in the circumstances.

B. Liability in respect of negligent conduct

a. Juridico-criminal negligence: features and configuration in the Penal Code

65. In negligent liability the legally-protected interest (in this case, the life, integrity and physical or mental health of the patient) is not harmed intentionally. Liability is based rather on the author's —whoever he may be— breach of certain duties of care or diligence, as a result of which the legal interest has sustained harm. The intended purpose of the author in such cases is of little interest or is irrelevant to criminal law; indeed, the puspose may even be highly useful to society (for example, treating a patient). What is important is how the author has conducted himself, that is, the means and the use he has made of these means,[30] the lack of due diligence in his action which may have led to the unintended and perhaps even unforeseen outcome. Given the nature of this offence of negligence, it is this type of liability which generally-speaking arises most frequently in professional acts, particularly unlawful acts committed by physicians.

66. Since the reform of the Penal Code in 1989,[31] article 565 includes so-called reckless negligence as an offence ("any person who out of recklessness commits an act which, if

committed intentionally, would constitute a criminal offence, shall be sentenced to a term in prison." (CP, article 565.1);[32] simple negligence, with or without a breach of regulations, is considered to be a minor offence or misdemeanour ("any person who, out of simple negligence or carelessness causes to others harm which, if caused intentionally, would constitute a criminal offence, shall be liable to imprisonment for a term not exceeding thirty days and a fine of between 50,000 and 100,000 pesetas, provided that the negligence in question entails also a breach of regulations; where this is not the case, he shall be sentenced to imprisonment of between one and fifteen days or a fine of betwen 50,000 and 100,000 pesetas", (CP article, 586 bis.1).[33] The difference[34] between offences and minor misdemeanours involving negligence is that in reckless negligence the breach of duties of care is more serious, more inexcusable or clumsy compared with the less serious breach which leads to simple negligence; and the difference between the two types of simple negligence is that the author's conduct is more censurable and reprehensible where regulations exist which expressly set out the contents of his duty of care than when such provisions do not exist (here regulations should be understood in the widest sense, that is, anything from a law or statutory rule down to a circular or internal memorandum, as long as they take the form of a legal provision).[35]

67. On the other hand, reckless negligence may be aggravated when professional negligence or lack of expertise are involved also ("when death or injuries with the results provided for in articles 418, 419 or 421.2 occur and where professional negligence or lack of expertise are involved, the maximum sentences stipulated in the present article shall be imposed. These sentences may be increased by one or two degrees at the discretion of the Court when the harm caused is extremely serious", CP, article 565.2).[36] This provision on aggravation has been criticised by experts, some of whom argue that it should be deleted or at least that its effects be softened, as we shall see below.

68. To sum up, the Penal Code uses the term "imprudence" alongside "lack of expertise" and "negligence". The law uses these terms to denote the taking on of an excessive or "non-permissible" risk, which entails a breach of certain duties of care, although there are certain nuances of difference in the case of lack of expertise and negligence in the field of professional practice (in other cases, imprudence and negligence are synonymous).

b. The elements of offences of negligence: aspects of greatest relevance to medical practice

69. Notwithstanding the clarification given above, it would appear that a literal reading of the Penal Code is insufficient to enable us to grasp the scope of liability in respect of negligence and its repercussions for physicians. It is thus up to those whose job it is to interpret the law (at the end of the day, the judges who have to apply it) to determine specific examples of the elements through which liability has to manifest itself in order to have legal-criminal relevance.

In the case of offences of negligence as described in the Penal Code, the following elements must always be present: a) failure to observe the duties of care entailed in professional practice; b) the causing of death or injury to the patient; c) causal link between the conduct of the physician and the result; d) the existence of an unlawful link between conduct and result, or objective imputation of the result. Each of these elements will be examined in detail below, although we will focus only on the aspects which are of greatest relevance to the specific category of medical negligence.[37]

a'. Failure to observe the duties of care entailed in professional practice

70. Let us look first of all at conduct in which due care is not exercised. This is certainly the most complex element or component part of the offence, and the one which proves most difficult to unravel. In practice, in the final instance whether or not an offence of negligence exists will depend on this element, although it should not be forgotten that the other component parts of the offence must also be present.

This requirement stems from the criminal rule which lies at the root of offences of

negligence and which states that in their social life (in all areas of social life), citizens' behaviour must conform to certain duties or rules designed to ensure that legally-protected interests or not endangered are harmed, particularly where major risk is involved (traffic, public transport, dangerous industries, nuclear energy, certain sports, etc.; but also in apparently harmless activities such as looking after plants hung from a balcony or window). This is what is known as "the duty of care". Thus, citizens or professionals (for our purposes here, physicians or health-care professionals) whose conduct in the exercise of their profession conforms to these duties of care are in fact merely tailoring their conduct to the guidelines laid down by the rule. It is therefore necessary to compare the duty of care required in the particular sector of social life with the actual conduct of the author.

71. As is known, however, the precise legal content of this duty of care is not laid down specifically in the Law (a rather pointless task in any case, in view of the sheer number of conducts which are subject to certain duties of care) and thus it befalls the judge (with, of course, the appropriate expert advice on hand) to assess whether in a given case a duty of care has been breached. All physicians who treat a patient should observe minimum conduct guidelines to avoid committing a criminal offence, regardless of their level of training or their qualifications: the duty of care is an objective one. This was made clear in a recent ruling of the Supreme Court (2nd Chamber) dated 14 February 1991 when, in a health-related case, it stated that in order to constitute punishable negligence, the following was required: "an act or omission performed in breach of rules or regulations of caution or precaution — as required by the circumstances of the event, place and time—, which aimed to foresee and, where appropriate, avoid damage or harm". This criterion indicates the minimum level of necessary care or ability, below which there exists a duty to refrain from acting.

72. However, a number of authors have raised the point that the duty of care should be established in accordance with individual ability, and assessment of this duty should be determined not from the standpoint of culpability, as the majority would hold, but should be based rather on the description of the offence included in the law. Put another way, the duty of care is only breached when the person, in accordance with his ability, could have foreseen the outcome, which means that the level of this duty will vary from person to person. This represents an individual or subjective duty of care.[38] This notion of the duty of care is extremely important in the medical profession, particularly with regard to professionals of much greater ability than others practising the same specialist branch, given that if they fail to make use of this extra-special ability they will be in breach of the duty of care which is within their reach; from an objective point of view, this situation would also affect those of below-average ability: they would not be liable (not having breached the duty of care) if they used all the diligence they are capable of using, even though this is below the average ability of colleagues. The question arises only in relation to individual ability and not (exceptional) knowledge, since the latter is taken into account in the appraisal of objective foreseeability. Only insofar as failure to use this ability can be determined objectively can a case be made for the existence of a breach of the duty of care, which would give rise in turn to an offence of negligence;[39] if this is not the case, in certain situations an intentional offence may exist, whereas the rest would not be punishable.[40]

73. Objectively-due care is determined by the (intellectual) criterion of the objective foreseeability of the outcome (adequate causation), and is corrected and restricted by another (statutory) criterion, according to which only dangerous actions are prohibited, that is, actions which lead to an objectively-foreseeable outcome and which an intelligent and judicious person would refrain from committing.

a". Technical fault, breach of lex artis and of the duty of care

74. It is difficult to describe in more specific terms the content of the duty of care as conceived objectively, due to the tremendous variety and complexity of the conducts which

have to be appraised.

One could determine content on the basis of general laws which are applicable to cases which fit the legal description of the offence or ones of a similar nature. This set of technical rules and procedures is what is commonly known as *lex artis*, which naturally differs from sector to sector and from profession to profession. The implication of this is that a physician or health-care professional who has been guided by the *lex artis*, by what his skill and judgement indicate to be appropriate at each moment and in each circumstance, generally-speaking will not have breached his duties of care. This is an issue to which we shall return later.

Determining the existence or otherwise of a breach of the duty of care is also possible, although less frequent in the case of physicians, on the basis of technical or administrative provisions. As has been mentioned above, in such cases —and if injury is caused to the patient—, the offender shall have committed an offence of reckless negligence or simple neglignece involving a breach of regulations, depending on the circumstances.

75. A distinction must be drawn between three closely-related although not completely identical notions which, if confused, could give rise to hasty and erroneous consequences. The three in question are breaches of the objective duty of care, technical error or fault and infringements of the *lex artis*. Conceptually, the three are very similar, which is why it is crucial that as far as is possible the logical context of each should be clearly defined.

Technical error or fault, known also as professional error or fault, is a concept which is common also to other professions, most of which are of a technical or experimental nature (architects, engineers etc). Technical fault in medicine involves the *defective application of methods, techniques or procedures in the different stages of the action of the physician*[41] (examination, diagnosis, indication, administering of treatment). As used here, the concept of technical fault does not imply a legal appraisal but rather the de facto verification that a given medical situation is incorrect from the medical point of view. This neutral legal interpretation implies only that once it has been ascertained that an error resulting in harm has in fact taken place, it then becomes necessary to verify whether a breach of the duty of care has also occurred, given that it is possible for a technical error to exist without a breach of the duty of care. Technical fault or error, which is a scientific concept, does not entail negligence (legal concept) *eo ipso*;[42] in the eyes of the Law the decisive element is not the error in itself but rather the cause of any such error. To sum up, then, the existence of technical fault alone is of no value other than as an indication (as long as it is accompanied by a result of harm to the patient) which leads us to ascertain subsequently that objectively-due care has or has not been breached. Thus, it will not always be possible to state that criminal liability exists if, in this respect, the offence does not conform to this requirement.

Similarly, with regard to *lex artis* we may conclude the following: 1) technical error or fault does not necessarily suppose a breach of *lex artis*; 2) *lex artis* is not immutable nor does it exist in one form only, and thus it must be reconciled with individual freedom to use different methods and must remain open to new techniques and procedures, including less widely-used ones; 3) *lex artis* is valid solely (as has been stated above) for "typical" situations, for example, those described in scientific literature, whereas it is not valid for exceptional or "atypical" cases; 4) it is not possible to determine an identity based on content for both technical regulations and legal rules at the same time: each group pursues its own particular ends and therefore a breach of one does not necessarily imply that of the other. In conclusion, although the principle that physicians should observe the *lex artis* (in the broad sense referred to earlier) is still very much in force, a breach does not as yet entail a breach of the duty of care, although it often does constitute an indication thereof. Indeed, on occasions (in atypical situations) a physician's observance of the duty of care may even require him to distance himself from the *lex artis*.

76. The above general considerations regarding the three concepts are shared also by case law when, for example, it is said that medical practice is "subject to the *lex artis*, and that medical criminal liability does not originate from errors of diagnosis or lack of extraordinary expertise (given that infallibility cannot be made a requirement): rather, negligence arises when conduct does not conform to certain requirements and means...".[43]

b". Determining the existence of a breach of the objective duty of care: special features[44]

77. To begin with, account must be taken of certain aspects, such as how to assess a person's training or specialist knowledge (even though there is no specific ban on practising without the appropriate specialist qualification), the general need to update scientific knowledge and techniques, circumstances of time and place (e.g. rural area or hospital, etc), the duty of so-called "therapeutic information", etc.

20. Within the various phases of the curing process (anamnesis, diagnosis, prognosis, treatment, preventive or prophylactic measures) there are a number of particular circumstances to which consideration must be given when determining whether or not duties of care have been breached. In view of the amount of guess-work involved, greater leeway is allowable in diagnosis, although, as Supreme Court case law has held, this does not mean that criminal liability for negligence is completely ruled out.

b'. Death of or injury to patient

78. In order for criminal liability in respect of negligence to exist, negligent conduct by the physician of the type explained above is in itself insufficient. A harmful material result to the patient is also required, since in medical practice only a material result offence is possible; this point was clarified by the Supreme Court ruling of 14 February 1991 referred to earlier, which stated that 'concrete damage and harm must be caused, and this must be a consequence of the negligent conduct in its twin facets, namely, the lack of foresight or the "duty to know" and the lack of care or the "duty to prevent"'. In any case, it is not always easy to determine whether harm has been caused to the patient on the basis of how his condition has evolved.

This result may take the form of harm caused to the health or integrity of the patient and, in some extreme cases, even loss of life. Consequently, inadequate action on the part of a physician who has failed to observe due care, but which has not led to one of the aforementioned events or situations, shall not give rise to criminal liability of any kind, as we are reminded by article 565 of the Penal Code in which the expression "performance of an action leading to a result" is used. Conversely, the existence of a result of harm or damage to the patient does not necessarily imply punishable negligence on the part of the physician, given that it must be proven that his behaviour effectively breached the duty of care, in the terms outlined above. The presence of a result such as one of those listed above merely opens the way to a subsequent analysis of the conduct of the physician or health-care professional.

c'. The causal link between the physician's conduct and the outcome

79. Let us suppose that duties of care have indeed been breached and have resulted in harm being caused to the patient. This in itself is insufficient: it is necessary to ascertain whether the negligent conduct actually caused the result, that is, whether a causal link exists between the two, a point that has been stressed by the Supreme Court ruling of 14 February 1991: "a corresponding relationship of causation, of cause and effect, must exist between the negligent action and the harmful result; this in turn will generate liability when the blame can be attributed to a specific person". As was mentioned above, the subject's negligent action does not extend also to the subsequent outcome — this is a requirement of the offence— given that the subject's intended purpose was not to cause the result in question. This is why the causal link associating the action and the outcome —a link which must always exist— forms part of the legal description of the offence.[45]

This requirement has led to widespread difficulties as regards the furnishing of proof, and it is easy to understand that such difficulties arise most frequently in the field of health or medicine, given that medicine by definition is an inexact science involving a certain degree of guess-work and not everything is known about the physical and mental behaviour of human beings.[46] Hence, doubts as to the existence of this causal link shall lead to the person being acquitted, by virtue of the application of the principle of *in dubio pro reo* (presumption of

innocence).

d'. Unlawful link between action and outcome: objective imputation of the latter

80. In specialist literature and in case law it is considered that something else is required in addition to all the above. Firstly, a closer link between action and outcome than a merely causal link is required: the result in question must have been a consequence of the failure to observe objectively-due care.[47] Secondly, the result must be one which the regulations governing due care aimed specifically to prevent.[48]

It is difficult to provide clear-cut examples in the field of medicine, and hence we shall resort to another field in an effort to better understand the first of the above-mentioned criteria regarding imputation. Let us suppose that when driving along a stretch of road a motorist breaks the speed limit. Ahead of him is a cyclist who is riding rather erratically; the cyclist is knocked down and dies. Let us consider the circumstances: the driver has breached his duty of care by exceeding the speed-limit; a death results therefrom and certainly there can be no denying that he has caused that death. Is he guilty of an offence of negligence? Not in the eyes of the law, because the result did not stem from his negligent driving, and would have occurred equally if he had not broken the limit. We can take an example also from the field of health: during an operation an anaesthetist administers cocaine instead of the correct substance; the patient dies but the autopsy shows later that he would have died anyway given his serious condition. All the above requirements, including the causal link, are present here except for d) the unlawful link between action and outcome or the objective imputation of the result. Thus, the correct decision would be to clear the accused. Proving that the result would have occurred in any case, even if the duty of care had been observed, will depend to a large extent on the skill of the defence lawyer, although as long as it seems possible or likely,[49] as long as doubt exists, a court should give the benefit of doubt and find the accused not guilty.

c. Aggravated liability in respect of professional negligence or lack of expertise

81. As far as these aggravated offences are concerned, we have little to add to what we have stated elsewhere.[50] Lack of expertise and negligence refer to professionals although their meaning differs: professional negligence implies a breach of technical duties incumbent only on professionals in the course of their work;[51] however, it does not follow that all negligence on the part of a person who happens to be a professional will render him liable to an aggravated sentence (for this to be the case he must breach his duty of care also).[52]

Although this aggravation of the offence is questionable,[53] bearing in mind that there are other activities in society which may be performed by professionals and laypersons alike (for example, the driving of motor vehicles), it is not as wide of the mark as might at first seem (provided it is kept within the appropriate limits). Bear in mind also that certain professions cannot be practised by non-professionals, such is the case with physicians (and also architects, engineers, pharmacists, etc.), and that authorisation to practise is dependent on the person holding the appropriate qualifications (presumption of aptitude). Thus, it is understandable that breaches of duties of care, as set out in technical regulations, or illegal practice by a person who does not have the necessary qualification should be viewed as being more serious. In the light of this consideration, then, there would be no grounds for an objective aggravation of liability.[54]

C. Team Work in Medical and Health Care

82. Team work,[55] which is becoming increasingly common in hospital medicine, poses particular problems, although it can prove extremely important and useful as regards determining liability, bearing in mind that in criminal law liability is strictly personal (each person is answerable for his own conduct). In cases such as these, one may apply the criterion adopted by Spain's Supreme Court —in a road traffic case first of all—, which has become

known as the principle of trust, according to which each person taking part in an activity may trust that in their respective missions the others will act in accordance with their duties; the same goes for joint activities, under the principle of the sharing out of functions. In this way, a surgeon may trust that his anaesthetist is using the appropriate parameters and carrying out the necessary verifications in the course of the operation; that the nurse will hand him the appropriate instruments; for her part, the nurse may trust that the instrument or drug requested is the correct one (and the dosage indicated is correct); the internist can trust that the nurse will give the prescribed doses at the times indicated; both physician and nurse may trust that the medicine or drug has been made correctly by the laboratory and that the labels indicate the exact content and expiry date.

The sharing out of functions also means that superiors will not ask their subordinates to perform any tasks which exceed their level of training or their allotted work or which they themselves should do. If they do assign such work, it is their duty to supervise that their orders or instructions are carried out correctly.

III. Civil Liability

83. Civil liability (whether linked or not to an offence)[56] aims to afford reparation in respect of harm caused to someone and, where appropriate, to compensate for any damages caused by the punishable event.[57] This usually takes the form of financial compensation, although other forms may occasionally used. This type of liability may be based on the contractual relationship which exists between the patient and the health professional, in accordance with the provisions of article 1101 and related articles of the Civil Code, or, alternatively, on so-called extracontractual fault which gives rise to extracontractual liability, governed by article 1902 of the Civil Code.[58]

The distinction between the two forms of liability as applied in the field of medicine has led to a great deal of doctrinal discussion, not to mention controversy. Both doctrine and case law have given ample recognition to the existence of a contractual relationship between physician and patient where said relationship stems from an earlier legal relationship *inter partes*.[59] Although contractual medical cover is becoming increasingly common, the importance of situations where this is —emergency operations, occasional gaps in contractual cover, etc.— makes it inappropriate to examine here the contractual basis of civil liability derived from medical practice.[60] Notwithstanding the different legal regimes of contractual and extracontractual liability[61] —the need to be of legal capacity to enter into a contract (in the case of the former type), time-limits for the lapsing of contracts, proof of fault, etc.— case law has on occasions approximated the two in rulings on reparations.[62] The theoretical grounds for this lies in the circumstance that here both types of liability come in to play, that is, it can be ascertained that the general duty of *alterum non laedere* has been breached, as has a duty stemming from contractual obligations,[63] even though both become merged in one single claim for compensation. Moreover, as laid down in the Supreme Court Ruling of 11 November 1990,[64] these obligations are derived from another which is common to all health professionals, whether or not they are under contract, namely, the obligation which is not necesarily to ensure the recovery of the patient. Put another way, it is not an obligation which involves a specific result, but rather one involving means: the professional's obligation is not to cure the patient but rather to provide him with all the care required, in accordance with the state of the art in science.

84. Which is all the more reason not to draw a distinction between contractual and extracontractual liability when considering cases of civil liability.[65] For our purposes here it will suffice to consider the common elements between the two, taking as our starting point articles 1101 and 1902 of the Civil Code which deal with the failure to observe certain duties of care incumbent on the author.[66] The conditions or circumstances of this form of liability include the following:[67]

a) Harmful conduct: this consists of an action or omission,[68] which leads to a result of harm to the patient. In order for this conduct to be relevant in terms of civil liability it must be unlawful, that is, it must transgress a legal rule based on the principle that one shall not harm others.[69] Moreover, "the harm on which the alleged liability is grounded must be a consequence of an action or omission circumscribable to the scope of activities related to the health-medical profession".[70]

In cases where the physician-patient relationship is governed by a contract, there is debate as to whether "liability waiver" clauses should be deemed valid. However, the limitations imposed by articles 1102-1104 —which invalidate waivers with respect to liability derived from fault or an intentional act— and articles 1255 and 1258 of the Civil Code —which annul the validity of clauses which are contrary to the law, to morals or public order or which entail consequences that do not conform to good faith or proper usage—, substantially curb the efficiency of agreements which exonerate the professional from civil liability in cases where strict liability is involved.

b) The causing of harm: although this element is extremely difficult to determine, in the field of health or medical care it entails so-called bodily harm (although in the broad sense, which includes also harm of a mental nature) as well as material and moral harm, mental and physical pain and loss of profit or earnings.[71] The harm caused must be real in all cases. Even more complex than the determination of harm is the question of how it can be assessed for the purpose of compensation: the importance of the harm caused depends on personal circumstances, which are difficult to compare in absolute terms for all patients alike. Hence, to a large extent it is the law, having weighed up the specific circumstances of the case, which has to establish the nature and *quantum* of any reparation to be awarded in respect of civil liability.[72]

c) Causal connection between the conduct and the harm caused: this is a perectly logical requirement and is explained above;[73] it might be appropriate here to recall once more the difficulties involved, although not so much those regarding the furnishing of proof (which we will examine in a moment) as those which arise in seeking a general criterion which will enable us to construct —or rule out— the causal connection satisfactorily. In the area of negligence, for example, Spanish case law has adopted the notion that causation should be deemed to exist if the harmful result would have been avoided with diligent conduct; although this criterion appears clear and defendable, it is somewhat imprecise as regards the weighing up the likelihood that the result would have been avoided.[74] Furthermore, a lack of diligence —which would enable the conduct to be viewed as being negligent— is often associated with causation, when it is more correct initially at least to analyse the two separately. Only after a causal link has been seen to exist between conduct and result is it appropriate to assess the matter of whether the action was negligent or not.[75] Perhaps it is for these reasons that case law is not guided by one single criterion alone in establishing the causal connection: although the *conditio sine qua non* formula is widely accpeted, there is another current in case law (backed by a sector of doctrine) which stresses the failings of this principle, for example, it is not capable of settling correctly cases involving several causal processes which lead to harm being caused, and it would rule out finding possible grounds for objective liability, etc—. This second body of opinion prefers other criteria and is supported by the Supreme Court ruling of 11 July 1987, which sided with the theory of adequation. Having said that, the *conditio sine qua non* formula continues to afford the surest means of establishing the causal link between conduct and harm. This does not mean, however, that it is not possible to perfect the legal relevance of causation either by extending civil liability to cases of objective liability —given that the problem is one of culpability, that is, strict liability—, or by limiting it in accordance with the modern-day category of objective imputation.

Objective liability will be dealt with in the next section, although it is important to recall here that objective imputation is a category which covers a range of criteria, which can be used to rule out liability in respect of a conduct which has been considered previously to have been

the cause of a harmful result. This is why objective imputation may be considered as acting in the opposite sense to objective liability,[76] which broadens the scope of liability, whereas the former serves to limit the attribution of harmful results to conducts for which a causal connection can be established and thereby reduces the scope of civil liability. In this way, the ruling of the Supreme Court (2nd Chamber) of 11 February 1987 acknowledges that "the causal link between the action and the result is not in itself sufficient, (...) it is necessary also to add to the notion of cause, as understood by the natural sciences and as translated into the doctrine of "conditio sine qua non" or equivalence of conditions, the legal-criminal relevance of any such causal connection". Furthermore, objective imputation leads to the author being made responsible for conducts which, strictly-speaking, are not the actual causes of the harmful result —as is the case, for example, with acts of omission—.[77]

Objective imputation is being introduced into Spanish civil law doctrine particularly in view of its potential as a criterion which limits criminal liability and any derived civil liability consequences. It is destined to play a decisive role in the determination of the legal relevance of causal conducts in medical practice.

d) Culpability of the causer of the harm: although civil law specialists acknowledge that there are two accepted meanings of the term fault —in the broad sense as comprising intention also, and in the stricter sense as the breach of certain duties of diligence and foresight—,[78] it is used more frequently in the stricter of the two senses, and in particular in relation to the health professions to denote negligent conduct from which civil liability may be derived.[79] The sense of article 1104 of the Civil Code is adopted therefore.[80] Moreover, and here one can discern the influence of French doctrine, the category of "medical fault" has gradually been introduced into Spanish law to denote breaches of duties of diligence by medical professionals in the course of professional practice.[81]

Here again we encounter difficulties in attempting to arrive at a precise definition of what constitutes a breach of said duties. These difficulties stem from the relative nature of the two factors which are generally advanced by our case law as requirements for an act to be deemed to be blameworthy, namely, the degree to which the harmful result is foreseeable and avoidable.[82]

Objective liability is a crucial issue in civil liability and has considerable implications for medical practice. In order for it to be deemed to exist, and thus give rise to an obligation to make reparation, the causal link between the conduct and the harm suffices and no fault needs to be present. This could be taken to mean that the requirement of culpability is replaced by the assumption of risk in the performance of the dangerous conduct.[83] To date, this type of liability has been used only exceptionally in Spanish law, as we shall see shortly. However, the use of the reversal of the burden of proof may be understood as meaning that some Supreme Court rulings have opened the way to objective liability.

85. This element increases further the importance of the problem of proof, a subject which is still very much open to debate today. We mentioned earlier that harm was a necessary circumstance for determining civil liability and that it was extremely complex to assess this in the context of a physician-patient relationship. Generally-speaking, this relationship is created when an unwell patient goes to the doctor and seeks his help to improve his condition or to attenuate the negative effects of his illness or accident. The objectives, unfortunately, are not always achieved and hence the problem arises of how to assess a lack of improvement or a worsening of the patient's condition. Clearly, an evolution of the patient's health along these lines could well be due to the action of the physician and thus it has to be decided whether or not such action was found wanting. However, it should not be ruled out that the worsening state may be due to the very process of the illness or the accident sustained by the patient and could not have been halted by the physician's diligent action.[84] Thus, the other circumstances of civil liability come into play and certain general aspects must be proven: the existence of harm,[85] the nature of any such harm, the causal connection, and fault or lack of fault- depending on who has to furnish the proof— on the part of the physician.

A general principle of civil liability is that the existence of harm must be proven by the person alleging its existence, and it is up to the judge to appraise whether this is in fact the case.[86] Abundant examples exist in civil law case law of examples of attacks on people's honour, privacy and personal image,[87] which show how interesting the perspective described here is, that is, splitting the concept of culpable harm into its two elements and conferring a separate identity on the problem of the determination of harm (of a moral nature in the above-mentioned case law examples). In the field of medical liability this perspective is justified in view of the conflict which exists between the two categories of bodily and moral harm: partial recovery of sight,[88] causing of blindness, worsening of one's physical appearance following plastic surgery designed to do just the opposite, etc.[89] and even death (from the point of view of the moral harm caused to next-of-kin.[90] The number of circumstances in which it would be necessary to ascertain and prove the existence of harm in order to make the physician answerable for unlawful conduct could well be endless. In the case of organ transplants, for example, how is one to weigh up the rejection of the organ which worsens the patient's pre-operation condition? How can the success or failure of plastic surgery be appraised? To what extent and in which cases does the violation of professional secrecy give rise to moral damage? and so on...

For their part, the other problems —proof of the causal link and fault on the part of the physician— are addressed in the text of the ruling of the Supreme Court (1st chamber) of 11 March,[91] in which it is stated that: "the contractual or extracontractual obligation of physicians and health professionals in general is not necessarily to achieve the recovery of the patient. Put another way, they are obliged not to attain a given result but to use means: the professional is not obliged to cure the patient but rather to provide him with all the care required, in accordance with the state of the art in science. Moreover, more or less objective liability of all types is generally rule out in the case of health professionals and their conduct, while the reversal of the burden of proof (which has been accepted by this Chamber with repect to harm arising out of circumstances of a different nature) is also excluded, and hence it is up to the patient to prove the existence of a causal connection or link and of fault".[92] This and other rulings have firmly established the current of case law which places on the shoulders of the plaintiff the burden of proving each and every one of the requirements.

As was stated above, the reversal of the burden of proof may lead to the objectivation of liability: the plaintiff will not have to prove the negligence of the medical action which caused the harm.[93] Such cases are few and far between in Spanish case law;[94] for example, the Supreme Court ruling of 1 December 1987, taking into account the difficulties a patient would face in proving fault on the part of the physician in the application of radiotherapy, reversed the burden of proof when, in establishing the latter's liability, it considered that it was sufficient to recognise the causal link between the injuries suffered by the patient and the harmful conduct —excessive dosis of radiotherapy—, without the defendant having proven that he had used the all his diligence in using a means considered to be dangerous.[95]

Notwithstanding what has just been said, doctrine[96] tends to acknowledge that it is inappropriate to burden the patient with the task of furnishing the proof in cases involving medical liability. There are a number of reasons which explain this. Firstly, the patient or his heirs may find themselves in a situation of helplessness as a result of the harm caused by the medical action. Secondly, and more frequently, they will be unable to obtain the appropriate information concerning the entire medical surgical process undergone, they will not have access to proof and will be unable to identify those truly responsible when several persons have taken part in the treatment. Neither will they be in a position to assess all these elements properly. Above all they will face the insurmountable obstacle placed in their path by the "cruel corporatism of professionals".[97] For these reasons, and on the basis of the principle that each side should be allowed to fight with equal weapons —a principle laid down by the German Constitutional Court in its resolution of 1 April 1979—, Spanish doctrine has found in objective liability the remedy to attenuate the inequalities in the field of medical liability which stem from the principle that the onus to prove charges lies with the plaintiff. However, it is important to stress here that this form of the reversal of the burden of proof should not be taken

to mean that strict liability or liability without fault is accepted fully —given that lack of fault would not necessarily prevent the physician from being held responsible. It is a case rather of the burden of proof being displaced in the direction of the person who is better placed to furnish evidence that he acted with the necessary diligence.

IV. The Liability of the Public Health Authorities

86. Where criminal liability in the strict sense does not exist, there are a number of cases in Spanish law in which someone who did not actually cause the harm is obliged to provide reparation. Thus, for example, —and as is laid down in the Constitution (article 106)— the State is held to be liable for harm derived from the functioning of public services, which means that it has to acknowledge liability for the actions of professionals who provide their services in the different national health authorities.[98]

A. Direct State Liability

87. Although provision is made in the Civil Code for civil liability on the part of the State (article 1903 number 5), this is further reinforced by other administrative legislation such as the Compulsory Expropriation Act of 16 December 1954 (article 121 onwards) and the Act of 26 July 1957, which sets out the Legal Regime of the State Administration (article 40 onwards).

The latter states in article 40 that "private individuals shall be entitled to receive compensation from the State for all injuries suffered to their properties and rights, except in cases of force majeure, provided that said injuries are a consequence of the normal or non-normal functioning of public services or the adoption of measures which cannot be reviewed by courts for administrative disputes. In all cases, any harm alleged must be real in nature, must be assessable in financial terms and must have been suffered by an individual or group of persons". This type of liability is enforced using administrative channels and expires one year after the date of the event giving rise to the claim for compensation.

The fact that this liability is considered not to be a form of indirect responsibility or liability in respect of the actions of others, but rather as direct liability,[99] which is not grounded on the unlawful nature of the harmful act or the negligence of the public servant involved, means that we are once again in the sphere of objective liability.[100]

88. Private individuals are also entitled to demand that the authorities and civil servants, irrespective of their rank and status, provide reparation for injuries and harm caused to the former's property or rights as the result of serious fault or negligence committed in the course of their duties (article 43). The Administration, for its part, can claim against its authorities, officials or agents for liability caused by serious fault or negligence on their part, irrespective of whether the State awards compensation to third parties who sustain harm as a result. It may also take action in respect of liability for harm and damage caused to the properties and rights of the State (article 42).

89. This then constitutes the basic legal rules governing cases of harm or injury caused in state-run hospitals. Liability is grounded not on a contract (even where one exists between patient and physician) but on the law itself, and as a result any such liability is extracontractual in nature.

90. The Supreme Court (4th Chamber, which deals with claims instigated against the administration) has also handed down rulings on this issue and generally-speaking has confirmed the liability of State institutions or bodies, along the lines of what has just been explained above. However, the sentences consulted by the present authors do not state whether or not the action which gave rise to the harm was of a specifically medical nature. Furthermore they involved provincial authorities only (rulings of 12 March 1975 and 4 July 1979).

91. It is clear that liability is based on the existence of injury, which, as we saw earler, is a

requirement laid down in article 40 of the Act which sets out the Legal Regime of the State Administration. Here again it may be understood that the concept of injury is a purely de facto one, and is accepted in a manner similar to the way the notion of harm is accepted by civilists, as was explained above ("injury" in the criminal law denotes an attack made on a legally-protected interest and implies that the interest in question is undermined, even though this cannot always be assessed in monetary terms).

92. In some exceptional cases, the State has also assumed liability which is not catered for in current legislation. Such was the case when it assumed responsibility for the repercussions of the so-called toxic syndrome (where thousands of people were poisoned by adulterated cooking oil), by virtue of the RD of 19 October 1981 and 18 June 1982.

93. The Administration's concern led it to include in the State Budget for 1991 insurance contracts to cover professional civil liability (Sixth Additional Provision): "Civil liability insurance. Insurance may be taken out to cover the professional civil liability of employees of the State administration, its autonomous bodies, management agencies and social security services, where the circumstance warrant cover. The head of the department, body, organisation or service concerned shall decide which specific functions and circumstances should be included in any such cover". To give effect to this provision the Ministry for Health and Consumer Affairs must take the appropriate steps, as it has done so already with a private insurance company.

B. Liability on the Part of the Social Security System

94. Let us examine now the situation of a person covered by Social Security who makes a claims for liability in respect of medical assistance provided in a social security hospital.

It should be noted first of all that the Social Security (to simplify matters here we shall not differentiate between the National Institute of Social Security, which manages the system, and the National Institute of Health —INSALUD, in Spanish— which actually provides the health care) is a public albeit autonomous body, although it is expressly excluded from the regime put in place for autonomous state-run institutions. As we shall see in a moment, this consideration is important for the question of the most appropriate avenue of jurisdiction to be used.

It is also important to point out that two very different types of legal relationship are involved in health care which is provided under the Social Security system. The first is the employer-employee relationship which exists between the health professional and the Social Security system, while the second is the (statutory) national insurance link between the Social Security and the person covered by the system. It is clear from this that no legal contractual relationship exists bewteen the health professional and the patient. Hence, liability stemming from the actions of the former is extracontractual and is based on the above-mentioned statutory provisions of the Civil Code. This means that a claim may be made *jointly* against the Social Security system and the professional, under article 1903 of the Civil Code (see also the rulings of the Supreme Court —Civil Chamber— of 20 February 1981 and 28 March 1983).

95. It is also possible to claim *directly* against the Social Security using the courts for labour disputes, on the basis of the national insurance link which exists between the system and those affiliated to it. Support for this can be found in article 2.b) of the Labour Procedures Act of 27 April 1990. Such claims would involve making the National Institute of Health directly liable for the supposedly incorrect granting of services it is obliged to provide (see rulings of the Supreme Court —Labour Disputes Chamber— of 20 November 1982 and 21 November 1983). As we have already seen, the fact that there is no legal relationship of any type between the physicians employed by the Social Security and the beneficiaries of the system, this avenue of direct liability (or the legal basis thereof) cannot be extended to include the employees of the system (although, as we have also seen, extracontractual liability remains an option).

Just as when the State is held to be directly liable (as was mentioned above in the

previous section), the advantages afforded by this avenue of jurisdiction —Social Security liability— are clear for all to see. The physician who may have provided imperfect services is relegated to a secondary role and his professional competence and prestige are not compromised to the same extent. Furthermore, and bearing in mind the rather closed nature of the medical profession, it opens the way to greater objectiveness when it comes to determining the actual facts and furnishing means of proof. All of which means that the patient-beneficiary is afforded greater assurances that he will receive adequate compensation in respect of the harm produced. It should be said, however, that much will hinge on the flexibility and breadth of the criteria adopted by case law until such times as doctrine governing the matter becomes fully consolidated.[101]

C. Vicarious Liability on the Part of the Administration

96. We shall now examine briefly the question of vicarious liability on the part of the health authorities.

In principle, all criminal offences give rise to civil liability. A decision regarding both criminal and civil liability is made in the criminal law procedure, save where the (private) accusation expressly indicates the contrary. The Penal Code makes provision for —or perhaps it would be more accurate to say that it can be deduced from the Code— vicarious civil liability of the State, Insalud and other public health authorities in respect of offences or fault committed by employees who are found to be criminally liable and who are unable to pay the compensation awarded by a court (article 22). These institutions must cover the civil liability of an insolvent health care professional as determined by a court. We should add also that vicarious civil liability is understood by Spanish courts in the objective sense, that is, that the institution or body deemed to be liable is answerable even where it has not been at fault (*in eligendo, in vigilando* fault is presumed to exist), and no proof that it exercised all diligence or care can be admitted.

§ 3. Quality Assurance: Review Boards

I. Quality Assurance

97. Like its neighbouring countries, Spain has based its health model on the notion of the coexistence of public and private action. However, it falls upon the authorities to guarantee the right to health, regardless of private sector involvement, because health is viewed as a public service;[102] these are the principles which have shaped medical care in Spain.

When speaking of quality assurance it is necessary to return once more to the constitutional principle contained in article 43.2 of the Spanish Constitution, which defines the role of the public administrations in this regard as follows: "the public authorities are charged with the organisation and assurance of public health through preventive measures and the necessary services and facilities. The Law shall lay down the rights and duties of all concerned".

The principle is taken up once again in article 1.1. of the General Health Law (LGS), the goal of which is "the general regulation of all actions to give effect to the right to the protection of health, as recognised in article 43 and others of the Constitution"; article 6.4 of the Law stipulates that the actions of public health authorities shall aim, among other things, to assure health assistance in all cases where a los of health occurs; article 9 sets out the duty of the authorities to inform users of public health services, or associated private services, of their entitlements and duties; article 10 lists the rights of the various public health administrations; article 30 deals with the intervention of the authorities in the inspection, control and appraisal of the activities and functions of all health centres and institutions; articles 32-37 deal with health-related infringements and sanctions. More specifically, articles 32 and 33 regulate the disciplinary powers of the Administration where civil and criminal actions are involved also; articles 34 and 35 set out guidelines and principles governing the classification of infringements of regulations as minor, serious and very serious, while article 36 lists the sanctions applicable

in each case.[103]

Mention should be made at this point that Title V of the Law, governing pharmaceutical products, confers quality assurance powers on the Administration. These powers include the evaluation of the suitability of drugs, medicines and other health products (article 95.1). Authorisation of medicines and drugs is subject to their being safe and efficient, and of sufficient quality and purity; moreover, they must have been manufactured by suitably able natural or legal persons endowed. All these aspects must be guaranteed by the procedure for authorisation, which extends also to other aspects such as tolerance, purity, stability and information, in accordance with statutory requirements (articles 95.3 and 95.4). The Administration is also charged with drawing up standards governing the quality, production, storage, advertising and dispensing of drugs and medicines (articles 98-103).[104] These provisions are developed fully in the Drugs and Medicines Law 25/1990 of 20 December. The explanatory meemorandum to the Law states as its primary objective that it shall "contribute to bringing about safe, efficient and quality drugs and medicines, which are correctly identified and accompanied by appropriate information". After setting forth a series of principles, the Drugs ands Medicines Law proceeds to lay down regulations relating to safety guarantees and others governing non-toxicity or tolerance (article 12), efficacy (article 13) quality, purity and stability (14) identification (15, 16 and 17), information (19) and accident prevention (19). Of note also is Chapter Five which deals with pharmacopoeia (article 55) and quality control (article 56). The latter article stipulates also which bodies are competent to draw up quality control programmes.[105]

These provisions provide the bases for the control of health care activities.[106]

98. In addition to the above, a further and complementary avenue through which quality control is assured in medicine, this time from the perspective of citizens as users of the health care system, is opened up by the Constitution itself. The opening paragraphs of article 51 state that

> 1. The public authorities shall guarantee the defence of consumers and users by protecting, through efficient procedures, their safety, health and legitimate economic interests.
> 2. The public authorities shall promote consumer and user information; they shall encourage the setting up of such organisations and shall hear them in matters affecting consumers and users, in accordance with the terms laid down by the Law.

These stipulations are developed further by the Consumer and User Protection Law 26/84 of 19 July 1984,[107] which sets out as its objective the defence of consumers and users, in accordance with article 53.3 of the Constitution. This defence is one of the general principles which shapes Spain's legal order. The terms consumers and users are used to denote all "natural or legal persons who acquire, use or enjoy as the end users moveable or non-moveable properties, products, services, activities or functions, irrespective of the nature (public or private, individual or collective) of the producer(s), provider(s) or issuer(s) of said goods" (article 1, parts 1 and 2). The Royal Decree of 8 March 1991, which lists the products, goods and services covered by the Consumer and User Protection Law, includes in Annex I section C health, medical, hospital and pharmaceutical services among those which must be given priority and for which the authorities, either directly or in cooperation with consumer or user bodies, should organise quality control campaigns and programmes.

Chapter II of the Law is devoted specifically to the protection of health and safety, and Chapter VII to related guarantees and responsibilities. Of particular note is article 31 which puts in place a system of arbitration which is empowered to give binding decisions for the settlement of complaints or claims filed by consumers or users.

99. In addition to the above, Chapter V of the Code of Medical Ethics —a set of ethcial rules and principles intended to inspire and guide the professional conduct of physicians (article 1)— is devoted to "The quality of medical care":

Article 21.1. All patients are entitled to medical care of scientific and human quality. Physicians have a responsibility to provide such care, regardless of their field of practice, and undertake to use all the resources of medical science adequately for their patients, in accordance with existing medical craft and the possibilities available to them.
2. Save for emergency cases, physicians should refrain from performing actions which exceed their ability. In such cases, they shall propose that the patient seek the help of a suitably qualified colleague.

Article 22.1. Physicians should be able to enjoy professional freedom and the technical conditions necessary to enable them to act independently and in a manner which will assure the quality of their work. Where these conditions do not exist, the body responsible for the assistance provided to the patient should be duly informed.
2. Physicians, either individually or through professional bodies, should draw the community's attention to any deficiencies which hinder correct professional practice.

Article 23. The practice of medicine is a service based on scientific knowledge. Up-dating this knowledge is both an individual ethical duty incumbent on each physician and an ethical commitment on the part of all the organisations and authorities involved in the regulation of the profession.

Article 24.1. Until such times as non-conventional forms of medicine acquire an acceptable scientific basis, physicians who practise them are obliged to record objectively their observations in order to facilitate assessment of the efficacy of their methods.
2. The following practices are unethical: practices inspired by charlatanism, and those which lack a basis in science or which offer impossible cures to patients or to their next-of-kin; illusory procedures or ones which for which sufficient proof is not yet available; the application of simulated treatments or fictitious operations; the practice of medicine exclusively by letter, telephone, radio or through the press.
3. Facilitating the use of a surgery to an unqualified person for the practice of medicine, or aiding and abetting any such person, is unethical.

These purely ethical principles should be placed in the context of RD 1018/80 (Ministry of Health and Social Security) of 19 May 1980, which approves the General Statutes of both the Organisation of Colleges of Physicians (abbreviated to OMC in Spanish) and the General Council of Colleges of Physicians. Article 3.2 of the statutes of the former states that the function of the OMC is to "safeguard and observe the ethical and social principles of the medical profesion, as well as its dignity and prestige. To that end it shall draw up and apply the appropriate Codes".

100. This system of control of medical services is complemented by further provisions concerning treatment provided in a public hospital or care centre. RD 521/1987 of 15 April governing the structure, organsiation and functioning of hospitals under the management of the National Institute of Health, provides for the creation of a Hospital Users Committee (article 19.1), "a body designed to enable the community to participate in the planning, control and assessment of the running of the hospital and the quality of care provided". The functions of the Committee include proposing to the Hospital Management any measures it deems appropriate in terms of health needs and with a view to improving the quality of care" (article 20.2 f); article 23 provides for the setting up of a Social Welfare Committee, a collegiate advisory body charged among other things with "examining specific aspects which might improve care" (article 23.2 c); finally, article 32 provides for the creation of a Patient Care Service to channel and give written form to any claims which might arise. These claims are

forwarded to the heads of the Division concerned, and replies must be given in writing and signed by the director or person appointed by him. Two representatives of Consumer and User Organisations sit on both Committees.[108] It should be pointed out, however, that in practice the application of the Decree provisions is far from satisfactory: in 1989 only 28% of the Social Welfare Committees had been set up and were working; Patient Care Services recieved 13,005 complaints —less than 1% of the total number of activities carried out in hospitals—.[109] It is considered that the "chief cause of the low number of complaints would appear to be people's misgivings that lodging a complaint serves any useful purpose".[110]

The same could be said for the other avenues of complaint open to a patient who wishes to enforce the his rights contained in the Bill of Patient Rights. These avenues are as follows: the Patient Admission and Care Services which exist in health centres; the Complaints Register which is available in all centres belonging to the National Institute of Health (INSALUD); the Medical Services Inspectorate and the head offices of INSALUD in each province.

II. Review Boards

101. One of the most important recommendations of the Helsinki (1964) and Tokyo (Helsinki II, 1975) Declarations was the setting up of independent committees to oversee medical research protocols, particularly where experiments involving human beings are concerned. In the United States these recommendations led to the creation of Institutional Review Boards, which have had a major influence on the regulations governing Clinical Trials Committees throughout the world, and also on recent Spanish provisions.[111] These committees were set up primarily to review medical research protocols and those governing the consent of subjects once they have been duly informed of the importance, consequences and risks entailed in the treatment or operation to be undergone.[112]

The review carried out by the Committees prior to the clinical test is designed to protect the patient by ascertaining whether he has given his free consent and also the scope of any such consent, the appropriateness of the information given, particularly with regard to potential risks and benefits. The overall aim is to ensure that he is not subjected to any experimentation to which he has not given his express consent and authorisation and that his rights are protected. The rights of the researchers involved are protected also in that a clear framework of responsibility is created. The same is true also of the host institution, whose reputation is thus kept intact.[113] Appraisal and control by Committees of this type are strictly scientific and legal-administrative in nature. They do not enter into the ethical considerations of the test performed. On this last point, notice has been drawn[114] to the confusion which exists in Spanish legislation between Clinical Trials Committees, which limit themselves to the purely scientific and medico-legal aspects, and Bioethics Committees, whose job it is to settle conflicts of values which arise in the course of medical practice. Article 64 of the Drugs and Medicines Law, under the heading "Clinical Research Ethics Committees", stipulates the following:

> 1. No clinical test may be performed without a preliminary report drawn up by a Clinical Research Ethics Committee, which shall be independent of the instigators of or the researchers involved in the test and shall be duly authorised by the competent Health Authtority, which shall notify such authtorisation to the Ministry of Health and Consumer Affairs.
> 2. The Committee shall weigh up the methodological, ethical and legal aspects of the proposed protocol, as well as the anticipated risks and benefits of the test.
> 3. Ethics Committees shall be made up of, at the very least, an interdisciplinary team comprising doctors, hospital pharmacists, clinical pharmacologists, nursing staff and non-health professionals, of whom at least one shall be a jurist.

102. The confusion in terminology is still present, for instance, in article 69 of the same Law. In section 1 it is stipulated that "details of authorised clinical trials shall be published in scientific journals and mention shall be made of the Ethics Committee which drew up the

preliminary report".

103. The attribution of scientific-legal and ethical supervisory functions had already been included in the Ministerial Order of 3 August 1982, which developed Royal Decree 944/1978 governing clinical trials on human beings of pharmaceutical and medicinal products. The Order itself has recently been updated by Royal Decree 561/1993, which sets out in article 42 the general functions of Clinical Research Ethics Committees, namely, to weigh up "the methodological, ethical and legal aspects of the proposed protocol, as well as the risks and benefits entailed".

104. It has to be interpreted therefore that the process under way in Spain is one which turns Clinical Trials Committees, essentially comprising doctors and researchers, into Bioethics Committees, in that independent persons are appointed to serve on them and also that the Committee's functions include the ethical appraisal of the trials submitted to them for consideration.[115]

105. By 1988, the Ministry of Health had authorised the setting up of 143 Clinical Trials Committees.[116]

§ 4. Biomedical Ethics Committees

106. There are three main aspects to be noted in connection with Bioethics Committees in Spain.

To begin with, the health authorities would appear to be rather short on clear ideas as to how these Committees should be insitutionalised. The authorities are clearly concerned at the problem, perhaps due to the constant worries expressed by hospital staff and specialists, who have denounced this vacuum and have put forward proposals and solutions in the light of the administration's failure to act.[117] The signs are that when the question is finally tackled by the authorities, they will opt for a model of ethics committees along the lines of those that currently exist in English-speaking countries, which have influenced greatly the committees set up in Europe, particularly France and Germany. This first aspect —the lack of action by the authorities— could be said to be the root cause of the other two aspects.

Secondly, as was mentioned in § 2 of this Chapter, the nomenclature used in the (few) statutory provisions governing such committees is at the very least confusing. Reference is made both to Clinical Trials Committees and/or Ethics Committees. This can be explained in part by what has happened (intentionally no doubt) in countries which pioneered the creation of such committees: committees originally made up of experts were subsequently entrusted with an ethical role and came to include also persons from outside the health professions.[118] Mention of this development was made earlier in the section dealing with the regulation of clinical trials under the Drugs and Medicines Law. Article 6 of the Law sets out the functions of what it calls Clinical Research Ethics Committees. In reality, the role entrusted to the first Committees which were created in hospitals —the selection of patients to receive high technology treatment where this was not available to all, the protection of hospitalised patients from abuses of or attacks on their personal dignity[119]— gave an early indication of just how difficult it would be to avoid a clash between Clinical Trials Committees and Ethics Committees as regards ethical assessment. From the outset, non-health professionals were required to participate in the weighing up ethical considerations.

Having said that, it should be pointed out that the make-up and functions of the two types of committees (Clinical Trials and Ethics) could lead to different although nonetheless valid criteria, provided that the appropriate coordination existed between them. The efficiency of the former depends to a large extent on the participation of clinical research experts capable of weighing up aspects of methodology and the viability of the trial, and who are advised by jurists on the legal implications involved. These committees need not be large and could well function in small hospitals.[120] Any agreements adopted by them would subsequently be

reviewed by an interdisciplinary Ethics Committee which would endeavour to solve problems of conflicts of values which might arise in the planned research or trial, even values which might take precedence over technical-juridical arguments.[121]

The competences of Ethics Committee would not be limited to supervising agremeents adopted by the research committees. In keeping with their raison d'être, they would consider also the ethical implications of other matters such as the treatment of terminal patients, assessment and diagnosis of brain death, problems arising out of the donation and transplantation of organs, the revival of critically-ill patients, ethical problems in perinatology, etc.[122]

Thirdly and lastly, one would have to say that Ethics Committees in Spain represent a poorly-coordinated and non-uniform response. Specific institutional committees are urgently required to regulate certain types of intervention, such as organ transplants or assisted reproduction. The problem is that, in the absence of an appropriate legal framework, hospitals have created their own ethics committees to solve such conflicts.

107. Let us look in more detail at some of the institutional responses to the aforementioned problems.

A Ministerial Order issued by the Ministry of Health on 25 August 1980 created the *National Transplant Advisory Committee*, provided for in the 5th Final Provision of RD 426/1980 of 22 February, which in turn developed further Law 39/79 of 27 October 1979 governing the removal and transplantation of organs.[123] This national committee was set up to inform and advise the Secretary of State for Health on matters pertaining to the registration, approval and authorisation of centres of health wishing to perform organ transplants. Another of its functions is to advise on health education, health campaigns and any other measures deemed necessary to increase the number of transplants. Although strictly-speaking its function is to advise on administrative matters, the very nature of its role entails important ethical implications which must be taken into account in health education and campaigns aimed at the public.

As part of the plan to make health care in state-run hospitals more "human", it was decided that each Social Security hospital should have a Committee (called literally the "Committee for the Humanisation of Care") to monitor compliance with the Bill of Patient Rights and Duties, examine the information collated by the Patient Care Service and study specific aspects which might improve assistance (diet, catering, visits, information provided to patients and next-of-kin, surveys taken among hospitalised patients). Given that the Bill is essentially ethical in content, the role of the committee is also partly ethical, and in this respect the committee fits the notion of ethics committees as they exist in other European and English-speaking countries. However, the very make-up of the committees seems inappropriate in that it does not allow them to deal with particularly complex or wide-ranging ethical questions (the committees comprise the director of the hospital, a nurse attached to the Patient Care Service, social worker, nurse, a senior member of the catering department, and one from Admissions). Moreover, the rights and duties of patients as listed in the Bill have been included in almost exactly the same form in the General Health Law (LGS) of 25 April 1986, which means that they are no longer merely a statement of intent but rather true rights which are enforceable through the appropriate administrative or legal channels. The Patient Care Service, which is also part of the "humanisation" plan for hospitals, was set up to attend and give guidance to patients and their families, maintain direct contact with patients, handle any proposals and suggestions made by them or their families concerning ways of improving hospital services, receive and deal with complaints regarding hospital services and staff, monitor compliance with hospital regulations governing patients and their families, and compile and analyse data with a view to drawing up proposals concerning hospital policy and organisation designed to bring about a more personal form of care. Indirectly, then, the Service may come to hear of conflicts of an ethical nature and contribute to a solution.

Chapter VII of the Law on Techniques of Assisted Reproduction of 22 November 1988 provides for the creation of a *National Committee on Assisted Reproduction* and other similar committees at regional level. The Committee is made up of two technical committees and one

social or ethics committee, comprising representatives from various walks of life. The functions of the Committee are to provide guidance, advice and organisation; at the same time, it is empowered to authorise research projects or experiments using such techniques and to consider special requests for their use and other activities relating to assisted reproduction.

108. As was stated above, the Drugs and Medicines Law of 1990 in article 64 provides for the setting up of Clinical Trials Committees. Clinical trials are described in article 59 of the Law as "any experimental evaluation of a substance or medicine which is administered or applied to human beings for any of the following purposes: a) to illustrate its pharmacodynamic effects or to obtain data regarding absorption, distribution, metabolism and excretion of the substance in the human body; b) to determine its efficiency for a given therapeutic, prophylactic or diagnostic purpose; c) to gain insight into adverse reactions and to determine the safety of the substance. Any such trials shall be undertaken only after a preliminary report by a Clinical Research Ethics Committee, which must be independent of the instigators of and researchers who take part in the research[124] and must be duly authorised by the competent health authority, which shall notify such authorisation to the Ministry of Health and Consumer Affairs. The Committee shall weigh up the methodological, ethical and legal aspects of the proposed protocol, as well as the anticipated risks and benefits of the test. Ethics Committees shall be made up of, at the very least, an interdisciplinary team comprising doctors, hospital pharmacists, clinical pharmacologists, nursing staff and non-health professionals, of whom at least one shall be a jurist" (article 64).

109. So far the Administration has not regulated satisfactorily Ethics Committees. Its silence on the following issues is of particular concern:

Several ethical problems have arisen from the fact that with the Penal Code Reform of 25 June 1983 (and subsequently Organic Law 3/1989 of 21 June, which updates the Penal Code) sterilisation is now authorised in Spain, with no restrictions as to the aim (curative, prophylactic, eugenics, economic-social). Problems surround, for instance, the age as of which sterilisation is advisable, whether consent of the spouse is required, the number of children already born to the patient, etc. In order to solve these problems, some hospitals and centres of health have created small committees or groups, although these are not recognised by law. There can be no questioning the good intentions behind the setting up of such committees and their efforts to fill existing gaps in some rather delicate areas, or that for the most part they have used rational criteria and common sense to solve problems. However, in imposing certain restrictions they are limiting the statutory provisions laid down in a law which itself does not impose any such restrictions.

When an expectant mother attends a hospital for treatment and later to give birth and makes it known that, for whatever reason, she does not wish to keep her child and asks the hospital authorities to make the appropriate enquiries and take the necessary legal steps for the baby to adopted by another couple, a committee is needed to examine as objectively as possible the question of which couple will adopt the baby after birth. Some hospital committees have been created for this specific purpose.

Following a heated debate and an appeal based on alleged inconstitutionality, abortion was depenalised partially in Spain by the Organic Law of 5 July 1985. This was followed shortly afterwards (31 July) by a Ministerial Order governing the carrying out of abortions in hospitals or other centres of health. The Order stipulated that "evaluation committees" should be created in such centres to ensure compliance with legal provisions, as well as to inform and advise on any potential problems or difficulties and to compile information and statistics, at all times observing the confidential nature of the cases involved. These were mixed committees in the sense that they were entrusted with administrative and advisory functions which, although not mentioned explicitly, could well entail ethical considerations. The Order was subsequently derogated and replaced by the Royal Decree of 21 November 1986 on approved centres and rules for the legal performance of voluntary terminations of pregnancy. However, the Decree made no mention of the aforementioned committees, perhaps reflecting the confusion to which they gave rise and the difficulties which they placed in the path of voluntary terminations of

pregnancy.

110. Clearly, then, there is a need for uniform ethical criteria to govern the supervisory role of Ethics Committees. Similarly, the creation of a National Bioethics Committee is crucial. In spite of several attempts by the Ministry of Health and Consumer Affairs no national body of this type has yet seen the light of day.

The involvement in hospital work of specialists from non-medical or non-hospital disciplines and the growing ethical repercussions of ever-increasing medical activities have led to the setting up of in-house ethical committees. The lack of clearly-defined ideas on the part of the Spanish health authorities —it seems at any rate— has propitiated the creation (either by the authorities themselves or by hospitals) of certain committees with varied and often vague roles such as to provide technical advice or administrative and even ethical control, or simply committees which serve purely bureaucratic purposes. The committees are made up almost exclusively of doctors or health/hospital staff and, on occasions, unusual people (although their presence may be justified by the limited nature of the role assigned to the committee, for example, catering staff serving on the hospital "humanisation" committee). However, strictly speaking, the majority of these committees cannot be considered to be "ethics committees" in the sense explained above.

NOTES

1. See ROMEO CASABONA, *El médico ante el Derecho*, cit., p. 5: 'Medicine has extendidng its scope considerably and at the same time has at its disposal a wide range of increasingly efficient and sophisticated procedures and techniques. This situation in turn makes it essential that doctors possess a body of knowledge and techincal skill that is also constantly expanding. As a result, a greater degree of specialization, with the accompanying depth of knowledge of this narrower field, is demanded... Trough this gradical process Medicine has become a complex and interdependent activity.

2. This is perhaps the constitutional provision of greatest relevance to professional colleges, although reference to them is also made in articles 52 and 26. Art. 52 sets out that "the law shall regulate professional organistions that defende their own economic interests. Their internal structure and procedures must be democratic". And in art. 26: "Honourary tribunals are prohibited in the area of civil administration and professional organistions".

3. This was acomplished through Law 74/ 1978 of 26 December.

4. Following a certain amount of doubt, which continues even today, as to whether membership of a college should be compulsory or not, clause 34 of the Law which established the bases of the National Health Service (1944) stated that it was indeed compulsory for physicians. See art 35. 1 of the RD 1018/1980 of 19 May, which passed the General Statutes of the OMC, in relation to art. 3.2 of Law 2/1972 of 13 February, on Professional Colleges. Failure to comply with this obligation may be viewed as constituting illegal practice and give rise to criminal liability.

5. Aside from the obligation to register with a College, and with the appropriate social scurity scheme, there is also a right to join a College if one holds the necessary degree and meets all the other conditions are satisfied (art. 3. 1 of the Professional Colleges Law). The right to join a medical college cannot be denied —except in those cases established by the Statutes of the OMC (art. 38)—, which means that the right to practise a profession is guaranteed (art. 35 of the Constitution).

6. See art. 1 of the Statutes of the OMC and art. 1 of the Professional Colleges Law.

7. There are also colleges in Ceuta and Melilla, to wich the Statutes of the OMC apply. Their jurisdiction is limited to the respective municipal areas.

8. See arts. 33 and 34 of the Statutes of the OMC.

9. Art. 27 of the Statutes of the OMC stipulates that the following sections are obligatory: Head Physicians, Rural Medicine, Hospital Physicians, Social Security Outpatients' Physicians, Physicians in group practices, Physicians in private practice, Recent graduates (those who have graduated in the last five years and/or are still following a course of training) and Retired Physicians.

10. Agreements adopted by the General Assembly are binding on all college members. Nevertheless, in colleges with more than 500 members, or where specific provision has been made in the statutes of the college concerned, and in all cases where there are more than 2000 members, the Assembly may delegate its functions to an Assembly of Delegates elected by personal vote in a secret ballot of all members.

11. In addition to the registration fee payable on joining, members must pay monthly subscriptions, the minimum level of which is set by the General Council. These amounts may be increased by the individual colleges subject to approval by the General Assembly (arts. 50, 51 and 52 of the Statutes of the OMC).

12. The Associations' jurisdiction must correspond to the territorial organisation of the Spanish State (art. 4 of the Statutes of the OMC). If the Colleges of Physicians are provincial and the General Council's powers cover the entire country, it follows that the Associations should have as their jurisdiction the Autonomous Communities, although it might be argued that they have an area of jurisdiction smaller than the Autonomous Community, but larger than the province. In these cases, the Professional Colleges Law stipulates that Associations of Colleges shall have a General Council (art. 4.4).

13. The General Assembly is the highest organ of government of the Council and is made up of the presidents of all the official colleges of physicians, as well as national representatives of the obligatory Sections and other persons (president of the Council, Vice-president, general secretary, etc.)

14. According to art. 23 of the Statutes of the OMC, these are: a) an Ethics, Medical Law and Authorisation Committee; b) a Research and Medical Education Committee; c) a Committee for Realtions with Medical Societies and Royal Academies of Medicine; and d) Committee for Taxation Coordination.

15. See the more extensive provisions of art. 9 of the Professional Colleges Law and the Statutes of the General Council of Colleges of Physicians.

16. In this way, apart from the relevant legal regulations, traditionally physicians have drawn up their own codes and regulations for ethical professional practice. In the new Code of Medical Ethics the issue of professional conduct towards colleagues has not been overlooked. Chapter seven of the new code devotes three lengthy articles to relationships between physicians.

17. This meaning is conveyed in art. 33. 1 of the new Code of Medical Ethics, which reads as follows: "*fraternity* among physicians is a primordial duty: only the rights of the patient have priority over this duty. Physicians must treat one another with due

the patient have priority over this duty. Physicians must treat one another with due deference, respect and loyalty, whatever the hierarchical relationship between them". Section 5 of this article also states that "a doctor who informs his college in an objective manner and with due discretion of breaches of the rules of medical ethics or professional competence committed by a colleague shall not be deemed to have failed to comply with this duty".

18. The Code of Medical Ethics expresses it thus in art. 33.2: "they have the duty to defend a colleague who is the victim of unjust attack or accusations and they shall unreservedly share scientific knowledge".

19. Art. 5 m) of the Professional Colleges Law.

20. C. SEGURA/ L. MARTÍNEZ CALCERRADA, *Derecho Médico I*, (Tecnos, Madrid 1986), p. 59.

21. Through assimilation to the Administration's powers in matters of discipline. With regard to the appropriateness of this avenue in terms of the Administration's disciplinary powers, which we shall examine further on in relation to medical employees of the Social Security system, see Supreme Court Rulings of 11 February 1985, 16 June and 21 October 1986, and 4 April 1988.

22. Although this formula seems quite clear, there are certain problems in defining accurately the exact scope of application, particularly in the light of statutory regulations drawn up after the Statutes which extend the number of situations governed by the latter. For details see J.A. OÑORBE DE TORRE (Coordinator), *Manual de Procedimiento Disciplinario del Personal Médico de la Seguridad Social*, (Ministerio de Sanidad y Consumo, Madrid 1989), pp. 23 ff. For this reason article 1 of the Statute is complemented by a series of provisions, including the following; Ministerial Orders (Ministry of Health and Consumer Affairs) of 19 June and 5 September 1986, on employees of University Teaching Hospitals; Royal Decrees 187 and 417 of 23 January and 27 February 1987 respectively, by the Ministry for Relations with Parliament and the Government Secretariat, offering the staff of Autonomous Centres which joined INSALUD, as well as those of the Institutional Administration of National Health, "Santa Cristina" Health Centre and the School of Midwives, the possibility of inclusion in the corresponding Statutes. See, in relation to this statutory regime, Constitutional Court Rulings of 2 June, 3 and 8 July 1980; Supreme Court Rulings of 3 May 1985, 17 March and 23 June 1986, 21 December 1987 and 1 February 1988.

23. Under article 1.4 of the Ministerial Order (Ministry of Health and Consumer Affairs) of 23 October 1986, the taking of statutory measures is the competence of the the Office of the Under-Secretary of State for Health and Consumer Affairs.

24. See OÑORBE DE TORRE, *Manual de Procedimiento Disciplinario*, cit., p. 29. The author refers also to article 25.2 of the Spanish Consitution banning forced labour and quotes the opinion of the Legal Department of the Ministry of Health and Consumer Affairs that "deduction of wages implied the performance of forced labour". For this reason punishment entailing "loss of wages" has been replaced by the Office of the Under-Secretary of State for Health and Consumer Affairs by "suspension from work without pay" for the same period of time. For more details on the procedure involved, see OÑORBE DE TORRE, cit., pp. 30-40.

25. See SEGURA FUENTE/ MARTÍNEZ-CALCERRADA, *Derecho Médico, I,*, cit., p. 58 on the need for regulation; ROMEO CASABONA, *El médico ante el Derecho*, cit., pp. 6 ff.

26. See SEGURA FUENTE/ MARTÍNEZ CALCERRADA, *Derecho médico* I, cit., p. 56, in line with the views of Rico Pérez.

27. ROMEO CASABONA, *El médico ante el Derecho*, cit., pp. 5-10.

28. On this point see ROMEO CASABONA, *El médico ante el Derecho*, cit., 8-10; J. SANTOS BRIZ, 'La responsabilidad civil de los médicos en el Derecho español', in *Revista de Derecho Privado*, (julio-agosto) 1984, p. 644.

29. Liability in this case would come under the general regime laid down in article 489 of the Penal Code, for the offence of omitting to fulfill one's duty to help; no specific offence is mentioned for qualified professionals.

30. See J. CEREZO MIR, *Curso de Derecho Penal Español. Parte General I. Introducción. Teoría jurídica del delito/I,* (Tecnos, Madrid 1990), pp. 267 ff and p. 380.

31. Organic Law 30/1989 of 21 June. See C.M. ROMEO CASABONA, 'Los delitos culposos en la reforma penal', in *Actualidad Penal*, 1990, pp. 241 ff.

32. Of between six months and one day and six years.

33. The sentence is known in Spanish as "arresto menor", which covers a period of between one day and one month in prison.

34. CEREZO MIR, *Curso de Derecho Penal Español. Parte General I,* cit., pp. 390 f.

35. Reckless negligence also admits a breach of regulations (see CEREZO MIR, *Curso de Derecho Penal Español. Parte General I,* cit., p. 393). Similarly the representation of the result or the absence thereof (conscious or unconscious fault) may be present in both; see CEREZO MIR, cit., p. 392; S. MIR PUIG, *Derecho Penal. Parte General*, (PPU, Barcelona 1990), p. 291.

36. See references to case law in J.M. MARTÍNEZ-PEREDA RODRÍGUEZ, *La responsabilidad penal del médico y del sanitario*,(Colex, Madrid 1990), pp. 63 ff.

37. See C.M. ROMEO CASABONA, *El Médico y el Derecho Penal, I. La actividad curativa*, (Bosch, Barcelona 1981), pp. 211 ff.

38. See M. COBO DEL ROSAL/ T.S. VIVES ANTON, *Derecho Penal. Parte General.* (3ª ed., Tirant lo Blanch, Valencia 1990), p. 477; G. QUINTERO OLIVARES, *Derecho Penal. Parte General,* (2ª ed., Marcial Pons, Madrid 1989), p. 353 (although with slight nuances). The issue is dealt with in greater depth in CEREZO MIR, *Curso de Derecho Penal Español. Parte General I*, cit., p. 381 f.; A. JORGE BARREIRO, *La imprudencia punible en la actividad médico-quirúrgica*, (Tecnos, Madrid 1990), pp. 41 ff.; MIR PUIG, *Derecho Penal. Parte General*, cit., p. 298 f.; ROMEO CASABONA, *El Médico y el Derecho Penal, I*, cit., pp. 215 ff.; A. TORIO LOPEZ, 'El deber de cuidado en los delitos culposos' in *Anuario de Derecho Penal y Ciencias Penales*, 1974, pp. 25 ff.

39. MIR PUIG, *Derecho Penal. Parte General,* cit., p. 299.

40. For more details see CEREZO MIR, *Curso de Derecho Penal Español I*, cit., p. 382. JORGE BARREIRO, *La imprudencia punible en la actividad médico-quirúrgica*,

cit., p. 42, opts rather for the alternative of intentional or negligent homicide, depending on the case.

41. See ROMEO CASABONA, *El Médico y el Derecho Penal, I*, cit., p. 233 ff.; M. CORCOY BIDASOLO, *El delito imprudente*, (PPU, Barcelona 1989), pp. 101 ff.

42. A. QUINTANO RIPOLLES, *Derecho penal de la culpa*, (Bosch, Barcelona 1958), pp. 505 and 510.

43. Supreme Court Ruling of 5 February 1981, which uses these very terms and others. A Ruling of 7 October 1986 develops the criterion further and summarises doctrine on medical negligence: "1. No incrimination for scientific error; 2. A lack of extraordinary expertise is not deemed to be punishable either. 3. Culpability stems from cases where the doctor could have avoided the conduct which led to the harmful outcome; 4. Immutable general considerations should be avoided in the search for punishable medical liability".

44. See ROMEO CASABONA, *El Médico y el Derecho Penal, I*, cit., pp. 242 ff and 252 ff.

45. CEREZO MIR, *Curso de Derecho Penal Español. Parte General I*, cit., p. 280. See also Supreme Court Ruling of 20 May 1981.

46. On the determination of the causal link in accordance with the criterion of "the loss of life expectancy", see J.A. GISBERT CALABUIG, *Nuevos aspectos de la responsabilidad médica: el ejercicio de la Medicina de grupo o en equipo,* (Real Academia de Medicina de Valencia, 1979) passim; ROMEO CASABONA, *El Médico ante el Derecho*, cit., pp. 83 f.

47. See CEREZO MIR, *Curso de Derecho Penal Español. Parte General I*, cit., pp. 396 f; MIR PUIG, *Derecho Penal. Parte General,* cit., pp. 304 ff (in which further views and critical considerations are given); ROMEO CASABONA, *El Médico y el Derecho Penal, I*, cit., pp. 226 ff.

48. See CEREZO MIR, *Curso de Derecho Penal Español. Parte General I*, cit., pp. 399 f; MIR PUIG, *Derecho Penal. Parte General,* cit., pp. 304 ff (in which some further views and critical considerations are given); ROMEO CASABONA, *El Médico y el Derecho Penal, I*, cit., p. 228. This second criterion of imputation by itself, without the first, is advocated by E. GIMBERNAT ORDEIG, 'Infracción del deber de diligencia y fin de la norma en los delitos culposos', in *Revista de Derecho de Circulación*, 1965, p. 675.

49. There has been a great deal of debate as to the degree of likelihood, or even certainty, which can be required. See C. ROXIN, 'Infracción del deber y resultado en los delitos imprudentes', in *Problemas básicos del Derecho penal* (Spanish translation and notes by D.M. Luzón Peña), (Reus, Madrid 1976), pp.147 ff.

50. See ROMEO CASABONA, *El Médico y el Derecho Penal, I*, cit., pp. 229 ff.

51. See J. CORDOBA RODA, 'Zum Verkehrsstrafrecht in Spanien', in *Zeitschrift f. d. g. Strafrechtswissenschaft*, 1961, pp. 122 f.

52. See Supreme Court doctrine, which is similar, on such types of lack of expertise or professional negligence: rulings of 24 November 1984, 21 February 1986, 5 May 1988, 27 May 1988; 6 May 1990 (Barcelona Provincial Court).

53. However, in its present form the text means that aggravation could not be applied in a substantial number of cases, in accordance with the limitations set out in article 565.4 for the punishment for negligence as compared with that which is applicable to offences of intent. See ROMEO CASABONA, 'Los delitos culposos en la reforma penal', cit., pp. 261 ff. In any case aggravating the punishment by one or two degrees seems excessive.

54. See CEREZO MIR, *Curso de Derecho Penal Español. Parte General I*, cit., pp. 393 ff. A critical view is taken also by J. BUSTOS RAMIREZ, *Manual de Derecho Penal. Parte General*, (3ª ed., Ariel, Barcelona 1989), p. 236.

55. For an extremely thorough study of this issue, see JORGE BARREIRO, *La imprudencia punible en la actividad médico-quirúrgica*, cit., pp. 113 ff. See also ROMEO CASABONA, *El Médico y el Derecho Penal, I*, cit., pp. 247-252; G. STRATENWERTH, 'Arbeitsteilung und arztliche Sorgfaltspflicht', in *Eb. Schmidt-Fest., (Vandenhoeck und Ruprecht, Göttingen, 1961)*, pp. 383 ff.; D. WILHELM, 'Probleme der medizinischen Arbeitsteilung aus strafrechtlicher Sicht', in *Medizinrecht, 1*983, pp. 45 ff.

56. On the legal nature of liability stemming from a physician's acts, see E. LLAMAS POMBO, *La responsabilidad civil del médico*, (Trivium, Madrid 1988), pp. 92-109; on jurisdictional limits see L. GONZALEZ MORAN, *La responsabilidad civil del médico*, (Bosch, Barcelona 1990), pp. 19-32.

57. As laid down in article 100 of the Civil Procedure Code (Ley de Enjuiciamiento Civil). For the specific differences between the function of civil and criminal liability, see Articles 20, 21, 22 and 101 of the Penal Code.

58. The starting point for contractual and extracontractual liability is the same, namely, the notion of reparation and compensation; on this point, see Supreme Court Ruling of 19 June 1984. The same ruling outlines the differences between both types of liability, which are governed by different legal systems despite the fact that the basic goal involved is one and the same. On situations where both contractual and extracontractual liability may be involved, see L. GONZÁLEZ MORAN, *La responsabilidad civil del médico*, cit., pp. 36-48.

59. On this point, see Supreme Court Ruling of 19 June 1984.

60. As argued by E. LLAMAS POMBO, *La responsabilidad civil del médico*, cit., p. 100.

61. See in this regard the Supreme Court Ruling of 30 December 1980.

62. Note, for example, how the Supreme Court Ruling of 16 December 1986 admits the possibility of extracontractual liability even where a contract exists.

63. See G. GARCIA VALDECASAS, 'El problema de la acumulación de la responsabilidad contractual y delictual en el Derecho español', in *Revista de Derecho Privado*, 1962, pp. 834 ff; L. GONZALEZ MORAN, *La responsabilidad civil del médico*, cit., pp. 36 ff; E. LLAMAS POMBO, *La responsabilidad civil del médico*, cit., pp. 100 ff.

64. In line with the Rulings of 6 November 1990, 7 February 1990, 12 July 1988 and 13 July 1987.

65. In this regard, see Supreme Court Rulings of 24 March 1952, 7 February 1990 and 22 February 1991.

66. Article 1101: "Any person who, in the performance of his obligations, commits wilful misconduct or negligence or defers his obligations excessively, or who in any way transgresses the spirit of said obligations, shall be liable to compensate for any damage or harm caused by his actions".
Article 1902: "Any person who through his actions or omissions causes harm to another either wilfully or negligently is obliged to make good the harm caused".
In addition to this statutory requirement one has to consider also article 1903, which allows a claim to be brought against the centre or institution in which the physician provides his services. In this regard, the Supreme Court Ruling of 5 May 1988 is significant: "there existed culpable action on the part of the institution (...) in consenting to the use of health equipment in a deteriorated condition without providing sufficient guarantees that it was working properly and could be used in such a delicate health situation. This was responsible for the death of the patient being treated; the harm sustained was clear and substantial and was the result of an undeniable relationship of cause and effect, which was directly attributable to INSALUD because of the poor state of the material used in the hospital".

67. See Supreme Court Rulings of 6 November 1990 and 11 March 1991.

68. This active or omissive conduct must be voluntary. A degree of confusion surrounds the possibility of inferring civil liability from involuntary acts when the basis used is the antinomy which exists between "voluntary behaviour" and "negligent behaviour". Attributing a harmful outcome to negilgent behaviour supposes that the outcome was not intended by the author, although this does not mean that the behaviour itself was not voluntary; the author voluntarily breaches the duty of care, even though it is not his wish to produce the harm in question. Cf. E. LLAMAS POMBO, *La responsabilidad civil del médico*, p. 210; J.L. LACRUZ BERDEJO, *Elementos de Derecho Civil II*. Vol. Primero, (Bosch, Barcelona 1985), pp. 498 f. A similar line to that taken here can be found in J. SANTOS BRIZ, *La responsabilidad civil. Derecho sustantivo y Derecho procesal,* (5th edition revised and updated, Montecorvo, Madrid 1989), pp. 26-27. The distinction between voluntary and involuntary behvaiour is not valid either to explain civil liability; cf. infra.

69. On this point see SANTOS BRIZ, *La responsabilidad civil*, cit., pp. 28 ff.

70. E. LLAMAS POMBO, *La responsabilidad civil del médico,* cit., p. 211.

71. See also J. ATAZ LOPEZ, *Los médicos y la responsabilidad civil*, (Montecorvo, Madrid 1985), pp. 323 ff.

72. In this regard see ATAZ LOPEZ, *Los médicos y la responsabilidad civil*, cit., pp. 327-29.

73. On this issue see infra and particularly ATAZ LOPEZ, *Los médicos y la responsabilidad civil*, cit., pp. 335-46; J. FERNÁNDEZ COSTALES, *Responsabilidad civil médica y hospitalaria*, (La Ley, Madrid 1987), pp. 154-59; LLAMAS POMBO, *La responsabilidad civil del médico*, cit., pp. 239-44.

74. See ROMEO CASABONA, *El médico y el Derecho Penal, I*, cit., p. 227; CEREZO MIR, *Curso de Derecho Penal español. Parte General I*, cit., p. 396. Moreover, this criterion should be complemented (restricted) by that of foreseeability, even where the

causal link between conduct and harmful outcome can be established; see CEREZO MIR, cit., p. 396 and also the Supreme Court Rulings of 13 July 1987 and 7 June 1988 mentioned above.

75. Cf. Supreme Court (2nd Chamber) Ruling of 11 February 1987.

76. See infra.

77. See CEREZO MIR, *Curso de Derecho Penal español. Parte General I*, cit., pp. 280-81.

78. In this regard see M. TRAVIESAS, 'La culpa', in *Revista de Derecho Privado*, 1926, pp. 273 ff (reference taken from ATAZ LÓPEZ, *Los médicos y la responsabilidad civil*, cit., p. 274 and p. 370.

79. See LLAMAS POMBO, *La responsabilidad civil del médico*, cit., pp. 213-30. In our opinion this is the sense in which one has to understand the "element of intent" which, according to the Supreme Court (1st Chamber) Ruling, is required along with the causal connection in order for liability to be found to exist.

80. Article 1104: "Fault or negligence consists in the omission of the diligence whic is required by the person's obligations and which corresponds to the circumstances of people, time and place (...)".

81. See ATAZ LÓPEZ, *Los médicos y la responsibilidad civil,* cit., p. 290.

82. Significant in this regard is the Fourth Principle of Law of the Supreme Court Ruling of 11 March 1991.

83. On all these points see ATAZ LÓPEZ, *Los médicos y la responsabilidad civil*, cit., pp. 257-62.

84. See ATAZ LOPEZ, *Los médicos y la responsabilidad civil*, cit., pp. 340 ff.

85. It is quite a different matter if the harm is caused by an unlawful intervention. As was stated, the existence of harm is indicated by the impairment sustained by the patient's health, but this does not necessarily mean that it can be made good through civil liability. This acceptance can be inferred from articles 1101 and 1902 of the Civil Code: the obligation to make good the harm arises when said harm is caused by someone who commits, for instance, negligence, that is, it arises when the harm is culpable; however, there exists also harm caused by non-culpable behaviour; cf. SANTOS BRIZ, *La responsabilidad civil,* cit., pp. 140-41 (NB the meaning given in note 144 coincides with that considered here).

86. See GONZÁLEZ MORÁN, *La responsabilidad civil del médico,* cit., pp. 118-9.

87. The need to lay down the precise content of such rights and guidelines for determining whether infringement constitutes moral harm led the Constitutional Court to give rulings (in sentences handed down on 23 March and 5 October 1987 and 2 December 1988).

88. In Supreme Court Ruling of 6 November 1990; the appeal was dismissed for lack of proof that the doctor concerned had acted negligently.

89. An abundance of examples of case law on bodily harm can be found in

GONZÁLEZ MORÁN, *La responsabilidad civil del médico*, cit., pp. 121-4.

90. Although it is not a case involvinf medical liability, it is cited as an example by GONZALEZ MORAN, *La responsabilidad civil del médico*, cit., pp. 115 and 117.

91. Rapporteur Luis Martínez Calcerrada y Gómez. Prior to this, Supreme Court Ruling of 6 November 1990, following others of 13 July 1987, 12 July 1988 and 7 February 1990. One possible argument in this sense is that based on the liability which could be established in cases involving omission, where the causal link could not be determined.

92. On the reference to the reversal of the burden of proof in harm of a different origin, see Supreme Court Rulings of 29 December 1975, 2 April 1986 and 20 March 1987, which base civil liability on the existence of a harm that can be indemnified and, where appropriate, the presumption of culpability in the causal behaviour.

93. The reversal of the burden of proof does not lead to objectivation of liability in the strict sense of the term: in fact liability shall not be deemed to exist where the defendant can prove that he acted diligently. However, where this, and culpability, cannot be proven, he will have to answer for the harm caused by his action and thus it is in this sense that one can speak of objective liability; cf. ATAZ LÓPEZ, *Los médicos y la responsabilidad civil*, cit., p. 259.

94. Cf. Supreme Court Ruling of 13 July 1987 (rapporteur Santos Briz), cited by GONZÁLEZ MORÁN, *La responsabilidad civil del médico*, cit., p. 93.

95. For more details on objective medical liability in case law see GONZÁLEZ MORÁN, *La responsabilidad civil del médico*, cit., pp. 215-30.

96. See for instance GONZÁLEZ MORÁN, *La responsabilidad civil del médico*, cit., pp. 92-94 and 207 ff.; LLAMAS POMBO, *La responsabilidad civil del médico*, cit., pp. 423 ff. Also SANTOS BRIZ, *La responsabilidad civil de los médicos*, cit., p. 673, in which he shoulders the patient or his heirs with the burden of proving both the negligence of the physician and also the causal link between the negligence and the harm. However, it is generally acknowledged that the injured party is not in a position to furnish full and convincing proof of the negligence, the harm caused and the causal connection between the two; see GONZÁLEZ MORÁN, cit., p. 133.

97. GONZÁLEZ MORÁN, *La responsabilidad civil del médico*, cit., p. 207.

98. See supra. Supreme Court (1st Chamber) Ruling of 22 February 1991 (rapporteur Francisco Morales Morales), which is based on article 1903 of the Civil Code, establishes direct not vicarious liability, which can be demanded directly of the employer because of his own "culpa in vigilando" or "in eligendo", regardless of the type of liability attributable to the material author of the deed. The ruling follows Supreme Court Rulings of 22 June 1988 —which held INSALUD alone responsible for the lack of diligence of an unidentified nurse— and of 17 June 1989 and 30 January 1990.

99. See also GONZÁLEZ MORÁN, *La responsabilidad civil del médico*, cit., p. 149, and Supreme Court Ruling of 11 March 1991.

100. In this regard, Supreme Court Ruling of 16 December 1987, which, "without there being a clearly negligent action on the part of the professional, independently of whether said professional or other health professionals in the hospital incurred in

organisational liability (...)", establishes the direct and objective liability of the hospital and INSALUD in respect of the serious harm caused to the patient; ruling cited by GONZÁLEZ MORÁN, *La responsabilidad civil del médico*, cit., p. 218.

101. See for instance the Supreme Court Ruling of 1 November 1991, with regard to "a private hospitalisation contract. It adopted a criterion of fault, as opposed to the objectivation of liability and different to the criterion established for public hospital liability"; in PEDREIRA ANDRADE, 'Ejercicio de los derechos y reclamaciones de los usuarios. Diversas vías de actuación', in *Jornadas sobre los derechos de los pacientes*, (Madrid 10-14 December 1990, Instituto Nacional de la Salud), pp. 581-89. See also Supreme Court Ruling of 24 April 1990 and the legal grounds provided by article 1089 of the Civil Code.

102. See F. GARRIDO FALLA, *El modelo económico en la Constitución (vol. I)*, (IEE, Madrid 1981), pp. 72 ff, cited by M. BEATO ESPEJO, 'El sistema sanitario español', cit., p. 403 note 41. Fuller treatment is given in J.M.RODRIGUEZ PASTRANA, *El servicio público de la Sanidad: el marco constitucional*, cit., pp. 26-39.

103. See infra.

104. See M. BEATO ESPEJO, 'El sistema sanitario español', cit., p. 413.

105. The recent Royal Decree 561/1993 of 16 April approved Regulations which develop further the provisions of the Drugs and Medicines Law. It regulates the functions and responsibilities of participants in clinical trials and the requirements for authorisation in the drugs and medicines sector, thus updating the provisions of Royal Decree 944/1978 of 14 April and the Ministerial Order of 3 August 1982.

106. See J.M. RODRIGUEZ PASTRANA, ibid.; M.A. RODRIGUEZ BERZOSA, 'El servicio público de la sanidad', in L. MARTÍNEZ-CALCERRADA, *Derecho Médico (vol. I: Derecho Médico General y especial)*, cit., pp. 786-8.

107. On the drafting of the Bill see F. RICO PÉREZ, *La responsabilidad civil del farmacéutico*, (Trivium, Madrid 1984), pp. 206 ff.

108. Cf. F.J. ELOLA SOMOZA, *Crisis y Reforma de la Asistencia Sanitaria Pública en España (1983-1990)*, cit., p. 195.

109. Figures taken from the "Memoria Fundacional de S.G. de Gestión de la Atención Hospitalaria de 1989" (Hospital Care Management Report for 1989), cited by F.J. ELOLA SOMOZA, ibid.

110. F.J. ELOLA SOMOZA, ibid.

111. F. ABEL, 'El Comité de ética', in *Labor Hospitalaria*, n. 209, 1988 (3), p. 210.

112. F. ABEL, 'El Comité de ética', cit., p. 207.

113. See *Ensayos Clínicos en España*, (Monografías Técnicas 17, Ministerio de Sanidad y Consumo, Dirección General de Farmacia y Productos Sanitarios, Madrid 1990), p. 17; F. ABEL, 'El Comité de ética', cit. p. 210.

114. F. ABEL, ibid.

115. F. ABEL, 'El Comité de ética', cit., pp. 210-11.

116. Information taken from *Ensayos Clínicos en España (1982-1988)*, cit., p. 53.

117. These ideas were raised in papers presented to the Symposium on Bioethics, and in particular hospital ethics committees, held in Barcelona on 26-27 April 1991.

118. See F. ABEL, 'El Comité de ética', cit., p. 210.

119. F. ABEL, 'Els Comitès d'ètica en els hospitals' (Hospital Ethics Committees), paper delivered to the Symposium on Bioethics, Barcelona, 26-27 April 1991, p. 1.

120. This was already illustrated by M.A. GASULL I DURÓ in a paper on 'Problems and Organisation: make-up and relations' delivered to the Symposium on Bioethics. Hospital Ethics Committees, Barcelona, 26-27 April 1991.

121. On this possibility, see M.A. GASULL I DURÓ, ibid. and F. ABEL, ibid.

122. F. ABEL, 'El Comité de ética', cit., pp. 210-11.

123 See the report, which subsequently gave rise to the Draft Bill on Organ Removals and Transplants and to the law currently in force, by C.M. ROMEO CASABONA, *Los trasplantes de órganos. Informe y documentación para la reforma de la Legislación Española sobre trasplantes de órganos*. (Bosch, Barcelona 1978), passim. A study of regulations governing transplants in Spain is contained in A. GORDILLO CAÑAS, *Trasplantes de órgano: "pietas" familiar y solidaridad humana*, (Civitas, Madrid 1987); of particular interest is his assessment of the situation in pp. 111-5.

124. Article 63 of the Law defines the meaning of instigator, monitor and senior researcher: 1. The instigator of a clinical trial is the legal or natural person who has an interest in it being undertaken, signs the request for authorisation by the Ethics Committee or the Ministry of Health and Consumer Affairs and assumes responsibility for the trial. 2. The monitor of a clinical trial is the qualified and clinically-competent professional chosen by the instigator to directly monitor the trial. He acts as the link between the instigator and senior researcher where they are two different people. 3. The senior researcher is the person who is in direct charge of the practical trial and who, together with the instigator, signs the request for authorisation and makes himself jointly responsible for the trial. The instigator and senior researcher may be one and the same person. Only a health professional who is suitably qualified to evaluate the response of the substance, drug or medicine under study may act as the senior researcher. In all cases, clinical trials should be undertaken under the supervision of a physician who has the clinical competence required.

Part II. The Physician-Patient Relationship

Chapter I. General Description

§ 1. Rights and Duties of Physicians and Patients

I. General Context

111. Traditionally, the relationship between physicians and their patients in Spain has been based on trust, although the former are renowned for their overtly paternalistic approach. Over the years Spain has become increasingly sensitive to the need for effective protection of patient rights, and particular concern has been paid to respect for the principle of patient autonomy and more "humane" treatment, something which has been conspicuously absent in hospitals. Moreover, the growing involvement of medical activities in disputes of a moral nature and the increasing complexity of medical practice have created the need for recognition of physicians' specific rights and duties, as well as those derived from their relationship with their patients.

In this regard it is important to stress the impetus provided by the Spanish Constitution, which is scrupulously loyal to the principle of respect for people's individual rights and is open to social and ideological pluralism. This disposition has found its way through to a wide range of sectors of society, although it took considerable time for the process of the incorporation of these rights into our legal order to mature, and lead eventually to the passing of the General Health Law (LGS) of 25 April 1986. On the other hand, the recognition, protection and respect of the rights of patients and physicians do not depend exclusively on their being enshrined by the community as worthy ethical values. Rather, as shall be shown below, they are first and foremost civil or constitutional rights of patients[1] and physicians as citizens; this means that it is up to the legal order to provide legal support for patient and physician rights. Thus, it is necessary first to examine the question of how and where these rights have become enshrined in positive Law.

112. The Spanish Constitution of 1978, which underpins the country's political and legal system, contains a series of provisions from which it is possible to discern both the core of the legal-health structure, as conceived by the Constitution, and also a set of individual rights. Some of these manifestations are of particular importance for hospital patients. A number of the aforementioned rights are considered to be public rights and freedoms to which privileges and reinforced constitutional guarantees are applicable, especially where they are given the status of fundamental rights (articles 53.1 and 2, and 54 of the Constitution), in which case direct protection may be provided by ordinary courts and even, in certain cases, the Constitutional Court (article 53.2); other rights, meanwhile, are derived from obligations contracted by the authorities via the Constitution, based on the principles which govern the State's economic and social policy. Protection of these rights results from the contents of the laws drawn up to give effect to them (article 53.3).

Of the aforementioned laws, there are several which have direct implications for health, and more specifically hospital care. The list provided here is by no means exhaustive and should not be viewed as reflecting priorities of any kind:[2] 1. The right to equality before the law, with no discrimination on the grounds of birth, race, sex, religion, opinion or any other personal or social condition or circumstance (article 14 of the Constitution). 2. The right to life and to physical and moral integrity; in no circumstances can a person be subjected to torture, or to inhuman or degrading punishment or treatment (article 15). 3. The right to freedom and security (article 17.1). 4. The right to ideological and religious freedom and freedom of worship (article 16.1). 5. The right to one's honour, and to personal and family privacy, to one's image, and to legal restrictions on the use of computerised information (article 18.1 and 4) 6. The right to secrecy in communications (article 18.3). 7. The right to strike (article 37.2). 8. The right to health protection (article 43.1). 9. The right to have public health organised and protected by the authorities (article 43.2), with special consideration to be given to persons

suffering physical, sensory and mental handicaps (article 49), the elderly (article 50) and consumers and users (article 51.1). 10. The right to health and physical education (article 43.3).

Having listed the rights which affect patients, it is appropriate to refer specifically to two crucial legal provisions. The first enshrines freedom, justice, equality and political pluralism as superior values of the legal order (article 1.1), while the second states that the dignity of a person, his inherent rights, the free development of his personality, respect for the law and for the rights of others, all constitute the foundations of political order and social peace (article 10.1). In spite of the enormous complexity surrounding the interpretation of both provisions as regards their direct applicability (article 1 at least) and their scope as statutory regulations placed alongside the fundamental rights enshrined in the Constitution (and even the hierarchical relationship between them), all experts acknowledge that they are crucial at least as principles which help interpret the aforementioned fundamental rights and which exercise a major influence on the content of these. It should not be forgotten that these values inevitably take on even greater importance in the case of hospital patients.

II. Rights and Duties of Physicians

A. Objection on the Grounds of Conscience

113. Objection on the grounds of conscience by physicians and other health-care professionals arises chiefly with regard to abortion and in particular where professionals, as specialists or because they are assigned to certain services, find themselves compelled to carry out a legal abortion contrary to their ideological views, religious beliefs or personal ethics. The problem of the right to object on such grounds arises mainly in public hospitals (such as those belonging to the Social Security system), although it may also affect (albeit to a lesser degree) private centres. Objection on the grounds of conscience has also arisen on occasions with regard to non-therapeutic sterilisation or, more rarely, in connection with certain forms of assisted reproduction.

The right to object for reasons of conscience has been accepted unreservedly by jurists, although the exercise of such a right must be governed by certain limitations or regulations to ensure, for example, that any woman who so desires should have the choice of being able to abort or to the carrying out of the activity objected to. Put another way, this choice must not be hindered by the existence of conscientious objectors among physicians. This issue was not addressed in the law which legalised abortion, nor has it been regulated overall by the General Health Law which, although at pains to include patient rights, did not follow suit with regard to the rights of health-care professionals. The subject is addressed however in the Code of Medical Ethics of 1990: "1. It is ethical for a physician, on the grounds of his ethical or scientific beliefs, to refrain from participating in abortions or in issues relating to human repoduction or organ transplants. He shall notify without delay the reasons for his actions, and where necessary will offer appropriate treatment for the problem on which he has been consulted. At all times he shall respect the freedom of the persons concerned to seek the opinion of other physicians. 2. The physician must not be conditioned by actions or omissions which are immaterial to his own right to object on the grounds of conscience. In all cases, the College of Physicians shall provide all necessary advice and help to the physician" (article 27). The aforementioned rules do not prevent a physician from invoking directly his right to object, in accordance with article 16.1 of the Constitution, which recognises the fundamental right of ideological and religious freedom.[3]

The right to object on grounds of conscience may be invoked by health-care professionals (physicians and others) who find themselves involved in a process of abortion (or other medical practice contrary to their conscience) under article 417 bis of the Penal Code: the physician asked to perform or direct the abortion, other physicians (anaesthetists, for instance), their assistants and colleagues in the would-be abortion, and also any specialists asked to provide the preliminary report required by law (there is some debate, however, as to whether the right covers this last group). Objection covers the three lawful indications for

abortion, including therapeutic indication (where the life or health of the pregnant woman is in grave danger). However, in this last case there are certain limitations imposed by rules governing offences of failure to give help (article 489 of the Penal Code) and offences committed by omission, which are implicit in the Penal Code; one of the limitations imposed by the Constitution in article 16, and one which is specified in the Organic Law on religious freedom of 5 July 1980, is "the safeguarding of safety, *health*, and public morals" (article 3, paragraph 1), although there is some discussion as to whether the word "health" denotes public health alone or that of the individual also. The possible interpretations — in the restricted or broader sense— could well alter the scope of the right. Objection should be limited to acts designed to destroy the fetus,[4] although it could be considered to cover also the writing of the preliminary report, in which case it would extend only to the signatory or signatories of the report.

With regard to case law, to our knowledge in only one ruling[5] has the Court recognised the right to object on grounds of conscience in relation to abortion. In this ruling it stated that "doctors on call, who are conscientious objectors, cannot be forced to perform medical acts of any kind which lead directly or indirectly to abortion, either prior to or during termination of the pregnancy". However, the ruling goes on to add the restriction that "physicians shall provide all necessary assistance to patients admitted for such a purpose in all other situations or pathological states which may arise, even where these are a direct consequence of the abortion performed".

Similar criteria are applicable to conscientious objection in relation to other medical activities, provided that failure to act does not at the same time entail serious danger to the life or health of the patient.

B. The Right to Strike

114. The right of health professionals to strike is recognised also.[6] Some specific cases are regulated by the Royal Decree of 2 February 1979 governing the assurance of services in public hospitals; the regulations make it obligatory for public services to be maintained and provided in all such centres (article 1). The Royal Decree of 19 October regulates in a similar manner the assurance of Social Security services and confers authority on head and provincial offices to enforce minimum staffing and service levels. Regrettably, isolated cases of patients dying as a result of not receiving treatment during a strike have been reported in this country. If proven, the cases should give rise to, at the very least, criminal liability for negligence.

C. The Right of Exclusive Practice

115. The high degree of scientific and technical qualification required for medical activities justifies the fact that practice is limited exclusively to qualified physicians. Excluded from practice are those who are not qualified as physicians or specialists, those who have not registered with the corresponding professional college and not expressly authorised by the authorities to engage in certain practices. All this makes up the exclusive right of practice granted to physicians, a right which is afforded criminal protection against illegal practice by unauthorised or insufficiently qualified persons. As was explained earlier (Part. I, Chapter II) the illegal practice of medicine is included as a punishable offence (called literally encroachment or impersonation) in the Penal Code.

116. Another aspect of exclusive practice is the ban on the *issuing of prescriptions* by unauthorised persons. Social Security or Municipal Welfare prescriptions are deemed to be "official documents" and hence unauthorised issue is considered by the courts to be forgery (Penal Code, article 303).[7] However, the prescriptions of private practice physicians working for private hospitals or for private health-care companies are not deemed to be official documents, although forgery is also punishable if it causes harm or harm is intended (Penal Code, article 306). Harm of this type has been perceived by the courts on occasions. "Where the name, book of prescriptions and signature of a physician who has not actually made out the

prescription have been used, it must be considered that the physician's prestige, professional reputation and action have been damaged, because the unscrupulous use of his name and title is sufficient to cause moral harm and affect the reputation and professional honour to which he is entitled" (Supreme Court Ruling, 2nd Chamber, of 22 January 1981). Nowadays, most forgeries of prescriptions are committed by drug addicts to obtain psychotropic substances in chemists.[8]

D. Duties of Physicians

117. A physician's most important duties arise from his recognition and respect of the corresponding rights of patients, as we shall see below. There are, however, a number of more specific statutory duties which must be observed.

118. *Duty to denounce the commission of offences*. The legal authorities impose certain duties on physicians regarding the obligation to notify the appropriate authority of any offences which a physician detects either when treating a patient or in other circumstances: "Physicians who perceive signs of poisoning or another offence in a person whom they are treating or in a corpse and who do not immediateley notify the authorities shall receive a term of imprisonment of between five and fifteen days and a fine of between 5,000 and 50,000 pesetas, provided that the circumstances do not warrant greater liability" (Penal Code, article 576). The punishment is slight because the offence is a minor one although, as the article itself makes clear, the physician may incur more serious liability when he omits to notify the authorities of an offence against the life of a person or one which seriously damages the integrity, sexual freedom or the safety of a person or persons (Penal Code, article 338 bis, paragraph 2). In such cases, punishment shall consist of imprisonment of between one month and one day and six months, as well as a fine of between 100,000 and 1,000,000 pesetas. Note, howver, that this obligation derived from article 338 bis is incumbent on all citizens and not just health-care professionals. For its part, the Criminal Procedure Code stresses the obligation of physicians to notify the authorities of offences which come to their knowledge during the course of their professional practice (Criminal Procedure Code, article 262).

With regard offences of the type referred to in article 576, Supreme Court case law has ruled as follows: "From the outset, the accused suspected that the abortion had been caused by the rupturing of the amniotic membrane and the subsequent septic state became a toxic one. The accused did not notify the circumstance so as to avoid further harm to the insured party and because he did not have the necessary proof until the examination and intervention were completed. His aim from the outset was to do all in his power to cure the patient and, if her progress had proved satisfactory, to avoid the punishment applicable to unlawful abortion. If the accused did indeed suspect thus and if this was his unlawful intention, he clearly committed the offence set out in article 576 paragraph 1 in relation to article 267 of the Criminal Procedure Code, in that having suspected a criminal abortion he was under an obligation to denounce it not to the Inspectorate of Health, which he subsequently did when the enquiry was ordered, but to the authorities who were competent to prosecute for the offence".[9]

This duty to notify offences which come to the attention of the physician in the course of his work has been criticised a great deal from the point of view that if, in so doing, he betrays his patient he is in breach of his duty of secrecy towards the latter, and is also betraying the confidential relationship which should exist between the two, as recognised by the General Health Law of 1986 (article 10.1 and 3). In such cases a conflict of duties arises (the duty to report the offence and the duty of confidentiality towards the patient) and the problem thrown up is which is of greater value. The solution is by no means easy, although we would side with the duty of confidentiality since it relates to respect for personal privacy, which is recognised by the Constitution as being a fundamental right (article 18.1).

119. *Duties to assist.* To begin with, the duty of human solidarity obliges a physician to act to help others, either as a result of his professional status, as a public servant, or as an ordinary citizen just like any other. A physician who fails to act in such cases may be criminally liable. If

he is a public servant and "is asked by a person to give help, which he is obliged to give because of his position, in order to prevent an offence or other wrong being committed and he fails to give help without good cause", he shall have committed an offence in refusing his aid (Penal Code, article 371.3) and shall be liable to a fine of between 100,000 and 500,000 pesetas and shall be barred from office (loss of position and corresponding earnings and barred from engaging in similar work for the duration of the sentence) or suspended (from practice and prevented from performing similar functions for the duration of the sentence). It should be noted, however, that the notion of public servant as used in the Penal Code does not coincide with that used in Administrative Law. The Penal Code concept is much broader and is based on more formal conditions: "A public servant is considered to be any person who by law or through election or appointment by a competent authority participates in the carrying out of public functions" (Penal Code, article 119). As a result, physicians employed by the public health authorities and who provide their professional services in certain public institutions such as hospitals of the Social Security system, hospitals and psychiatric hospitals belonging to provincial or island governments, etc.

However, as far as the aforementioned offence is concerned, convictions of physicians are extremely rare;[10] in some cases physicians have been convicted of failing to visit the home of a patient when under a duty to do so.[11]

120. Even if a physician is not a public servant he may still be called upon to give help by a third person, just like any other citizen and regardless of his professional status. The offence in this case is denoted *omission to fulfill one's duty to help*: "Any person who fails to help another person who is in need of help and in serious and manifest danger, when the granting of such help does not entail risk to himself or to a third person, shall be sentenced to imprisonment of between one day and six months or fined between 100,000 and 200,000 pesetas. The same punishment shall apply to any person who, not in a position himself to give help, does not urgently request the help of another. If the victim is the victim of an accident caused by the person who omits to give help, the person shall be sentenced to imprisonment of between six months and one day and six years" (Penal Code, article 489, paragraph 3). This last offence arises frequently in relation to road accidents, particularly where victims are not helped by passing drivers or even by the very driver reponsible for the accident. Physicians may find themselves exposed to this offence to a much greater degree in view of the fact that the offence can be committed without physical contact with the person in need of help being necessary. It suffices to learn of the situation of need, and people frequently turn to a physician first for help because of the latter's professional know-how (of course, even as a professional the physician is not under any specific obligation or one which is greater than that incumbent on the community at large), when the local physician is unavailable or when no other physician (in a hospital, for example) is present in the area. In non-serious cases the minor offence contained in article 586, paragraph 2 may be applicable ("Any person whose help is sought by another in order to prevent the occurrence of a greater wrong or harm, but who fails to give the help requested, provided that giving such help would not have entailed harm to his own person and provided that the offended party files a complaint in respect of said refusal"). The offence will not have been committed if the person gives the help which was possible in the circumstances, even if this did not succeed in preventing the death of the patient or irreversible bodily harm. Some courts have convicted physicians for the offence or the minor offence referred to above;[12] indeed, a physician who was holding surgery in a Social Security health centre and who failed to respond to repeated requests by several people to treat a person who had been seriously injured in a road accident was considered to have committed an offence: "clearly one cannot equate the (health centre's) patients' need for advice and prescriptions with the urgent needs of a person lying injured, helpless and in serious and manifest danger on a public road".[13]

III. Rights and Duties of Patients[14]

121. The General Health Law (LGS) of 1986 sets out in articles 10 and 11 a series of rights

and duties of patients and users of public (and, in some cases, private) health services. These are truly subjective and claimable rights. The rights are as follows:

Article Ten:
"All persons enjoy the rights listed below in relation to the different public health administrations:
1. The right to one's personality, to human dignity and intimacy, and the right not to be discriminated against on the grounds of race, social background, sex, morals, or economic, ideological, political or trade union grounds.
2. The right to information concerning health services to which they are entitled and concerning any requirements governing the use thereof.
3. The right to confidentiality in respect of all information concerning their medical condition and their stay in public health institutions and in private institutions which cooperate with the public system.
4. The right to be notified if the prognosis, diagnosis and therpaeutic procedures applied to them is likely to be used as part of a teaching or research project. In no way shall the project entail any additional danger to their health and in all cases the patients' prior written must be sought and authorisation given by the physician and the management of the health institution concerned.
5. The right of patients and their next-of-kin or relations to be given full and constant verbal and written comprehensible information on the process, including diagnosis, prognosis and alternative forms of treatment.
6. The right of a patient to choose freely between options given by the physician in charge of his case. The written consent of the user shall be necessary for all interventions, save for the following cases:
a) Where non-intervention entails a public health risk.
b) Where the patient is incompetent to take decisions, in which case the right shall pass on to his next-of-kin or those closest to him.
c) Where the emergency situation rules out delays which might cause irreversible injuries or where there is a risk that the patient may die.
7. The right to have a physician assigned to his case. The physician's name shall be notified to the patient and he shall serve as his main health care interlocutor. In the absence of the physician appointed, responsibility shall be assumed by another member of the team.
8. The right to be issued with a certificate attesting his state of health, where the presentation of such a certificate is a statutory requirement.
9. The right to refuse treatment, except in the cases referred to in section 6 above. In order to exercise this right the patient must ask to be discharged voluntarily, in accordance with the terms of section 4 of the next article.
10. The right to participate, through community institutions, in health activities, in accordance with the terms laid down in the present Law and any statutory provisions which develop the Law further.
11. The right to have the entire process certified in writing. On completion of his stay in hospital, the patient or his next-of-kin or persons close to him shall be issued with the corresponding Discharge Report.
12. The right to make use of channels created to enable patients to lodge complaints or propose suggestions within the appropriate time-limits. In either case the patient shall receive a written reply within the stipulated time-limit.
13. The right to choose his physician and other qualified health-care professionals in accordance with the conditions laid down in the present Law, as well as in any provisions drawn up to develop the law further and those regulating the functioning of health-care centres.
14. The right of a patient to obtain drugs and medicines and health products considered necessary to promote, conserve or restore his health, in accordance with the terms laid down by the State Administration.

15. While the specific regime of each health service shall be respected, the health rights contained in sections 1, 3, 4, 5, 6, 7, 9 and 11 of the present article shall be exercised also in respect of private health services".

Article Eleven:
"The following constitute obligations of citizens towards health institutions and bodies:
1. To comply with general health regulations governing the population and also with any specific health service regulations.
2. To treat facilities with care and to cooperate in the up-keep of health care institutions.
3. To ensure that appropriate use is made of the services provided by the health care system, in particular the use of services, procedures for certifying sick leave and permanent disability, and therapeutic and social services.
4. To sign voluntary discharge documents if the patient does not wish to accept the treatment offered. If a patient refuses to sign, the hospital management, at the suggestion of the physician in charge of the case, may proceed to discharge the patient".

The drawing up of this list of rights and duties should not mislead us as what was actually intended. The General Health Law does not exhaust the entire range of rights in its regulations, and it is quite possible to find legal grounds for other rights which experts have tended to include in their lists or which have already been set out in so-called Bills of patients' rights and duties. Support could thus be found for others aside from those expressly laid down by the General Health Law (in article 10 or others) or, alternatively, the content of the rights the Law does list could be expanded. Note also that some patient rights are endorsed only by the General Health Law, since they are set out and specified in it alone. This is the case particularly with rights derived chiefly from the intended goal of the General Health Law, namely, "to regulate in general all actions which help give effect to the right to health protection as recognised by article 43 and others of the Spanish Constitution" (article 1.1). It is the job of the Law to enforoce the constitutional mandate laid down (principally) in article 43 governing to health protection. Some patient rights included in article 10 of the General Health Law are merely the result or a derivation of the scope accorded to the right to health protection and, with a few exceptions, could well have been inferred from other provisions.

122. As can be seen from all the above, in order for patient rights to be classified correctly and systematically a specific methodology is required, which would consist of inferring them from the Constitution, the General Health Law or any other applicable legal provision.

The opening words of article 10 of the General Health Law, which uses a general and ambiguous term ("all"), poses the problem of defining exactly which subjects are entitled to the rights listed therein. Clearly, the reference is not merely to sick persons but rather to *all the users* of the health services, whether ill or not. Healthy people also may require certain health facilities and thus they too have rights.

A. Respect for Human Dignity and Equality

123. The General Health Law is expressly linked to the Constitution, as is made clear in the first section of the rights it lays down (article 10.1), which alludes specifically to respect for dignity and personality (article 10.1 of the Constitution). It adds also intimacy and equality (non-discrimination), which are also enshrined as rights by the Constitution (articles 18.1 and 14, respectively): "[all persons have the right] to respect for their personality, human dignity and intimacy, and not to be discriminated against on the grounds of race, social background, sex, morals, or economic, ideological, political or trade union grounds"; this statement may be viewed as the main axis of the patient rights which article 10 of the General Health Law then lists. Lastly, human dignity takes on even greater relevance with regard to research and experimentation involving human beings, as we shall see in a moment; however, personal dignity cannot be considered independently but rather only from the point of view of its bearing

on other fundamental rights, and thus it is with regard to these rights that one has to ascertain whether dignity has been harmed.[15]

B. Rights of Access to Health Care

124. The General Health Law stipulates that all Spaniards and foreigners resident in Spain are entitled to health protection and health assistance (article 1.2); there are provisions also covering non-resident Spaniards and foreigners (article 1.3). As a result, all Spanish citizens who fall ill have the right to health assistance, a provision which is of crucial importance to patients, even if it does not actually stated thus in article 10 of the General Health Law.

The principle of social and economic equality means that the General Health Law goes even further in this respect (at least as far as its intended purpose is concerned, given that the Law itself states that public health care shall be extended progressively, with particular attention to be paid to mental health, 5th Transitory Provision). The Law states that public health assistance shall extend to the entire population, that access to facilities and services shall be on the basis of effective equality and that health policy shall aim to do away with territorial and social imbalances (article 3). Where considerable delays are encountered in the public system, or where the treatment is not available, a patient who uses a private health service or physician is entitled to claim full reimbursement of any expenses incurred; however, the courts require that the assistance required must have been requested in the first place and have been refused. It does not suffice for the patient to allege refusal on the basis that considerable delay would have been encountered, save in emergency cases involving risk to the patient's life, which made it necessary to seek the services of other physicians.[16]

A number of the rights included in article 10 of the General Health Law derive directly from this right to health care: information concerning health services to which patients are entitled and any requirements governing the use thereof (article 10.2); the right to have a physician assigned to their case (article 10.7); the right of the patient to be issued with a certificate attesting his state of health (article 10.8); the right to participate in health activities (article 10.10); the right to make use of channels for complaints and suggestions (article 10.12); the right to choose one's physician (article 10.13); the right to obtain drugs and other medicines (article 10.14) under conditions of equality (article 93.1 of the Drugs and Medicines Law of 1990). Beyond these, the General Health Law establishes the duty of the authorities to provide users with information concerning public (or associated) health services and their rights and duties (article 9), and to ensure that when needed the assistance provided is adequate.[17] Several of these rights have not been developed appropriately as yet. Unlike with other bills of rights, no specific provision ensures that treatment and hospital stays are "humane", although this is achievable indirectly, for example, Hospital Users' Committees ("a body enabling the community to participate in the planning, control and assessment of the running of the hospital and the quality of care provided", article 19.1), Social Welfare Committees (collegiate advisory body, article 23) and Patient Care Services (article 32);[18] representatives of Consumer and User Associations sit on both the aforementioned Committees. Moreover, the National Institute of Health (INSALUD) drew up a Hospital Care Plan in 1984 to "humanise" care.[19] The plan contained a series of measures, notably the drafting of a *Bill of Patient Rights and Duties*. Special committees (known literally as Committees for the Humanisation of Care) and Patient Care Services were set up to monitor observance of the Bill and also to help make hospitals more "humane" places.

C. Patients' Rights to Self-Determination

125. *General principle.* There is no disputing nowadays a patient's right to decide with respect to his own treatment. This implies the need for consent on his part (or, where he is not in a position do do so, that of his legal representative) once he has received the necessary information ("informed consent") and also his right to refuse consent if he considers it appropriate for his personal interests. The General Health Law assumes this twin right and stipulates that patients and their next-of-kin or relations shall be given full and constant verbal

and written comprehensible information on the process, including diagnosis, prognosis and alternative forms of treatment (article 10.5), and also that the patient shall be entitled to choose freely between options given by the physician in charge, in which case the written consent of the user shall be necessary before any intervention may be carried out (article 10.6), save where the patient does not have the capacity to take decisions (the consent would then be given by his next-of-kin or those close to him). The Law states also that a patient may refuse treatment, in which case he shall request to be discharged of his own wish (article 10.9). This last requirement has come in for criticism,[20] and rightly so, except if it is to be understood that his refusal covers all treatment, including alternatives proposed by the physician. This issue will be examined in the next section. For the moment we will limit ourselves to certain specific cases.

126. *The right to refuse life-saving treatment.* One of the most controversial rights involves the possibility that a patient may refuse treatment on which his life depends. The problem usually arises with moribund patients, and shall be examined in the section which deals specifically with such patients (Chapter II, § 3).

127. *Refusal of a blood transfusion on religious grounds*. Major difficulties can arise when adults refuse certain forms of treatment for reasons of religion, for example, when Jehovah's Witnesses refuse blood transfusions.[21]

Beliefs and religious behaviour of this kind can pose serious care and legal conflicts when refusal is accompanied by serious risk to the life of the member of the religious group, such as, for example, one who is bleeding severely following an accident or who is to about to undergo an operation which is likely to require a blood transfusion (this possibility is catered for in some foreign hospitals which, if they have time, take a sufficient amount of the patient's own blood —self-transfusion— prior to the operation for use if needed; Jehovah's Witnesses do not seem to object to this solution).

Respect for the patient's religious freedom, where treatment contravenes his religious beliefs or dictates of conscience, such as blood transfusions in the case of Jehovah's Witnesses, must be taken into account by physicians if they wish to avoid subsequent liability (offence of coercion, article 496; offences against freedom of conscience, article 205 and following articles,[22] although it is doubtful that the blood transfusion example could give rise to one of these offences —except perhaps coercion— as worded at present, because the patient is not prevented from practising the acts of his religion or obliged to change religion, but rather to contravene certain requirements of it). Respect for the wishes of a patient poses no major problems and should prevail if the physician has foreseen the situation and can offer alternative, albeit more difficult and risky, forms of treatment.

The situation is vastly different where no therapeutic options are available to replace or mitigate a life-saving blood transfusion. The fundamental issue here is whether the refusal can be deemed to constitute a suicidal attitude. Jehovah's witnesses stress that they are not suicidal nor are they exercising the "right to die" when they refuse a transfusion.[23] Such arguments are acceptable and easy to explain: their view is that they wish to live but without transgressing their religious beliefs, a stance which is deserving of respect. However, when no other therapeutic alternative exists and the blood transfusion is considered to be the only means of eliminating the immediate danger to the life of a patient of that religious persuasion and if, in order to remain faithful to his religion, he continually refuses to undergo a transfusion, it must be acknowledged that in adopting such a stance the patient is contemplating the possibility of death, and thus, if he is aware that there is no other means of saving his life, the patient is expressing a desire (albeit an indirect one) to die. This acceptance of death, from a legal standpoint, is equivalent to a suicidal attitude,[24] which is equally to be respected from the ethical standpoint, in that it stems from a personal valuation based on individual conscience. From a legal perspective, the correct solution is awkward given that at stake is an interest of particular value, to which the legal order affords reinforced protection. However, insofar as the decision is a conscious one taken by an adult after great thought and without undue pressure, it should be respected and even supported by the Constitution (articles 15, 16 and 18).

In contrast to this interpretation, Spain's Supreme Court has on occasions taken the opposite view,[25] and confirmed the warrant granted by a judge to a physician who asked for authority to perform a blood transfusion, which saved the life of a Jehovah's Witness who had refused it previously. The Jehovah's Witness instigated legal proceedings against the judge in question. The Supreme Court's decision endorsed the judge's action, on the grounds that he was obliged and entitled to intervene in the way he did in order to avoid committing a punishable offence by lending his passive cooperation to suicide (article 409) or to avoid committing an offence by omission (article 489 bis). His action was justified also by the existence of a situation of need (article 8.7). In a later ruling, the Supreme Court declared also that a blood transfusion carried out on a member of the same religious sect on the orders of a judge was lawful, in spite of the fact that the patient died subsequently.[26] This time the decison was of interest because the arguments used were different —albeit complementary— to those of 1979: the court ruled out the possible existence of an offence of coercion and attack on personal freedom, and argued in the case of the latter that, under the *Organic Law on religious freedom* of 5 July 1980, such freedom was limited, among other things, by the need to "safeguard safety, *health* and public morals" (article 3, paragraph 1). In this same case, appeal was made to the Constitutional Court to protect the constitutional rights of the appellant, although the Court ruled out the defencelessness alleged and upheld —indirectly, given that it did not address the substance of the case— the legal arguments advanced by the Supreme Court.[27] Authors have discussed the question of whether in its mention of limitations the Law on religious freedom refers to individual health or public health, and —if the latter is the case— whether it takes in individual health also. However, as has been pointed out,[28] the truly significant aspect here is that what is at stake in such delicate situations is not health (individual or collective) but the life of a person. The correct solution continues to be referral to the Spanish Constitution and to acknowledge that for certain groups in society there exist values deserving of respect, which in certain circumstances are superior to life itself,[29] and which the principles of tolerance towards minorities and ideological pluralism should encourage us to keep in mind; however, considerations such as these clash with the stance adopted by case law, which surely would not have arrived at this outcome if it had been a case of deciding solely the matter of recognition of the right to refuse treatment out of respect for another fundamental right, rather than the issue of a judge's decision to authorise life-saving treatment against the wishes of the patient. Until such times as the Supreme Court or Constitutional Court provide new guidelines, it seems inappropriate to advise physicians to refrain from giving life-saving blood transfusions against the wishes of the patient, because they risk being denounced for abetting suicide or for wilful homicide by omission; however, if the patient were to die as a result of the physician respecting his wishes, the physician would in all probability be acquitted of all charges; indeed, even if he does go ahead with the transfusion against the patient's wishes, and his action is supported by a judge, he shall not be liable either, as the aforementioned case law decisions reveal. The whole situation, then, seems something of a paradox.

The considerations outlined thus far refer only to a decision involving the patient's *own life* and freedom of conscience, and are not applicable when the *life of another* is at stake. This means that in no case should the law give preference to religious freedom over the protection of the right to life in cases involving minors (or incompetent persons, that is, mentally-ill patients or those suffering from mental disorder). Respect for parents' freedom of choice between different values is inadmissible where their children are concerned; parents have a duty, which doubtless takes in religious education also, to do all in their power to benefit the health and life of their children until they reach adulthood and can make use of their own religious freedom and take personal responsibility for their decisions. Refusal to allow a minor child to receive treatment because of religious beliefs (eg, to receive a blood transfusion) would constitute an abuse of parental authority, and the physician should act to save the patient's life. Any such lawful intervention would be backed by the legal authorities.[30]

128. As we shall see below (Chapter III, § 7), the ban which the Constitution imposes on

inhuman or degrading treatments limits research and experimentation involving human subjects.

129. The *right to move freely* and the right to security (article 17.1 of the Constitution) can prove particularly complex when the patient is suffering from certain illnesses. Similarities may be drawn with the European Convention for the Protection of Human Rights and Fundamental Freedoms of 1950 (article 5.e, considers that detention is lawful in the case of the lawful internment of a person liable to spread a contagious disease, or a mentally-deranged person, an alcoholic, drug addict or vagrant), and the International Covenant on Civil and Political Rights of 1966 (article 12.3). Both international instruments have been signed and ratified by Spain.

The Spanish Constitution states that no person may be deprived of his freedom, except in situations set out in the Constitution itself and in cases provided for in law (article 17.1). As a result, in situations of emergency or need the competent health authorities are empowered to protect public health by adopting examination, treatment, hospitalisation or control measures, under the conditions laid down in the Organic Law on Public Health Contingency Measures of 14 April 1986, without such measures being deemed to infringe constitutional rights.[31] In this respect, the General Health Law includes exceptions to the need for consent (article 10.6,a) and the right to refuse treatment (article 10.9).

130. The detention of a mentally-ill person against his will is subject to judicial authorisation and control (article 211 ff of the Civil Code; articles 8.1 and 8.2, 9.1 and 9.2 of the Penal Code, governing mentally-ill persons who have committed an offence) to ensure that the rights of such persons are respected, as we shall see below.[32]

D. The Right to Information

131. Although it is closely bound up with consent to the medical act, it should not be forgotten that the right to information is justified in its own right and is wholly independent of all others. Information given to a patient entails a number of considerations. The first is clearly tied to consent, as was mentioned above; only after a patient has been given the relevant material information will he be in a position to give conscious and valid consent. However, the right to information goes beyond this and need not even be linked to a voluntary act on the part of the patient, as is acknowledged by article 10.5 of the General Health Law, where it is stated that the information in question need not always be conceived as being a prior condition for a patient to choose freely and give his consent. It implies also that the patient has the right to know about his condition and the treatment process, as well as the right to be given therapeutic information. Reference is made also to his right to receive a discharge report on leaving hospital (article 10.11),[33] and to be granted access to his health or clinical records (article 61). However, in view of the close ties between information and consent to a medical act, we will dwell on the subject for a moment.

§ 2. Informed Consent

132. Informed consent is another patient right which has been naturalised in Spanish legislation, particularly in the General Health Law. Article 10 of the Law categorically sets out the right to information, which is defined in very broad terms ("the right to be given full and constant verbal and written comprehensible information on the process, including diagnosis, prognosis and alternative forms of treatment", article 10.5), and also the need for prior consent, which must be given in writing before intervention ("the right to choose freely between options given by the physician in charge of his case. The written consent of the user shall be necessary for all interventions, save for the following cases...", article 10.6). A few years earlier, the Law on the Removal and Transplantation of Organs of 27 October 1979 had regulated the right to information prior to consent not only in the case of live donors (article 4) —as is only logical— but also recipients, stating that "the necessary immunological histocompatibility studies between the donor and future recipient, or other appropriate studies,

have been carried out by a laboratory authorised by the Ministry of Health and Social Security" (article 6, b). It goes on to state that "the recipient, in the case of an adult who is legally responsible for his actions or, where mentally-retarded patients or minors are concerned, their legal representatives, parents or guardians, shall consent in writing to the transplant" (article 6, c).

Some observations are necessary with regard to consent-related information. In general, information is a requirement which conditions the validity of subsequent consent to he medical act; however, the act need not necessarily lead to treatment or intervention, which is why information in its own right is construed as an autonomous right enjoyed by the patient, regardless of whether he is to give his consent. On the other hand, consent and information are frequently linked and hence the the two rights are not entirely unrelated given that when the patient has to give his consent he must know what he is consenting to and needs information to do so. Moreover, whoever provides him with the information should be the person(s) who will treat him or perform the intervention. Hence the references to informed consent, which Spanish jurists had called for in precisely these terms prior to the passing of the General Health Law and which is now a legal requirement beyond all doubt.

Very little needs added to what has been said above, especially with regard to the need for information, the amount of information, disclosure, understanding ("comprehensible information"), form ("verbal and written"), and persons to whom it shall be given (the patient and his next-of-kin, although, in the case of the latter, without violating the respect for the privacy of the patient), etc., given that everything can be inferred from the aforementioned paragraphs of the General Health Law. It should be noted however that not all the information has to be given in both verbal and written form: the choice will depend on the nature of the information and the link between it and a subsequent intervention requiring patient consent. In addition, it should be noted that although Spanish jurists are generally in favour of the criteria governing so-called "therapeutic privilege", case law support is not yet at hand because the courts have yet to give rulings on the issue. It could be said, however, that restrictions on the right to information on the grounds of therapeutic privilege can be justified to a certain extent.

From the legal standpoint, and in the light of the explicit wording of the General Health Law, the duty to inform admits no exceptions. As we have seen, information must be full and constant and cover the entire process, including diagnosis, prognosis and alternative treatments. In Spain, however, some debate exists as to whether in spite of this (and in particular in view of the situation which existed prior to the passing of the General Health Law) some restrictions of or exceptions to this duty to inform may be admitted, especially where a serious or fatal diagnosis and/or prognosis is involved. In line with Latin and Germanic tradition, as opposed to that which prevails in English-speaking countries, and in keeping more with the principle of paternalism than that of patient autonomy, physicians have been allowed a certain degree of discretion in their observance of this duty, although this does not in any way constitute an undermining or derogation of the patient's right, which is recognised fully by the General Health Law. Although the physician is obliged to give clear and adequate information to his patient, it is possible for him to give partial or gradual information only, provided that in doing so his intended purpose is not to fraudulently evade his duty and that in his sound judgement, and in view of the specific circumstances of the case, he considers that full information might seriously impair the patient's recovery and hinder beyond repair the success of the treatment. Where information is restricted, the patient should be given an approximate idea of the seriousness of his condition, and under no circumstances should he be totally misinformed. Brief or limited information given to a patient should in all cases by accompanied and compensated for by fuller information given to the next-of-kin, since at the end of the day they will have to serve as substitutes for or complement the self-determination of the former.

Clearly, then, physicians have to tread extremely carefully in such situations, since they are bound by the provisions of recent legislation, which unquestionably comes down on the side of information. As a result, we cannot now reaffirm beyond all doubt that is it is possible to dispense with information in extremely serious cases or where prognosis indicates death, contrary to what was advocated previously —albeit in exceptional circumstances— prior to the passing of the General Health Law. Spain's Code of Medical Ethics of 1990 coincided with the

view that a certain amount of discretion could be used where prognosis is very serious, and in exceptional circumstances only, in order to safeguard the patients's right to decide on his own future (article 11). Nevertheless, it should be remembered that the Code serves as a guideline only and has no legal force, and thus does not take precedence over the General Health Law. From the disciplinary point of view it is interesting to note that whereas the General Health Law does not envisage sanctions for violations of recognised patient rights (although some indirect disciplinary avenues do exist), it might be possible to invoke the General Statutes of the Organisation of Colleges of Physicians, which stipulate that "failure to meet a request for a certificate or information in ethical terms where this does not entail danger to the patient" (article 64.2.a) is considered to be a less serious offence; hence, if it can be shown that providing information does entail danger to the patient, failure to give the information shall not be construed as being an offence and therefore no punishment is due; conversely, where this is not the case, the physician is obliged to provide information and renders himself liable to disciplinary action if he does not do so. Lastly, it should be noted that the patient may legitimately and of his own accord (that is, he must be free from any kind of pressure or outside influence) waive his right to be informed, in which case the physician is exonerated from his duty to provide the information.

133. Spanish law caters specifically for a number of situations, among them the information which has to be given to blood donors. In this case, where analysis of the donated blood or other tests performed on the donor reveal that he is carrying antibodies linked to disease of any kind (eg, Aids) the physician must make this known to him, in accordance with the Royal Decree of 9 October 1985 regulating blood donations and blood banks (article 6.2 d: "All donors shall enjoy the following rights: the right to receive information on any abnormalities detected in the course of clinical examinations or analyses carried out for the purpose of the donation") and the Ministerial Order of 4 December 1985, which regulates the matter further (article 6 paragraph 2). Failure to comply with the above constitutes one of the administrative offences laid down in the Royal Decree of 1985 (article 21.5, last indent, serious offence: "any other activity which seriously endangers or causes direct and serious harm to public health"), given that an omission of this nature increases the risk that the disease may be passed on to others; this obligation is reinforced by the General Health Law (article 10.8: the right of a patient "to be issued with a certificate attesting his state of health, where the presentation of such a certificate is a statutory requirement"). The Royal Decree also states (article 22) that any punishment in respect of this offence shall be imposed in accordance with the health-related sanctions included in the second additional provision of Law 26/1984 of 19 July, governing the consumer and user protection. If the donor falls sick or dies as a result of being unable to take the appropriate measures due to ignorance of his condition, the physician could be held to be criminally liable for negligence, provided that all the other requirements of the offence are met also.

134. As was stated above, there can be no doubt that an adult patient who has received adequate information, that is, a patient who is conscious of the repercussions of his decision, is entitled to refuse treatment. The General Health Law could not be more explicit on this point: "All patients have the following rights... the right to refuse treatment" (article 10.9). To do so, the patient must ask to be discharged and sign the appropriate discharge form; should he refuse, the hospital management, at the suggestion of the physician in charge of the case, may discharge the patient (article 11.4). However, the Law also establishes certain exceptions to the above, which have given interpreters of the law cause for confusion: "...except in the cases described in section 6..."; cases in which consent is neither necessary nor admissible.

135. To sum up, physicians must respect a patient's refusal of treatment where the latter is aware of the repercussions of his decision. If, in spite of this —and notwithstanding opposition on the part of the patient or, in the case of an incompetent patient, his guardian, next-of-kin or those close to him— a physician chooses to intervene, and performs surgery or any other form of treatment requiring hospitalisation, he shall be held to be criminally liable as

the author of arbitrary curative treatment, provided that all the measures taken were of a clearly curative nature (otherwise liability would probably be more serious, if the patient's personal integrity were undermined), or even for having unlawfully deprived the patient of his freedom, if the appropriate authorisation was not sought and obtained from a judge. An attack of this nature on the patient's personal freedom shall be liable to punishment under the offence of coercion (Penal Code article 496 or 585.4 if the coercive action is deemed to be minor) or that of unlawful detention (Penal Code, article 480), depending on the case. Physical or moral compulsion must be present or actual deprivation of freedom —displacement— of the patient for the purpose of carrying out the intervention shall be required; if this is not the case, civil liability may be claimed. Spanish criminal courts, however, have not tried any of the above cases, except for a number involving the involuntary confinement in psychiatric hospitals of mentally-ill patients or violent or threatening persons, where it was deemed that the offences of coercion and unlawful detention, respectively, were applicable.[34]

§ 3. Privacy

136. The right to personal privacy is the one that traditionally has been disregarded most frequently in hospitals, a situation which reflects perhaps the little importance attached to it by society. However, awareness of this right is currently on the increase due mainly to its inclusion in the Constitution (article 18.1). Various aspects can be inferred directly or indiectly from this right.

137. In the first place, it entails going only as far as is strictly necessary in a medical examination (eg, questions concerning the patient's private, family or social life) needed to arrive at a correct diagnosis. Above all, however, it alludes directly to the *corresponding duty of confidentiality*, to professional secrecy, which was afforded scant protection in our legislation until recently and is still inadequately protected in certain fields, among them the field of health. This duty covers all aspects relating to an illness, including hospitalisation, and, if a patient so requests, obliges the physician to keep information secret from next-of-kin (even though next-of-kin are listed among those who should receive information in the General Health Law: article 10.5). Contrary to what is often understood, the duty is binding on *all* health-care professionals, regardless of rank or function, and not just nurses and physicians. The General Health Law is very clear as to this right to confidentiality (article 10.1 and 10.3) and even stipulates elsewhere that a patient's right to personal and family privacy, as well as the duty of secrecy incumbent on any person who, in the course of his work, has access to clinical records, must be fully guaranteed (article 61). This constitutional right to privacy, together with the right to one's image, which is of equivalent rank (article 18.1 of the Constitution), prohibits the publication in scientific works (and, of course, in the media) of photographs or other information likely to reveal the identity of the patient without the latter's prior consent, although in article 10 the General Health Law is not as explicit on this issue as it might be. As regards personal details included in medical prescriptions, Royal Decree 1910/1984 of 26 September, governing prescriptions, which establishes that personal privacy shall be protected (article 9), should be understood as including pharmacists and their employees also. The duty of confidentiality is not applicable only where expressly laid down in the law[35] or where authorisation is granted by a judge on legal grounds.

138. A true test of the right to privacy is posed by the *computerised processing of personal information* concerning hospital patients or out-patients. Such technology, with all the advantages it affords, is here to stay and throws up a greater likelihood that patients will become more vulnerable to invasions of privacy.[36] Until legislation was passed in 1992 (to conform with the requirement laid down in the Constitution) to restrict the use of computerised information so as to safeguard the honour and personal and family privacy of citizens and assure full enjoyment of their rights (article 18.4 of the Constitution), a lead was taken from the provisions of the European Convention for the protection of persons with respect to the processing of personal data, done in Strasbourg on 28 January 1981. The Convention became

part of internal law in Spain following ratification in 1984, although application often proved complicated because certain crucial parts had not been developed fully by the appropriate legislation. It is worth mentioning that article 6 of the Convention stipulates that personal data disclosing racial origin, political views, religious or other beliefs, as well as information concerning health or sex life may not be processed unless adequate safeguards are provided by internal law. The Convention refers to "sensitive data" and thus affects health-related data, and thus one is led to wonder whether hospital computer data bases containing medical records and other sensitive information concerning patients do not constitute a breach of the Convention. The Government and Parliament dragged their feet as regards regulation of such issues although it must be said that at long last an *Organic Law regulating the processing of personal data* was passed by the latter on 29 October 1992; this recent Law stipulates that health-related data may only be collated, processed and passed on when, in the general interest, the Law so provides or when the person to whom they refer gives his express consent (article 7.3). Public and private health institutions and health-care professionals are authorised to process personal data of persons who seek their help or who are treated by them in accordance with the provisions of the General Health Law, the Drugs and Medicines Law of 1990, Organic Law 3/1986 of 14 April governing Special Public Health Measures and other health laws (article 8). The reference which the new Law makes to certain articles of these other laws would not seem to provide truly reinforced protection of processed health data of a personal nature, given that the reference is merely a way of linking up to more general protection of confidentiality and information in the field of health. Thus, it can only be hoped that the European Community's Draft Proposal for a Directive on the same subject (1990)[37] will afford much more effective protection of patient data than currently exists.

139. The General Health Law says little with regard to the *freedom and confidentiality* of patients' correspondence and communications, although both are included as fundamental rights in the Spanish Constitution (articles 20.1 and 18.3, respectively) and are protected by criminal law (articles 497 and 497 bis, and 192 and 192 bis of the Penal Code).

140. *Ideological and religious freedom and freedom of worship* are entitlements of hospitalised patients also, notwithstanding the fact that the General Health Law prohibits only discrimination on grounds of ideology (article 10.1). This right means that patients shall be allowed to engage in acts of worship of their religious persuasion and also that they shall not be obliged to undergo treatment which contravenes their beliefs. Where this is not possible, and as long as they are competent adults, they are entitled to refuse treatment. This right is not enforceable in the case of a minor whose parents refuse treatment, as was explained above with reference to Jehovah's Witnesses. Here again account should be taken of the the problems raised by the right to do as one pleases with one's life when the treatment refused is of a life-sustaining nature.

Although the General Health Law does not explicitly recognise freedom of worship, this is recognised in the Constitution (article 16.1) and in a series of other statutory provisions, beginning with Organic Law 7/1985 (July) governing Religious Freedom, which guarantees freedom to practise acts of worship, the right to receive religious assistance of one's own persuasion and the non-imposition of other religions (article 2.1.d); moreover, the rights recognised by this law are afforded constitutional guarantees (article 4). Religious assistance in hospitals[38] is assured as follows: of the *Agreements between the Spanish State and the Holy See*, the one governing "Legal Affairs"[39] provides for measures of religious assistance in hospitals: "1. The State recognises and guarantees the exercise of the right to religious assistance of citizens interned in prisons, hospitals, psychiatric hospitals, orphanages and similar public and private centres. 2. Catholic religious assistance and the pastoral activities of priests and other members of religous orders in the aforementioned public centres shall be regulated by common agreement between the Church and State authorities. In all cases, people's right to religious freedom and respect for their religious and ethical principles shall be safeguarded" (article 4). Under the Ministerial Order (Ministry of Justice) of 20 December 1985 the Agreement shall be displayed publicly in all public hospitals. Lastly, mention should

be made also of the Convention of 23 April 1986 on catholic religious assistance in hospitals belonging to the National Institute of Health.

§ 4. Secrecy

141. Penal protection of professional secrecy in medical practice is insufficient.[40] Civil protection exists in the form of the Organic Law on civil protection of the right to honour, personal and family privacy and to one's own image of 5 May 1982, which in article 7.4 considers that the disclosure of private data concerning a person or family which is learned in the course of professional or official activities constitutes unlawful invasion of privacy. In the previous section on patient privacy we referred to the repercussions of this right for the physician's duty of secrecy. Health-care centres belonging to the Social Security system are also bound by professional secrecy with regard to details of patients' illnesses, in accordance with rules of ethics.[41] However, it should be remembered that the General Health Law imposes an obligation on health-care staff to facilitate information to the health authorities or their agents (article 35, B.5 and C.5), an obligation which must be rendered compatible with the duty of the confidentiality imposed by the very same Law.

Similarly, the duty to report any offences which come to their knowledge is incumbent upon physicians also, as we saw earlier, despite the fact that this represents a clear restriction on the duty of secrecy.[42] Although under the Constitution (article 24.2) a physician shall not be obliged to break professional secrecy by giving testimony on alleged offences, the cases in which such secrecy may be maintained must be set out specifically in a law, which has yet to be passed.

§ 5. Complaints

142. A patient whose rights are violated may seek protection from the courts and request compensation for any harm sustained, especially in serious cases. Patients or their relations, as users of health care, can avail themselves of a number of avenues to submit complaints regarding assistance or the manner in which they are treated during their stay in hospital. Royal Decree 521/1987 of 15 April, which approves the Regulations governing the structure, organisation and functioning of hospitals belonging to the National Institute of Health, set up Patient Care Services (article 32) to deal personally with patients or their next-of-kin, representatives or persons accompanying them; in article 32.2 and 3 it is stated that the Service shall provide patients and their families with information on the organisation of the hospital, on working and visiting hours and other aspects which might be of help to them or which might make their stay more comfortable. Complaints are channelled through the Service, which shall pass them on to the appropriate department head and ensure that a written reply, signed by the director of the hospital or person appointed by him, is given to the patient. Several private hospitals have set up their own patient care services along similar lines to those of their public counterparts.

Since references to the functions of Patient Care Services are few and far between in the Royal Decree, efforts have been made to outline more clearly the activities which they should carry out in order to raise the level of hospital care and provide a better service to users. Service activities include a) finding out the views of users on the functioning of the hospital by undertaking surveys and examining complaints, suggestions and expressions of gratitude; b) overseeing the correct application of patient rights and duties; c) ensuring that adequate information is made available to users (general written information and correct signposting of hospital facilities); d) the promotion of appropriate levels of access and comfort in hospitals; e) passing on complaints to the hospital management and ensure that replies reach the patient; f) providing information to patients and their next-of-kin regarding the characteristics and functioning of the hospital, as well as on the bill of patient rights and duties; g) providing information concerning mechanisms for public participation in hospitals and citizens' bodies to channel general complaints; h) providing information (and advise) with regard to other avenues of complaint. The Service is designed to be independent, neutral and impartial, advisory and

non-executive, and should endeavour to serve as a link between patients, patient and user bodies, the hospital management and health-care professionals, and to allay any apprehensions among the latter that the Service is there to police or monitor their work.[43]

143. *Complaints concerning the violation of patient rights.*[44] The General Health Law establishes a list of health user rights in article 10. If they are to be exercised effectively, a disciplinary system is needed to ensure respect for these rights and to punish health-care professionals who violate them. One initial possibility is to lodge a complaint against the hospital through the Patient Care Service, although there is no guarantee that a reply will be given within a given period of time, or even that the complaint will be heeded.

When violation constitutes an offence, or gives rise to civil liability[45] on the part of the professional or direct or vicarious liability of the Administration, the patient may take the appropriate legal action.[46] In other cases, the confusion surounding the issue makes it difficult to decide which system of infringements and sanctions should apply. Although the General Health Law provides for a general system of infringements and sanctions in article 32 and the following articles (particularly 35 and 36), no direct mention is made of infringements of user rights. Thus, we will have to wait until the government draws up the framework statute for health-care professionals envisaged by article 84 of the Law, which will include, among other aspects, a disciplinary regime. However, we should not forget the health authorities' own means of corrective action to deal with violations of or disregard for certain rights, the disciplinary powers of Colleges of Physicians (article 63 ff of the General Statutes of the Organisation of Colleges of Physicians, under the Royal Decree of 19 May 1980) and the relevant disciplinary aspects which may be inferred from the Legal Statutes of Social Security Medical Personnel (article 65 ff),[47] which is still in force, and the Consumer and User Protection Law of 19 July 1984 (article 34 ff).

§ 6. Access to Medical Records

I. Legal nature and Ownership of Medical Records

144. This issue raises new and interesting legal problems in that patients who previously had never materially or intellectually held their medical records can now take them with them —at least in part— on magnetic electronic memory cards used to store clinical records digitally. The solution to the question of the extent to which a physician is the owner of clinical records, computerised or otherwise, is crucial, for instance, for determining procedures of lawful disclosure of data and the right of patient access to medical records. In addition, the widespread computerisation of clinical and other patient data has opened up new possibilities, which have led to a strengthening of the protection of such data and access by the persons to whom they relate. The Spanish Parliament has passed the *Organic Law on the computerised processing of personal data* (29 October 1992), which ensures overall reinforced protection for health-related data, although at the same time it also authorises health-care centres and professionals to access and use patient data (see § 3, above).

Opinions on the issue have been divided in Spanish law:[48] some authors strongly oppose giving physicians any intellectual rights over medical records. Others, however, argue that some degree of intellectual (scientific) creation is present in a medical record drawn up (partly at least) by a physician, particularly the components which go beyond a simple list of details or information, namely, appraisal of diagnosis and prognosis or the various judgements and appreciations made by the physician throughout the treatment process; this second argument tends to be used in denying patients access to their own medical records.

Opponents argue that the question cannot be addressed in a global manner in Spanish law: only in a rather farfetched manner, involving considerable distortion of the Intellectual Property Law,[49] which considers as property original creations of a literary, artistic and scientific nature which are expressed in any means or form (the Law includes computer software under this heading), could any other argument be made to stand. However, software

should not be confused with factual events or data, which, although stored digitally and is accessed and retrieved by software programmes, are nothing more than digitalised information as opposed to a logical operating programme developed by a person who should be credited with the original creation. Moreover, a physician's copyright would be devoid of content; there would certainly be no material or moral right of authorship, save the right and duty to prevent information contained in clinical records from being used for unlawful purposes or passed on to an unauthorised person.

For their part, advocates of intellectual property rights over hospital and medical records in general stress the undeniably scientific-intellectual content of many of the most important elements recorded therein (diagnosis and prognosis, prescribed treatment, and other appraisals and observations included in the record),[50] and argue that this creativity is accepted by the Intellectual Property Law as being subject to protection (articles 1 and 10).

145. We take the view that, from the legal standpoint, hospital records comprise different components. In the first place, one can distinguish elements relating to the organisation and administration of the hospital; secondly, the details which identify the patient and other data relating to his illness which he himself furnishes or which are deduced by the physician, even without the patient's knowledge; thirdly, and finally, the results of direct examinations or examinations using instruments or substances, insofar as such examinations entail an element of judgement or deduction based on the professional knowledge of the physician (who is often not the physician actually treating the patient), as well as assessments for diagnosis and prognosis and the prescription of any appropriate treatment. Only this third group of data may be construed as being a scientific creation governed by rights of intellectual property and owned by the physician(s) who took part in the creation. However, where the professional provides his services in a state-owned hospital (or where he is a paid employee of a private one), ownership corresponds to the public (or private) institution, although the physician may have certain powers of control over use of the information by third parties, as we shall see below. It should be said in support of this conclusion that the Intellectual Property Law states that transfer to an employer of rights of use of any work created within the context of an employer-employee relationship shall be governed by agreements contained in the contract of employment, which should be of a written nature; in the absence of a written agreement (which is usually the case), it is presumed that when said work is handed over to the employer under the aforementioned relationship, rights of use are transferred exclusively and to a sufficient degree so as to enable the employer to perform his usual activity (article 51.1 and 2). Hence, there can be no doubt that a physician who provides his services in a public hospital or as an employee of a private one is covered by the type of relationship described in the Intellectual Property Law and thus transfers the rights of use (reproduction, distribution and transformation) over the hospital record in order that the hospital may carry out its activities. Having said that, deciding the legal nature of hospital and other medical records does not appear to be decisive for our purposes here, although it does help clear up doubts regarding the ownership of the hospital record. Ownership corresponds to the hospital concerned and regardless of the extent of recognition of patient access to his records, he cannot demand that the original document be transferred elsewhere.

II. Patient Access to Hospital Records

146. Spanish law has resolved the issue of patients' access to their hospital records by granting unrestricted access under the General Health Law, which stipulates that hospital or health records "shall be made available to patients" and that "the authorities shall adopt measures to guarantee these rights and duties" (article 6.1).

147. Two comments need to be made with regard to this statutory provision. Firstly, in referring to hospital records in a general sense, regardless of whether they are stored on computer or in written from, the provision covers all forms in which records may be kept; hence, the right of access to the record as recognised in the General Health Law extends also to

any information stored on computer.

Secondly, a question mark surrounds exactly which parts of the record a patient is entitled to from the point of view of the precautions provided for in comparative law to avoid negative consequences for a patient who is granted direct access which is not "filtered" by the physician. Similarly, the requirements of the physician who wishes to safeguard his own privacy if the record includes his subjective opinions concerning the patient must be borne in mind. As we have seen, the General Health Law entrusts the job to the authorities, albeit in a partial sense since it refers only to measures to guarantee the rights and duties mentioned in the same Law (article 61). In this case, a doubt arises as to whether restrictions to access that cannot be inferred from the Law may be introduced. However, no form of restriction which is currently applicable can be deduced from the aforementioned Law.

148. As regards how recognition of access to the hospital record ("shall be made available") can be reconciled with the presence of highly subjective components (the physician's subjective appreciations concerning the patient's attitude or behaviour and his reactions), which might affect the physician's own privacy (it should be remembered that the Law does not actually list rights and duties, but merely entrusts the job of establishing them to the authorities), it is important to consider the patient's intended purpose in making use of the records made available to him:

a. To obtain further personal information

149. If his aim is to learn more about himself, on completion of treatment, or even during treatment or while in hospital, it does not suffice to argue that the information, one of the rights recognised by the General Health Law and included in the list of user rights (article 10.4 and 5), can be provided in full by the physician, who serves as the link between the patient and his hospital record, and thus nothing justifies the patient having direct access to the record. Neither can access be denied on the grounds that on leaving hospital the patient is entitled to receive a Discharge Report[51], which will necessarily include an extract of the hospital record,[52] and hence the information is being made available to him. These arguments are unacceptable because the rights laid down in the aforementioned laws are different to those recognised in article 61. As a result, the requirement which is specifically recognised in the Law must be satisfied by providing the patient with a copy of his record, from which the physician's subjective opinions have been deleted previously in order to protect the latter's privacy. In this way, it is acknowledged that availability is not direct and has to be reconciled with the right of the physician. However, it need not necessarily be the physician who provides the information or copy: this role could well be performed by the hospital's records department.

b. To continue or commence treatment in another hospital or under another physician

150. In this case the interests of the patient are more important than his right to information as explained in the previous section, and therefore it is necessary to keep in mind the interests of the physician who wrote the parts of the hospital record containing his subjective views, which may prove extremely useful to the colleague about to treat the patient. If the patient so desires, a full copy of his record shall be sent to the new hospital or physician, who must also keep the contents confidential since they have an obligation of professional secrecy towards the colleague in question. However, if the patient requests that the record be given to him personally, he may receive the extract referred to in the previous section.

c. Use in legal proceedings

151. Where the patient requires the record for legal proceedings (for example, to claim damages against the physician) the criteria to be applied are those described below in the section dealing specifically with this issue.

III. Access for the Purposes of Inspection, Statistics or Science

152. Access for such purposes is clearly a possibility, particularly in the case of computerised information, which can contribute greatly to scientific activities (teaching or research, for instance), inspections or the compiling of statistics.

In the article which grants access to patients (article 61), the General Health Law also stipulates that records may be made available for medical inspections or for scientific purposes, on condition that the patient's right to personal and family privacy and the duty of secrecy on the part of any person who in the course of his work is given access to the records are guaranteed.[53] In the case of statistical studies, secrecy to ensure the protection of data collated by statistics offices, belonging to the Administration or otherwise, is ordered by the Statistics Law (articles 13 to 22).[54] In the case of both research and statistics, respect for the privacy of the patient and the duty of secrecy call for patient anonymity, that is, neither his name, other details or photographs (eg for publication in scientific journals) which might identify him shall be given without his prior consent. Although it cannot be inferred from the text of the law, it would be appropriate that neither researchers or statisticians be given access to patient data. This is something that should be borne in mind by the authorities when it drawing up statutory measures to guarantee the rights of patients. Identification of the patient would appear to be appropriate to ensure proper inspections, although the duty of secrecy must always be observed.

Turning once again to the questions of ownership (or rights of use) of medical records by the physician's employing institution and the possibility of patient access, it should be noted that a physician's intellectual property rights over some parts of the record is restricted in another sense also: he may not refuse access by third persons for the aforementioned purposes, particularly for scientific aims (research). However, a requirement could be established that reference be made to the source of the record(s), with mention of, for example, the service or hospital involved or the physician who drew up the report, depending on the case.

IV. Access to Records for Judicial Enquiries

153. Hospital records can be of crucial documentary importance as elements of proof in legal processes.

In the case of a criminal process, the accused may be either the physician or the patient. In the latter case, physicians and hospital authorities in general can allege professional secrecy which, as is known, is afforded scant guarantees in our legal order, a situation which has posed problems for certain professions, notably journalism and medicine. It has already been mentioned above that the Constitution of 1978 stipulates that it is up to the law to regulate the cases in which, on the grounds of professional secrecy, a person shall not be obliged to give testimony with regard to alleged offences (article 24.2). To date, however, no law has done so, although in view of the fact that this legal principle is placed alongside other fundamental rights in the Constitution it has been suggested by some that professional secrecy may be used as a direct argument not to hand over hospital records to a judge.[55] It is doubtful whether this can in fact be done, since —as the Constitution itself indicates— the law shall determine the situations in which it is possible.

The situation seems rather more complex when records have to be handed over in proceedings in which the physician himself is the defendant, probably on charges of alleged negligence in treating one of his patients (the person to whom the records refer). It has been argued on occasions that the physician is not obliged to deliver up the records on the basis of his right not to testify against himself (article 24.2 of the Constitution); neither is the hospital, since it is merely the depositary of the records.[56] However, it does not seem to us that a physician incriminates himself by handing over the records, given that such records and any interpretation which are made of them are merely one of the elements which, taken together with the other elements of proof, will lead the judge to decide whether or not he was at fault. Furthermore, as part of his fundamental rights the patient is entitled to receive effective protection by courts and judges in exercising his legitimate rights and interests, and under no

circumstances can he be placed in a situation of defencelessness (article 24.1 of the Constitution). This means that access to the full records is legitimate. Where the request for access is made by the patient's next-of-kin (eg where a patient dies during treatment and his death leads the family to take legal action), it should be noted that no right of access is actually recognised in their case, although it should be granted for the same reasons outlined just now, so that they may take the appropriate legal action.

In the case of other civil, labour or administrative proceedings, account must be taken at all times of the patient's right to confidentiality and the protection of his privacy —which, as we have seen, is reinforced in matters pertaining to health—, so that no hospital records are made available to a judge without the patient's consent. Similarly, the patient's right of access to his records must be taken into account. Note also that on occasions he may stand to lose from such access, while on others access will be to his benefit.

NOTES

1. See J. ESCORIHUELA MORALES, 'Los derechos del enfermo', in *Jano*, n. 664, 1985, p. 1279; C.M. ROMEO CASABONA, 'Configuración sistemática de los derechos de los pacientes en el ámbito del derecho español', in *Jornadas sobre los derechos de los pacientes 1990*, (Insalud, Madrid 1992), pp. 173 ff.

2. See L.C. MARTINEZ AGUADO, *Los derechos del paciente en el hospital publico* (unpublished dissertation) (Zaragoza, 1986), p. 26.

3. See Supreme Court Ruling 53/1985(11 April), legal principle n. 14 (relating to the depenalisation of abortion) and a previous one dated 23 April 1982 (on an issue not relating to health). A. CUERDA RIEZU, 'El delito de aborto ante la Propuesta de Anteproyecto del nuevo Código Penal', in *Documentación Jurídica*, n. 37/40, 1983, p. 382; M. GARCIA ARAN, 'La objeción de conciencia del médico en relación a la interrupción del embarazo', in *El aborto. Un tema para debate*, (Madrid 1982), pp. 119 ff; R. MARTIN MATEO, *Bioética y Derecho*, (Ariel, Barcelona 1987), p. 84.

4. CUERDA RIEZU, ibidem; GARCIA ARAN, 'La objeción de conciencia del médico en relación a la interrupción del embarazo', cit., p. 128.

5. Ruling of the Territorial Court of Oviedo (Court for Administrative Disputes), 29 June 1988.

6. The right to strike is regulated generally in Royal Decree-Law 17/1977 of 4 March.

7. See Rulings of Supreme Court (2nd Chamber) of 18 April 1989 and 22 April 1991.

8. See Ruling of Provincial Court of Valencia, 18 January 1990.

9. Supreme Court (2nd Chamber) Ruling of 15 January 1974.

10. Rulings of Supreme Court (2nd Chamber) of 2 June 1969 and 7 December 1973.

11. Rulings of Supreme Court (2nd Chamber) of 21 June 1989 and 2 October 1989.

12. Rulings of Supreme Court (2nd Chamber) of 28 January 1961 and 19 December 1981.

13. Ruling of Provincial Court of Valencia, 23 March 1990.

14. See ROMEO CASABONA, 'Configuración sistemática de los derechos de los pacientes en

al ámbito del derecho español', cit., pp. 178 ff.

15. Constitutional Court Ruling of 27 June 1990, fj n. 4.

16. Supreme Court Rulings of 12 December 1991 and 15 January 1992.

17. Royal Decree 521/1987 of 15 April, which approves the Regulations governing the Structure, Organisation and Functioning of Hospitals managed by the National Institute of Health, creates Patient Care Services and states that their task is to provide patients and their next-of-kin with information regarding the organisation of the hospital, services available, working and visiting hours, and any other activities which might help them and make their stay in hospital more comfortable (article 32.2).

18. See Royal Decree 521/1987, cit.

19. See previous works on the subject. Various authors, 'Derechos del enfermo', in *Labor Hospitalaria*, n. 179-180, 1981, passim; Various authors, *La Sanidad Española desde la perspectiva del usuario y la persona enferma* (Encuentro Ediciones, Madrid 1983), passim.

20. D. GRACIA GUILLEN, *Fundamentos de Bioética,* (Eudema, Madrid 1989), pp. 181 f.

21. See M. BAJO FERNANDEZ, 'La intervención médica contra la voluntad del paciente', in *Anuario de Derecho Penal y Ciencias Penales*, 1979, pp. 492 ff; by the same author, 'Agresión médica y consentimiento del paciente', in *Cuadernos de Política Criminal*, 1985, pp. 127 ff; L. MARTIN-RETORTILLO BAQUER, 'Derechos fundamentales en tensión (¿Puede el juez ordenar une tranfusión de sangre en peligro de muerte, aún en contra de la voluntad del paciente?)', in *Poder Judicial*, 1984, pp. 31 ff; C. M. ROMEO CASABONA, *El Médico y el Derecho Penal, I,* cit., pp. 372 ff.

22. Article 205 of the Penal Code states as follows: "The following shall be liable to a period of imprisonment of between six months and one day and six years: 1. Anyone who uses violence, intimidation, force or any other unlawful means to prevent a member or members of a religious persuasion from practising or attending acts of worship of their religion. 2. Anyone who uses similar means to force another to practise or attend acts of worship, or perform actions revealing his religious persuasion or lack of persuasion, or to force him to change his persuasion".

23. See also BAJO FERNANDEZ, 'La intervención médica contra la voluntad del paciente', cit., p. 498.

24. J.L. DIEZ RIPOLLES, 'La huelga de hambre en el ámbito penitenciario', in *Cuadernos de Política Criminal*, n. 30, 1986, p. 609; ROMEO CASABONA, *El médico y el Derecho Penal, I,* cit., p. 375.

25. Ever since the Supreme Court edict of 14 March 1979.

26. Supreme Court edicts of 22 December 1983 and 25 January 1984.

27. Constitutional Court edict of 20 June 1984.

28. MARTIN-RETORTILLO BAQUER, 'Derechos fundamentales en tensión', cit., p. 38.

29. C.M. ROMEO CASABONA, *El Médico ante el Derecho,* cit., p. 49.

30. MARTIN-RETORTILLO BAQUER, 'Derechos fundamentales en tensión', cit., p. 38;

ROMEO CASABONA, *El Médico y el Derecho Penal, I,* cit., p. 384.

31. On this and the following situation, see E. COBREROS MENDAZONA, *Los tratamientos sanitarios obligatorios y el derecho a la salud,* (HAEE/IVAP, Oñati 1988), pp. 334 ff, and 369 ff.

32. See below, Part II, Chapter II, § 2.

33. Ministerial Order of 6 September 1984 regulates the obligatory nature of the Discharge Report.

34. Supreme Court Rulings of 16 April 1959 and 24 October 1978, respectively.

35. See COBREROS MENDAZONA, *Los tratamientos sanitarios obligatorios y el derecho a la salud*, cit., p. 267.

36. See F. MADRID CONESA, *Derecho a la intimidad, informática y Estado de Derecho*, (Publ. Universidad de Valencia, Valencia 1984), passim; F. MORALES PRATS, *La tutela penal de la intimidad: privacy e informática,* (Ed. Destino, Barcelona 1984), passim; F. MORALES PRATS, 'Confidencialidad, intimidad e informática: la protección de los datos del paciente. Perspectiva jurídico-penal', *Jornadas sobre los derechos de los pacientes 1990* (Insalud, Madrid 1992), pp. 131 ff; C.M. ROMEO CASABONA, *Poder Informático y Seguridad Jurídica,* (Fundesco, Madrid 1988), pp. 25 ff; C.M. ROMEO CASABONA, 'La reforma penal ante las nuevas tecnologías de la información', in *Informática e Diritto*, 1987, pp. 115 ff; C.M. ROMEO CASABONA/ E. DOMINGUEZ GARCIA, *El Derecho ante las nuevas tecnologías* en el ámbito sanitario (Report commissioned by the Ministry of Health and Consumer Affairs) (La Laguna 1991); E. SOLA RECHE, 'La protección penal de la intimidad informática', in *Anales de la Facultad de Derecho de la Universidad de La Laguna*, n. 11, 1991, pp. 179 ff.

37. Draft Proposal for a Council Directive approximating certain laws, regulations and administrative provisions of the Member States concerning the protection of individuals in relation to the processing of personal data.

38. Recognition has existed for some time of patients' right to spiritual assistance in hospitals belonging to the Social Security system: General Regulation governing the regime, government and services of Social Security health-care centres (Ministerial Order of 7 July 1972, article 148.5).

39. Signed on 3 January 1979, and ratified on 4 December of the same year (Official State Journal, 15 December 1979).

40. See D.M. LUZON PEÑA, 'Tratamiento del secreto profesional en el Derecho español', in *Poder Judicial*, special number XIII, 1990, pp. 133 ff; E. OCTAVIO DE TOLEDO, 'Algunas reflexiones sobre el tratamiento jurídico del secreto profesional', in *La Ley*, n. 612, 1983, p. 1 ff.

41. See General Regulation governing the regime, government and services of Social Security health-care centres (Ministerial Order of 7 July 1972) article 148.3.

42. See Part II, Chapter I, § 1, II and § 6.

43. Various authors, *Actas del II Congreso de Servicios de Atención al Usuario de la Sanidad* (Zaragoza, November 1988) (Hospital Miguel Servet, Patient Care Service, Zaragoza 1989), passim; P. HERNANDO, 'Servicio de Atención al Paciente en el Hospital', in *Todo Hospital*,

n. 62, 1989, pp. 67 ff.

44. See A. PEDREIRA ANDRADE, 'Ejercicio de los derechos y reclamaciones de los usuarios', cit., pp. 199 ff.

45. For example, for breaches of privacy "resulting from the disclosure of private data concerning a person or family which come to be known in the course of the professional or official activity of the person who discloses them", the specific regime contained in article 7.4 of the Organic Law on the protection of honour, personal and family privacy and one's image of 5 May 1982 is applicable.

46. See Part I, Chapter III, § 2.

47. Decree 3160/1966 of 23 December.

48. See on this subject R. DE ANGEL YAGÜEZ, 'Problemas legales de la historia clínica en el marco hospitalario', in *La Ley*, n. 1647, 1987, pp. 1 ff; A. LUNA MALDONADO, 'Problemas médico-legales de la historia clínica en el ejercicio libre de la Medicina', in *Los Derechos del enfermo*, (Consejería de Sanidad y Consumo, Murica 1987), pp. 73 ff; A. LUNA/ E. OSUNA, 'Derecho del paciente al acceso a su historia clínica', in *Medicina Clínica*, n. 88, 1987, pp. 59 f; F. VALENZUELA/ A. VALENZUELA/A. LUNA, 'Problemas médico-legales de la historia clínica: el acceso a la misma', in *Los derechos del enfermo*, (Consejería de Sanidad y Consumo, Murcia 1987), pp. 83 ff.

49. Law 22/1987 of 11 November, on Intellectual Property (article 10).

50. See DE ANGEL YAGÜEZ, 'Problemas legales de la historia clínica en el marco hospitalario', cit., p. 3.

51. Article 10.11 of the General Health Law: "All persons have the right to have their entire process recorded in writing. On completion of their stay in hospital, the patient, next-of-kin or person close to the patient shall be given a discharge report". Article 10, final paragraph, establishes the same right in respect of private hospitals also.

52. See Ministerial Order of 6 September 1984, which regulates the obligatory nature of the Discharge Report. The report must be given to patients who have been admitted to and treated in a public or private health-care institution (article 1.) Article 3.4.e states that the information given must include summaries of the hospital record and the physical examination of the patient.

53. This duty extends also to private centres in general (article 10, final paragraph, of the General Health Law). Where rights contained in article 18 of the Constitution (among others) are injured, and where this is determined by a court ruling (article 67.4 of the General Health Law), any Agreement which might exist between the private centre and the Administration may be rescinded.

54. Law 12/1989 of 9 May. The General Health Law states that one of the competences of the State Administration is to compile statistics (article 40.13), although without prejudice to the competences of the Autonomous Communities, some of which have their own legislation governing such matters.

55. In this respect, see DE-ANGEL YAGÜEZ, 'Problemas legales de la historia clínica en el marco hospitalario', cit., p. 5.

56. As understood by DE ANGEL YAGÜEZ, 'Problemas legales de la historia clínica en el

marco hospitalario', cit., p. 6.

Chapter II. The Physician-Patient Relationship in Specific Terms

§ 1.The Minor Patient

I. The Relevance of the Wishes of the Minor Patient

154. The relationship between the physician and a minor patient poses specific problems, relating chiefly to the obtaining of consent for treatment and any other measures required, as well as to ensuring that the minor is not subjected to abusive conduct. As a rule, the minor's legal representatives (parents or guardian) should grant their consent, although certain are laid down in this respect. In addition, there are a large number of statutory provisions which prohibit or restrict certain medical actions which are not of direct benefit to the health of the minor.

155. Spain's legal order stipluates explicitly that the actions of a minor's legal representatives in exercising their authority shall "at all times aim to benefit their children, in accordance with their personality" (Civil Code, article 154, paragraph 2). This means that parents or guardians must always conduct themselves in accordance with the interests of the minor child for in their charge and not to further their own interests. The Civil Code also provides that where a conflict of interests arises betwen parents and child, the former may not exercise legal representation of the latter in the situations or acts relating to the conflict. Needless to say, all this is directly applicable to decisions concerning medical treatment provided to a minor. Let us consider briefly moment some of the most salient aspects involved.

156. In essence, two hypotheses may be considered, namely, that the minor patient is assisted by his parents or guardians (legal representatives) or, conversely, and for whatever reason, he is not.

II. Intervention of Legal Representatives

157. The age of political and civil majority in Spain is eighteen (articles 12 of the Constitution and 315 of the Civil Code, respectively). However, before reaching this age a minor has the capacity to carry out certain acts, or at least to be heard, if he lives an independent life, which means that he must give his valid consent to such acts; moreover, even where he is not fully independent his consent is necessary if the act affects his most personal interests. This is true, notwithstanding the Civil Code's statement that "parents with rights of parental authority are the legal representatives of their non-emancipated minor children" (article 162). The Code goes on to list a number of exceptions where this provision does not apply, including one which is of interest to us here: acts relating to the rights to personality or others which the child, in accordance with the law and his level of maturity, may carry out for himself. The duties and faculties inherent in parental authority include the power to "represent them (the children) and administrate their property. Children who have sufficient intellectual judgement shall be heard always before the taking of decisions which affect them" (article 154, paragraph 2.2).What this means is that parents (with rights of parental authority) are the legal repesentatives of their non-emancipated children, except with respect to acts relating to rights of personality if the children concerned are capable of acting on their own behalf. Clearly, if a child is to undergo medical treatment these rights are affected and thus in order to determine whether the child is able to decide for himself it is necessary to take account of what is known as his natural capacity for judgement, regardless of biological age. Put another way, what counts is the child's real capacity to understand the nature and the effects of the treatment about to be given. Admittedly, there are practical difficulties involved in ascertaining the degree of maturity of a minor patient, although this will only be necessary when the minor and his parents disagree with respect to acceptance of the physician's orders. In such cases, as we have mentioned above, parents are obliged to act in the best interests of their children (as the Civil Code puts it, they must "at all times aim to benefit their children, in accordance with their personality"), although they are

afforded support in the sense that in the exercise of their parental authority they can seek the help of the authorities (article 154 of the Civil Code); lastly, the General Health Law confirms that a minor's family may intervene where the child does not have the capacity to take decisions (article 10.6.b).
Where disagreement exists between the parents and the physician, and if the latter considers that the parents' attitude is clearly harmful to the child, as happens when parents reject treatment without good cause, he may intervene directly, in view of the state of necessity (article 8.7 of the Penal Code and 10.6.c of the General Health Law), as long as the situation is urgent and the patient's life is under threat; where treatment is not urgent he may seek the help of the legal authorities (Juvenile Court), which will issue the appropriate instructions, and may even restrict or withdraw parental authority. Paediatricians have a special role to play when they are asked to treat children who have clearly been physically abused by their parents. In addition to the aforementioned option open to the paediatrician, he is legally obliged[1] to notify the criminal court (or duty magistrates' court, where appropriate) so that the necessary criminal proceedings may be taken.

158. Parental duties, among them the duty to provide religious education, oblige them to do all that is necessary to benefit the health and life of their children, until they come of age and can exercise for themselves their religious freedom and take personal responsibility for their decisions. Refusal to allow a minor to be treated on religious grounds (eg refusing permision for a blood transfusion) constitutes an abuse of parental authority in that parents' freedom to choose between different values is not admissible in this case since it affects the children and suits not the children's interests but rather those of the parents. In such circumstances, the physician is obliged to act to protect the life of his patient and any intervention will be supported by the legal authorities. Where the minor himself refuses the life-sustaining treatment becuase it contravenes his religious beliefs (blood transfusion, for instance) account must be taken of his natural capacity for judgement, that is, his capacity to understand the importance and the repercussions of his refusal of treatment, if his right of personhood is affected, as stipulated in the Civil Code. However, although in a given situation the minor's maturity may be acknowledged, it should be noted that the decision-making powers of adults which our legal order recognises in such cases are also limited, or at the very least the subject of controversy, following a Supreme Court ruling which expressly rejected recognition. Most authors, however, tend to consider that the patient's wishes should be accepted. The problem with a minor is that his civil rights are not recognised fully until he reaches the age of majority. The same applies also to his freedom of conscience or religious freedom, at least in the case of a life-threatening refusal of treatment on religious grounds. In any case, and even though it must be acknowledged that in practice it can prove difficult to assess accurately, a minor's wishes in other situations must necessarily be heeded provided that he shows that he has a reasonable degree of maturity.

III. In the Absence of the Minor's Legal Representatives

159. If, for any reason, the minor cannot be assisted by his parents, the physician must follow the guidelines mentioned above regarding natural capacity for judgement. Where this capacity does not exist and where the situation is urgent the physician may intervene immediately; in other cases, he shall consult other relations or persons close to the minor (General Health Act, article 10.6.b). If the minor is independent, it will be up to him to take the relevant decisions, given that in the eyes of the Civil Code he is acknowledged as being capable of governing his own life, just like any adult (article 323).
Newborn and very young children are not in a position to express their preferences because they have not formed their own opinions. Legally-speaking, with newborn babies medical action will have to be based on the possibilities of attaining the goals of medicine, that is, to improve the child's health or keep him alive, and not on the likely quality of life he will enjoy in the future. If the medical goals are attainable, even though the quality of life of the child will be less than perfect, the physician is legally obliged to act (for example, Down's syndrome

sufferers with an organic pathology); if the objectives appear unattainable there is no obligation to intervene (anencephalia). Where doubts exist with regard to prognosis, the benefit of the doubt should always be given and treatment provided (eg reanimation).

IV. Specific Cases

160. The above constitute general rules. However, consideration should aslo be given to exceptional or specific cases which generally-speaking do not involve curative action as such. A minor under the age of eighteen or an incompetent person, or his legal representatives, cannot consent to becoming live donors of a transplant organ;[2] there is however one exception which covers donations of bone marrow: given that it is a tissue which can regenerate itself, donation poses no —or should pose no— major risks for the donor and is extremely suitable for use between brothers and sisters (although the exception is not limited expressly to such relations).[3] Neither can minors donate blood.[4] They may only take part in clinical trials if they themselves stand to benefit from them. Special caution must be taken with trials of this nature and the consent given by the minor's legal representatives[5] is subject to this principle, as we have already managed to infer above from the Civil Code.

An incompetent person or a minor under the age of eighteen (some authors, in our view incorrectly and on the basis of arguments which need not be entered into here, put this age at sixteen), or any such person's legal representatives, cannot consent to sterilisation, except where this is for strictly therapeutic reasons, in which case the general regulations governing curative actions are applicable; sterilisation of a minor is also permitted when the minor has been certified as being incompetent by a judge, is suffering from serious mental disorder and when the intervention is authorised by a judge at the request of the minor's legal representative. Authorisation will be granted only after he opinions of two specialists and the public prosecutor's office are heard and following examination of the minor (Penal Code, article 428, 2nd paragraph).

Turning to abortion, unlike with sterilisation there is no express stipulation that the consent given by a minor (or incompetent) girl or by her legal representatives is not valid (as can be inferred from article 417 bis paragraph 1 of the Penal Code). Notwithstanding other criteria which advocate that the basis used should be the expectant girl's civil capacity or the imputability of or capacity for criminal liability, consent shall be valid to the extent that the girl's natural capacity for judgement and understanding enable her to grasp the significance of her decision to abort,[6] which means that she must understand that she will not merely undergo an intervention on her own body but will also destroy a living fetus. Under these conditions, her wishes will have to be respected, even if she chooses to continue with the pregnancy, save where the life or health of the minor (or mentally-ill or mentally-deficient person) are in serious danger,[7] and her degree of understanding does not permit her to grasp the importance of the risk which the pregnancy entails for her. If she does not have natural capacity for judgement, and as a result valid consent cannot be obtained, the minor's legal representatives (parents or guardians) may act, although at all times they must observe their duty to assure the well-being of the girl in their charge and must not act in accordance with their own interests or ideologies. In cases such as these, any conflict of views between the expectant minor and her legal representatives is of no legal relevance because, under the general rules governing representation, the decision of the latter will take precedence. Where the conflict (or any conflict-free decision taken, ie, to abort or continue with the pregnancy) is the result of abusive conduct on the part of the legal representatives, the matter should be referred to a legal authority for a decision in the best interests of the expectnat mother, except where the situation is so urgent that the physician himself must take a decision, with the legal backing afforded by article 8.7 of the Penal Code governing situations of necessity. Another possibility, albeit an extremely rare one in practice, is that a court may rule that the girl is incompetent but recognise that she can give consent to abortion (article 267 of the Civil Code).

Lastly, it should be noted that certain age-restrictions apply to techniques of assisted reproduction: donors of semen must be over the age of eighteen, as must any woman on whom

the techniques are to be used.[8]

§ 2. The Mental Patient and Involuntary Placement

161. Treatment of mental patients or mentally-deficient persons poses several legal problems,[9] ranging from admission to a hospital to (informed) consent to treatment. One question which must be decided beforehand is whether or not, for the purpose of consent (or authorisation), these two aspects are linked or are entirely separate. We shall examine briefly the conditions of admission to and treatment in a hospital according to the different potential situations with respect to the validity of the mental patient's consent, namely, whether or not he has been declared incomptent by a judge, whether internment is urgent and whether he is to be treated for an organic or mental illness.

I. Voluntary Admission and Treatment

162. There can be no denying that psychiatric patients who are admitted of their own accord to a mental health institution are entitled to receive information, give informed consent and also to refuse treatment. It is quite possible that the extent or the nature of the patient's illness do not prevent him (ie he is not incompetent) from taking decisions such as to contact of his own accord a mental health institution or other centre with such facilities and ask to be admitted for treatment. His decision must be accepted and residential treatment provided if it is indicated medically, given that in such cases the principles of consent based on the person's natural capacity for judgement and his grasp of the importance of his decision are applicable.[10]
Where the patient's condition and mental health worsen, or where his pathological picture on admission was already serious even though no significant deterioration is observed, the question arises as to what should be done if he refuses to continue treatment and wishes to be released from care but from the medical point of view continuation is advisable and his mental condition causes his fitness to take the appropriate decisions to be doubted. He would then be in the same position as an incompetent patient and the same criteria would therefore apply: if the patient decides he wishes to leave hospital but is prevented from doing so by the medical practitioner or the hospital management, notification must be given to a judge, who shall decide as appropriate. The situation is exactly the same as that of the involuntary internment (or, to be more accurate, extending internment)[11] of an allegedly incompetent person for reasons of emergency. It should be stressed that the hospital's decision to prevent the patient from leaving should not be based on the need for treatment but on any potential risks which his release might entail for his own or others' health or life.

II. Involuntary Admission and Emergency Treatment

A. Treatment of Organic Illnesses

163. If admission is urgent and the physician considers that treatment is urgently required because the patient's life is in danger but the latter is unable to give valid consent and his family or guardian are unavailable, the physician must admit the patient and may intervene to treat an organic or somatic problem (that is, one which has nothing to do with his mental illness). In this regard, he will be protected by the provisions governing exemption from liability in situations of necessity (article 8.7 of the Penal Code) should he face legal action for allegedly violating the patient's freedom; this possibility is catered for expressly by the General Health Law, which authorises the physician to intervene (in legitimate exercise of his profession, article 8.11 of the Penal Code) without the consent of the patient, next-of-kin or persons close to him when the extent of the emergency does not permit delay in view of the potentially irreversible injuries or risk of death which might be caused by any such delay (article 10.6.c). The procedure is fully justified to avoid irreparable organic consequences caused to the patient as a result of the delay in obtaining for prior consent. To sum up, the physician should act as he would with any other patient in a similar emergency situation, and in this case the patient's

mental illness has no bearing on the decision.

164. If in the situation described just now the mental patient or mentally-deficient person is conscious and refuses admission and treatment, but his mental capacity does not permit him to take decisions because he is incapable of grasping the importance of his refusal and of his situation, intervention is possible under article 10.6.c of the General Health Law, provided that, as in the previous case above, no next-of-kin or guardian is available (article 10.6.b).
In our view, mental patients are not covered by the Civil Code examples of compulsory confinement of supposedly incompetent patients (article 211), given that the examples provide for confinement of persons suffering organic injuries or illnesses as opposed to the mentally-ill. Nevertheless, Law 6/1984 on the *habeas corpus* procedure (article 1.b) does not exclude the possibility of a patient or his representative seeking a judge's ruling on the legality of the confinement, both in this case and in others mentioned below. Several experts advocate that the aforementioned Civil Code procedure should be used also in cases where confinement of a mental patient is necessary for the treatment of somatic illnesses which have no bearing on his supposed mental incompetence. This would certainly safeguard the patient's interests better, although it would not necessarily be in the best interests of his somatic health, because treatment would be subject to the authorisation of the judge and medical intervention could thus be delayed (save where the emergency procedure is used, as is more frequently the case). However, at the same time it would also considerably increase the workload of the courts, at times unnecessarily. We are of the opinion, therefore, that the *habeas corpus* procedure, which would be open to a person who considers he has been unlawfully confined, is more appropriate.

B. Treatment of Mental Illness

165. Where the same situation of emergency arises but where admission is required to treat a mental illness the mental health unit of the institution or the psychiatric hospital may admit the patient and should follow the procedure laid down for emergency confinements of suuposedly incomptetent or incapacitated patients. They should notify the judge, who shall authorise or refuse confinement (article 211 of the Civil Code). Confinement must be notified as soon as possible to the judge and certainly within twenty-four hours. Certain practices under which authorisation is always sought from the judge prior to confinement, including in emergency cases, are deemed to be contrary to law and, if as a result of the delay caused by such action harm is sustained by the patient or a third person, could give rise to liability.
There is no stipulation as to who must notify the judge of the emergency confinement. Logically, it should be the physician who has taken the decision or the director of the centre of confinement, since they are the ones that actually deprive the patient of his freedom (and who may be held liable for unwarranted confinement). Moreover, since the ultimate aim is to help the patient, a suitably-qualified person should be the one to weigh up whether emergency confinement is called for.[12] Notification must include details of the interned patient, the circumstances surrounding and leading to the decision, and the reasons substantiating the request for confirmation by the judge of the measure taken. It must also include an estimation of the foreseeable length of stay, where this can be predicted in the short or medium term. Although the Civil Code does not state explicitly who can take the initiative to request emergency confinement, what is relevant is not that aspect (it could be anyone)[13] but the decision of the hospital to admit the mental patient on the grounds of emergency.
The judge shall authorise or refuse authorisation in accordance with the procedure of voluntary jurisdiction provided for in the Criminal Procedure Code (regrettably, the Code does not stipulate a time-limit within which the request must be dealt with). The judge shall give his decision after 1. examining the person concerned, thus giving the latter the opportunity to express his opposition to confinement;[14] 2. hearing the opinion[15] of a medical practitioner appointed by the judge himself. Although it is not specified in the law, the practitioner shall not be the one(s) who ordered confinement and presumibly notified the judge to that effect (and enclosed the corresponding report). In this way the impartiality of the opinion of the

practitioner designated by the judge shall be guaranteed.[16] The judge shall also notify the circumstances to the public prosecutor's office, which shall take the necessary steps to have the internee certified as being incompetent, where grounds exist to do so, in accordance with the provisions of article 203 of the Civil Code (article 211.2), particularly where confinement is expected to be lengthy, in order that the interests of the patient may be safeguarded (by appointing a guardian).[17]

Once confinement has been authorised, the judge is obliged by law to *review the situation of the internee*. This is one of the most important guarantees laid down in current legislation. He shall gather information regarding the need to extend the period of confinement when he considers it appropropriate and at least every six months; every six months also he shall examine the internee again and seek the opinion of a practitioner whom he himself shall appoint. He shall then give a ruling on whether treatment should be continued or ended (article 211.3). This form of personal monitoring by the judge is independent of and cannot be replaced by the information on the situation of the incompetent patient which the guardian is obliged to submit annually to the judge (article 211.3 and 269.3).

Clearly, the *ending of confinement* may be authorised by the judge after his (at least) six-monthly review of the situation, at which time he is legally obliged to take a decision one way or another. However, and although the law does not say anything to that effect, we consider that there is nothing to stop the physician who is treating the patient[18] (or one working in the special training centre) from ending confinement between judicial reviews, either of his own initiative or at the request of the patient or his family,[19] if it is considered appropriate from the point of view of care and if the medical reasons for confinement no longer exist. The decision must be notified to the judge, in view of the latter's role as guarantor and person responsible for reviewing the patient's situation. However, there is nothing in the law which states that release of the patient must be authorised by the judge beforehand, unlike the case of a mental patient who has been confined by a criminal court in connection with the commission of an offence (article 8.1 paragraph 2 of the Penal Code). The judge can, however, under article 211.3, review the physician's decision although this is only possible when he is asked to order further confinement by those entitled to request the confinement of the patient if they disagree with the physician's decision.

C. Intervention by Next-of-Kin and Guardians

166. Still in the hypothetical cases outlined above, if the next-of-kin or persons close to the patient are available (as indicated by article 10.6.b of the General Health Law) they shall give consent on behalf of an unconscious patient, save where he has already been certified as being incompetent and has a guardian, in which case consent should preferably be given by the latter, even though this is not actually mentioned in the aforementioned law;[20] however, the preference of the guardian is not exclusive, or, put another way, if the guardian is not available, next-of-kin or other persons close to the patient may decide. If the patient is conscious but (legally or de facto) "incompetent" to take decisions, the same procedure shall be used for organic illnesses, both for admission (clearly, the guardian does not need a judge's permission to intern the patient in anything other than a psychiatric unit or special training or education centre, article 271.1 of the Criminal Code) and for treatment. Lastly, where confinement is necessary to treat mental illness, the procedure to be followed shall be that laid down by the Civil Code for involuntary internment of a (conscious or unconscious) patient, as described above.

III. Involuntary Non-Urgent Admission and Treatment

A. Treatment of Organic Illnesses

167. In non-urgent situations where treatment is necessary, and if the patient is not competent to take decisions, the physician should seek consent from the guardian, next-of-kin or persons close to the patient (article 10.6.b of the General Health Law). This should be understood as

referring both to unconscious patients and also supposedly incompetent persons or ones who have already been certified as being incompetent. As was stated above, these rules are valid for general interventions or medical treatment where confinement is not realted to the cause of incompetence, that is, cases not involving persistent physical or mental deficiencies or illnesses which prevent the person from acting on bis own behalf (article 200; as inferred from article 211 of the Civil Code).

B. Treatment of Mental Illnesses

168. Where the aim is to detain a supposedly incompetent person against his will (in a psychiatric hospital or other health-care institution in order to treat the illness which has caused the incompetence) and the case is not of urgent necessity, the patient's next-of-kin should apply beforehand to the judge for authorisation for detention, in accordance with the conditions and procedures laid down in the Civil Code (article 211.1, referred to above).

169. To sum up, consent to treatment need not always be given by the person who takes the decision regarding admission or detention. Under normal circumstances treatment decisions shall be taken by the next-of-in or persons close to the patient or by the guardian where appropriate, while decisions concerning detention shall be the responsibility of the judge. This separation of powers might well place the physician in a curious position if, for example, a judge authorises detention but the next-of-kin do not give the go-ahead to the treatment proposed by the physician.[21] On the other hand, doubts surround who should consent to treatment when a judge has ordered the detention in a psychiatric institution of a deranged person who has committed an offence; in principle, consent would be given by the next-of-kin, because the rights recognised by the General Health Law apply to "the different public health-care administrations" and also "private health-care services" (article 10, first and last paragraphs).
In any case, the legal authorities may intervene in treatment-related disputes or conflicts concerning respect for the wishes of the patient when, in spite of his illness, he is competent to give consent. A similar situation may arise also where a judge orders detention (which presupposes that the internee cannot act on his own behalf) but the patient refuses the proposed treatment, if at that time he has sufficient capacity to understand the nature of his decision.

§ 3. The Dying Patient

170. Where a patient is terminally-ill, that is, on the verge of death, the physician is faced with two questions: how far should he go in taking curative or symptom-relieving measures without breaching his duties or bringing forward death in a punishable way? Secondly, how should he appraise the wishes of his patient, in particular when the latter decides (where he is in a position to do so) to refuse all forms of treatment, including life-saving treatment?

I. Treating a Dying Patient

171. With terminally-ill patients who are close to death, the most relevant duties of health-care professionals and staff of health-care institutions are to provide moral assistance and help them die in a dignified manner, without discriminating against them by basing treatment on the possibility that they will recover. Particularly humane treatment is an absolute must in such circumstances, and every access must be given family members and to persons who can provide the spiritual help corresponding to the patient's religious beliefs. The patient must also be allowed to take decisions relating to his material interests (work, property, last will and testament), and even to be discharged if he so wishes, and where his condition and family circumstances so warrant, so that he may return home and die in the company of his loved ones. All these measures derive from his rights as a patient. When no treatment can bring about improvement or recovery, helping the patient die properly without shortening his life (through the use of drugs or other means to alleviate his state of helplessness) is not only lawful[22] but is

also one of the physician's duties. It has been said that breaches of this duty by a physician could even lead to an offence of failing to fulfill the duty to provide help (article 489 ter of the Penal Code).[23] This type of treatment, and others which are not merely designed to relieve symptoms, may also be provided in special centres or units to patients who suffer terminal illnesses (such as cancer).

172. Generally-speaking, the giving of drugs or other pain-relieving measures which entail a negligible and unintended shortening of the patient's life (known as indirect euthanasia) is considered lawful, as is the gradual increase in doses of certain painkillers (morphine for instance) when the patient's body becomes increasingly insensitive to them, even where the increased doses risk depressing the respiratory apparatus to the extent of causing failure. In such cases no offence of wilful homicide shall exist, because the author's intended purpose is not to shorten the patient's life but rather to alleviate his suffering. Although some would argue here in favour of possible intentional homicide,[24] ie that the physician foresees that the result —bringing forward of death— may occur but continues anyway, we consider that it should be ruled out given that in truth the physician is not really allowing for that eventuality but is taking the necessary steps to relieve pain, without at the same time shortening the patient's life in a manner which might be determined causally.

173. Possible negligent homicide, where the result was foreseen or at the very least foreseeable, shall depend on whether the physician has complied with his duties of objective care and stayed within the limits of permissible risk, in accordance with how a judicious colleague would act in similar circumstances.[25] This conduct is determined by subjecting the physician to the requirements of the indication of the therapeutic measure and of *leges artis*. Treating pain is without doubt one of the functions of medicine, as attested by the existence in some hospitals of pain units whose specific job is to treat pain in extreme cases and also by the creation of hospices. Consequently, the judicious giving of drugs or use of equipment to control or alleviate pain in terminally-ill patients does not entail a breach of the duty of objective care, nor does the eventual shortening of life constitute a punishable offence of negligence.[26] Bear in mind also that although it is possible in theory, in practice it is extremely difficult to determine precisely this shortening of life. The most viable solution, in our opinion, would be to consider that in cases such as the above the physician is exculpated on the grounds of the state of justifiable necessity, in that the *risk* of shortening the patient's life is of less significance than the *effective* and necessary relief of pain. Our view is shared by the current Code of Medical Ethics (1990), which states in article 28.2: "when dealing with incurable and terminal illnesses, physicians should limit themselves to alleviating the patient's physical and moral pain, and insofar as possible maintain the quality of the life which is about to end. Physicians should avoid commencing or continuing hopeless, useless or obstinate therapeutic actions. They shall assist such patients to the end, and observe the respect due of human dignity".

II. Respecting a Patient's Wishes Regarding the Cessation of Treatment

174. If a patient asks his physician to suspend or discontinue treatment his wish should be respected, particularly where recovery is completely ruled out. The question arises here of whether the physician may be liable for omitting to give treatment, a situation which has been raised in connection with so-called passive euthanasia. Where there is no hope of recovery the patient's wishes can be said to pose no problems whatsoever. However, where treatment is crucial to keeping the patient alive during the (pre)terminal phase of his illness, and death is not imminent, and where failure to give the treatment will accelerate the process, the answer is rather more complex. We stated above,[27] that the patient is entitled to refuse treatment, although in this regard the General Health Law imposes a series of restrictions where the right is not enforceable, for example, where public health is placed at risk, where the patient is incompetent to take decisions, and where treatment is so urgent that delay might cause irreversible injuries or entail risk of death (article 10.9). The first two restrictions are self-

explanatory, unlike the third which is ambiguous[28] and might be construed as suggesting that life-saving treatment cannot be refused. It also raises problems concerning the duty to protect the patient's life in certain circumstances, some of which have already been examined above[29] and are affected also by the arguments which we shall look at now.

175. Article 15 of the Spanish Constitution is crucial to this issue. It states that "everyone has the right to life and to moral and physical integrity; under no circumstances can any person be subjected to torture or to inhuman or degrading punishment or treatment (...)". Clearly, then, life is the basis on which the exercise and enjoyment of all other rights to which human beings are entitled rest, and this circumstance justifies the special protection afforded to life in our legal order. It does not need to be stressed, therefore, that the scope of protection extends to all individuals, particularly those in a critical situation or who are at a disadvantage: incurable or terminal patients, invalids, the elderly, mentally-ill or mentally-deficient persons. The provision poses several problems of interpretation, some of which have been resolved by the Constitutional Court's ruling[30] on an appeal lodged by prisoners who went on an indefinite hunger strike until the prison authorities met their demands. Of most interest for our purposes here is the question of whether or not there exists a constitutional right to do as one pleases with one's own life, an issue which has a direct bearing on the lawfulness of euthanasia and refusal to accept treatment on the grounds of religion or conscience or for other personal reasons. A great deal of debate surrounds this highly complex and controversial grey area and the entire constitution needs to be examined in order to arrive at a satisfactory answer.
To begin with, it cannot be inferred from article 15 of the Constitution alone that a person is entitled to do as he pleases with his own life, since the provision serves first and foremost as the guarantor of the right to life. Neither does it empower third persons to intervene in the lives of others.[31] However, precisely as a result of this role of guarantor (vis à vis the State and third persons), it cannot be inferred either that there is a duty to live against one's wishes, that is, that the State's obligations allow it to intervene when someone has expressed his desire not to carry on living. Lastly, a re-reading of article 15 in the light of the superior value of freedom (article 1.1 of the Constitution) and of respect for human dignity (article 10.1) leads us to conclude that the absence of a duty to live against one's wishes becomes not a right but rather the freedom to do as one pleases with one's own life. A further conclusion to be derived from this is that a physician cannot continue to treat a patient against his wishes, even if this means that his death will be hurried along.

176. Thus, to discontinue or interrupt treatment of a person who has no objectively-determinable prospects of continuing to live does not run contrary to the notion of the dignity of the person. Rather, the exact opposite is true. To do otherwise could well be tanatamount either to using the patient as an instrument for the physician's own interests or even to unnecessary and aggressive treatment ("acharmenement thérapeutique"), in violation of the ban on inhuman and degrading treatments (article 15 of the Constitution), which in turn is a specific violation of human dignity.[32] The Constitutional Court ruling of 27 June 1990 (legal principle no.9) states that no torture or inhuman or degrading treatment exists "where authorisation is given for medical intervention, such as that challenged by the appellants [force feeding], which in this case was not ordered to inflict physical or mental punishment or to cause harm to the integrity of those subjected to the treatment, but rather to prevent where medically possible the irreversible effects of voluntary starvation and to mitigate or lessen the harm caused to the body". The ruling goes on to state that "the fact that force feeding, aimed at preventing the deaths of the appellants, cannot be deemed as constituting inhuman or degrading treatment due to the nature of the goal pursued, does not mean that it may not be considered as such, due to the means used to achieve this goal or in the sense that it prolongs suffering without in the process managing to prevent death". It may be deduced from this that adequate treatment to maintain life is neither inhuman nor degrading, which is not the case when it serves only to prolong suffering without preventing (but merely delaying) death.

177. In the light of the above considerations, the General Health Law, where it does not

recognise the right to refuse emergency treatment when delay might cause irreversible injuries or entail risk of death (article 10.9), should be interpreted in the restrictive sense, ie that intervention by a third party may be ruled out if the patient does not wish to continue living. The Constitutional Court would appear to share this view when it rules that "one thing is the decision of the person who assumes the risk of dying through an act of his own volition which affects him and him alone, in which case it could be held that compulsory medical assistance or any other means of preventing the fulfilment of this wish is unlawful; however, a totally different case is that of persons who in a special context of imprisonment...". "Thus, this constitutional right [to physical and moral integrity] shall be affected when medical assistance is imposed upon a person against his wishes, which may be based on a variety of reasons and not just a desire to die; coercive medical assistance shall, therefore, constitute a restriction which vulnerates the fundamental right, unless justification for the assistancecan be found in the Constitution".[33] A revised constitutional interpretation of the aforementioned General Health Law provision (article 10.9) would imply that even in this case refusal of treatment is possible, and that the exception included in the law refers only to cases in which the patient is unable to give consent (eg an unconscious patient) and his next-of-kin or persons close to him are unavailable to give it on his behalf; thus, in view of the situation of life-threatening danger (or irreversible injuries) treatment is proceeded with without first awaiting the consent that would otherwise be required. Put another way, and in criminal law jargon, the physician may intervene because he is legally protected by the existence of a situation of necessity (and is thus covered by article 8.7 of the Penal Code).

III. Euthanasia

A. Lawful Conduct in Relation to Euthanasia

178. Earlier, in discussing the terminally ill, we outlined the requirements governing the actions of physicians in such situations. These may include the administration of drugs that may, as a side effect, reduce the lifespan of the patient (indirect euthanasia). This would not constitute an offence so long as the physician acts in accordance with *lex artis*. It was even argued that the doctor should respect the patient's decision to discontinue treatment, a situation that brings us into the realms of what is known as passive euthanasia.

179. *Passive euthanasia.* Passive euthanasia raises extremely complex issues. What is crucial from the criminal law perspective is the prior establishment of the different 'acts' (omissions) which entail passive euthanasia. Unfortunately there is disagreement in the literature as to where these limits lie.

180. In the first place we must identify, delimit and legally appraise the concept of orthothanasia, which, while similar in certain respects to passive euthanasia, has a completely different meaning. The word orthotanasia means "justified death in the sense of death that occurs at the right moment".[34] Orthothanasia, therefore, consists in the "cessation of special treatments intended to revive the incurably ill when in a state of profound irreversible coma, in the terminal phases of an illness, those whose lives are being maintained artificially or who are on the point of death" (Roskam). Orthothenasia is clearly lawful in the situation where the patient has died though some bodily functions continue because they are artificially maintained by machines that control respiration and circulation. These are patients who have suffered brain death (irreversible lack of all functions from the brain stem) who can remain in the same condition almost indefinitely. Disconnecting machines or mechanisms or discontinuing treatment (medication, intravenous feeding) does not constitute homicide in the eyes of the law, given that the subject is clinically and *actually* dead.

181. *Disthanasia* is another neologism with the opposite meaning to orthothanasia. It means (from the Greek *dys*, bad, anomalous and *thanatos*, death) 'bad death', that is to say

prolonging the natural course of death — rather than life — by all available means despite the fact that death is inevitable in the circumstances. This is something that arises chiefly in hospitals as one of the negative consequences of the constant progress made in the biomedical sciences. At the same time as achieving spectacular results with patients who would have been considered beyond help in the not to distant past and thus improving considerably the life expectancy of the population as a whole, the biomedical sciences have made it possible to delay death, which can imply prolonging the pain and suffering of the patient. This is a clear instance of how the advantages and disadvantages of technical progress are not always under our control. Awareness of these situations, with the enormous economic burden they imply for the families concerned and for the community, and the unlikely prospect of a change in the patient's condition or prognosis, has led to justifiable anxiety at the risks of medicine becoming excessively technical and of *unnecessary therapeutic cruelty* to the patient. This awareness, in turn, has led to greater sensitivity towards what is often termed 'the right to die with dignity' or 'the dignity of death'.

Beginning or continuing treatment when it is no longer called for because there is no realistic hope of the patient's regaining consciousness, demonstrates at the very least a serious lack of respect for the dignity of the human being, since it amounts to simply delaying death. It is also, therefore, a serious violation of a basic legal principle and limitation of positive law[35] which is explicitly recognised in our Constitution art. 10.1).[36] For this reason it has been rightly contended that such actions constitute "inhuman and degrading treatment", explicitly prohibited by the Spanish Constitution in art. 15.[37] Respect for human dignity is applicable also to the death of the individual, although it can often prove somewhat complex. It might be deemed indignant (subjectively-speaking) to subject the patient to artificial means or machinery which serve an objectively therapeutic purpose, although such an approach, if adopted, would considerably lessen knowledge of the ways and means that medicine can combat disease and death. If there is something that identifies the science of medicine and sets it apart, it is precisely this capacity to alter the course of nature in our favour. On the other hand, dying with dignity can also be understood in the sense of an individual who withstands physical pain and moral suffering and is able to rely on others (the doctor, the family) to do everything possible to fight death, even in hopeless situations where the prognosis is grim. This positive view of life should also be respected. Nevertheless, prolonging the life of the person when it is not in his interests to do so or assisting him to die, would amount to an offence in cases where the decision is not based on ethical principles, but for the economic benefit of the family, the health care system or for political or other reasons.[38]

The primary purpose of medicine continues to be health care, which implies preserving and prolonging human life, but this does not mean that suffering should not be alleviated or eliminated, as we said above.[39] Nevertheless, the doctor's duty of care is limited to the obligations imposed by *lex artis*; *lex artis* in fact demands that all treatment and any artificial measures to prolong biological life that are unnecessarily cruel should be discontinued where there is no rational reason to believe that the patient might recover (excluded from this of course are palliative measures to alleviate pain that are appropriate in the circumstances). Meeting these demands would not, therefore, constitute a punishable omission. This is worth clarifying and underlining.

In accordance with this function, fulfilment of the duty of care for the doctor is limited, (*limitations of the duty of care*) as are all legal duties to act, to circumstances in which effectively prolonging life — not death — is practicable from the outset. The treatment must imply objective and rational possibilities of recovery. This is not the case, for example, of individuals in irreversible comas who will not regain consciousness because the reactivation of cerebral function is not possible, even when the situation arises as a result of a substantial deterioration in the patient's condition. The same goes for newborn infants with incurable abnormalities that will inevitably result in death in the short term. It is even less the case if there is some other pathological condition that occurs jointly with the abnormality or illness in question. Once the situation has been recognised, it is irrelevant for the criminal law that the decision involves the cessation of treatment with drugs, non-performance of a surgical operation or the switching off of any machines that are maintaining vital functions.

B. Juridico-Penal Evaluation of Strictly Passive Euthanasia

182. What remains therefore of passive euthanasia in the strict sense of the term and what is its legal position in the eyes of our positive Law? It is from this point onwards that the wishes of the individual concerned become relevant (and the issue more disputed). If the patient himself refuses life-saving treatment, however, the law recognises his right to do so, as we said above.
Withdrawing treatment from a seriously-ill patient where the *possibility of survival* still exists, even though the quality of life will be worse than prior to the illness or accident that has led to the condition (e.g. hemiplegic patients, non-terminal cancers, non-terminal kidney failure) constitutes legally punishable passive euthanasia if the patient has not given his consent, even where death is foreseeable in the long term. In such cases it does not matter if the person's life is being maintained by means of machines (respirators, pace-makers, kidney machines etc.). The criminal law's response is to consider such cases as unlawful homicide (or murder or parricide depending on the circumstances) committed by omission, since the physician is in a position to guarantee life in such cases, as we shall see below, and has not been relieved of this responsibility by the patient giving his consent. This position as guarantor is a necessary condition for homicide by omission to exist. However, accurate apparaisal by the criminal law requires further consideration of the nature of the physician's duty of care in such cases. If the physician has breached his duty, liability may arise, but not otherwise.
The legal duty of care occurs (*source of duty of care*), in principle, when the person wo treats the individual in need of treatment has a special relationship with this person, a relationship known literally as 'a position of guarantor'.[40] This is to be understood as the situation of vulnerability that arises in relation to the legally protected interest (in this case, the patient's life) as a result of the special relationship created between the physician and the legal interest. The vulnerability of the life or health of the patient is the result of his submitting to treatment, from the point when the patient or his representatives cease to avail themselves of the services of all other doctors apart from the one treating the patient. Once the position of guarantor has been established it follows that a duty of care exists. To establish the limits of this duty of care the wishes of the patient must be taken into account. If the doctor wishes to begin or continue a treatment but the patient is opposed to this, the doctor is not obliged to act in all cases. In fact, the LGS recognises the right of all who avail themselves of the public and private health care services "to refuse treatment, except in those circumstances indicated in section 6. Patients refusing treatment shall request voluntary discharge in accordance with section 4 of the following article" (art. 10. sections 9 and 15).

183. There are two objective criteria that may help those concerned decide how to act in such circumstances. The first of these is from the patient's point of view (as we shall see, it is in reality an objective-subjective criterion), the second is from the point of view of the doctor.

1°. The appropriateness or lack of appropriateness of a treatment or operation depends primarily on whether or not it is necessary from a therapeutic perspective, that is to say, once the possible risks and advantages that the treatment involves have been weighed up. The more delicate the patient's health, the greater the risks entailed and the lack of certainty with regard to outcome. This means that its therapeutic indication is reduced accordingly, and the treatment becomes elective. The weighing up of the therapeutic indication of the treatment corresponds to the physician who shall base his decision on his scientific and technical knowledge; however, the actual taking on of the risk must always rest with the patient regardless of the seriousness of the illness (all the more so when the illness is serious and prognosis uncertain). The patient is entitled to refuse treatment, even vital treatment, if the risks are very high and there is no guarantee of improvement. The physician's decision is an objective evaluation, which should be arived at without taking the patient's ulterior motives into account, since these may influence the objective considerations. For example, the patient may wish to die so as to put an end to the suffering caused by the illness or to refuse a blood transfusion for religious reasons (however,

let us just suppose that there is good reason to believe that the blood is contaminated by some pathogen: the hepatitis virus or HIV. This would constitute an objective fact with regard to the indication, in this case, a contraindication), etc.. In a wider context, and as has been recalled above, the doctor must not use professional regulations or superior knowledge (principle of paternalism) as grounds to decide what is best for the well-being of the patient. It is the patient who is best able to decide with respect to the risks he is willing to take (principle of autonomy or self-determination).[41]

184. Beginning, continuing and extending treatment is obligatory only when there is a possibility that the physician (or to be more accurate, medical science) can bring about a cure. In the light of the patient's condition, if this is not possible and it has been established thus in accordance with the criteria of *lex artis*, there is no duty to treat the patient (aside from palliative measure to counteract pain and suffering). This would be the case in the terminal phases of an illness for which, by medical standards, no effective treatment exists. If, on the other hand, there is some chance of improvement or of the patient's regaining consciousness (or of this occurring at a later stage of development in the case of newborn babies) the obligation to treat the patient holds good, and if it is not fulfilled the physician risks prosecution for homicide by omission (art. 407 of the Penal Code), provided that the position of guarantor exists. All these considerations are particularly relevant in cases where the patient cannot express his wishes for whatever reason (comatose state, newborn etc.), although similar criteria apply also when the family and legal representatives act on the patient's behalf, in accordance with the terms of the LGS (art. 10 n°6, b).

185. *The living will.* The Spanish Law makes no reference to the validity or effect of a 'living will' (known also as biological or euthanasic will), but neither does it expressly prohibit such a thing. In fact the Spanish Association for the Right to Die with Dignity ('Asociación Derecho a Morir Dignamente') and the Spanish Episcopal Conference have drafted a model for this type of declaration (even though the objectives it might seek to fulfil are many and various), which leads one to suppose that in the future physicians may have to confront the issue of how to act legally in response to such a document furnished by the patient or his legal representatives. There are two fundamental issues to resolve: the validity of advance directives stating the patient's wishes, and, secondly, the validity and scope of the contents, that is to say, whether or not one can refuse life-sustaining treatment in writing (as is the case of biological wills).

To take the first issue, the main argument that is usually raised against recognising the effectiveness of such directives is that the individual's feelings and state of mind frequently change when they are confronted by a life threatening situation. People often subsequently question their reasons for signing a document refusing treatment, though this in no way implies that they made the declaration lightly. The psychological state of a healthy person is very different from that of someone faced with death and it should not be forgotten that this is very special type of statement of wishes is particularly susceptible to subjective changes. At the critical moment, it is argued, the person often changes his mind and 'clings' to even the remotest chance of survival. Clearly, this is a very delicate issue, which affects the validity of any consent given in the document in so far as the signatory cannot appreciate fully the specific circumstances in which the advance directive might be implemented. However, the difficulty only arises when the patient is unconscious (this is where the crux of the issue of how to act in such situations lies), since a conscious patient can confirm or revoke the contents of his directive. Factors which condition the patient's ability to express his free will should always be taken into account, in the same way as they would be in any request for the cessation of treatment (depressive states, mental confusion caused by the illness itself, a sense of uselessness or of being a burden on others, etc.). In this regard it is indicated that even when the patient is unconscious the validity ('authenticity') of the document has to be accepted if it is seen to be coherent with the patient's value system and general attitude to life, particularly in the period immediately preceding the illness. Starting from the hypothesis that recognises the patient as being capable of making a decision, there should be no obstacle to also accepting the

declaration as valid, so long as there are sufficient guarantees that it was produced soberly and after a period of reflection. The hypothesis as to the patient's change of mind at the vital moment still holds good, but in this case, since the patient is unconscious there is no way of knowing whether such a change of heart has indeed occurred.
Therefore, the other question still remains: should these documents be considered valid when the patient has lost consciousness? The answer is conditioned by the legal recognition of the patient's right to forego life-sustaining treatment. As we have said earlier, such a right is compatible and coherent with Spanish law.
Even so, all possible precautions must be taken at the time that the directive comes into effect and any real doubt should be resolved in favour of continuing the treatment: *in dubio pro vita*. For example, validity should not be accepted if the person is overcome by mental illness after making the declaration and later falls ill or is seriously injured in an accident. In such a case we would not have sufficient information at hand to be certain as to his wishes or whether or not he would still have agreed with the instructions if he had not become mentally ill. In brief, if all the above-mentioned precautions have been satisfied, the same force should be given to so-called 'biological' wills as to any declaration made at the moment in which the decision to continue or discontinue treatment is taken, so that the physician who chooses not to intervene out of respect for the patient's wishes as expressed in the will could not be accused of unlawful passive euthanasia. In any case, the value of advance directives as an indication of the patient's wishes should not be underestimated.

C. Active Euthanasia

186. Direct active euthanasia is always punishable. If the patient has asked that the act be performed (only a conclusive statement from the individual concerned to the effect that he wishes to die will make the person who performed the act a mere accessory), the individual who performed the act should be punished as an accessory to suicide,[42] even when this person is a member of the family, in which case the crime of parricide (which applies in principle when one kills a parent, child or spouse), which carries a heavier penalty, is not applicable.

187. If, on the other hand, the patient did not consent because he was unable to as a result of his condition (unconsciousness due to a somatic illness, mental illness or deficiency, age), or was opposed to the act (a situation in which it would be difficult to imagine anyone committing homicidal euthanasia) or simply 'allowed it to happen' (a completely passive attitude), the act falls within the bounds of wilful homicide or, most probably, murder, because it is considered that there is premeditation — one of the necessary conditions for murder — when one takes the life of a helpless and defenceless person. The Criminal law responds to such cases with uncompromising force, and the Penal Code imposes its maximum punishment for the crime of murder.

D. Premature or Neonatal Euthanasia

188. There should be no difference between paediatric medical practice and medicine applied to adults and, as a result, the legal responses (or lacunae) should not differ greatly. The life of a child is worth just as much as that of an adult. Nevertheless, when the patient is a child or newborn infant there are specific aspects of such complexity that they make it difficult for the law to provide a clear-cut response. One of these is that in some cases it is not possible to know the child's wishes or preferences, since the child simply lacks wishes or preferences, which develop with age.
What we must clarify first of all is what is meant by the expression 'premature euthanasia'. In fact the expression itself is inappropriate as it does not refer to euthanasia in the strict sense of the word, which is what we have been discussing up until now. It does not concern helping someone who is suffering to die, but the elimination, by action or omission, of newborn infants (hence the term 'premature') who are viable, but who are seen to have deformities or serious brain damage. Such actions are in all probability eugenic, involving the elimination of

beings who are devoid of 'valuable life', against whom the law does not discriminate (it could not do so), as we shall see further on. Furthermore, the right to life most definitely comes into play here, but not (for obvious reasons) the right to do as one pleases with one's life —or death— given that at the end of the day third parties and not the newborn baby take the decisions.

189. Direct active euthanasia of a newborn infant attracts the same firm legal response as its adult counterpart, with the difference that consent is not an attenuating factor in the homicide, murder or parricide of the newborn infant.

190. When it comes to the failure to provide treatment to a newborn infant with serious abnormalities, the same situation arises and the same problem occurs as with adults, particularly those who are in a comatose state. Once again it is necessary to establish the limits of a duty of care or a duty not to treat. The abnormality itself must not constitute the main reason for making the decision as it is irrelevant as an excuse before the law. A duty of care is maintained in principal and what should influence the doctor's decision is the child's life expectancy. Clearly this is where disagreement may arise.

191. We can distinguish a body of proposals that emphasise the child's future capacity to relate to others. Those who hold this view ask whether we should demand that the child be kept alive when the abnormality is irreversible and so serious that there is no chance of him being able to perceive and communicate.[43] The German Society for Medical Law (DGMR) has proposed a series of Recommendations (*Einbecker Empfehlung*) of which the following deserve mention: the following are cases in which the doctor should not continue treatment: a) when lasting life cannot be maintained and it is simply a question of delaying certain death, b) despite treatment any possibility of the newborn child ever communicating with its environment has been discounted and c) when the child's vital bodily functions can only be maintained in intensive care facilities.[44]
Other experts focus only on the child's chances of improvement, while also considering the disproportionate nature of the relationship between the effort involved and the suffering caused. This perspective has the advantage of reducing to reasonable dimensions the question of evaluating quality of life and therefore seems more manageable. We have emphasised throughout that children and adults should be treated equally and in the case of children the risk of causing additional suffering should be weighed up against the possible results of the treatment. It is thus held that there should be no intervention when there are multiple injuries and where the treatment will only cause suffering without actually stabilising the health of the child. The Department of Health and Human Services in the United States (DHHS) has set out the following circumstances as being situations in which feeding or medical or surgical treatment should not be provided: 1. if the newborn infant is in a chronic or irreversible coma; 2. when the treatment would only prolong the inevitable process of dying, would not be effective or would not overcome or correct the life threatening situation and plays no role in the survival of the foetus; and 3. when, apart from the other two sets of circumstances, the treatment would be inhumane.[45]

E. Attenuation of or Exemption From Criminal Liability in Punishable Euthanasia

192. In the first place, we can conclude that the *consent* of the individual concerned is not sufficient basis on which to ground the lawfulness of direct active euthanasia, though it is enough for treatment refused by the patient, even vital treatment, to be discontinued. This is particularly so when discontinuing the treatment does not imply any immediate risk to the patient's life or when the treatment itself involves additional dangers that the patient is not willing to face.
Nevertheless, consent does have certain attenuating effects on the unlawfulness (or wrongfulness) of the act, given that without consent the act would in some cases (active euthanasia for instance) constitute murder or parricide. This would not, however, appear to be

a satisfactory solution, for example, when euthanasia is practised by the mother of the newborn infant. In fact, in this case the courts would convict the mother of parricide despite the fact that the blood relationship between the mother and child should be deemed an attenuating circumstance and not an aggravating factor (as is the case with parricide), given that an act of euthanasia carried out in favour of a member of one's family seems less deserving of reproach. Despite the altruistic motive of compassion — not, it should be said, merely the desire to dispense with the economic and emotional burden of having an abnormal or seriously ill child — this family relationship is seen as an aggravating circumstance. Killing a healthy child with the intention of concealing an unwanted pregnancy, which is after all a selfish motive[46] and is compatible with 'cold calculation',[47] constitutes the crime of infanticide (art. 410 of the Penal Code), which carries a much lighter penalty.

193. The *motive of pity or compassion*, which is an altruistic characteristic that generally holds true for the forms of euthanasia analysed here, makes the act criminally less deserving of reproach when the motive can be clearly demonstrated, regardless of whether or not the act was requested by the victim. The basis for this attenuating circumstance is the temporary reduction of the mental faculties of the person who acts under the emotional strain and distress of watching the other person suffer[48] (circ. 8ª art. 9º),[49] especially when the person is a family member, a friend or close acquaintance. The same applies also to altruistic motives even when no significant distress exists (e.g. a doctor or nurse), in which case the attenuating circumstance is applicable by analogy (circ. 10ª art 9º).[50] Both attenuating circumstances, according to the case, qualify the offence considerably and can lead to a substantially lighter sentence (one or two degrees); thus, for example, the penalty for being an accessory to suicide, which is twelve years and a day to twenty years imprisonment, may be cut to a sentence of up to six months and one day in the most favourable circumstances. In such cases the court may then opt for a suspended sentence or remission (a suspended sentence means that any period of imprisonment is suspended).

194. In extreme circumstances *incomplete exemption* from criminal liability may be considered, once more based on the diminished mental faculties of the accused, as is the case of incomplete temporary mental breakdown (circ. 1ª art. 9º, in relation to nº1 art. 8º of the Penal Code).[51] It has even been argued[52] that it is possible — though rarely and only where the relationship between the two individuals is particularly close — that the mental disturbance may be so complete at the moment of performing the act — or omission — of euthanasia, that the defendant is unable to comprehend the unlawful nature of his conduct or to act in accordance with his comprehension. In this case, the criminal law would not attach blame to the person for his unlawful act and would completely exonerate him from punishment (nº 1 art. 8º of the Penal Code).

NOTES

1. Articles 338 bis and 576 of the Civil Code, and 262 of the Criminal Procedures Code. See Part II, Chapter I, § 4.

2. Law on the Removal and Transplantation of Organs of 27 October 1979, article 4, a and b.

3. See Second Additional Provision of the Law of 27 October 1979, and Second Final Provision of the Royal Decree of 22 February 1980.

4. Royal Decree 1854/1993 of 22 October (art. 6.1), regulating minimal conditions for Blood Donations and Blood Banks.

5. Article 5.2 of the Ministerial Order of 3 August 1982, which develops the Royal Decree of 14 April 1978 governing clinical trials on human beings of pharmaceutical products and

medicines. See also article 60.6 of the Drugs and Medicines Law 25/1990 of 25 December, and Chapter 3, § 7 below.

6. In this regard see L. ARROYO ZAPATERO, 'Los menores de edad y los incapaces ante el aborto y la esterilización', in *Estudios Penales y Criminológicos,* t. XI (Serv. de Publicaciones de la Universidad de Santiago de Compostela, Santiago de Compostela 1987), pp. 14 and 23; A. CUERDA RIEZU, 'El delito de aborto ante la Propuesta de Anteproyecto del Nuevo Código Penal', cit., p. 377; J.L. DIEZ RIPOLLES, 'Análisis de los elementos de la causa de justificación del art. 417 bis del Código Penal', in *Comentarios a la Legislación Penal, t. IX (La Reforma del delito del aborto)* (Edersa, Madrid 1989), pp. 237 f; D.M. LUZON PEÑA, 'Indicaciones y causas de justificación en el aborto', in *Cuadernos de Política Criminal*, n. 36, 1988, p. 637; C.M. ROMEO CASABONA, 'El diagnóstico antenatal y sus implicaciones jurídico-penales', in *La Ley*, vol. 3, 1987, p. 813.

7. See ARROYO ZAPATERO, 'Los menores de edad y los incapaces ante el aborto y la esterilización', cit., pp. 16 and 24; LUZON PEÑA, 'Indicaciones y causas de justificación en el aborto', cit., p. 637; J. DE-VICENTE REMESAL, 'El grave peligro para la salud psíquica de la madre en la nueva ley del aborto', in *La Ley*, 1985, p. 5.

8. Articles 5.6 and 6 respectively of Law 35/1988 of 22 November governing Techniques of Assisted Reproduction.

9. For a more detailed study see C.M. ROMEO CASABONA, 'El tratamiento jurídico del enfermo mental en el Consejo de Europa y sistemas de garantías en el derecho español', in *Actualidad Penal*, 1991, pp. 329 ff.

10. Circular n. 2/1984 from the Attorney General's Office acknowledges the validity of these voluntary admissions, although it expresses considerable reservations and urges caution concerning the persistent use thereof and the possibility that they conceal admissions made under duress.

11. S. GARCIA ZARANDIETA, 'Internamientos psiquiátricos', in *Privaciones de libertad y derechos humanos* (Ed. Hacer, Barcelona 1987), p. 50.

12. In this sense, see Circular n. 2/1984 of the Spanish Attorney General's Office. However, this does not mean that the judge cannot be notified of the confinement directly by the next-of-kin immediately.

13. See F. RIVERO HERNANDEZ, 'La capacidad de obrar y la incapacitación judicial' in *Jornadas sobre Psiquitría Forense* (Centro de Estudios Judiciales, Madrid 1990), p.245.

14. See Rulings of Supreme Court (1st Chamber) of 2 February 1988 and 12 June 1989 (commented upon by R. BERCOVITZ RODRIGUEZ-CANO, 'El examen por el Juez del presunto incapaz en el procedimiento de incapacitación', in *Poder Judicial*, n. 15, 1989, pp. 141 ff) for references to details of the examination used to determine incompetence; to a large extent the criteria may be extended to cases of compulsory confinement.

15. Notwithstanding the legal expression used, there does not seem to be anything to prevent a written opinion being given. See J.M. GOMEZ PAPI, 'El internamiento del enfermo mental', in *Jornadas sobre Psiquiatría Forense* , cit., p. 274.

16. S. GARCIA ZARANDIETA, 'Internamientos psiquiátricos', cit., p. 52.

17. R. BERCOVITZ RODRIGUEZ-CANO, 'La protección jurídica de la persona en relación con su internamiento involuntario en centros sanitarios o asistenciales por razones de salud', in

Anuario de Derecho Civil, 1984, p. 965; E. COBREROS MENDAZONA, *Los tratamientos sanitarios obligatorios y el derecho a la salud*, cit., p.389.

18. C.M. ROMEO CASABONA, *El Médico ante el Derecho*, cit., p. 53. The opposite view is taken in Circular 2/1984 of the Attorney General's Office, which considers that the decision must be taken by a judge.

19. There is another option open to someone who has been certifed as being incompetent: he could request a new court decision to annul the previous ruling that he was incompetent (articles 212 and 213), and this could have a bearing on his status as a patient and at the same time lead to authorisation of confinement to be withdrawn. See C.M. ROMEO CASABONA, *Peligrosidad y Derecho Penal Preventivo* (Bosch, Casa Editorial, Barcelona 1986), p. 185, note 480.

20. A similar opinion is held by F. BUENO ARUS, 'El consentimiento del paciente en el tratamiento médico-quirúrigico y la Ley General de Sanidad', in *Estudios de Derecho Penal y Criminología,* (UNED, Madrid 1989), p. 170.

21. In this regard see J.J. CARRASCO GOMEZ, *Responsabilidad médica y Psiquiatría* (Colex, Madrid 1989), pp. 181 ff.

22. M. BAJO FERNANDEZ, *Derecho Penal (Parte Especial). Delitos contra las personas* (Ceura, Madrid, 2d. ed. 1991), p. 96; J. BUSTOS RAMIREZ, *Manual de Derecho. Penal, Parte Especial* (Ariel, Barcelona 1986), p. 50; C.M. ROMEO CASABONA, 'El marco jurídico-penal en la eutanasia en el Derecho español', in *Revista de la Facultad de Derecho de la Universidad de Granada*, n. 13, 1987, p. 191.

23. A. TORIO LOPEZ, 'Instigación y auxilio al suicidio, homicidio consentido y eutanasia como problemas legislativos', in *Estudios Penales y Criminológicos*, vol. IV (Serv. Publicaciones de la Universidad de Santiago de Compostela, Santiago de Compostela 1981), p. 191.

24. Cf. E. GIMBERNAT ORDEIG, 'Eutanasia, Constitución y Derecho penal', in *Jano*, n. 920, 1990, pp. 987 f., who considers that the offence of participation in suicide (article 409, or omission of the duty to give help, article 489 ter., depending on the circumstances) exists, although he subsequently argues that there are grounds to justify such action and therefore the conduct should not be punished.

25. A. TORIO LOPEZ, 'Instigación y auxilio al suicidio, homicidio consentido y eutanasia como problemas legislativos', cit., pp. 191 f.

26. M. BAJO FERNANDEZ, *Derecho Penal (Parte Especial). Delitos contra las personas*, cit., p. 96; A. TORIO LOPEZ, 'Instigación y auxilio al suicidio, homicidio consentido y eutanasia como problemas legislativos', cit., p. 193.

27. In Part II, Chapter I, § 1.

28. F. GONZÁLEZ NAVARRO, *El Proyecto de Ley General de Sanidad (Informe Jurídico)* (Instituto de Estudios Económicos, Madrid 1985), p. 100; E. VILLANUEVA CAÑADAS, 'El límite del deber de curar', in *Los Derechos del Enfermo*, (Murcia 1987), p. 139 f.

29. See above, Chapter I, § 1.

30. Constitutional Court Ruling of 27 June 1990.

31. In this regard, see Constitutional Court Rulings of 27 June 1990 (f.j. n.7) and 19 July 1990 (f.j. n.5); see also, prior to these rulings, C.M. ROMEO CASABONA, 'Los derechos del enfermo a la luz de la Constitución española', in *Todo Hospital*, n. 62, 1989, p. 29.

32. See C. ALVAREZ-LINERA, 'El derecho a la vida y a la integridad. Prohibición de la tortura', in *La Ley*, n. 1763, 1987, pp. 1 ff; F. BUENO ARUS, 'Límites del consentimiento en la disposición del propio cuerpo desde la perspectiva del Derecho Penal', in *Poder Judicial*, 1985, p. 14; ROMEO CASABONA, ibid.

33. Constitutional Court Ruling of 27 June 1990, legal principles 7 and 8 respectively.

34. G. HIGUERA, 'Eutanasia: precisiones terminológicas', in *Dilemas éticos de la Medicina actual*, (Public. Univ. Comillas, Madrid 1986), p. 149.

35. J. CEREZO MIR, 'La regulación del estado de necesidad en el Código Penal español', in *Estudios Penales y Criminológicos*, X (Santiago de Compostela 1987), pp. 87 and f.

36. Art. 10.1 of the Spanish Constitution can be translated as follows: 'The dignity of the individual, the independent development of personality, respect for the law and the rights of others are fundamental to public order and peace in society'.

37. BUENO ARUS, 'Límites del consentimiento en la disposición del propio cuerpo desde la perspectiva del Derecho Penal', cit., p. 14.

38. A. ESER, 'Límites del deber del tratamiento médico desde el punto de vista jurídico', in *Nuevo Foro Penal*, 1985, p. 447.

39. ESER, 'Límites del deber de tratamiento médico', cit., p. 446; ROMEO CASABONA, *El Medico ante el Derecho*, cit., pp. 4 and ff.

40. See on this issue J.M. SILVA SANCHEZ, 'La responsabilidad penal del médico por omisión', in *La Ley*, n. 1632, 1987, pp. 1 and f.

41. A. ESER, 'Problemas de justificación y exculpación en la actividad médica', in *Avances de la Medicina y Derecho Penal* , (ed. S. Mir Puig, PPU, Barcelona 1988), p. 46.

42. BUSTOS RAMIREZ, *Manual de Derecho Penal, Parte Especial*, cit., p. 50.

43. Arthur KAUFMANN '¿Relativización de la protección jurídica de la vida?', in *Avances de la Medicina y Derecho Penal*, (ed. S. Mir Puig, PPU, Barcelona 1988), p. 46.

44. For the full text of the Deutsche Gesellschaft für Medizinrecht recommendations see 'Einbecker Empfehlung', in *Grenzen der ärztlichen Behandlungspflicht bei schwerstgeschädigten Neugeborenen,* (H.D. HIERSCHE/ G. HIRSCH/ T. GRAF-BAUMANN, eds.), (Springer, Berlin 1987), pp. 183 and ff.

45. M. BUENO SANCHEZ, 'Bioética y Pediatría', in *Anales Esp. de Pediatría*, 1991; N. KING, 'Federal and State Regulation of Neonatal Decision-Making', in *Euthanasia and the Newborn,* (R.C. McMILLAN, H.T. ENGELHARDT, JR., and S.P. SPICKER, eds.) (Reidel Publ. Co., Boston 1987), pp. 90 and ff.

46. E. CUELLO CALON, 'El problema penal de la eutanasia' in *Tres temas penales,* (Bosch, Barcelona 1955), p. 157.

47. See BAJO FERNANDEZ, *Derecho Penal, Parte Especial*, cit. p. 104.

48. BUSTOS RAMIREZ, *Manual de Derecho Penal. Parte Especial*, cit., p. 50.

49. States as follows: " Acting under the effect of such powerful stimuli that have produced uncontrollable rage, or any other similar state of mind".

50. It reads thus: "These are attenuating circumstances: 10. And, finally, any other circumstances analogous to those previously mentioned."

51. According to circ. 1ª of art. 9º "Those circumstances enumerated in the previous chapter, when the necessary conditions for exemption from liability are not met in their respective cases". The previous chapter referred to is composed of art. 8º, only the first clause of which states: "The following are exempt from criminal liability: 1. individuals who suffer a temporary mental breakdown, so long as this has not been deliberately sought for criminal purposes".

52. Mª. D. FERNANDEZ RODRIGUEZ, 'Problemática médico-legal de la eutanasia', in *Estudios Penales, I,* (Serv. Publ. Univ. Santiago de Compostela 1977), p. 200.

Chapter III. Specific Activities

§ 1. Termination of Pregnancy (Abortion)

I. The Offence of Abortion in Spanish Law

A fuller understanding of the complex question of abortion in Spanish law can only be achieved through a discussion of the legal rules relating to abortion and the cases in which it is punishable.[1]

195. *The legal interest protected by the abortion law.* As a general rule it can be said that from a criminal law perspective abortion consists of causing the death of the embryo or human foetus either in the womb or through causing its premature expulsion from the womb.[2] In the case of the latter some argue in favour of a lack of viability and maturity in the expelled foetus.[3]

The legal interest protected by the offence of abortion is the life of the conceived (embryo or foetus). This conclusion is reinforced in so much as the life of the conceived is a legally protected interest under the terms of the Spanish Constitution (art. 15), as was upheld by the Constitutional Court on 11 April 1985, and the Penal Code granted this protection under the Criminal Law in view of the vital interests of the individual and the community. It is normally accepted that alongside this primordial and basic interest there are also other secondary interests, such as the freedom of the pregnant woman, as can be seen in the longer sentences applied if the freedom of the pregnant woman is also impinged upon. Accordingly, the *material object* of the aggressive conduct is the embryo or the live human foetus implanted in the woman's uterus. Therefore, the offence is deemed to have been committed regardless of whether at the moment of termination the conceived is viable or non-viable outside the uterus, whether the action is performed inside or outside the womb, whether it occurs after expulsion or in fact involves provoking expulsion with the aim of terminating the pregnancy; beyond the parameters of the law are spontaneous abortion of non-viable foetuses (the embryo is always deemed non-viable) as well as ectopic pregnancies, since these are non-viable inside the uterus; neither is the destruction of an embryo that is the result of 'in vitro' fertilization deemed to constitute abortion, so long as the embryo has not been implanted and nested in the uterus. The offence may be committed at any time between the moment of nesting (although the Penal Code does not define this explicitly) and the moment of birth. Up to this latter point no interest exists to which effective protection may be give under the Penal Code, whereas after the birth there is an independent human life that deserves protectio of a different type; deformed foetuses or monsters are also covered by the offence, provided that they are viable inside the uterus.

196. *Classes of offence under abortion law.* Let us now go on to examine the chief characteristics of the classes of criminal acts in relation to abortion law.

In the abortion regulations we find an offence with regard to what is understood to be a case of negligence.[4] However, the matter is far from clear-cut since both case law and a certain branch of legal doctrine offer a range of criteria on the issue. Case law has traditionally allowed the application of another general offence of negligence (art.565) when the requirements of art. 412 are not met, a criterion that can be disregarded if it is acknowledged that art. 412 refers solely, or at least, at the same time to cases of blameworthy negligence. In terms of the other grounds for the existence of an abortion offence, intent is required in all cases, both where third parties are involved and in the case of the pregnant woman herself.

There are three types of offence for which the pregnant woman is punishable: self-induced abortion, when it is the woman herself who causes the abortion (art. 413 of the Penal Code), where she is assisted by others or consents to the abortion being performed by another, or in both cases where she seeks to hide her shame by aborting (art. 414; e.g. when the pregnancy is the result of extra-marital relations unknown to third parties and the woman seeks to conceal these circumstances in order to avoid negatively affecting her social position). In reality these offences are applicable not only where the woman actively seeks to procure an

abortion herself, but also her merely consenting to (or requesting) performance of the abortion by a third person.

The provision for a criminal offence stemming from an abortion is procured by another person is excessively worded and casuistic. The Spanish Penal Code differentiates between abortion *with the consent* and without the consent of the woman. In fact it is a lesser offence if the woman has consented and a heavier sentence is given if she has not (art. 411 nº 2 and nº 1 of the Penal Code respectively). The Penal Code provides for the heavier sentence of between six and twelve years imprisonment with the maximum period applied in cases where violence, intimidation, threat or deception have been used to obtain the woman's consent (art. 411.2). The woman's *parents* benefit from a slight extenuation if they procure or cooperate in the abortion with the consent of their daughter, in an effort to conceal her condition, even in cases where the abortion leads to death or serious injury (art. 414. 2).

Aggravating circumstances are deemed to exist for abortions carried out by third parties on the basis of *the result caused*: if, as a result of an abortion or abortive practices performed on a woman who is not pregnant but who the third party believes to be pregnant, or if inadequate means to procure an abortion are used and result in the woman's death or in certain types grievous bodily harm being done to her (such injuries are enumerated in nº 2, art. 421), the offence is punishable by imprisonment for a period of between twelve years and a day and twenty years and a day[5] and between twenty years and a day and thirty years and a day if any other type of grievous bodily harm is caused (art. 411, last paragraph.) These circumstances, which give rise to the harsher sentences envisaged, must be, at the very least, negligent (that is to say, intent may also be involved).[6] Despite the restrictions governing the applications of this offence, one can be critical of its existence, form the point of view that the gravity of the sentence imposed does not always reflect the degree of fault on the part of the perpetrator.

Specific aggravating circumstances are also established for professional and habitual practice (art 415 of the Penal Code). The first of these refers to qualified medical staff who, in abuse of their profession, procure an abortion or cooperate in it (art 415.1). Included within the category of qualified medical personnel are not only the medical practitioner, but persons holding other health care qualifications (art. 415.4). The aggravating circumstances of habitual practice (art. 415.2) are deemed to apply to those who do not hold health care qualifications, but habitually perform abortions. This category of aggravation seeks to include those without professional qualifications who perform clandestine abortions and who generally engage in such activities as a means of earning a living, although this in itself is not a requirement of this class of offence.

The provision or distribution of the means by which an abortion can be performed also constitutes a offence. Therefore the *pharmacist* who, without the required prescription, provides an abortive drug (art. 415.3)is included, as are any persons in his employment who do so (art. 415.4). In a more specific manner the Penal Code punishes the *furnishing of the means of abortion.*[7] These are acts preparatory to the abortion, specifically punishable as independent offences, because otherwise they would not be punishable at all. To be so the acts in question must constitute punsihable conduct which is unrelated to the act of abortion itself, given that when such a connection exists the acts would constiotute accesories to the fact[8].

Pofessionals and non-profesionals alike who are found to have committed the offence of abortion shall receive in addition to the corresponding sentence, a special disqualification which includes, along with its own general effects (arts. 36 and 37 of the Penal Code), bars the individual from work in any public or private clinic, health care institution, gynaecological surgery, for a period of between six and twelve years (arts. 417 and 30 of the Penal Code).

197. *Abortions performed outside Spain on Spanish citizens.* In accordance with the provisions of the "Ley Orgánica del Poder Judicial" of 1985, which is concerned with, among other things, the territorial jurisdiction of Spanish criminal law, abortion is only punishable when committed in Spain (art.23.1), except where, under the complmentary principle of personality (art. 23.2), it is also punishable in the country where it was performed (principle of double incrimination), apart from other requirements. As a result, Spanish women who travel to neighbouring countries where voluntary abortion is legal may not be prosecuted in Spain,

notwithstanding the fact that the Spanish Penal Code would consider this as an offence, since the Spanish courts do not have jurisdiction over an act which is not an offence in the other country. This interpretation has been confirmed both by the Supreme Court[9] and Constitutional Court.[10]

II. Voluntary Abortion

A. Reform of the Penal Code: System Adopted and Scope

198. Since the reform of the Penal Code under *Organic Law* 9/1985 of 5 July —once the hurdle posed by an appeal on the grounds of alleged unconstitutionality had been overcomeand the Bill amended in line with the Constitutional Court ruling of 11 April 1985—, abortion is legally permitted under Spanish law in any of the circumstances established by art. 417 bis of the Penal Code, which does not include indication for socio-economic reasons.[11] Clearly the Legislature has followed the criterion of rule-exception in this regard. The rule is that wilful abortion is banned in all cases, and is punished accordingly under the criminal law, even when the pregnant woman herself agrees to the abortion. The exception is that under certain circumstances authorized by the Law abortion is lawful, when specific conflicts of interests occur, in which case specific principles apply. The Spanish Legislature has opted for a system of indications, as opposed to one of time limits (which also responds to an assumption of conflict) or to an across-the-board right to abortion. To sum up, the current situation in Spain is as follows: if the life or physical or mental health of the mother are seriously endangered (therapeutic or medical indication) or if the woman has become pregnant following rape (ethical or criminological indication) or, finally, if through prenatal diagnosis or some other procedure, evidence emerges that the foetus is likely to be born with significant abnormalities (eugenic indication), an abortion may be performed.

199. Art. 417 bis. 2 clears the pregnant woman of criminal liability even when the abortion has not been performed in an accredited centre or when the required certificates have not been produced (therapeutic and eugenic indications)[12], provided that the requirements governing the indication, treatment or the supervision of such treatment by a medical practitioner are met and that the statutory time limits (ethical and eugenic indications) are adhered to or that the obligation to report the crime of rape to the authorities is satisfied (criminological indication). This is a personal exoneration from punishment (by virtue of being incapable of fault) granted to the pregnant woman, which is based on the fact that she cannot be required to adhere to the law[13], even where the general guarantees are not met. In any case it has a secondary scope of application, that is, in the case of the mother not being protected by any of the general defences listed in art. 8 of the Penal Code. A claim for the personal exoneration of the mother does not extend to any other persons who take part in the abortion (whether or not they are physicians or third parties acting under a physician's orders or independently). It should be said, however, that such persons may have recourse to other avenues of exemption (in very exceptional circumstances) or diminished liability. In sum, if the woman sees a physician and the latter proceeds to perform the abortion, he is still held to be liable, wheras the woman is not, having obtained exemption at the physician's expense. If, on the other hand, the woman fails to observe the requirements concerning certificates of opinion and approved centres, and also the requirement for medical supervision, she herself is deemed liable. Haing said that, in spite of the fact that this statutory provision may sound rather confusing, it should be understood that the pregnant woman is exempt from criminal liability when one of the authorised indications is present, both when she procures the abortion herself or it is procured with her consent by a third party[14].

200. The grounds for the justifiable causes included in the indications for abortion as laid down in the Spanish Penal Code are two-fold. The first is that there exists a conflict of interests involving the mother and the life of the foetus which the Legislature has resolved in

favour of the mother, confirming the criterion previously inferred from the general rules of the Penal Code governing the therapeutic indication (exemption in the case of necessity), and leaning towards *ex lege* in the case of decisions involving the other two indications. This principle applies to all persons who take part in the abortion and are covered by the justifying causes, including the pregnant woman. Secondly, justification is also based on the principle that the woman cannot be required to act in any other way, that is, to shoulder the burden of seeing out her pregnancy and giving birth to an unwanted child (in the case of rape) or to one that will suffer a serious physical or mental handicap; in both cases the conflict is resolved in favour of the mother on the basis of the criterion that no other conduct can be demanded of her.

In what can still be regarded as an isolated decision of the Supreme Court, an acquittal on the grounds of necessity (art. 8° n°7 of the Penal Code) was ordered in an abortion case in which the family context and economic situation of the woman's family led to the application of the socio-economic indication, thus marking a departure from previous case law doctrine, which had discounted the possibility of applying the defence of necessity in such cases. The Supreme Court acquitted the couple and a third party who had assisted them, but not the medical practitioner who performed the abortion and charged a fee for it, although he was later pardoned by the Government.[15] There are a number of reasons why one might take issue with the decision, though the extreme circumstances with which the court was confronted must be borne in mind. The court did not indicate in its ruling that the harm caused was not greater than that which the abortion sought to avoid, which is a prerequisite of the defence based on justifiable cause as contained in art. 8° n. 7°. The Supreme Court merely stated that a conflict existed, but did not deliberate on the question of the different harms involved or on the reasons why the harm done might be greater than or as serious as that avoided. In the final analysis, this ruling raises the question as to whether or not it has encroached upon what is in fact the province of the Legislature and whether the controversial reform of the Penal Code, as well as the preceding appeal on the grounds of alleged unconstitutionality which led to the introduction of the indications outlined above, was indeed necessary; the reform had been demanded by many sectors of society who felt that under the existing Penal Code provisions no conditions apart from therapeutic considerations rendered abortion lawful.

B. Indications for Abortion: General and Specific Requirements

201. The existence of the relevant indication is sufficient for an initial presupposition of lawfulness to stand and a presupposition that the conditions and requirements for abortion to go unpunished have been met. It is not a compulsory requirement that no less harmful means of resolving the conflict of interests produced in such situations are available (for example, providing the foetus or newborn baby with medical treatment to ameliorate or eliminate any abnormalities). This interpretation requires further comment, particularly in relation to the therapeutic indication, which the Penal Code requires states 'must be necessary', thus implying the existence of the situation of necessity stipulated by art. 8° n. 7 and the consequences entailed by such a situation.[16] In the other indications (ethical or criminological and eugenic) it is sufficient for the relevant indication to exist in order for the justification to be satisfied and to enable the pregnant woman to opt for abortion, since in the situation in question the conflict has already arisen.[17] Turning to the general and specific requirements of the indications the following aspects should be noted:

202. *The abortion must be performed by a physician or performed under his supervision.* The Legislature has deemed the participation of a qualified person necessary to safeguard the life and health of the pregnant woman, in view of the risks entailed in the performance of an abortion. Furthermore, the Legislatoure has rightly emphasised[18] that the participation of the physician provides an additional guarantee and professional supervision to ensure that the process of abortion is carried out in accordance with the law, firstly by ensuring that the indication which the woman claims to be applicable does in fact exist, as it is the physician who will be the first to benefit from the exemption from liability established by the law (ie physician who is to carry out or supervise the abortion). This does not mean, however, that the physician

should proceed to weigh up the interests concerned and the situation of necessity. He should simply verify that the case does conform to the apropriate indication (and its requirements), the therapeutic indication being an obvious exception to this since in this case the physician can safely deliberate. In relation to the other indications any such deliberation is *ex lege*.

The physician's participation, whether direct or indirect, that is, an abortion under his supervision, must conform to *lex artis* in all cases. Clearly, the most appropriate physician is a specialist in Obstetrics and Gynaecology,[19] but the participation of any other properly qualified physician capable of performing the abortion is equally lawful.[20] Supervision by a qualified physician, which the law offers as an alternative procedure, refers to the sharing out of functions among members of a team working together,[21] which implies that when the physician acts as supervisor he is still subject to *lex artis* as are all those who are physically involved. However, for the physician in this case *lex artis* primarily implies the evaluation of the capacity of the individual who performs the abortion under his supervision. As is discussed below, the complementary regulations distinguish between high risk pregnancies and abortions and those that do not entail such risks. Therefore, the physician's analysis of this situation is one of the most crucial elements in any consideration of the possibility of delegating (supervising) to another health care professional (general practitioner or specialist, intern or resident, midwife). This decision to delegate also depends on the intensity of subsequent treatment which may be required and the extent to which functions are delegated. These reservations are not sustainable, however, when the physician directs the pregnant woman herself, by instructing her as to pharmaceutical preparations that she should then administer herself or any other action that she should take (including performing the abortion herself under the physician's supervision). The same applies to members of the woman's family or her representatives (in the broad sense of the term): in such circumsances, as lay persons, they would not be prosecuted for illegal practice of medicine.

203. *Abortions may be performed only in approved public or private health centre or health care establishment.* This requirement stems also from the previous one, in that it seeks to lessen the risks which abortion enatils for the woman.[22] At the same time it provides a means of controlling and monitoring the number of abortions performed in Spain (by preventing clandestine abortions). As regards requiremetns concerning approval of centres or establishments, reference should be made to the regulations of the RD of 21 November 1986, which distinguishes between centres for the performance of abortions that do not imply high risk to the pregnant woman and for abortions performed within twelve weeks of conception and those centres which carry out abortions involving high risk and or after completion of the aforementioned twelve-week period (art.1°). The approval of public centres is automatic once they satisfy the established requirements. Accreditation of private centres is the reponsibility of the Autonomous Communities (art. 2° of the Royal Decree).

The requirement that the woman attend an authorised centre does not imply that the whole process must be carried out there. This enables the abortion to be performed in the woman's home (with or without the direct assistance of health care workers) if hospital admission or out-patients' services are not necessary,[23] provided that follow-up examinations are carried out by the centre, which shall also keep the woman's clinical hitory and other necessary documents (art.4° of the RD).

204. *The consent of the pregnant woman must be sought.* The woman's consent to the termination of the pregnancy must be *explicit*, although an exception to this is laid down in art 417 bis 1 circ. 1ª of the Penal Code which will be referred to below. The Legislature has excluded the father from the mother's decision to have an abortion of the type covered by lawful indications.

The form in which this consent is expressed is essentially unimportant. It may be either verbal or written. Nevertheless, the physician who performs the abortion may insist that it be in writing since this constitutes an administrative duty, in accordance with the terms of the RD of 1986 (art, 4°). It is beyond doubt that this consent must correspond to the requirements of *'informed consent'* to the medical act (the abortion), in the sense that information pertaining to

at least the essential features of the operation must be furnished to the 'patient' as a prior condition to the validity of consent, in order to ensure that this is indeed the expression of the pregnant woman's true wishes. The non-provision of information is acceptable either because this is deemed unnecessary as the pregnant woman is already well-informed or because the woman herself has explicitly stated that she does not wish to be informed for personal reasons. As a result, it is only in this sense that the guidelines specifically laid out in the RD of 1986[24] or those laid out in general terms by the LGS[25] itself may be interpreted as non-obligatory recommendations[26] from the point of view of the criminal law. It is only from this same perspective that non-compliance with this duty to provide information implies misconduct or breach of discipline on the part of the physician, although not affecting exemption from criminal liability. Therefore, not only must the pregnant woman know of all the circumstances pertinent to the legal indication for abortion, but also the risks she herself may be exposed to as a result of the performance of the abortion itself. Furthermore, consent must be freely given and not obtained as the result of erroneous belief (here once again the provision of information plays an important role), deception, force or coercion.[27] Lastly, another important point is the fact that in the criminal law one of the characteristics of consent as a defence is that it must be given prior to the deed it is called upon to justify.

205. The Penal Code envisages the waiving of the requirement for the pregnant woman's explicit consent in *cases of emergency* where the woman's life is in danger (therapeutic indication, art. 417. 1, 1st circ., 2nd parag.). The removal of this requirement is clearly based on the concept of necessity, but in referring to "explicit consent" it implies that the requirement of presumed consent is maintained. This means that in normal circumstances the physician can and must perform the abortion in these situations, but not if he is aware that the woman would be opposed to this were she able to express such opposition. In the case of a woman who is unable to express her consent, in the circumstances already discussed, where possible her legal representatives shall give consent on her behalf. Even so, in view of the fact that the Law refers to emergency circumstances involving mortal risk to the woman, only limited capacity for effective decision rests in the legal representatives, who must give their consent to the abortion if they do not wish to be liable for abuse of authority. There are however specific exceptional circumstances to this, such as when the abortion would not imply any reasonable possibility of saving the mother's life whereas the foetus could be kept alive.

206. *Subjective element*. The subjective element must be present in all those who are involved in the performance of the abortion and in the woman who will benefit from its performance, but it is reduced in its application to knowledge of the existence of one of the decriminalised indications and the willingness to carry out or undergo the abortion under the presupposition that the corresponding indication does indeed exist. What this means is that it is not always necessary to act out of necessity, save in the case of the therapeutic indication, and that the attendant motives for the decision to have an abortion are irrelevant.

207. Finally, it should be recalled that the termination of a pregnancy must never be for the purposes of donation or subsequent use of embryos or foetuses or their biological structures. Moreover, the medical team that carries out the abortion may not be involved in any subsequent use made of the foetus or embryo.[28]

III. Requirements of Each Specific Indication

A. Therapeutic Indication

208. This first indication for abortion occurs when a grave danger to the life or physical or mental health of the mother exists which can only be prevented if the abortion is performed (art. 417 bis. 1 1st circumstance of the Penal Code). In the literature there is no doubt that such circumstances were already regarded as lawful here prior to the reform of the Spanish Penal Code in 1985, since it was considered that the existing state of necessity (nº 7º of art. 8º of the

Penal Code) operated as a defence and was applicable in favour of the mother when there arose a conflict between the life of the mother and that of the foetus, it being understood that her life is more valuable to the Law than the life of the conceived. The psychiatric indication, expressly recognised since 1985, opened the door to other health-related aspects of health (particularly social repercussions) where the presence of a state of need was questionable as a general defence. Nevertheless it should not be forgotten that the risks of a pregnancy of this nature can be avoided by sterilization of the woman concerned. We will now proceed to an analysis of the most significant aspects of the requirements of this indication:

209. *Necessity of the abortion*. The abortion must be necessary, that is, the danger to the life or health of the pregnant woman must not be preventable by any other means apart from the abortion, which is the last resort that the law offers to resolve the conflict. It follows, therefore, that any other alternative must have priority if the danger can be prevented by appropriate medical treatment, or if the performance of the abortion entails greater dangers than those it prevents, or if the abortion is more dangerous than the birth itself. Finally, the abortion will not be deemed necessary if it is not likely to lead to the eradication or significant reduction of the negative prognosis for the woman or to some therapeutic benefit. Having said that, consideration attention must be given to each individual situation in order to determine the extent to which available alternative treatment may be used with the pregnant woman.

210. *Grave danger to the life or physical or mental health of the mother*. It must be a "grave danger". This alludes to the concrete and specific danger that in the relatively near future the pregnant woman will die or her health will be seriously damaged. It is no easy matter to establish the required degree of probability that such an event might occur; nevertheless, the degree required should be reduced in inverse proportion to the gravity of the threat, particularly where, for example, the woman's life is in danger.[29] Grave danger excludes from the indication all the usual discomforts and risks entailed in a normal pregnancy and birth. Danger to life may be of both organic and psychological origin. Extreme depression with suicidal tendencies would be classified as the second of these types of danger.

211. *Certificate of opinion issued by a specialist*. It is essential that a specialist issues the relevant certificate of opinion vouching not only that the danger to the life or physical or mental health of the pregnant woman actually exists, but also that the abortion is necessary to prevent the danger. The responsibility which rests with the physician is obvious, and the law also demands that he be a specialist in the relevant field, that is to say, in the type of illness from which the woman is suffering or from which she is probably suffering. In order to ensure the independence of the certificate of opinion the specialist who issues must not be the physician who is to perform or supervise the abortion. The requirement of the certificate may be waived in emergency cases of mortal danger to the life of the pregnant woman, that is, when her life is under threat.

B. Ethical or Criminological Indication

212. The ethical or criminological indication arises when the pregnancy is the result of an act constituting the crime of rape (art. 417 bis no. 1, 2nd circumstance). It requires:

213. *That the pregnant woman has been the victim of the crime of rape*. In this indication the crime of rape consists of— along with other elements that need not concern us here — the performance of the sexual act by a male person with a woman by force or intimidation, or while she is unconscious or by taking advantage of her mental deficiency or when she is under twelve years of age (art. 429 of the Penal Code); the indication does not include other sexual assaults that may give rise to unwanted pregnancy. It suffices for the act to be unlawful, even though the person accused of the rape has not been found guilty, that is to say criminally liable, as would be the case of persons below the age of criminal responsibility (under sixteen, art. 8° n° 2 Penal Code) or those who are mentally ill or deficient (art. 8 n° 1 Penal Code).

214. *That the pregnancy is the result of the rape.* This requirement literally demands that the pregnancy has been the direct result of the act of rape, which excludes, at least in theory, mere probability. Nevertheless, in practice there must be compliance with the presence of conclusive evidence: the age of the woman, prior or subsequent sexual relations, fertility at the time of the rape, etc. The physician is only required to satisfy himself that the rape has been formally reported to the Examining Judge.

215. *The time limitation.* Abortion must be performed within the first twelve weeks of gestation. For the calculation of this time period the starting date must be the same as that of the rape, since this act must be the cause of the pregnancy.

216. *Reporting the act.* Before the abortion is performed it is essential that the rape has previously been reported to the authorities, in compliance with the requirements of the Criminal Procedures Code (arts. 104 and 259 and ff.). The problem lies in whether or not merely reporting the act is sufficient or if legal proceedings must have begun, that is, as the Attorney General's Office argues,[30] a complaint or case that has been accepted and is under investigation. The Attorney General's Office position has in its favour the fact that it confers greater seriousness on the act of complaint because reporting an alleged rape automatically leads to legal proceedings. It should be noted that prosecution for rape is only possible if there has been a prior denunciation. This can give rise to false complaints and improper abortion based on them; these false complaints cannot be prosecuted under the crime of the same name (making false complaints, art. 325 of the Penal Code), given that for a crime to exist official proceedings must follow automatically (investigation by the authorities as a result of the mere fact of having knowledge of a presumably illegal act). This is not the case arising from rape, which must be reported for action to be initiated. However, offenders may face criminal action for simulation of a crime (art. 338 of the Penal Code), together with the offence of illegal abortion. The alleged rape must be reported prior to the performance of the abortion.

C. Eugenic Indication

217. The eugenic indication allows an abortion to be performed when there are risks that the embryo or foetus has grave genetic abnormalities of any kind or other physical or mental defects produced during the pregnancy (art 417 bis. 1, circumstance 3ª). The anxieties that this indication provokes concern the uncertainties of the prognosis are gradually being eliminated thanks to prenatal diagnostic techniques which enable a wide range of treatments to be carried out on the foetus with ever-increasing precision. The specific requirements of the indication are as follows:

218. *Supposition that the foetus will be born with grave physical or mental abnormalities.* This requirement is, strictly speaking, the eugenic indication itself, and therefore, the nucleus around which all other requirements revolve. In the first place, the Law states that there is a 'supposition that the foetus will be born with.' In principle, this supposition can be interpreted in the sense of a degree of certainty equivalent to objective and preferably statistical probability. Nevertheless, the objective criterion will have to be modified by the belief of the specialists who issues the medical reports, although they may base themselves on the percentage results of tests carried out. This situation makes any greater precision in the law impossible and inadvisable. The question becomes even more complicated when the percentage of risk of abnormality is similar to that for the absence of risk (e.g. in the case of certain sex-related diseases in males). Despite this, it is our opinion that the possibility of using the eugenic indication to terminate the pregnancy should be left open, though its appropriateness is more debatable as the probability of risk factors diminishes. The indication also exists when the abnormalities will only become apparent after birth, provided that in this case it is certain that they will occur and that they can be predicted (predictive diagnosis, in what is termed Predictive Medicine). In other words, the prognosis shall indicate that the foetus is the genetic

carrier of the factors that will *from birth* cause the grave illness required by the Penal Code.[31]

The meaning of the term "grave abnormalities" must be understood in the sense of their importance and enduring nature, as well as the extent to which they are treatable; if, in spite of their extensive nature, the abnormalities can be eliminated readily they would not give rise to the legal presupposition which underpins the indication, even though some would argue in favour of validity in this case also.

219. *The time limitation*. The abortion must be performed within the first twenty-two weeks of pregnancy. This deadline can be explained by the fact that some diagnostic tests can only be carried out when the foetus has reached a certain stage of development. Furthermore, time is required for the evaluation of such tests and the taking of the decision to terminate the pregnancy. The later the diagnosis is made the greater the certainty of its accuracy.

The imposition of this time limit has been criticised from the point of view that certain diseases resulting from the mother's illness or from other causes (exposure to radiation, prescribed drugs etc.) may affect the foetus after the deadline for the legal indication has expired.

It is of practical interest to establish from what point in time this period should be calculated. This is not stipulated by the Law, which implies, as is logical, that it begins at the moment of fertilization (date of pregnancy), but in practice this is not easily determined, since even the pregnant woman herself may not know when this occurred. In Medicine it is usual to turn to the date of the woman's last menstrual period[32] for all that pertains to the course of the pregnancy and the calculation of the date of the birth. This gives rise to a calculation in real terms of twenty-four weeks from the last period; others, meanwhile, prefer to take the moment of nesting as the starting point.[33] However, it should be said that both calculation bases produce the same result and enable similar criteria to be maintained between the two indications for which a time limit is stipulated.[34]

220. *Certificate of opinion issued by two specialists*. This must be prior to the abortion and the specialists must not be those that carry out or supervise the abortion and shall be attached to an accredited private or public centre or health care establishment. This certificate is intended to provide guarantees that the indication does in fact exist and to thus achieve a greater degree of protection for the foetus. On the other hand, in using the term "specialists" the Law entertains the possibility of the involvement in the report of other professionals who are not physicians, such as geneticists, provided that they work in a centre of the type just described. The responsibility for determining the presence of the indication rests solely and exclusively with the physician who is going to perform or supervise the abortion.

§ 2. Sterilization

I. Concept and Penal Scope

221. In terms of the Spanish Penal Code[35] sterilization consists of the permanent or lasting removal of the reproductive capacity of a fertile man or woman by whatever procedure, be it surgical (suture of the deferent ducts or tubal ligation), or by means of biochemical or hormonal substances (though contraceptive pharmaceutical products do not fall within this definition), or by exposure to so-called absorbable radiation. The crime of castration exists from the moment in which extirpation, amputation or the rendering useless of the masculine or feminine genital organs is produced, and it is subsumable under the type of offence in art. 418, since it falls within the bounds of the expression 'organ or principal member'.[36]

Sterilization is distinguished from castration on the basis that the latter implies the violent removal of the genital organs and has as a consequence not only the permanent loss of the ability to reproduce, as in sterilization, but also of other hormonal and endocrinal functions that affect the general behaviour of the individual, such as, in the sexual domain, diminished or total lack of libido and in the specific case of the male the very high accompanying risk of

coeundi impotence or the inability to perform the sexual act.

The offence of sterilization includes reversible sterilizations which require surgical operation or similar procedures to restore fertility to the person.[37] It goes without saying that this would not be the case, for example, of the removal of a diaphragm or intrauterine device (IUD), even where a physician has had to intervene.

II. Therapeutic Sterilization

222. The offence of sterilization is not considered to exist when it is therapeutic (e.g. in the treatment of prostate gland complications) or when it is the unavoidable outcome of some medical treatment (e.g. radiation treatment for cancer in the genital zone) provided that the following necessary requirements are met: medical indication, *lex artis*, curative purpose,[38] as well as, for other reasons, the informed consent of the individual concerned. Prophylactic or preventive sterilization may also come under therapeutic sterilization from the juridico-criminal point of view provided that the intended purpose is the avoidance of danger of certain grave injury to health or life in the future (e.g. if a woman in extremely poor health were to become pregnant).

Castration is not deemd to be an offence if performed for therapeutic or preventive reasons, where the life or physical or mental health of the patient is in danger. Even so, given the serious and irreversible consequences that it implies, therapeutic castration for psychological reasons is only permissable under the following circumstances:[39] a) proof beyond reasonable doubt that the abnormality or illness is not treatable by means of any other psychotherapeutic procedure; b) gravity of the abnormality or illness from the social point of view, rendering living with normal human dignity impossible or implying serious risks for the person affected; c) the consent of the patient. To these requirements we would add the age of the patient and also the need for sterilization to remain completely disassociated from any criminal process or sentence, so as not to influence or coerce the individual into making the decision (e.g. in order to procure a lighter sentence or a reduction in the time to be served) as well as the patient's age.

III. Limitations on the Lawfulness of Voluntary Sterilization in Spanish Law

223. Voluntary sterilization, that is to say sterilization to which the individual concerned has consented —whether the individual is single or not— has been lawful under Spanish Law, even when it is not therapeutic, since 1983, year in which the Penal Code was revised as regards the effectiveness of consent to bodily harm, which is acceptable in the exceptional circumstance of sterilization. The Penal Code states that 'notwithsatnding the provisions of the previous paragraph, free and explicit consent exonerates physicians from criminal liability in the case of organ transplants effected in accordance with the Law, sterilizations and transsexual surgery carried out by qualified physicians, except where consent has been obtained by foul means, through payment or reward, or if the consenting party is a minor or incompetent to give consent, in which case no consent given by him or his legal representatives shall be valid (art. 428.2 of the Penal Code). The previous paragraph referred to states that 'the sentences laid down in the previous chapter [concerned with offences of bodily harm] are to be imposed where appropriate, even when the injured party has given consent'. When the Penal Code was reformed in 1989 a new clause was added to the above-mentioned art 428.2 stating that sterilization of a legally incompetent person suffering from grave mental deficiency shall not be punishable when it has been authorised by the judge at the request of the mentally disabled individual's legal representatives and after hearing the opinion of two specialists, the Public Prosecutor and following an examination of the incompetent person.

A. Scope of the Lawfulness of Voluntary Sterilization

224. With art. 428.2 a position of clear liberalization was adopted in terms of the power to dispose of the legal interest, since it affords a wider implicit recognition of the individual right

to non-reproduction than can be deduced in practice from the depenalisation of the use of other contraceptive methods. For this reason the introduction of the legal provision discussed here was appropriate precisely in relation to non-therapeutic sterilization.

As a result, sterilization of the individual who has given consent is lawful under Spanish law, provided that the requirements stipulated in art. 428 of the Penal Code for non-therapeutic sterilization are met, when it is motivated by one of the eugenic indications, socio-economic considerations (family planning), but also when no indication of any kind exists and the interested party has freely consented. However, sterilization by imposition or coercion, that is, against the will of the individual concerned (e.g. for State demographic policy reasons), is not permitted since it is clearly unconstitutional.

B. Requirements

225. In the first place, sterilization muat be performed *by a qualified physician* and not by any other kind of person; frequently this physician will be a surgeon (for the removal of the fallopian tubes in the woman), but any other medical doctor capable of performing minor surgery is also appropriate (vasectomy in the male). The physician acts in the legitimate exercise of his profession and is authorised for this specific circumstance by the Penal Code itself. Nevertheless, for the physician's performance of the operation to be lawful consent must be given by the individual who is to be operated on.

226. All *other requirements* included in art. 428.2 for sterilization to be valid centre on the conditions that must be satisfied with regard to the interested party's consent. It must be freely given (without coercion and not obtained under threat) and explicit (verbal or written).[40] furnished without foul play (not obtained by means of deception or erroneous belief), without payment or reward and the consenting party must be an adult with full use of his mental faculties, ie must not be a minor or incompetent. In any case, where the sterilization of minors or legally incompetent individuals is concerned, in view of the therapeutic indication involved, the general rules governing consent to medical treatment apply rather than these specific rules.

In some family planning centres it is customary to ask both husband and wife to sign a document of consent, since the person who is not undergoing the operation will nonetheless be equally affected in terms of being able to produce offspring with his/her partner (all the more so in cases of vicarious or substitute sterilization). Although consent is a preventive measure designed to get round possible the problem of potential claims by the person who is not operated on (who might allege lack of knowledge of the performance of the operation or that he/she did not agree to its being performed), it is not a legal requirement and cannot therefore be demanded by law for the operation to be carried out.

C. Sterilization of Minorsand Mentally Handiccaped

227. Art. 428 stipulates that when the person who is to be sterilised for whatever reason is a minor he may not give valid consent, nor can such consent be given by the legal representatives; in other words, the individual cannot undergo sterilization. Minors do not generally present specific circumstances in terms of sterilization such as socio-economic or eugenic indications, but the case of the couple who have married before attaining their majority is of practical interest.

The first issue that must be settled is the meaning and scope of the term 'minor' as used in art 428.2 of the Penal Code. It is necessary to clarify from the outset whether the Law seeks through the use of this term to make a connection with the concepts of private (civil) Law or, alternatively, whether the opposite interpretation in keeping with similar figures in Criminal Law is intended: a minor in the Criminal Law (nº2 art. 8º) is a person under 16 years of age. This second interpretation must be rejected if no other arguments supporting its validity can be added, since there is no reason why the word 'minor' should have a single meaning for the Penal Code alone. Immunity from prosecution under the Penal Code to which one might seek to link the scope of 'minor' refers to the exclusion from criminal liability for a wrongful act

committed by persons such as those to whom it refers (minors), while the case that concerns us here is not one of the elimination of liability from the consenting party — the minor — but from a third party, who is the person who will act or perform the action which, in principle, is prohibited if the aforementioned consent has not been given — ie, the medical doctor to whom consent is granted. Consequently, what is of interest is when such persons do not have the recognised capacity to give their consent in view of their status as minors. Furthermore the reference to civil notions in art. 428.2 would appear to be unequivocal, as are the other requirements that must be satisfied for consent, and particularly the inclusion of explicit mention of the legal representatives, which is a figure that is completely alien to Criminal Law, but which has a precise description in Civil Law, being linked to the civil minor and the legally incompetent person. The intervention of the Criminal Law through art. 428 is aimed precisely at modifying these general provisions of Civil Law, by denying the representatives in the circumstances addressed by the article a representation that the Law recognises in principal (although we shall see below that this is not wholly accurate), albeit with important limitations when rights of personality or highly personal interests are affected. In conclusion, the Legislature has forged a link with the civil concept (art. 315 del CC).[41] As a result, only those of eighteen years or more who are not legally incompetent can give valid consent, and from this age onwards no restrictions may be imposed.

228. The *legal representatives* are not empowered to give their consent on behalf of the minor. The point of departure taken by the criminal Legislature (art. 428.2 of the Penal Code), which coincides with that of its civil counterpart,[42] is the principle that rights of personality are not transferable.[43] Neither may the *judicial authority* substitute for the will of the minor and authorise sterilization; though such intervention by the authorities is not prohibited by art. 428 of the Penal Code, civil legislation only foresees that the parents may, in exercising their paternal authority, seek the assistance of the authorities (art 154). This assistance may be regarded only as referring to those rights and duties recognised as resting in the parents in performance of their parental authority functions. Consequently, since they do not have the authority to substitute the will of the minor, it will be difficult for the judge to assist them in enforcing authority they do not actually have. Furthermore, in our legal order there is no explicit recognition of such powers of substitution or representation of the minor (art. 158 of the CC) by the Judge or Public Prosecutor. Therefore we may not arrive at the lawful sterilization of the minor by this route.

The only viable solution is to wait for pregnancy to occur in order to set in motion the mechanisms of abortion for eugenic reasons, which is one of the indications for decriminalization of abortion (art. 417 bis. 1. c Penal Code), in which case it is possible in one way or another to obtain valid consent to the performance of the abortion even though the woman is a minor.[44] In any case, it is not a problem of a comparable entity to that of the legally incapacitated person and thus the current legal position of not allowing the sterilization of minors under any circumstances, with no exceptions, until they reach the age of majority would seem to us to be correct.[45]

229. A great deal of interest and indeed conflict sourrounds the sterilization of the mentally handicapped, inview of the risks of an unwanted pregnancy occurring in the female, particularly when living in a communal environment (e.g. in special education centres and residential care). It should not be forgotten, however, that popular opinion has been moving towards the idea that these individuals should not be denied access to a sex life. In such cases a twin problem or indication occurs: that the child will be born with abnormalities or illnesses of genetic origin (eugenic indication), and the practical impossibility of maintaining the child financially and of carrying out the functions of motherhood, (or, where applicable, fatherhood). Note also that the mentally handicapped are normally deprived of their civil rights, such as parental authority (socio-economic indication).

230. The understanding of the expression 'legally incompetent' as used in art. 428.2 of the Penal Code has raised similar issues to 'minor': the issue of choice between the criminal sense

(the mentally deranged or persons who have suffered perceptual disturbance from birth or from early childhood, for example the profoundly deaf and dumb; n. 1 and n. 3 art. 8° respectively), or the civil sense (persons who have been certified as being legally incompetent). For the same reasons as those expressed above we should defend the second alternative, although leaving room for reciprocal interference from the two perspectives (the civil and the criminal). In fact, from the Civil Code we can deduce that the expression *incompetent* as used in art 428 of the Penal Code is distinct from that included in this body of law. Art. 199 of the Civil Code states that no-one can be declared incompetent, except by judicial decision in accordance with the causes established by Law.

What is relevant in terms of the criminal law for the reasoning behind art. 428 of the Penal Code to be applicable is that the subject can understand de facto (whether or not he/she has been certified as being incapompetent by the judicial authority) the scope and consequences of the decision to undergo the sterilization operation, and that he/she is in possession of the natural capacity to judge and understand the act.[46] Here, however, we encounter a limitation originating from Civil Law, namely, that if the person has been declared judicially incompetent apacitated he/she lacks the capacity to operate in civil life, which affects the validity of any legal actions carried out by the subject (such as entering into a contractual relationship with a physician for the purposes of a surgical operation). Referral to the terms of the incompetence stipulated by the judge in his decision is obligatory, given that otherwise the Law does not authorise the individual to voluntarily undergo a sterilization (art. 267 of the CC). If as frequently happens through oversight the judge's decision does not explicitly contemplate the incompetent individual subsequently consenting to sterilization for eugenic and/or socio-economic or other reasons, neither the incompetent person —under CC art. 267— nor his/her legal representatives (who are prohibited by art 428 of the Penal Code) may validly consent to sterilization. If, despite this, the individual has the de facto capacity to understand the nature of the act of consent (and given that the Penal Code does not place any obstacles to this situation), representation shall have to be made to the judicial authorities to modify the scope of the previous ruling of incompetence, as art 212 of the CC envisages, so that the individual may validly express the consent required by art 428 of the Penal Code, or, where applicable, his/her opposition to the sterilization operation.

To sum up, in the eyes of the criminal law incompetence denotes those who do not in fact possess the capacity for judgement, even though they have not been declared legally incompetent. Where such a person has been certified as being incompetent,he/she shall not be able to consent to consent to sterilization, even in the hypothetical case that te person has the natural capacity of judgement to understand the nature of the procedure.[47] An exception to this would be where there is an explicit statement to the contrary in the judge's ruling on incompetence. This means that the civilly incapacitated individual for whom this competence is recognised may validly consent —or express opposition— to his/her own sterilization which is a plausible situation in the case of persons suffering only slight mental disorders and who are capable of understanding the scope of certain important decisions. This solution would not be satisfactory, however, in cases of profound psychiatric disturbance, in which case neither the individuals concerned nor their legal representatives may consent to sterilization.

231. Under the reformed Penal Code of 1989 an exception for those who are most profoundly disabled has been envisaged, since it is these individuals who are most seriously lacking in the ability to prevent a pregnancy through their own actions and since there is no good reason to repress their natural capacity for sexual expression and affection. The 1989 reform clarified and resolved the issue by permitting sterilization of an incompetent person suffering serious intellectual disability. The requirement here is that sterilization shall be authorised by the judge at the request of the the legal representative of the incompetent person, and such authorisation shall be given only after hearing the opinion of two specialists, the Public Prosecutor and following an examination of the individual concerned. This formula uses the same terminology that we discussed elsewhere above.[48]

The term 'incompetent' which the law uses again in this new clause of art. 428.2 maintains the same meaning as that attributed by us with regard to the first clause,[49] with one

qualification: given that the law says that sterilization shall be requested by the legal representatives, 'incompetent' now refers exclusively to the individual who has previously been certified as being so by the civil judge, and not to the de facto (or presumably) incompetent person who would not have legal representatives in the first place nor could they act on his/her behalf.[50] Disability should be understood to mean a (serious) mental handicap of perinatal origin, that is to say, limited to mental deficiencies; furthermore, if one of the circumstances that are cause for incompetence under the the CC (art. 200), given that this article distinguishes between illnesses and deficiencies, the term should have a stricter and different meaning in the Penal Code also; finally, if the CC demands in the same clause that deficiencies should be 'persistent', it alludes at the very least to the lasting nature of such deficiencies, if not their de facto irreversibility; all this leads to the conclusion that the legal expression does not refer to psychiatric illnesses that are distinguishable from deficiencies. That they should be 'serious' alludes to a profound disability, of the kind that rules out any valid consent on the part of the sufferer, in the sense that consent is an expression of sufficient maturity and the natural capacity for judgement, that is, those cases that the reform of the Penal Code has covered. Finally, a minor who presents a serious mental deficiency that is reasonably likely to 'persist into adulthood' (art. 201 CC) may be sterilised under this legal procedure in so far as this situation is covered by the exception included in the 1989 reform,[51] although here also doubts may be raised.

Exclusive responsibility for initiating the procedure rests with the legal representatives so that undesirable interference from third parties and the State itself may be avoided, given that neither the judge nor the public prosecutor can do anything until the parents take the initiative. The judge and prosecutor, for their part, will satisfy themselves that the sterilization is being performed for the benefit of the mentally-deficient person and not in the exclusive interests of the legal representatives. The certificates of opinion issued by the two specialists shall refer both to the psychiatric condition of the incompetent subject as well as to environmental circumstances that may make the operation advisable or otherwise. The judge's examination of the incompetent minor enables him to assess the situation better and weigh up the possible repercussions of sterilization.

In conclusion, decision-making by third parties is designed to protect the interests of the incompetent person, by favouring him/her in the areas of personality which may develop without the individual become stigmatised, such as the affective and sexual domains; in all cases, however, the circumstances of each individual shall always be kept in mind and generalisations avoided completely.

§ 3. Medically Assisted Reproduction

I. Social Context and Legal Background

232. The fact that there are more than one hundred and eighty thousand infertile couples between the ages of 20 and 35 in Spain would appear to indicate that the use of assisted reproduction techniques will certainly grow here. According to the calculations of the 'Sociedad Española de Fertilidad' (Spanish Fertility Association), a proportional increase in the number of medical centres where such techniques are available will ultimately have to reach a figure of some 38/40 such centres to meet the needs of the current population.

233. From the legal point of view this raises a number of issues of a mainly civil nature — especially regarding family law and inheritance law — though some problems of a criminal nature and others in the realm of administrative law in relation to health care also arise. In response to the need for regulation of the aforemtntioned techniques a specific law was passed, which was the result of work undertaken by a Parliamentary Select Committee on the study of human in vitro fertilisation and artificial insemination.[52] The committee's work was carried out over several sessions during the second half of 1985 and concluded with a Report (*Informe Palacios*) which was subsequently passed by the House.[53] The report itself ends with a list of recommendations (155 in all), as well as a number of suggestions from parliamentary groups

regarding points over which there was disagreement.

234. Law 35/1988 comprises 7 chapters, preceded by an extensive and well-documented Preamble, which is extremely useful in that it provides precise definitions of certain terms (e.g. the definition of pre-embryo) and insights into the purposes of and reasoning behind some of the regulations. It also contains a transitional provision and four final provisions which have not yet been developed by the appropriate statutory provisions. The Law was not passed with the consensus sought by the Report, as can be gauged from the fact that not only were three vetoes lodged against the Bill in its entirety but also a string of partial amendments were tabled by parliamentary groups (most of which were rejected). From other, mainly technical, juridico-civil and legislative, perspectives the Law has come in for a good deal of criticism.[54]

235. The Law applies to the various assisted human reproduction techniques currently available (art. 1. 1): artificial insemination with the husband's semen (*ex* art. 5. 8. and 8), with that of the partner when the couple are not married (*ex* art. 9. 3) with a donor's semen (*ex* art. 5); *in vitro* fertilization with embryo transfer and intratubal gamete transfer. The Law allows the reception of an egg by an infertile woman who will complete gestation, and also the reception of a pre-implanted embryo (also called a pre-embryo) whose gametes of origin are not those of the couple, or the woman's egg and her partner's semen or that of a third party donor (*ex* art. 5. 1). Surrogacy and substitution are not permitted (art. 10).

II. Purposes of Assisted Reproduction Techniques

236. The three purposes that the Law strives to fulfil and permits can be conventionally identified as follows: 1.A fundamental purpose, which consists in a medical remedy for human infertility by means of the above mentioned techniques; 2.Another purpose, which might be termed complementary or secondary, is the prevention and treatment of genetic and hereditary diseases; 3. A third purpose, derived from or made available by the other two purposes, is research using gametes or fertilised human eggs. We shall look at each of these purposes in turn.

237. *Fundamental purpose: combating human infertility.* As has already been stated the fundamental purpose of these techniques is to combat human infertility so as to facilitate procreation (art. 1. 2). The other purposes are, therefore, subordinate to this or derive from it. That we are concerned with a therapeutic remedy can be seen not only in the fact that the law seeks to facilitate the production of offspring by couples that encounter difficulties in this area, but also in that the techniques are to be used 'only when scientifically or clinically necessary' (art. 1. 1) and when 'other treatments are discounted as inadequate or ineffective' (art. 1. 2 last clause). This last clause would seem to limit the use of these techniques exclusively to those situations where there is proof that no effective or adequate alternative therapy is available. A literal reading would imply that if it were possible to make use of other procedures offering a certain guarantee of success (e.g. drug or hormonal treatment, surgery etc.) these should have preference. Nevertheless, it can be seen that the legal position in reality is open to other possible uses of assisted reproduction not necessarily bound up with the prevention of disorders such as human infertility. Faced with the dilemma that arises from allowing these procedures either as a therapeutic remedy or as an alternative form of procreation, the Legislature appears to formally decide in favour of the former approach but in fact finally opts for the latter of the two.

In the first place it can be seen that the law explicitly allows single women to make use of assisted reproduction techniques: '*Any* woman may be the recipient or user of the techniques that are regulated by the present Law...' (art. 6.1). No distinction is drawn as to state or condition. However, specific reference is made to married woman (art 6. 3: 'If she is married...') which implies some explicit recognition that she may be single, although this could be taked as meaning that the alternative is a woman who is unmarried but living with a man, a situation to which the Law refers later (art. 9.3). However, there is nothing in the text of the

Law or in the preamble that would lead us to conclude that the 'completely single woman' is to be excluded. The Preamble (section III, parag. 2º) leaves us without even the vaguest doubt: 'However, in respecting the rights of women to establish their own families in the terms laid down in international conventions and agreements on equality of the sexes, the Law must eliminate any limitation that undermines a woman's wish to reproduce and create a family unit freely and responsibly.'

238. The acceptance of the single woman does not in itself constitute an exception to or contradiction of the fundamental purpose of offering a medical response to human infertility, but may be viewed as leaning towards a particular approach, which may or may not be viewed as questionable. The doubt that has to be resolved is whether the woman must be infertile or whether she might also be fertile. The fact that there is no explicit reference to this in the text of the Law in its final form results in an almost certainly deliberate ambiguity.

If we turn to art. 1.2 (the fact that this is placed in the first Chapter and is entitled "Scope of the application of techniques of Assisted Human Reproduction" should not be overlooked), in general terms, that is taking its literal legal significance, it would appear to allow the application of these techniques in the prevention of human infertility, regardless of whether the woman is single or not, as in art. 6; however, they are not applicable to a fertile couple or single fertile woman. Art. 1.2 itself raises new doubts as to what is meant. The article indicates that the "*fundamental* purpose is medical response to human infertility": a fundamental purpose most certainly, but not the only purpose. Does it only allude to the other purposes mentioned above that are also mentioned further on in art. 1? Or does it imply acceptance of other exceptions, hypothetically included in the other articles of the Law, such as access by the single fertile woman? Moreover, given that there is no doubt whatsoever that art. 6 neither limits this possibility nor explicitly allows it, taking this provision in isolation would lead to the conclusion that since it does not prohibit it, it allows it (by virtue of the general principle that 'what the law does not expressly prohibit is understood to be permitted'). Furthermore, these circumstances are not included among the administrative offences that the Law envisions (art. 20). The issue would appear to be settled definitively by the section of the Preamble quoted above, which, it will be recalled, considers it a priority that the Law should eliminate any restrictions on a woman's desire to procreate and create a family unit freely and responsibly.

239. We accept this conclusion in part although we do not entirely agree with it, given that it has inevitable consequences for the scope of application of the Law. It is also reprehensible from a systematic point of view in that the true scope of the Law is not determined by the Chapter which addresses this very issue, but rather is dealt with further on in the text.

In accordance with the principle of constitutional equality proclaimed and utilised in the Preamble to the Law, the couple, married or otherwise, must have access to assisted reproduction techniques whether they are infertile or not without their necessarily having exhausted the possibilities of other therapies. If this is not so, there is discrimination against the couple in comparison to the single fertile woman. This means that all references to the clinical indication (art. 1.1), the medical response to human infertility (art. 1.2), become nothing more than verbiage devoid of content or meaning. To allow a single woman access to the techniques (especially if she is fertile) would entail another type of discrimination affecting the 'single male' and so on.[55]

If we have defended the freedom to procreate (which would include both natural and assisted procreation) by drawing on this constitutional support, we have also maintained (starting from the obvious statement that there is no such thing as an unlimited or absolute fundamental right) that the rights of third parties can legitimize the State's intervention in or limitation of access to these techniques legitimate in order to protect specific collective interests or those of the child itself. The well-being of the child, the right not to be deprived from conception of a father or mother (with the exception that the woman may make an individual decision to conceive without having a permanent partner or certain knowledge of who the father of the child might be), or, put another way, the obligation of public authorities to protect

the well-being of the future child,[56] bearing in mind that the child cannot be the object of a subjective right, has implications that the State cannot ignore without consequent ethical repercussions or undesired consequences. This in itself does not prohibit the woman from having access to motherhood (even if she is infertile), but means that recourse to the techniques available to the community is to a large extent administered by the State; it is in the couple (permanent or otherwise, fertile or infertile) that this right must lie, as a natural means of producing a child, with the obvious proviso that there being two parents is no guarantee that the environment is absolutely ideal for the child or that the identity of the true father is known. Adoption provisions, including circumstances where a single person is allowed to adopt, start from a different position, namely, to improve the situation of a child that has already been born and is without parents or whose parents have rejected him or made him available for adoption willingly or unwillingly (e.g. if the parents believe that the child will be better off with the adoptive parents).[57]

240. *The complementary or secondary purpose: prevention of genetic or hereditary illnesses.* The Law makes allowance for the use of assisted reproduction techniques to prevent genetic or hereditary diseases in the following terms: "These techniques may also be used in the prevention and treatment of diseases of genetic or hereditary origin, when sufficient diagnostic and therapeutic guarantees are provided that these techniques are strictly indicated" (art. 1.3). Consequently, the recipient or beneficiary of this provision is the unborn child (*concepturus nasciturus*). Antenatal (prior to conception or prenatal) diagnosis is used to determine if the conditions exist and action is performed exclusively upon the gametes or pre-embryos.[58] This means that the Law authorises the selection of healthy gametes or pre-embryos and the elimination of those that have deleterious genes or hereditary diseases in such a way that the unborn child is protected from the damage that these might cause. Diseases related to the sex of the child (e.g. diseases related to the X chromosome such as haemophilia and Duchenne's muscular dystrophy) are included here which means that selection on the basis of sex is permitted. It would seem logical that if it is possible to prevent inherited diseases through the techniques of assisted reproduction, all available scientific means should be used (negative eugenesia).

241. This legal provision does not include other diseases that only affect the parents (except infertility, with the above mentioned provisos, included in art. 1.2). It is not possible, as a result, to meet the parents' request to determine the sex of their child through assisted reproduction techniques without there being some pathological risk for the child that might justify this. This conclusion is not only arrived at through reference to the previously cited art. 1.3, which determines (in part) the scope of application of the Law, but also because 'the selection of the sex of the child or genetic manipulation without therapeutic purposes or for unauthorised therapeutic purposes' (art. 20.2.B.n) is regarded as a serious offence. Law 42/1988, of 28 December, on the donation of embryos and human foetuses or their cells, tissue or organs, is consistent with this position in allowing the use of genetic technology for therapeutic ends, the selection of sex to prevent the transmission of sex chromosome-related diseases (art. 8. 2. c) being a case in point. All other motives for the selection of sex are deemed unlawful.

A case involving choice of sex for reasons other than the prevention of genetic or hereditary illness, but rather in rseponse to the wishes of the parents, was settled by the Spanish courts A married woman who had given birth to five male children sought permission from the judge to have a daughter by means of artificial insemination with her husband's semen, after selection of the sex of the child. The judge granted permission, basing the decision primarily on the woman's claims, which were partially supported by expert witnesses, that the frustration of not being able to produce a daughter by natural means had resulted in various psychological problems (mainly depression) that could be resolved only if she were allowed to select the sex of her child. The Barcelona High Court reversed the decision[59] relying on carefully thought out legal reasoning along the lines presented above. The Court coincided with the argument used by the Public Prosecutor's Office (which had appealed the

original decision) that if the woman was suffering from reactive depression then she did not satisfy the requirements laid down in the Assisted Reproduction Law, namely, that the woman should be in good psychological health (art. 2.1.b).

242. *Purposes derived from or opened up as a result of the other purposes: research with gametes and pre-embryos.* Assisted reproduction techniques require continued research and occasional experimentation using human biological material. In achieving the other purposes these techniques make available gametes and pre-implantation embryos (or pre-embryos) that may be used for research purposes. The assisted reproduction Law allows for research and experimentation using gametes and fertilised human ova (art. 1.4), but seeks at the same time to control this use (arts. 14 to 17). The fact that Law 42/1988, which also deals with these matters and which followed a similar parliamentary process, was passed soon after raises the issue of whether or not it might have been preferable to leave such matters to this second law. The interests involved are, on the one hand, the right to carry out research and, on the other, the protection of the pre-implanted human embryo, that may not under any circumstances be used as if it were merely a piece of merchandise.

III. General Requirements

243. The first requirements[60] revolve around the medical indication and *lex artis*: reasonable chance of success; no serious risk to the health of the woman or the possible child (art. 2.1.a); in the case of *in vitro* fertilization involving the transfer of embryos, only the number of embryos sufficient to produce a pregnancy may be implanted (art. 4).

244. Other conditions refer to women reciptients, some of which are repeated unnecessarily in a later article specifically devoted to them(art. 6):

a)The recipient must have reached the age of majority, that is, eighteen years of age (art. 2.1.b), and

b) must be in good psycho-physical health (art. 2.1.b). This implies good physical health which is also an implicit requirement of the medical indication. If the woman were not in good physical health the use of the techniques would imply additional risks to her health —and to that of the foetus— thus jeopardising the success of the operation; sound psychological health is seen as necessary for the woman to cope with the tensions that motherhood via these new procedures might imply. It is also considered that the possibility of giving birth to a child of different genetic origin to that of her partner might provoke a number of reactions as a result of ethical and cultural concepts that are deeply entrenched in society. This implies the exclusion of mentally-incompetent women, (those suffering intellectual disabilities and psychiatric illnesses) and would also supposedly exclude women with some significant degree of emotional instability, since what is required is not just the absence of 'ill health' but 'good health'.

c) Informed consent. It is not sufficient for the woman to have simply given her consent. Clearly she must also have sought the treatment freely and consciously. Consent and acceptance require prior information and even legal advice (art. 2.1.b and 2). The information requirement also applies to donors. Information should be provided by the medical teams and those in positions of responsibility in the health centres or institutions where the treatment is to be carried out. The information (and the legal advice) should cover the various possible factors and implications arising from the techniques, as well as their outcomes and foreseeable risks entailed. Biological, legal, ethical or economic considerations arising from the techniques should be covered also. Apart from the fact that it is almost impossible to achieve the broad aims of this requirement (how are 'any other conditions arising from the use of the techniques' to be defined?') it would seem that information of an ethical nature is irrelevant as these are questions to do with the individual's personal moral views. It would also seem that other types of information are only relevant in so far as they affect the individual circumstances of those concerned (e.g. if there is a question of inheritance). Consent is to be expressed in writing on

an official consent form (art. 2.3) and all information relevant to the use of the techniques is to be recorded in the clinical histories of both donors and recipients. Confidentiality shall be maintained (art. 2.5). Clearly, these are all matters already dealt with in the LGS (arts. 10 and 61). The possibility of the woman recipient withdrawing her consent is recognised and the process must be interrupted immediately this occurs (art. 2.4). Although the woman's right to refuse to continue treatment is self-evident, determining exactly when this right ceases to be available is rather intricate. Once fertilization has occurred or once the pre-embryo has been implanted and has become fixed in the endometrium or nesting has taken place other legally protected interests exist, namely, the life of the conceived. Thus, 'removal' or 'extraction' from the uterus constitutes a punishable abortion unless this falls within the scope of and satisfies the requirements of the therapeutic or eugenic indications (a similar problem occurs with multiple pregnancies when it is necessary to remove some of the embryos so as to ensure the successful completion of gestation for the other(s)). Even so, the word used in the Law is 'suspend', which covers only the cessation of any process leading to the woman becoming pregnant but not any action designed to reverse the process of gestation once it has been initiated.

IV. Subjects of Assisted Reproduction Techniques

245. *Donors*. Donors must have attained the age of majority (eighteen) and have full capacity to act (an indispensable condition for the formation of a contractual relationship, in this case as a donor). They must be in good psycho-physical health to the standard stipulated in the compulsory protocol for donor suitability assessment, which shall include information relating to the donor's phenotype characteristics (so as to ensure similarity with the recipient) and verification that the potential donor does not suffer any genetic, hereditary or infectious diseases (art. 5.6), a requirement that is obviously included in *lex artis*. Provision is also made for the taking of measures to prevent more than six children being produced from the same donor (art. 5.7). The husband who provides semen for the insemination of his wife is subject to the same requirements governing normal donors, as are donations of spare gametes that might be used in the fertilization of any other woman (art. 5.8). It is understood, though not explicitly stated, that donation must be voluntary.

246. Donation can consist of gametes (semen and ova) and of pre-embryos. The contractual relationship involves no exchange of money and is formal and confidential with the donor and the authorised centre as parties to the contract (art. 5.1):

a. the reference to no exchange of money implies that donation may not be made for the purposes of financial gain (art. 5.3). The donor may not receive payment and the centre may not sell gametes or pre-embryos.

b. 'formal' here means that the contract shall take the form of a written agreement between the two parties, the donor having previously been informed of the purposes and consequences of the donation.

c. 'confidential' refers to the fact that the donation shall be anonymous.[61] The identity of the donor shall remain secret and the name kept in coded form only in the Banks and in the National Donor Register (which has yet to be drawn up). This is one of the points that has provoked debate among specialists particularly over the hypothetical right of a child to know his genetic origin, ie, to know the identity of the natural father. The donor's name can in fact be revealed (without there being any publicity) in two sets of circumstances: if the child's life is endangered or when disclosure is necessary in criminal proceedings. In both cases the name can be revealed only if it is absolutely indispensable to avoid the danger or to achieve the legal purpose (art. 5.5). Under no circumstances can disclosure of the donor's name lead to any kind of legal kinship relationship (8.3). Lastly, donations are not revocable except in the case of subsequent infertility on the part of the donor, who may then need his own gametes, in which case he must refund to the Centre all costs ensuing from the donation (art. 5.2). This extreme measure would be discriminatory if it placed a greater financial burden on the donor than it did on any normal recipients.

In the regulations relating to donation it is not very clear exactly how donation of pre-

embryos takes place or what the nature of the contractual relationship is from a formal perspective. Clearly this is a complex issue, given that the pre-embryo is the product of two gametes (sperm and ovum) from a man and a woman, which means that there are two donors who must give their consent.

247.*Users*. Apart from the issues discussed above (such as the possibility of access to the techniques for fertile and infertile single women, a series of general requirements and some more specific requirements are stipulated.

As regards general requirements, there is unnecessary repetition of virtually identical requirements to those mentioned above in art. 2 of the Law. The need for free, conscious and explicit consent is stipulated, as is the fact that users of these techniques must be eighteen or over and have 'full capacity to act' (art. 6.1). This expression does not fit very well the expression used earler which we discussed above —'in good psycho-physical health' (art. 2.1)—: doubts arise as to whether they are requirements aim to achieve the same purpose or different purposes. It would seem however that the requirement of art 2.1 is stricter than that of art. 6.1.

248. More specific requirements:

a. Specific information on the foreseeable risks both for the children and for the woman during the pregnancy should be provided for the recipient who is not of the right age (art. 6.1). This is really a question of medical indication for the treatment and of *lex artis*. If these risks are really significant the doctor should not proceed with assisted fertility treatment for a woman who is at an age where the risks are so great that the techniques should not be employed. This does not mean, however, that information regarding the proportionally greater risk to the older woman should not be given and it would be unnecessary to stipulate this anyway since it is an obligation which stems automatically from the requirement to provide all relevant information. It would also be erroneous to interpret this as meaning that having provided the necessary information the physician has satisfied all his obligations, without having to make use of his specialist knowledge. If he did not act in accordance with his specialist knowledge he could well be deemd to be civilly or criminally liable, depending on the circumstances.

b. The woman needs the consent of her husband, although with non-married couples partner consent is not compulsory. A husband must give his consent in the manner stipulated in the 'previous section' (art 6.3), which is in fact not the preceeding section (art. 6.2), but rather the first section of art. 6, which refers to the requirements governing user consent. Through this requirement it is intended that the husband takes on paternity of the child even when fertilization has been achieved with donor semen or a pre-embryo donated by third parties. Exceptions to this are couples who are legally separated or divorced or those who are in a de facto situation of separation and vouch to that effect. The Law makes no specific mention of annulled marriages (arts. 73 and ff. of the Civil Code), but it is understood that the consent of the former husband is not necessary in these circumstances. Neither would it be necessary if the couple were divorced, although in this case the Law does make specific mention, unnecessarily given that if they are no longer married he is no longer the husband.

If the couple are not married, the male party may give his consent prior to the use of the techniques, in accordance with the same conditions, so as to achieve the same effects in terms of paternity discussed below (art. 6.4). The issue of prior consent is not specifically mentioned in relation to the husband or the female user (consent given prior to the use of the assisted reproduction techniques). Despite these apparent differences in terms of the unmarried partner's consent, the characteristics are the same both before and after the utilization of the techniques and even after pregnancy has been achieved.[62] Finally, the possibility of the male partner (married or not) withdrawing his consent is considered, provided that this occurs before the techniques have been applied (art. 9.4) which would imply that the process would have to be interrupted if the woman is married (unless the couple have separated). Withdrawal of consent is only possible *before the techniques have been applied*. The real issue is where the time limit lies. Is it the beginning of the whole process or after an attempt at fertilization

(successful or otherwise)? In order to bring this into line with the woman's rights to interrupt the process, 'applied' would have to be understood to mean even after an attempt at fertilization. In this way the male partner might still withdraw consent even though the process had begun (e.g. he may have given his semen, ova may have been removed from the woman and fertilization attempted unsuccessfully) so long as fertilization had not been achieved. This is the same line of reasoning we followed above.

c. The female user may not choose the donor. This condition stems from the anonymous donor requirement: users may not choose from among the donors available at the centre or provide their own donor, except in the case of an unmarried couple and then the donor partner would have to take on the corresponding obligations arising from paternity. Nevertheless, it would appear that the Law does not foresee the possibility of an unmarried male providing his own semen since it makes no reference to this. In such a situation the man would be considered an ordinary donor. In any case, the Law does not refer either to insemination with the husband's semen, which is clearly lawful; moreover, since it allows *post mortem insemination* with either the husband or the unmarried partner's semen (art. 9) there is all the more reason for considering that the unmarried male partner can provide semen for fertilization while he is still alive.

As a result, the decision as to choice of donor is made by the medical team on the basis of strictly medical criteria, and others stipulated by law, which are designed to guarantee the greatest phenotype and immunological match of the donor as well as the maximum level of compatibility with the woman and her family environment (art. 6.5). In reality, the Legislature does not seem to have understood just how such a choice might combine genetic compatibility with compatibility with the woman's family environment, which is after all a social factor, once the other requirements (designed to prevent interracial pregnancy, which might well raise other problems for the woman — e.g. the single woman — who wants to produce children of this kind) have been met.

249. *Parents and children.* What reference the Law makes to parents and children relates, in the first case, to the participation of parents in the techniques and the assumption of legal, though not genetic, paternity that this participation implies, and, in the case of the children, to relationships of affiliation.[63]

250. The Law provides special regulations (art. 7.1), choosing to leave overall considerations with regard to relationships of affiliation to the general regulations contained in the Civil Code. The special issues dealt with are the possibility of withdrawal of consent, mentioned above, the fact that registration of the birth in the civil register must make no reference to the use of assisted reproduction techniques (art. 7.2) so as to avoid any possible future discrimination against the child and, finally, the fact that disclosure of the donor's identity in the cases where this is permitted does not imply legal paternity, as has alrerady been stated above.

a. The case of the married couple. If the semen donor is the husband, no specific problem relating to paternity and affiliation arises except in the situation where the husband does not consent or withdraws his consent before fertilization. If the semen donor is the husband but fertilization is achieved after his death (*post mortem* fertilization),[64] his consent is decisive from a civil law point of view, as is the moment it was given. The regulation states that no relationship of paternity exists and no legal consequences arise between the post-humus child and the deceased husband 'when his reproductive material is not found in the woman's uterus at the time of death' (art. 9.1). In other words, as we will see later, if he does not give his consent to the fertilization of his wife while still alive. If, on the other hand, he consented, in a public declaration or sworn testament to his reproductive material being used to fertilise his wife within six months of his death, the legal result is paternity within the marriage (art. 9.2). Leaving civil issues apart, the time limit once more must be determined. It would seem from a literal reading that it is not necessary for successful fertilization to have been achieved within this six month period but rather it suffices for the process to merely have been started. For example, an initial unsuccessful attempt may have been made and some of the deceased

husbands semen is still available and is used later or seminal or pre-embryo implantation has been performed and the results are still not known during the six month period.

When the married couple need a donor's biological material (consisting of either the ovum or the semen or of a pre-embryo) and both give their consent to this in the terms established by the Law, there exists an irrefutable assumption (*iuris et de iure)* of matrimonial affiliation with the child born out of the procedure. This affiliation may not be challenged (art. 9.1).

251. The case of the unmarried couple. If an unmarried male[65] gives his consent prior to fertilization of his partner in the manner described above, the document of consent will be considered to be a reliable document under art. 49 of the Civil Registry Law, which means that it will imply recognition of paternity, although this in itself does not rule out the possibility of a paternity claim being made at a later date (art. 9.2).

There is also the possibility of *post mortem* insemination using the semen of the unmarried man. The conditions described above with respect to the married man apply equally and with the same effects in relation to art. 49 of the Civil Registry Law (art. 9.3).

252. *Surrogate or hired mothers.* As was stated earlier, surrogate motherhood is not permitted under the terms of the 1988 Law. As a result any such contract is null and void, whether or not payment has been made and regardless of whether the agreement is between the couple seeking these 'services' or intermediaries and the woman concerned (art. 10.1). The affiliation of any children born out of surrogacy is determined by birth (art. 10.2), that is to say, maternity lies with the woman who gave birth to the child regardless of whether the ovum was hers or that of another woman or the semen that of the male partner of the couple concerned. If the male partner has provided the semen (or if it has been provided by a third party donor unconnected with an authorised centre or by a donor in collusion with the centre) the biological father can claim paternity (art. 10.3). This would also be the case under the general statutory provisions of the relevant part of the CC.

V. Offences and Sanctions

253. The Legislature has ultimately chosen not to create new criminal offences associated with assisted reproduction techniques, although initially it looked as if it would do so,[66] but has been content rather to create an extremely long list of (serious and very serious) administrative offences and their corresponding sanctions (art. 20). Offences can be grouped together as follows: a)failure to adhere to health administration regulations; b)violation of the rights or interests of the individuals concerned (users and donors); c)offences connected with the protection of human biological 'material' (gametes and preembryos); d)the use of assisted reproductions techniques for purposes other than those stipulated in the Law; and e) genetic manipulation.

One might well agree with the decision not to include new offences. It would seem appropriate to allow a moratorium on possible criminal intervention until the passing of a new Penal Code (a draft Bill has recently appeared) and to reflect upon possible future types of conduct that might seriously damage the integrity, identity and diversity of the human species, which might provide a rough guide to legal interests that might in future require legal protection. Cloning, parthenogenesis, the creation of interspecies hybrids, the fusion of gametes of different origins might ultimately constitute new offences, but for the time being the administrative offences and sanctions set out in the Law on Assisted Reproduction Techniques are in themselves sufficient.[67]

§ 4. Prenatal Diagnosis and Humans Genetics

I. Purpose and Lawfulness of Prenatal Diagnosis

254. Discoveries in the field of human genetics now make it possible to determine the genetic

characteristics of the foetus. They have also opened up a range of possibilities in terms of the treatment of diseases of genetic origin in the foetus. Prenatal diagnosis has made a major contribution to this field. This is understood to mean the medical procedures by which information on any congenital defects in the foetus can be gathered.[68]

With this diagnostic technique it is possible to detect disease and deformity and to predict the sex of the foetus. The latter is relevant in terms of hereditary diseases related to gender. These diseases may be detected in the foetus. When the couple are considered to be in danger of giving birth to children with abnormalities the technique facilitates early detection. The foetus is, as a result, the object of prenatal diagnosis. In preconceptive diagnosis, which is used to determine whether or not sterilization (or some other contraceptive procedure) is necessary for eugenic reasons, the two partners of the couple are the object. Prenatal diagnosis, like preconceptive diagnosis, is largely concerned with information of a genetic nature. A plethora of techniques is currently available for the early detection of foetal abnormality: sonar scans, embryoscopes, foetoscopes, X-rays, choriocentesis, direct testing of foetal blood, amniocentesis, etc. Although amniocentesis is the most reliable of these techniques, it involves an risks (albeit ever-decreasing) such as loss of the foetus (miscarriage or still birth), foetal infections and injuries, neonatal disturbances and complications for the mother (visceral perforation, premature detachment of the placenta, premature breaking of waters, infection, heart failure and death, uterine contractions, premature labour, *postpartum* haemorrhaging).

255. Given the wide range of diagnostic possibilities offered by these techniques, we will indicate the major purposes for which they might be used: a) to reassure high-risk parents that the baby is free from abnormality and illness; b) to allow surgical or drug treatment of the foetus or other types of foetal therapy to rectify or alleviate any abnormalities; c) to determine the most appropriate method of giving birth in accordance with the existing abnormality (e.g. by caesarian section); d) to ascertain what kind of treatment will be appropriate for the baby immediately after birth or later (predictive medicine); e) to decide that a eugenic abortion should be performed, if this is permitted by law, which it is in Spain (art. 417 bis nº1. 3ª of the Penal Code); f) to decide whether an abortion for the purposes of sex selection should be performed, if this is permitted by law (it is not permitted in Spain); g) to verify whether or not the child is abnormal and to set in motion the necessary legal processes for its adoption by third parties or placement in an institution[69]. The decision as to the various options rests with the parents and depends upon their personal beliefs and, in the case of abortion, the legal position. Thanks to the progress achieved in perinatology in recent years, the wide range of prenatal diagnostic possibilities offered by the techniques is not seen as necessarily giving rise to an indiscriminate rise in abortions.

There is no reason why prenatal diagnosis, involving as it does the *treatment* of the foetus as far as this is possible, should not be considered a therapeutic measure just like any other diagnostic method. For this reason it must be regarded from the criminal law point of view as not giving rise to the offence of causing bodily harm through action carried out on the mother or the foetus[70] for the purpose of diagnosis, because this is done for the potential benefit of both. It is essential that care is taken in determining whether or not the diagnosis is necessary, that all risks entailed are carefully considered and that any action taken conforms to *lex artis*. Techniques that are still to some extent of an experimental nature are included here also (therapeutic experimentation) as are those that imply some degree of risk, such as amniocentesis, as was discussed above. If the diagnosis is carried out with a view to a possible abortion (diagnosis permitted by Law 35/1988 on Assisted Reproduction Techniques, art. 12. 2), given the fact that the injuries caused by the tests are of a minor nature (the equivalent of a misdemeanour for bodily harm), they would be covered by the consent of the pregnant woman, who is the one who actually suffers the injuries in the first place.

256. In much the same way as preconceptive diagnosis and genetic screening, prenatal diagnosis has provoked discussion on whether it should be voluntary or obligatory. For the same reasons therefore, use of such techniques should be subject to the freely-made choice and the responsibility of the couple or pregnant woman, even though this may pose problems. The

Assisted Reproduction Techniques Law of 1988, stipulates that the couple or the woman must have been fully informed of the procedures, diagnostic investigation, possibilities and risks of the proposed therapy and have accepted these previously (art. 2. 2); we will return to this below in our discussion of foetal therapy, but it is appropriate to point out here that prior consent is required not just for the therapy, but also for the procedures and diagnostic investigations etc., which gives support to the line of argument used above. The Law only allows prenatal diagnosis where it serves the wellbeing of the *nasciturus* and its future development (art. 12. 2) or as supporting evidence for abortion in the case of the eugenic indication.

II. Foetal Therapy[71]

257. The foreseeable future developments in terms of foetal therapy open up new perspectives such as a reduction in the number of abortions performed for eugenic reasons because they will allow for certain foetal abnormalities to be corrected.[72] Doctors will then be confronted by the peculiar situation of treating a 'patient', the foetus, that differs from the ordinary patient in the sense that it is inside the body of another person — the mother. All foetal therapies must inevitably be carried out through the mother's body.[73] As a result, the application of the term 'patient' to the foetus has specific and peculiar legal characteristics. This is particularly so with regard to bodily harm inflicted on the mother (e.g. if a caesarian or some other surgical operation has to be performed on her to reach the foetus or when certain drugs are administered), any dangers which treatment entails for her life and health, and the fact that she gives her consent to a treatment that will not benefit her directly (although it is not unusual for the mother also to present symptoms of some kind), but the child she bears. It should not be forgotten either that foetal therapy can give rise to injuries in the foetus that become apparent only after birth. Foetal therapy may even cause the child to die before birth or soon after.

As we have already seen, in Spanish law the life of the child is a legally protected interest independent of the mother. For this reason the law punishes wilful abortion — (and in some cases negligent abortion, art. 412 of the Penal Code) while acknowledging legal exceptions that allow abortion and the destruction of the foetus. Nevertheless, strictly-speaking the Criminal Law cannot be said to protect the health or physical integrity of the foetus (except when its viability is affected, that is to say its life as such), nor does it punish death caused through negligence (with the aforementioned exception), all of which conditions the legal response to any conflicts resulting from foetal therapy. It is worth recalling, however, that on the international level there is a document of relevance here, namely, the Declaration of the Rights of the Child of 1959 which, despite its limited jurisdiction, recognises the right to treatment even before birth (art. 4).

258. Whatever the most appropriate solution to these problems might be, there is no doubt as to the lawfulness of any therapeutic action performed on the foetus with a reasonable expectation of some improvement, as was said above with regard to diagnostic tests undertaken beforehand. Nevertheless, the Assisted Reproduction Techniques Law establishes certain limitations and conditions for foetal therapy. The limitations restrict the therapy to treatment which will serve the child's wellbeing and development. All other treatments, although they might be deemed to be therapeutic, are excluded; the beneficiaries of foetal therapy, are, according to the Law, the embryo or foetus inside the uterus, or the foetus outside the uterus, if it is viable (art. 13. 2). The conditions imposed by the Law restrict the use of the techniques to serious or very serious illnesses or diseases that are amenable to precise diagnosis, when there is a reasonable chance of alleviating or solving the problem. A list of such illnesses to which therapy may be applied on the basis of scientific criteria alone should be made available;[74] the techniques may not be used to alter hereditary characteristics that are not pathological, or for the selection of individuals or of race; the therapy must be administered in authorised health centres by qualified teams with all the necessary equipment. Lastly, consent must be given by the couple concerned (art. 13. 3), an issue to which we will return later.

259. Problems arise when the time limits for the eugenic indication for abortion (twenty-two weeks) have expired. It may be, for example, that any abnormalities in the foetus remain undetected until the time limit has passed (the Legislature either failed to envisage this situation or chose not to consider it) or that the nature of these abnormalities is not serious enough. In neither case would eugenic abortion be justifiable. What normally happens, however, is that the mother who has discarded the possibility of abortion either voluntarily or because she has no choice, wants to do everything possible to ensure that her child is born in the best possible health and, therefore, she does all she can to see that this occurs. One cannot, however, dismiss the possibility of her rejecting the child, as can occur when not only her health but her religious convictions are at stake. In any case, it would be very difficult to provide an appropriate legal solution to each and every situation (consider, for example, the level of difficulty if the treatment is unlikely to be successful and at the same time entails serious risks for the mother.)

It may be that the foetal abnormalities are serious (we are still considering the circumstances in which the possibility of eugenic abortion is excluded), in which case it is essential to evaluate the risks for the mother. If medical evidence confirms a high level of risk, the decision is in the hands of the mother. Coercion must not be used to pressure her into having the treatment,[75] as this could give rise to an action for causing bodily harm. We draw support here from the fact that the *current*[76] conflict between the health of the mother and the life of the foetus is resolved by Spanish law in favour of the mother (therapeutic indication for abortion, art. 417 bis nº 1. 1 of the Penal Code); this includes specific surgical operations performed on the mother so as to gain access to the foetus and a series of treatments that are still at the experimental stage, the consequences of which for the mother and the foetus are not easily predicted.

260. In cases where there is no danger whatsoever to the mother but the life of the foetus is under threat it would be possible to claim a state of necessity (art. 8º nº7 of the Penal Code) to justify intervention on behalf of the foetus' or, better still, to act in fulfilment of the duty to save the life of the foetus (art. 8º nº 11 of the Penal Code), given that this situation produces a conflict of duties for the doctor.[77] It is difficult to determine how far this solution is compatible with the ruling given by the Constitutional Court (April 11 1985) which, it should be said did, not specifically deal with this issue in any way. The decision concerned the decriminalization of abortion and established a rangking as regards conflicts of interests affecting the mother and the conceived child. Notwithstanding the mother's rights in terms of personal freedom, ideological freedom and freedom of belief, there is a conflict between the mother's privacy and dignity and the life of the foetus. Such a conflict may also arise in the situation we are discussing here, although in such circumstances attention should be directed to the life of the conceived child.[78]

261. Finally, in the hypothetical situation that no danger exists for the foetus or the mother it may prove difficult to force the mother to undergo treatment against her will, given that 'only' the health of the foetus is at stake, even though the treatment could successfully eliminate the abnormalities diagnosed and common sense would indicate that it is appropriate. Although in principle it would be possible to allege a state of need or fulfilment of a duty, clearly in each case there is a conflict between interests (personal freedom or conscience, among others, for the mother and the health of the foetus) that are protected by the Spanish Constitution and other provisions[79] — a conflict that is not easily resolved. The Constitution also protects the integrity and health of the conceived child (art. 15), while acknowledging that differences of appraisal may operate depending on whether the child has been born or not. These differences are dealt with in other regulations and are resolved in favour of the mother, as can be seen in the fact that only her interests are protected by the criminal law (the interests of the foetus are protected in the Civil Code, art. 29: "... the conceived is considered born for any purposes which may be favourable to it...") which means that the legal duty to attend to the needs of the foetus is of lower rank than the duty to avoid conduct that is harmful to the mother (conflict of duties), or

—if we do not adopt this criterion which is in principle preferable, as we have already said — the harm caused would be greater than the harm the act sought to avoid (the state of necessity), that is to say, the infringement of the mother's personal freedom would be more serious than the intended purpose of preventing diagnosed injuries to the health of the foetus. As a result, the factors that determine the legal applicability of a state of necessity are not present.

262. In conclusion, the above considerations, which have drawn from the Spanish Constitution and the logical conclusions that can be inferred from both it and the Penal Code, should be seen in the light of the third legal reference that addresses the issue more specifically. The Law on Assisted Reproduction Techniques makes provision for foetal therapy in the strict sense used here (it also covers preembryo and *in vitro* therapy) and lays down limits and requirements. In terms of the requirements — discussed earlier— the need for consent on the part of the couple or the woman on her own is significant (these requirements also pertain to the preembryo *in vitro*), which would seem to resolve the hypothetical question as to whether it is possible to act against the mother's will. Nevertheless, a more correct interpretation is to view the fulfilment of this requirement as essential in general terms, but not to the exclusion of other criteria such as those we have analysed in the exceptional cases referred to above. We remain sceptical, however, as to whether treatment to improve the health or save the life of the foetus which involves no significant risk for the mother can be carried out if she is opposed to it. Furthermore, demanding the consent of the couple is not justifiable when it is only the mother who will be affected by the risks of the foetal therapy. It is she who undergoes the treatment and assumes the risk involved, and therefore she alone need consent (despite what the Law says).[80]

III. Human Genetics

A. Legal Framework

263. Spanish law, albeit in a partial and sectoral manner, contains regulations which apply directly or indirectly to genetic innovations and studies of the human genome.

Two laws passed in 1988 have a much more direct effect on the various manifestations of human genetics: Law 42/1988 of 28 December governing the donation and use of human embryos and foetuses or their cells, tissues or organs; and Law 35/1988 of 22 November governing Techniques of Assisted Reproduction. The former deals with the donation and use of human embryos and foetuses or of their cells, tissues or organs, for diagnostic, therapeutic, research or experimental purposes (article 1), and refers specifically to gene technology; the second law regulates various aspects relating to techniques of assisted reproduction, as well as research and experimentation with gametes and pre-embryos or preimplantation embryos. Both laws include a list of conduct prohibitions, and contemplate the imposition of administrative (not penal) sanctions for such offences.

Recently, the Spanish Government introduced a new Draft Penal Code (1992). To the human genetics offences included in the two 1988 laws mentioned above, the Draft adds new ones which are designed to punish particularly serious misconduct.

In Spain, the international debate on the Human Genome Project has been echoed in recent years in two important international seminars on "International cooperation for the Human Genome Project" The seminars took place in Valencia in 1988 and 1990, and were organised by Prof. Santiago Grisolía (President of UNESCO's Scientific Coordination Committee for the Human Genome Organisation, HUGO) with the support of the Fundación Banco Bilbao Vizcaya (FBBV) and the Fundación Valenciana de Estudios Avanzados. The seminars produced two Declarations (the Valencia Declarations) concerning scientific activity and cooperation and ethical aspects of the Human Genome Project.[81] Another International Seminar along similar lines was organised by the same Foundation (FBBV) in May 1993 in Bilbao, and examined the most important legal implications of the Human Genome Project. Recently has been created the Chair of "Law and Human Genome", which is based at the University of Deusto (Bilbao). Its creation has been sponsored and promoted by the BBV

Foundation, the Diputación Foral (Statutory/County Council) of Vizcaya and the University of Deusto. It is the first Chair that exists in the world with this specific characteristics, that is to say, it is dedicated to the investigation, study and special teaching of the legal implications of research on the human genome, as well as to the results and uses for society. The Chair has a database and a library containing information about these themes avalaible for consultation on the part of the investigators and doctorate students of other national or international centres. From 1994 it edits a Review in Spanish and English concerning the legal questions which are most relevant to genetics; it will also publish other monografic works. Moreover it organises investigation seminars and specialist courses.

B. Some Specific Legal Implications of Human Genome

264. To take Civil Law first, the Spanish Constitution of 1978 empowers the law to permit investigation of paternity (article 39.1). This constitutional authorisation is included in the Civil Code, which enables paternity and maternity to be investigated in affiliation suits, using all kinds of proof, including biological proof (article 127.1), — and genetic proof—, even though no absolute certainty is recognised. Nonetheless, paternity research poses certain limitations derived from the presumptions of paternity as contained in the Civil Code: moreover, the Constitutional Court has ruled that these tests cannot be made obligatory or carried out against the wishes of the person concerned, although courts may take a refusal into account when determining paternity.[82]

265. As regards labour relations, the Constitution stipulates that discrimination on the grounds of race, sex, religion, or opinion is unlawful, and extends these grounds to "any other personal or social condition or circumstance" (article 14), which means that personal health may also be included as a factor of non-discrimination; the Constitution also recognises the right of personal and family privacy (article 18.1). This principle of non-discrimination and the right to privacy are also recognised in the General Health Law (Ley General de Sanidad) of 25 April 1986, having been included in the list of patients' rights (article 10.1), although it should be noted that these are applicable in relation to public health administrations and private health services only. Meanwhile, the Workers´Statutes Law (8/1980) of 10 March states in article 4.2,c), second paragraph, that workers "may not be discriminated against on the grounds of physical, mental or sensory handicaps, providing that they are fit to perform the work or job in question"; the law goes on to recognise in part e) of the same section the "right of persons to have their privacy respected, together with due consideration of their dignity". Hence, firms' attempts to carry out gene probes on their employees are prohibited to the extent that they represent an invasion of their privacy.

266. Spanish patent legislation makes no provision for regulating the patentability of the human genome, and covers animals and vegetables only. Article 4.1 of Patent Law 11/1986 of 20 March establishes the general principle that "new inventions which involve inventive activity and which may have industrial applications are patentable". Article 5 then lists the exceptions to the above: 1) The following may not be patented: a) inventions which, if published or exploited, would run contrary to public order or to proper customs; b) vegetable varieties covered by the provisions of the Law of 12 March 1975 governing the protection of vegetable by-products. c) animal breeds. d) essentially biological procedures for obtaining vegetable and animal by-products. 2) The provisions of b), c) and d) shall not apply to microbiological procedures or to the products obtained from such procedures".

C. The Use of Human Embryos and Fetuses for Genetic Research or for Other Non-Therapeutic Purposes

a. Introductory Considerations

267. Doctors, researchers and jurists are fully aware of the ethical and legal problems raised

by scientific breakthroughs which have proven to be effective in certain types of treatment and which have contributed to a marked reduction in child mortality and morbidity, (such as pathologies linked to Rh and the respiratory system). They have served also to increase our understanding of aspects of nutrition, foetal endocrinology and pharmacology, prenatal diagnosis, improved delivery and abortion techniques, human fertility, etc.

In spite of the proven advantages of such practices, many people have stressed the need for control and regulation in order to prevent risks to and manipulations with live foetuses during pregnancy, which may give rise to malformations which in turn would manifest themselves after birth, and also to prevent the risk of deliberately provoking pregnancies and/or abortions for the purposes of undertaking research with the fetus or to make use of use its tissues, with the consent of the mother (perhaps in return for financial or other type of reward). Equally important is the question of how the law should appraise and treat experiments carried out with live human foetuses extracted surgically in the course of legal terminations of pregnancy. Lastly, embryos obtained in vitro, prior to implantation in a woman (or even those which are not intended to be implanted) are valuable research material which is relatively easy to obtain. Furthermore, all such human biological components are liable to be used, and indeed are used on occasions, in the making of pharmacological and cosmetic products.

Hence the differing positions which have been adopted with regard to the problem of foetal investigation. Along with the promotion of freedom to engage in research (which is recognised as a fundamental right in the Spanish Constitution, article 20.1.b), and, through it, scientific progress which will benefit future (and present) generations, protection must be afforded to embryos and foetuses, irrespective of their state or ultimate destiny (alive or dead; viable or inviable; inside or outside the womb; conceived naturally or in vitro; whether from an abortion or otherwise; presenting serious or non-serious risks; for the benefit of the foetus or for that of science in general, etc.).

b. Embryos which are the Result of Artificial Reproduction Techniques ("in vitro")

268. As was stated above, the ease with which pre-embryos or preimplantation embryos can be obtained in laboratories for subsequent implantation in a woman to enable her to fulfil her dream of motherhood raises a number of problems concerning the ultimate use which is made of them. For example, in order to achieve a successful pregnancy by implanting an embryo obtained in vitro, several ovules are fertilised and these produce a similar number of embryos, which are then used for multiple implantations given that successful first attempts are quite rare. Thus, spare embryos are frequently left over after the pregnancy is achieved and scientists have asked to be able to use them for their research.

This is a question which, like others relating to artificial reproduction techniques, has given rise to a wide body of opinions, ranging from calls for a total ban to acceptance under certain (or no) conditions.

Similar concerns have been expressed in Spain, as reflected in the Report and workings of Parliament's Select Committee on the study of human in vitro fertilisation and artificial insemination, which was set up in 1986. However, Spain has gone even further in promulgating the aforementioned Law which regulates the donation and use of human embryos and foetuses or their cells, tissues or organs, and the Law on Techniques of Assisted Reproduction). The former, in its Explanatory Statement, falls closely into line with the guiding principles behind Spain's Law on the removal and transplant of organs, which was passed on 27 October 1979.

269. Law 35/1988 on Techniques of Assisted Reproduction authorises the use of gametes for basic or experimental research, although they can not then be used for reproduction (article 14.1 and 3). Research into the obtaining and maturation of ovocytes, the cryopreservation of ovules and the hamster test with human spermatozoa (article 14.2 and 4). It seems somewhat excessive that fertilisation between human and animal gametes is authorised by the authorities (article 14.4).

Law 35/1988 also imposes limitations on investigation or experimentation with pre-embryos (that is, those which have not yet been implanted in the woman). Such investigation is permitted for diagnostic or therapeutic purposes where a real benefit is involved: if for the purpose of diagnosis, it can only be for assessment of viability or non-viability, detection of hereditary diseases in order to treat them where possible, or to advise against transfer for procreation (article 12.1); if for therapeutic reasons, it can only be used to treat a disease or prevent transmission thereof, as long as reasonable and proven guarantees exist (article 13.1).

270. Where intervention serves a different purpose, particularly investigation and experimentation, the following general conditions (among others) are required also: informed consent must be obtained from the persons from whom the pre-embryos are taken, including the donor; the pre-embryos must not be developed more than fourteen days following fertilisation, not counting any period of cryopreservation; the investigation must be carried out in approved and qualified centres (article 15.1). In the case of viable in vitro pre-embryos the investigation must be a diagnostically-applied one, for therapeutic or preventive purposes, and the non-pathological genetic heritage/patrimony must not be altered (article 15.2). Where the pre-embryo is non-viable, the intervention may be extended to other types of investigation, provided that it is not possible to perform the same type with an animal model; the project must be submitted for monitoring and the authorised time-limits complied with (article 15.3). Lastly, aborted pre-embryos are deemed to be dead or non-viable and can, therefore, be used for investigation or experimentation; in the case of the former (dead) they may be used for scientific, diagnostic or therapeutic purposes, whereas if they are non-viable they may be used for pharmaceutical, diagnostic or therapeutic purposes (article 17). Certain investigative actions using gametes and pre-embryos are expressly authorised, while prohibitions are placed on a long list of others which are deemed to be undesirable (article 16). However, the provision allowing any other type of investigation authorised by the regulations (no indication is given as to which) or, in their absence, the multidisciplinary National Committee (not yet set up), would appear to be somewhat excessive given the ambiguity and potential scope involved, in an issue of such complexity; in any case, it should be understood that this procedure cannot be used to override prohibitions.

271. By way of conclusion, it may be said that, the legislation, in spite of several technical shortcomings —most notably its casuist and repetitive nature—, does appear to be quite appropriate as far as its general content is concerned, although it many places it is rather imprecise; it is in keeping with the guidelines of Council of Europe Recommendation 1046 (1986) and Recommendation 1100 (1989).

To sum up, although regulatory provisions do exist in Spanish legislation, we believe that these issues should remain open to discussion and reflection, until such times as the widest possible agreement is reached as to what should and should not be allowed.

c. Embryos or Fetuses in Utero or Expelled from the Uterus

272. Experts generally coincide in rejecting investigation or experimentation in live human fetuses. Where these have not been taken from the mother's uterus, therapeutic measures only should be applied, that is, measures which attempt to improve the foetus itself rather than another person. Experts also advocate a ban on sales of fetuses, in accordance with he prevailing general principle that no trade should take place with anything connected with the human body (for example, the sale of transplant organs is usually banned; see Spain's Law on the removal and transplant of organs of 27 October 1979, article 2).

Although by no means an exhaustive list, bearing in mind that we have attempted to address a number of complex issues and set them in their legal context with the corresponding limitations and prohibitions, the following are some of the most important points as contained in the aforementioned Laws 35/1988 and 42/1988.

273. Law 42/1988 deals with the donation of embryos and foetuses or their biological

structures. Donation corresponds to the parents provided they consent to do so or to the use of the embryos and foetuses and they have been given the appropriate information; in the case of non-emancipated or incompetent minors, consent is given by their legal representatives; in case of death, consent is deemed to be given as long as no express opposition is known and, where death was accidental, authorisation must be sought from the judge. Financial gain from, or commercial transactions involving, the donation or subsequent use of embryos and foetuses is prohibited. Lastly, only clinically non-viable or dead embryos or foetuses may be used (article 2).

274. The fertilisation of human ovules for any purpose other than procreation is also banned (article 3 of Law 35/1988). Specific limitations and prohibitions are laid down for actions involving live and dead embryos and foetuses. In the case of the former, while they are still in the uterus only diagnostic or therapeutic actions, or actions to perform a legal abortion, are permitted (article 12.2, Law 35/1988); if no longer in the uterus, they may only be used if they are non-viable, and if they are viable any clinical manipulation must aim exclusively to favour their development and own vital autonomy; dead embryos or fetuses, once verification of death has taken place, may be used and donated for diagnostic, therapeutic, pharmacological clinical or surgical purposes, or for experimentation or investigation (articles 5 to 7, Law 42/1988. In the case of transplants of these biological human elements, the reference made to consent on the part of the recipient (article 4, Law 42/1988) is similar to the terms contained in the Law of 27 October 1979 governing the removal and transplant of organs.

d. Genetic Engineering

275. Law 42/1988 authorises genetic engineering for the following purposes (art. 8.2): a) For the purpose of diagnosis, for the prenatal diagnosis, in vitro and in vivo, of genetic or hereditary disorders, in order to prevent transmission or to treat or cure them. b) For industrial purposes of a preventive, diagnostic or therapeutic nature, such as the manufacture, by gene or molecular cloning, of sufficient amounts of health or clinical products without biological risk, where this is not covenient through other means, such as hormones, blood proteins, immunitary response controllers, antiviral, antibacteria, or anticancer agents or vaccines without immunitary or infectious risks. c) For therapeutic purposes, primarily to select sex in the case of disorders associated to sex chromosomes and particularly the X chromosome, in order to avoid transmission, or to create beneficial genetic mosaics through surgery by transplanting the cells, tissues or organs of embryos or foetuses to patients in whom these are biologically or genetically altered or absent. d) For research purposes and for the study of the DNA sequences of the human genome, as well as its location, functions and pathology; the study of recombinant DNA inside human cells or simple organisms, with the aim of perfecting knowledge of molecular recombination, expression of the genetic message, development of cells and their structures, dynamism and organisation, the ageing processes of cells, tissues and organs, and the general mechanisms of the production of illnesses and diseases, among others.

§ 5. Psychosurgical Interventions

276. The control of particularly aggressive treatments such as psychosurgery, electric shock therapy and the long term administration of psychotropic drugs[83] raise a number of complex legal issues, particularly when such treatments produce or lead to major irreversible or lasting changes in the behaviour and personality (even when this would be described as 'abnormal' or pathological in the first place) of the patient, even bearing in mind that psychiatric treatment always implies some degree of change in the behaviour with which the illness is associated. In these cases it is a question of reconciling occasionally opposing interests, including those of the patients themselves. The wishes of the psychiatric patient should be borne in mind whenever he is even minimally capable of comprehending the nature of the treatment or intervention, even where the patient has been certified as being incompetent. When the decision

has to be taken by third parties (e.g. legal representatives, relatives or physicians) it is essential that control mechanisms be put in place to guarantee that the treatment is absolutely necessary. Recourse to the courts and the public prosecutor may be necessary. Aside from this there is no specific reference to these matters in Spanish law.

§ 6. Removal and Transplantion of Organs

I. Relevant Legislation

277. Spain, like many other countries, has specific legislation with regard to human organ transplants. The key piece of legislation is the Law of 27 October 1979 governing 'Removal and Transplant of Organs'.[84] This legislation, which has a pyramid structure, has been complemented and enhanced by numerous provisions (a Royal Decree, various Ministerial Orders and a number of Resolutions and Circulars) some of which are recent. The General Health Law (LGS) and some administrative provisions on health care in general are also relevant here. On the whole, the legislation is very complete and covers the regulation of the various relevant issues relating to transplants in general as well as those of specific organs and specific types of tissue. The legislation addresses not only the legal issues involved in obtaining organs but also the crucial question of protecting and respecting the rights and interests of the individuals concerned. It also deals with organisation, coordination, accreditation and authorization, together with purely procedural matters.

278. As regards provisions which develop the law further, the following items are relevant: the RD of February 22/ 1980, which contributed to the Law on a number of important issues; the Order of the Ministry of Health of April 23 1980 on the recognition of the authorisations to obtain, prepare and use skin grafts, human organ and tissue transplants which were granted to hospitals previously under the old legislation; the Resolution of 27 June of the Secretary of State for Health relating to the National Organisation for Transplants and laboratories which performed histocompatibility testing; the Resolution, also of June 27, that lays down the Regulations for authorisations for the removal of organs and the Register of Volunteers, which was subsequently modified by a second Resolution of April 15 1981; the Ministerial Order of August 25 1980 establishing the National Advisory Committee on Organ Transplants; the Ministerial Order of 15 April 1981 which regulates the use of eyes from cadavers, the mobile units for their removal, the operation of Eye Banks and the carrying out of corneal transplants; the Ministerial Order of November 29 1984 setting out the minimum requirements for the accreditation of centres for heart and heart-lung transplants; the Ministerial Order of March 7 1986 creating the position of Transplant Coordinator in National Health Service hospitals; the Ministerial Order of August 8 1986 which establishes the pay scale for INSALUD staff, the staff of the 'Instituto Catalán de Salud' and RASSSA; the Ministerial Order of June 24 1987 on HIV testing of donated organs and the recipient patient. Also of relevance are art. 40.8 of the LGS (according to which the accreditation, recognition, authorisation and registration of centres and services is the responsibility of the State, without prejudice to the powers and duties of the Autonomous Communities set out in legislation concerning organ removal and transplant) and the appropriate legislation drawn up by the Autonomous Communities in this area; finally, and in addition to the above, mention should be made of Law 42/1988 of December 28 on the donation and use of human embryos and foetuses or their cells, tissues or organs, and the Ministerial Orders authorising each individual hospital to remove and transplant organs or to remove them only —separate authorisations being granted for removals and transplants —and the accreditation of Histocompatibility Laboratories, which are important initially in that they draw up patient waiting lists and thus facilitate the exchange of organs.[85]

Although this brief review of the Spanish legislation on transplants gives an impression of complexity, it should be said that the legislation is structured in such a way as to make it open to amendment in response to scientific developments, without the need to change the basic lines along which the legislation was constructed. Nevertheless, certain possibilities that are opening up in terms of organ and tissue transplants (sexual organs, the brain or parts of the

brain, nerve tissue and cells) or the implanting of artificial mechanisms or anatomical parts from animals raise specific legal issues to which the current legislation may not be able to provide clear and precise answers. The 1980 RD, at the least, requires review and updating.

279. *Objectives set out in the Law*. From the above the importance of a carefully thought out body of law which balances all the interests that come into play in the long and complex process of a transplant is self-evident. Our legislation addresses these important issues in line with current European and global trends and sets out three main objectives in an effort to clarify any potential technical and legal problems: 1. To facilitate the obtaining of viable — usable — organs for subsequent transplant operations performed on persons in medical need of such organs. 2. To adequately protect the rights and interests of the individuals concerned so as to balance any possible conflicting interests, chiefly those of the living donor, the deceased donor and the recipient. 3. To provide a legal framework for medical professionals and health authorities within which they may carry out such operations, unhindered by difficulties, an din accordance with guidelines which are, at least in theory, clear and easy to follow.

II. The Living Donor

280. Although the giving of organs by living persons for subsequent transplant to a person suffering from an illness who requires the organ affects the integrity of the body, which is in principle punishable by law (arts. 418 and ff. of the Penal Code on bodily harm offences), it is explicitly permitted by the 1979 Law and by the Penal Code itself (art. 428. 2). It is not enough for the operation to be performed by qualified personnel (a surgeon) for this exemption to come into effect. The donor must also give his consent and all other requirements of the Law (article 4) and the 1980 RD (articles 2 and 5) must be strictly adhered to.

281. *Age and legal capacity restrictions.* The donor must have attained the age of legal majority (18 years), be in full possession of his mental faculties and in sufficiently good health for the removal to be performed (art. 4. a and b of the Law). This means that minors may not give their organs (for example for use by a brother or sister who is suffering from an illness and who is also a minor), even where consent is given through the parents, as this is considered to exceed the scope of the rights and duties inherent in parental authority (arts. 154 and ff. and 162 and ff. of the Civil Code). This is intended to safeguard the interests of the minor, who, without such protection from the Law, would find difficulty in not succumbing to the moral pressure brought to bear by the family or and would be subject to the danger of the family consenting on his behalf (if he is unable to express his own consent) in the interests of the recipient and at his expense. The same principles underlie the exclusion of the intellectually disabled, those suffereing psychiatric illness or persons who for any other reason are unable to give their explicit, free and conscious consent. However, the 1980 RD (second final provision) makes an exception for bone marrow because of its capacity for regeneration and because donation and transplant usually concern siblings. For reasons similar to those given above, the donation of organs by the intellectually handicapped or mentally ill is not allowed.

282. *Limitations related to the organ*. The organ must be one whose removal is compatible with the continuing life of the donor and which does not seriously affect his bodily functions (art. 2. b of the 1980 RD). As a result, the law allows the donation of organs or tissue provided that removal does not permanently affect the health or endanger the life of the donor. The donor's physical or psychological capacities should not be diminished by the removal of the organ nor should it result in the loss of any important bodily function. For this reason single vital organs may not be removed nor may single remaining organs from pairs (in cases of the prior damage to or loss of the second organ as a result of illness or injury). Limbs are also excluded as are any parts of the body the removal of which would involve diminished bodily functions. The removal of paired or double organs is permissible when the remaining organ can act as a functional substitute. The same is true of regenerable tissue (blood,[86] bone marrow, bones, cartilage, etc.). A full and thorough medical examination of the donor is

therefore needed to determine whether or not his current health would result in him being seriously affected by the removal of the organ. If the donor's physical and mental health are good enough for the removal to go ahead, a physician other than the one(s) who will perform the operation must make a statement to that effect (art. 3. 1 of the 1980 RD). This physician is also responsible for providing the donor with all necessary information.

283. *Donor information and consent*. The donor must previously have been informed of all consequences stemming from his decision and must have freely, consciously and impartially given his express consent. This is the key to the donor consent requirement, which is fundamental. In the first place, for consent to be valid it is essential that the donor has previously been fully informed as to the foreseeable somatic, emotional and psychological consequences involved and the long-term implications that donation may have in terms of his personal, family and professional life. At the same time he should be provided with information about the benefits that the transplant might be expected to imply for the recipient (art. 3. 1 of the 1980 RD). The relevant information must be given in writing. Consent must also be given in writing in the presence of the judge in charge of the Civil Registry, the physicians who provided the information and the doctor who is to perform the removal of the organ.

Clearly, valid consent can only be given for the donation of the organs and tissues referred to above, in view of the fact that in Law valid consent to endangering one's own life cannot be given (for example consent to donating a vital organ). Neither is consent valid if it has been obtained under pressure or through coercion (e.g. from members of the family of the would-be recipient of the organ) or where financial or material interests have influenced the decision to give the organ concerned, as we will see below. The possibility of the donor wihdrawing consent is considered. Consent may be wihdrawn at any time prior to the operation without any further formality being required. Wihdrawal of consent cannot give rise to any kind of claim for compensation.

284. *Restrictions governing the subsequent use made of the organ*. The Law stipulates that the organ must be for transplant in a specific individual with the purpose of substantially improving the person's chances of survival or quality of life (art. 4. d, 1979 Law). This requirement, which may seem obvious, implies that the whole process of donation must revolve around a specific potential recipient, in most cases a member of the donor's family. The process, therefore, begins with histocompatibility studies of both parties along with all other tests deemed necessary to guarantee the viability and success of the transplant operation. As a result, the process of donation by a living person may not commence until a candidate recipient has been selected, nor can the organ subsequently be donated to someone else as this would mean beginning the process all over again in order to comply with all the requirements of the Law. The clearly therapeutic nature of the operation, as stipulated by the Law, rules out donations for primarily experimental or research purposes, although this does not mean that the operation may not involve a certain degree of uncertainty as regards a successful outcome.

285. *Anonymity of the recipient*. Finally, the law stipulates that the anonymity of the recipient must be guaranteed. Clearly, we are faced here with a 'lapsus Legislatureis' if this is also to be understood to apply to the donor, which would run counter to the other (and particularly the last of the) requirements noted above. Donations by living donors are usually made for members of their own family as a sign of solidarity and affection. This requirement, which is not adhered to in practice, does make sense in the case of donations after death as it would thus prevent members of the donor's family later taking advantage of the situation by demanding some kind of material or financial compensation from the recipient (alleging, for example, that the donor was the sole source of financial support for the family). It is, however, possible to arrive at a more satisfactory interpretation that eliminates this apparent incoherence, as we shall see shortly.

286. *Consequences of donation: the lawful removal of the organ.* Adherence to all the above-

mentioned requirements means that the attack on the physical integrity of the donor that the donation implies is lawful, as is the operation performed by the surgeon. Failure to comply in any way with the regulations (regulations are understood to mean material and substantial requirements and not merely formal or procedural requirements which would only give rise to an administrative offence only) is equivalent to the offence of mutilation and is severely punished by the Penal Code (arts. 418 and 419).

These observations are endorsed by the 1983 reform of the Penal Code (June 25) which explicitly recognises the possibility of consenting to attacks on one's physical integrity if this takes place in accordance with the provisions of the Law governing Organ Transplants. This proviso is laid down in art. 428. 2 of the Penal Code, which sets out the various conditions that must be fulfilled. These are essentially the same as those contained in the 1979 Law on removal and transplant, which can thus be regarded as being unaltered by the reform of the Penal Code.[87] Furthermore, the fact that the Penal Code makes explicit reference to this Law means that the other requirements continue to be applicable where the provisions of the Penal Code are not sufficient.

III. The Deceased Donor

287. The Law on transplants (art. 5 of the 1979 Law and art. 10 the 1980 RD) and to an even greater extent the Penal Code[88] seek to guarantee effective medical assistance and protection of the life of a potential *post mortem* donor while even the most minimal chance of recovery exists. Nevertheless, this very real protection is compatible with the possibility of obtaining organs for subsequent transplant in the case of the death of the potential donor. It is on this question that the Law has been particularly explicit as regards resolving potential legal problems. At the same time it is here that most disagreement exists. There are two conflictive issues which we will examine now.

288. *Definition, diagnosis and verification of death*. Within the biological process of destruction entailed in the death of living things a precise moment at which the process is irreversible must be fixed. Once this point is reached there is no possibility of saving the life of the individual in question (precisely because death has occurred). The moment must also be established early enough to ensure that organs and tissues may be removed and that they have not been affected by the process of destruction and are therefore suitable for transplant. A balance must, therefore, be struck through an early but faithful diagnosis of the moment of death, from which point on it is possible to remove the organs in biological conditions consistent with transplant.[89] Any doubt as to determining the moment when death occurs must be resolved in favour of the potential *post mortem* donor to the exclusion of all other interests no matter how important and pressing they may seem.

In contrast to the previous legislation (of 1950) the current Law has rightly established the point of reference for determining death as not depending on the cessation of certain vital functions, such as circulation or breathing, which can now be maintained artificially almost indefinitely. The Law takes as an alternative point of departure permanent irreversible brain damage which is incompatible with life (art. 5. 1). This starting point and the other guarantees that are required for the death certificate to be issued should be viewed as being highly positive, given that in current medical practice an irreversible comatose state is considered to be sufficient basis for certifying that death has occurred. The 1980 Royal Decree stipulates the conditions that must be fulfilled before such a diagnosis can be made (art. 10), namely, certain signs deemed to be incompatible with life. The RD also sets out the criteria that would render the diagnosis invalid: "Organs for the transplant of which it is necessary to ensure viability may only be removed from the body of the deceased after there is proof that brain death has occurred, this being based on the verification that for a period of at least thirty minutes six hours after the onset of the coma the following signs are present: One. Lack of cerebral response, with complete loss of consciousness. Two. Lack of spontaneous respiration. Three. Lack of cephalic reflexes with muscular hypotony and mydriasis. Four. A 'flat' electroencephalogram as evidence of lack cerebral bio-electric activity. These signs are not

sufficient in cases of artificially induced hypothermia or where drugs that depress the central nervous system have been administered [...]". However, the scientific and current practical worth of these statutory requirements is somewhat dubious (in situations of death due to cardio-respiratory arrest, anencephalic donors and children, rigid application of the criteria in cases of hypothermia and barbiturates etc.). In any case, in situations of doubt or in those in which the Royal Decree stipulates that the signs of death quoted above are not sufficient, physicians may add further criteria or perform additional tests or allow a longer period of time to elapse without contravening the RD, if in this way death can be established beyond any shadow of doubt.

289. The specific conditions that the diagnostic team must fulfil in transplant cases constitute additional guarantees for the potential donor: the team must comprise three physicians, at least one of whom should be a specialist in procedures for determining death.[90] All three physicians must agree to certify death and must not be involved in the removal and subsequent transplant of the organ.

290. *Deceased donors; relevance of wishes.* Major conflicts arise where there is a legal assumption that anyone who dies is a donor unless during his lifetime he has explicitly stated that he does not wish to be a donor: 'The removal of organs or other anatomical parts from deceased persons may be performed for therapeutic or scientific purposes so long as he has not explicitly expressed opposition to this.' (art. 5. 2 of the Law).

Despite the somewhat striking nature of this sentence it should be noted that it is not so striking as previous legislation, in which the notion of assumed willingness to act as a donor was included as a third subsidiary procedure in potential donor cases that were subject to legal intervention (instances of violent death, as is known, are usually the most suitable for organ donation from the medical point of view) and the lack of opposition referred not to the deceased but to his family. A criterion similar to that of the Spanish Law of 1979 was adopted by the Council of Europe and proposed to Member States in Resolution 78 (29). The World Health Organisation takes a similar approach in its Guiding Principles for the Transplant of Human Organs (1991).

Of the various alternative criteria which the Legislature could have opted for the folowing deserve mention: a) express wishes of the deceased made known during his lifetime authorising donation; b) the same criterion with the addition of the subsidiary criterion (in the absence of consent on the part of the deceased) of consent by the deceased person's family; c) absence of explicit opposition on the part of the deceased or his family; d) lack of opposition on the part of the deceased alone; and e) no consideration given to the wishes of the individual concerned.[91]

291. Independently of what has just been stated, it is necessary to analyse the drawbacks that the alternatives imply in an effort to better understand the Spanish Legislature's reasoning in rejecting them:

a) Positive act of personal donation. In the first place, we have the criterion of voluntary personal donation, that is to say, a positive declaration of the desire of the individual citizen to freely donate his organs, to take effect after death. This solution causes a variety of problems, particularly with regard to the fact that there is a very high potential demand for the organs of deceased persons and the difficulties involved in finding a donor and recipient who are biologically compatible. Furthermore the cadavers that fulfil the stringent medical conditions that provide minimum guarantees of transplant viability are rare. Only those killed in road accidents (slightly fewer than 6,000 in 1991) and a further small number from accidents in the workplace with very localised head injuries (haemorrhages, tumours, vascular accidents) or cardiac arrest are usually considered to be genuinely viable candidates for organ donation, with the additional proviso that they die in a hospital equipped to remove organs. Public information campaigns designed to create a favourable attitude to organ donations are costly and are slow to produce what are not particularly satisfactory results in the long term. They must reach the

entire population and be repeated over and over again to maintain the desired level of awareness among the population. As we shall see below the task of providing information is, nevertheless, extremely important and is dealt with in the Spanish regulations.

b) Irrelevance of the wishes of the individual. Neither does it seem appropriate to disregard altogether the wishes of the deceased, as made known during his lifetime. A series of cultural norms — of social and religious origin — in our society seek to maintain respect for the dead through a kind of spiritual bond between society — particularly family and friends — and the deceased. The Law has weighed up these collective sentiments and has regarded them as worthy of protection. For this reason the Penal Code punishes profanation of cadavers when there is a lack of respect for the memory of the dead (article 340). Respect for the deceased's memory also implies observing whatever wishes he would have expressed in terms of his body during his lifetime (so long as these do not violate any other public order requirements), for example, as regards his willingness or opposition to having parts of the body removed and transplanted to another person suffering from an illness. Transplant legislation seeks to respond to this concept in requiring the restoration and preservation of the cadaver (art. 9.2 of the 1980 RD).

292. *The irrelevance of the deceased's family's wishes in the Spanish legislation.* The Spanish Law does not require the consent of the family of the deceased except where minors or mentally-deficient persons are concerned.[92] The reasoning given above is also valid here. It is a question of respecting the wishes of the deceased, not those of his family — whose wishes may be in conflict with those of the deceased — although at the same time it is recognised that the family are most likely to know or be able to indicate the wishes of the deceased if they were made known during his lifetime. But this does not mean that they have property rights over the cadaver, because no such right exists. Furthermore, from the humanitarian point of view it woud seem ill-advised to subject the family to a further emotional burden after being informed of the sudden tragic death of a loved one — husband, son or daughter etc.. To do otherwise would be tantamount to burdening them with moral responsibility for deciding if another person should continue to live or have a better life as a result of their consent. They should not have to take on this responsibility in the first place, nor are they in the best position to do so. Because of this the Law makes no mention of them and the 1980 RD only indicates that the family should be informed unless circumstances prevent this.[93] Nevertheless, it is customary for physicians (or transplant coordinators) to seek the agreement of the family of the deceased, which is a sensible precaution as long as it is done tactfully.

Finally, it should be noted that even though no real conflict of interests arises in practice, the intangibility of the cadaver and the respect for related wishes in this regard (such as society values) are played off against the life and health of other persons. If any conflict were to occur the criminal law would provide the appropriate answer and would normally come down in favour of the life and health of the recipient.

293. As a means of recording possible opposition to the removal of organs, procedures for the provision of information and a register of volunteers have been established in authorised hospitals. It is clear that recourse may be made to other means apart from those established by the Regulations (arts. 8 and 9 of the 1980 RD) to ascertain any possible opposition on the part of a potential donor (written declarations, membership of religious or ideological groups that are clearly opposed to interference with the cadaver, information from the family of the deceased, etc.). Possession of a donor card —one which is compatible with legal requirements— such as those issued by Associations of Patients (Federación Nacional ALCER), some Autonomous Communities or by the National Transplant Organisation or other such regional organisations makes the task of determining the wishes of the deceased very much easier.

IV. The Recipient

294. In contrast to the legislation of other countries, which do not concern themselves with this question, Spanish legislation includes guarantees to protect the recipient of the organ, as it is the recipient who is in fact subject to the main risks. These guarantees are as follows: that the operation is for therapeutic purposes; that the necessary medical tests have been performed prior to the operation and that all appropriate specific preparation has been undertaken and that the patient has been fully informed and has given his consent or that the family or legal representatives have consented in the case of minors and the mentally disabled (art. 6 of the Law). The Law has been particularly meticulous and scrupulous in its efforts to protect the legal interests of the recipient of an organ transplant, and anticipated the rights established by article 10 of the LGS, which also apply here.

Given that decisions taken are always of the greatest importance to the recipient, it is essential that the information requirement is scrupulously fulfilled prior to the transplant. Information is normally provided on two occasions: when the need for the transplant becomes evident and the patient's name is put on the waiting list and again when an organ becomes available for the recipient. The 1979 Law (art. 6. 1 and 2) and the 1980 RD (art. 12. 3) are unequivocal as regards this information requirement, as is the LGS on a more general level (art. 10. 5).

A problem arises in the selection of recipients and the criteria used to establish priority of one recipient over another. Clearly, only strictly objective medical criteria agreed upon by professionals can be considered in decisions concerning selection and priority. First and foremost it must be established that the patient is not suffering from a serious illness the risks of which would be greatly increased by surgery and, secondly, that he is in urgent need of the transplant. Optimum histocompatibility between the organ and recipient (and therefore the optimum chances of success) is also a prime consideration. A secondary criterion would be the length of time the patient has been waiting. On no account should social considerations be brought to bear [94] or should a patient be rejected because he suffers from another (corregible) illness (e.g. an alcoholic recipient of a liver transplant).

V. Other General Guarantees

295. The guarantees described above refer to the requirements for transplants and are designed to protect the interests of donors and recipients alike. There are, however, further requirements that also protect these individuals, albeit less directly, and that in one way or another contribute significantly to the achievement of the objectives enumerated at the beginning of this section. The successful putting in place and functioning of the legal mechanisms designed to serve these objectives depends on these requirements. It should be said that many of these go beyond the limits of the purely legal framework, as they depend on the existence of the appropriate structure, organisation and planning of health services and on funding.

296. *Prohibition on the use of organs for commercial ends*. Organs may not be bought or sold nor may the donor or members of his family or third parties ('intermediaries', hospitals, pharmaceutical or research laboratories) receive money in exchange for organs. The costs of donation should not have to be met by the donor or his family (art. 2 of the Law). By this means injustices that might easily occur both in the case of recipients and potential donors with limited financial resources or other limitations (e.g. prisoners seeking a reduction in their sentence) can be avoided. Even if in Spain no instances of the sale of organs of living persons have actually occurred, despite occasional attempts, the possible damage that can be done by simply offering such organs for sale in the media should not be underestimated. Such offers would cause great confusion among the general public and could even lead people to withdraw their names from donor lists.

This issue has acquired on great importance in recent years because of claims that a black market in organs in developing countries benefits patients in the developed world or in rich countries. In Spain the buying and selling of organs from living persons is not only prohibited, as we have just seen, but severely punished by the Penal Code (arts. 418 and 428).

The World Health Organisation plans to adopt various measures in an effort to stamp out these practices elsewhere: the World Health Assembly adopted resolution WHA 42. 5 on the prevention of the buying and selling of organs on 15 May 1989, while its *Guiding principles for the transplant of human organs* of 1991 devoted principles 5 to 9 to prohibition: "The human body and its parts may not be used for commercial transactions. As a result, paying for or receiving payment (including non-financial forms of compensation or promises) for organs must be prohibited" (Guiding Principle 6). "Doctors and other health workers must not participate in organ transplant procedures if they have reason to believe that these organs have been used for commercial transactions" (Guiding Principle 7). "People or institutions that participate in organ transplants must not receive any additional payment apart from the fees that they are entitled to receive for the services performed." (Guiding principle 8). Art 14 of the Council of Europe's Resolution (78) 29 also prohibits profit making.

A significant preventive measure with regard to the trafficking of organs taken from cadavers is the use of all possible means to guarantee that the recipient should not know anything that would identify the donor or his family and, similarly, that the donor's family at the same time should have no information about the recipient and his family. Responsibility for maintaining this level of confidentiality lies with the staff of the health care centre, regardless of their professional status or the nature of their duties. Although it is not explicitly stated in the current regulations with regard to organ transplants, the requirement must be adhered to in view of the right to privacy and confidentiality established by the LGS (art. 10. 1 and 3).

297. *Intervention by the legal authorities*. The removal of organs from those who have died of unnatural causes (through accident or any other kind of violent death) requires prior authorization by the Judge responsible for the case (arts. 335 and 342 of the Criminal Procedures Code). He shall give this authorization where removal does not present any obstacle to the pre-trial investigation, the cause of death being apparently clear (art. 5. 3 of the 1979 Law). Strictly-speaking this is not a guarantee relevant to the transplant process but rather to the work of the Judge in that it prevents the removal of organs in situations where this would hinder the establishment of the causes of death in cases where death may give rise to liability (either civil or criminal) or an insurance claim etc.

298. *Recognition of hospitals and medical teams*. Authorisation is only granted to those hospitals and teams that meet the stringent material, technical and professional conditions established by the law and that can provide evidence of adequate training and experience in these techniques and in associated treatments.[95] The health authorities take responsibility for supervising the work of these hospitals and teams and may even withdraw authorisation if performance is unsatisfactory or falls below the standards for which authorisation was initially granted.

299. *Organisations for the exchange of organs from cadavers. The National Transplant Organisation and Regional Organisations*. In accordance with the Law (art. 7), these organisations enable maximum benefit to be obtained from organs made available for transplant by means, for example, of locating the most suitable recipient —or even the recipient in most urgent need. Organs can be made available through the the system to other centres in the same city or elsewhere in Spain and abroad. The system also controls the preservation of parts of bodies in 'organ banks' when this is scientifically feasible.

In order to achieve qualitative and quantitative improvement in transplant services it is essential to strengthen the regional health organisations and the national coordination of organ exchanges so as to ensure that the maximum number of organs can be removed and transplanted, optimum compatibility between the organ and the recipient can be achieved and also that patients in urgent need (hyperimmunised patients, those who are terminally ill as the result of the failure of single vital organs or the remaining organ from a pair) can be given the fastest possible access to transplants. This will help redress regional imbalances and give fuller effect to the principle of equality of access to medical assistance (art. 3 of the LGS). Responsibility for these functions lies with the National Transplant Organisation and the

Regional Transplant Organisations (Centro-Trasplante, Norte-Trasplante, Cataluña, Andalucía, Ebro-Trasplante, etc.), which must be coordinated and supervised by the National Organisation.

The creation of the position of Transplant Coordinator is a further important step in terms of the coordination and optimum use of organs or potential donors. Coordinators in each hospital involved in the removal and/or transplant of organs, regional coordinators for the Regional Organisations mentioned above and a National Coordinator (who is also the director of the National Transplant Organisation) have already been appointed.

The National Transplant Organisation was established under the Resolution of 27 of June 1980, but is also subject to the provisions of the Spanish Constitution of 1978 concerning the competences of the Autonomous Communities in the area of health and to the new health system structure put in place by the LGS. Another more recent procedure that has contributed to an increase in the number of transplants and to increased organ mobility is the removal of several organs from a single donor.

300. *Information and health education*. The 1980 Regulations (Second Additional Provision, 4) provide for the carrying out of frequent and extensive information and educational campaigns to increase awareness of the contents of the Law, particularly in relation to the obtaining of organs from cadavers, thereby reducing the difficulties entailed in informing the family of the deceased at the moment of death and eliminating the all too often need for medical staff to seek their approval in order to avoid complications.

301. *Non-applicability to foreigners*. The transplant legislation does not apply to foreigners unless they have explicitly requested the contrary (RD Seventh Final Provision). The principle of personality has been adopted in the application of the law (along with territoriality, although it is restricted by the former) such that the scope of the law is limited to Spanish nationals. This is so as to avoid any possible conflicts that might arise in the case of foreigners who come from very different cultures which might well clash with the innovative principles established by the law.

§ 7. Research with Human Beings

I. Conflicting Intererests

302. Research in Medicine and the Biological Sciences has gradually improved our well-being and indeed our life expectancy. In the final analysis, after the appropriate laboratory studies and experimentation on animals, research almost always requires the testing on human subjects of new techniques and substances to which beneficial or therapeutic effects are attributed. It is at this point that the question of certain individuals (healthy or otherwise) becoming subjects of experiments arises, with all the risks and dangers that experimentation entails, even though these risks need not necessarily affect the experimental subjects themselves. A potential conflict of interests or of crucial values arises: on the one hand there is the need to carry out research with the obvious benefits that this brings to society and, on occasions, to the individual who has acted as an experimental subject; on the other, there is the right of these individuals not to sustain any damage to their health or to expose their lives to grave dangers, not to mention the protection of other individual interests that may be affected, such as freedom. The need for research is fully recognised in our legal order, but when it comes to experimentation on human subjects a series of provisions directly or indirectly seek to prevent any injury or harm to the person, given that his most prized legal interests are at stake.[96]

303. Because of differing objectives, effects, limitations and possible legal consequences, it is usual to draw a distinction between therapeutic experimentation and pure experimentation. The former consists of the application to specific patients of treatments the efficacy of which has not yet been entirely established from the scientific point of view and which, therefore,

have not been included among medically recognised treatments. Pure experimentation refers to research carried out on those suffering from diseases or on healthy individuals with a view to obtaining scientific results that do not imply any immediate benefit to the person who acted as an experimental subject. This second type of experimentation is, therefore, governed by more stringent conditions.

II. Relevant Legislation

304. The Spanish Constitution recognises and protects the right to "literary, artistic, scientific and technical production and invention" (art. 20, 1, b), as one of the fundamental public rights. It is obvious that scientific and technical production and invention inevitably involve research. At the same time, given its social significance, our Constitution also stipulates in the chapter devoted to guiding principles of social and economic policy that "the public authorities shall promote science and scientific and technical research in the interests of the community" (art. 44, 2). Having said that, the fundamental right to scientific and technical invention and production is limited by the Spanish Constitution itself when it alludes to *respect for the rights recognised under the same heading* as the one in which this right is set out, namely, fundamental rights and duties (art. 20, 4).

In fact, the constitutional prohibition of inhuman or degrading treatment (art. 15) imposes limits on *research and experimentation on human beings*, and is confirmed here because Spain has ratified and officially published the International Covenant on Civil and Political Rights of 1966 (27 April 1977, Official State Journal of 30 April) and it thus forms part of our domestic law (art. 96.1 of the Spanish Constitution). The Covenant groups both aspects together when it states that 'no-one shall be subjected to torture nor to cruel and degrading punishment or treatment. *In particular*, no-one shall be subjected to medical or scientific experiments without their freely given consent' (art. 7). The LGS provides for the minimum precautions and guarantees necessary when it requires that the patient be informed and that he gives his consent prior to the experiment, that the doctor and the administration of the health care centre agree to the experiment and, above all, that 'under no circumstances should it involve additional dangers to health [that of the patient]'(art. 10, nº 4 of the LGS). These requirements, together with the principles of preservation of dignity and privacy and the avoidance of discrimination, underpin more specific legislation, namely, the Drugs and Medicines Law (Law 25/1990 of 20 December) and RD 561/93 of 16 April, which set out the requirements governing the carrying out of clinical trials of medicaments.

305. The new Drugs and Medicines Law established a number of basic principles regulating clinical trials (arts. 59 to 69), which have been developed further and completed by the aforemetioned Royal Decree of 1993. Aside from the relevant administrative controls governing the trials themselves, their funding and the publications that may result from the trials, the Law has created Clinical Research Ethics Committees with important functions in terms of laying down guidelines for the methodology to be employed, ethical considerations and the risks and benefits that may be entailed in the trials. The Law also introduces measures to guarantee respect for ethical principles, with the specific requirement that trials 'must be undertaken in conditions which assure respect for the fundamental rights of the individual and the ethical considerations which apply to biomedical research involving human beings, in accordance with the Helsinki Declaration and subsequent declarations updating these ethical considerations' (art. 60.2); similar terms are used in article 10.2 of the RD of 1993.

III. The Experimental Subject: Guarantees

A. Weighing up of Risks and Benefits

306. The weighing up of risks and benefits is fundamental in medicine and, by extension, in pure experimentation. This process of evaluation is essential because of the need for the researcher to observe a duty of care so as to avoid possible liability for negligence or liability

of another type. Nevertheless, it is generally agreed that the level of acceptable risk in healthy individuals is not the same as for those suffering from diseases. This holds true only when experimentation on patients is carried out for their benefit, that is to say, when experimentation is therapeutic.

The general principles established are as follows: a) preclinical data on the product under study should be reasonably sufficient to guarantee that the risk faced by the subject on whom the experimentation is to be carried out is admissible; b) the study should be based on current scientific knowledge and must involve progress in scientific insight into the human being or to improve his health, and should be designed in such a way as to reduce risk to participants to a minimum; c) the importance of the information being sought should justify the risks to which the subjects are exposed in the test (article 10.3 of the RD 1993).

307. Experimentation for scientific ends on *persons suffering from illnesses* is effected through the use of new substances or techniques that have no relation to the illness or that, although related to it, are not primarily for the treatment of the illness. In therapeutic experimentation these substances or techniques can take the place of proven and recognised medical treatments; this is the case of *placebos*, be they inert or active, or of drugs or surgical procedures whose properties, efficacy and secondary effects are still not fully understood. Clearly, then, excessive and, therefore, unacceptable risk would be involved if any measures were taken that would interfere unnecessarily with the course of the illness by prolonging or aggravating it or that would result in irreversible injury unrelated to the spontaneous pathological process.[97]

308. Needless to say, with *healthy persons* there is no risk of interference with preexisting illnesses. However, in view of the principles whereby, on the one hand, a person cannot do with his body exactly as he pleases and, on the other, the inviolability of the human body (which means that it shall not be violated by others), and given also that the health of such individuals will not be benefited in any way by the experimentation, the potential risks of physical injury should be weighed up very carefully; moreover, risk shall have to be justified by the benefit expected for society as a whole (article 11.1 RD 1993). The regulations governing clinical trials establish special guarantees and precautions for particular groups who may incur additional risks to their health: children and incompetent persons, pregnant women or women who are breast-feeding (art. 11.3, 4 and 5 of the RD 1993).

B. Consent

309. The experimental subject's informed consent (art. 12.1 RD 1993) constitutes the most important element in guaranteeing that the person may freely exercise his will and accept any risks involved. The subject may withdraw his consent at any time and is not obliged to give reasons for withdrawal, which under no circumstances will give rise to liability or loss of any kind (art. 12.7). Moreover, the exception provided for in emergency cases where it proves impossible to obtain consent from the subject or his legal representative is admissible only if the clinical test has particular therapeutic interest for the patient (art. 12.6).

The scope and efficacy of consent are conditioned by various factors — particularly relating to legal capacity to give consent — and the potential dangers to the subject's health. For this reason it would seem appropriate to draw distinctions between the most significant groups of experimentation subjects.

310. *Patients and healthy volunteers.* While the consent of patients who are to undergo experimental therapies poses no major problems, or, to be more accurate, these problems are similar to those that arise in the course of normal treatment,[98] very complex issues are entailed in the case of purely scientific experimentation, especially the requirement that the subject be informed prior to the experiment (applicable to both patients and healthy adults).

In fact, the free and informed consent requirement is often difficult to fulfil as it is incompatible with the nature and methodology of research itself. At some stages of the

experimental process (phase III), in a bid to avoid subjective influence the person is not told whether the new drug or a *placebo* is being administered. In some cases even the researcher is kept in the dark (simple blind, double blind, crossed double blind method).[99]

It would appear that these factors were not taken into account in the current regulations on clinical trials, judging from the emphasis they place on the duty to inform. These regulations stipulate that for the freely given consent requirement to be satisfied (preferably written consent or, failing that, witnessed consent; it must always be written if the test has no particular therapeutic value for the experimental subject) the subject must have been informed as to 'the nature, importance, scope and risks of the trial', and that he must have understood this information (art. 60.4, Drugs and Medicines Law); the RD of 1993 is more specific in this regard in that it requires that consent shall be given "after having understood the information furnished with regard to the objectives of the study, the benefits, inconveniences and risks envisaged, possible alternatives, rights and responsibilities" (art. 12.3); curiously enough, there is no mention that information should be given as to the methodology to be followed, although the fact that this is included in the proposed model for the informed consent form which must be signed by the subject would indicate that it is obligatory also (Annex 6.1, RD 1993). The best way to reconcile the two sides, in our view, is to provide full information on the trial process, at least in cases where there is no therapeutic benefit to the subject, including the use of a *placebo*, but to keep the subject in ignorance as to the point at which it will be administered or whether indeed it has been administered at all.

311. *Minors and incompetent persons*. The problems in relation to these groups are even more complex both from the ethical[100] and legal points of view. The Drugs and Medicines Law merely indicates that the information must be provided and that consent is the responsibility of the legal representative in the case of persons who cannot freely give consent, although the latter must express their agreement if they are able to understand the nature, importance and risks entailed in the experiment (at. 61. 6); the RD of 1993 adds that minors aged twelve or more shall give their informed consent, which, along with the consent given by the legal representatives, must be notified to the Public Prosecutor's Office prior to the carrying out of the test (art. 12.5).

In the case of *children*, it is stipulated that tests which hold interest for their health may only be undertaken when they cannot be carried out with subjects who are not affected by these special circumstances, due to the fact that the pathology under study is proper to children; however, testing which does not have purely therapeutic ends is also admitted if the Clinical Research Ethics Committee is satisfied that strict requirements are met (art. 12.2 and 3, RD 1993). Notwithsatnding the stringent precautions set out in the regulations, we are of the opinion that the participation of children in an experiment should only be allowed when they themselves will benefit. Consent given on their behalf by parents is only lawful when it is for the children's benefit, in accordance with the terms of parental authority set out in the Civil Code (art. 154). These requirements would clearly not be satisfied in the case of purely scientific experimentation.

Mentally-ill or mentally-deficient adults are considered to be experimentation subjects under the same terms as children and enjoy a similar level of protection, or at least this would appear to be the case, given that their legal representatives — their guardians — are obliged by law to 'look after their interests' (art. 269 of the Civil Code) and must 'act for their benefit' (art. 216), which would seem to imply that there is legal opposition to the participation of such individuals in experiments, particularly patients committed to psychiatric hospitals. It would therefore appear that they may only participate in therapeutic experimentation. Where doubt arises or where possible abuses have occurred it is appropriate to seek the assistance of the judge, whether or not the patient is subject to his authority (ie, regardless of whether he has been certified by the court as being incompetent or has been committed).

312. *Prisoners and soldiers*. For different, though fundamentally similar, reasons it is generally held that prisoners and soldiers should be excluded from any type of experimentation because of doubts as to whether or not they are in a position to give their consent without

undue pressure. However, Spanish law does not address the issue specifically.

The vulnerability of the first group —*those in custody and prison inmates* — would seem only too obvious, as they are particularly susceptible to all sorts of incentives unrelated to the research itself (privileges while in prison, reduction in sentence and even a sense of personal worth, etc.). In spite of this there is no explicit legal provision that excludes them.[101] Turning to *soldiers*, the same problems with the exercise of free will arise when the experiment is to be carried out in the context of military health services because soldiers are subject to a strict hierarchy and are in a position of subordination which makes their participation in trials inappropriate. Nevertheless, their participation in experimentation in civil health services should not be rejected out of hand, provided that it does not interfere with their military duties (e.g. health problems while on duty) as this would not be compatible with national defence needs.

313. *Self-experimentation.* It is contended that self-experimentation is acceptable since the researcher is in the best position to know and judge at each stage of the process the risks involved in the experiment. From the legal point of view there is in fact nothing to prevent it, even in the event of injury or damage being sustained, given that the Penal Code does not punish self-inflicted injury.[102]

IV. Payment

314. It is currently felt that all experimental subjects should have *insurance* cover for all the risks entailed. The Drugs and Medicines Law (art. 62; developed further by art. 13 of the RD 1993) establishes this as a prior condition in all cases and makes the instigator of the trial, the principal researcher and the medical director of the hospital where the trial is to be carried out jointly liable for any injury sustained that is not covered by insurance, even where they are not at fault (objective liability for risk);[103] the Law also establishes an assumption — although evidence to the contrary can be presented — that any injury to the health of the experimental subject occurring during the trial or up to a year later is the result of the trial.

Payment to *compensate* for expenses or loss of earnings incurred as a result of the experiment is also admissible, provided that this does not take the form of a truly financial reward and is not the only reason why the person has agreed to undergo the experimental treatment. The payment of an indemnity to cover possible injury or discomfort as a result of the experiment is a different matter that comes closer to the idea of remuneration. We will now turn to this issue.

315. The issue of *remuneration* in the strict sense of the word has been hotly debated in both bio-ethical[104] and legal circles. There is a tendency to see it as acceptable in countries with an Anglo-Saxon legal tradition but to reject it in continental Europe. In other legal texts where the possibility of a person making his body available is discussed there is an assumption that this is done without reward as an act of human solidarity.[105] Nevertheless, the Drugs and Medicines Law allows subjects to receive something in return for the service rendered (art. 60. 7), which leads one to think that this is a reference to remuneration as such, the appropriateness of which is debatable; however, the RD of 1993, in order to avoid financial compensation being turned into remuneration, makes clear that "in no case will the amount be so great as to induce the subject to participate for any motive other than interest in the progress of science" (art. 11.5). Compensation, if agreed upon beforehand, can be demanded, though needless to say any such amount will diminish proportionally to the participation of the experimental subject if he opts out at some point.

V. Guarantees in Relation to Research

316. Research in which human subjects are used must adhere to the strictest precautions in order that the interests of the individuals involved can be safeguarded. Regulations governing clinical trials of pharmaceutical products also address this issue in great detail, so much so in

fact that they have even caused irritation among some researchers. Obviously these regulations also apply to experiments on human subjects with non-pharmaceutical products.

317. Among the more important guidelines that might be mentioned are the following: the need for the research team to be in possession of professional and technical *qualifications*, the availability of appropriate staff and equipment in the centre and the fact that the scientific value of the experiment itself should be assessed (art. 65. 3 of the Law).

318. There is also *control* on the part of the Health Administration, whose prior authorisation is required ('Directorate General for Pharmaceutical and Health Products', art. 65. 1 of the Law and arts. 24 ff. of RD 1993). Monitoring and inspections ensure that the entire clinical trial process is formalised and time periods and conditions are established for the carrying out of any such trials.

319. In certain cases the Ministry of Health and Consumer Affairs may interrupt a clinical trial or insist that modifications be made to the protocol. This is possible in situations where the law has been broken, where the conditions under which authorisation was granted are altered or where the above-mentioned ethical principles are not adhered to. The aim of such intervention is to protect trial subjects and to protect public health (art. 65. 5 of the Law and art. 31 of the RD). Needless to say, criminal liability may arise in serious cases involving homicide or grievous bodily harm, in addition to any liability in relation to the Administration.

§ 8. Transsexual Interventions

320. Sex change surgery in response to the phenomenon known as transsexuality raises a range of legal problems of considerable importance. Proof of its complexity is provided by the doctrinal controversy that has arisen over some recent decisions of Civil Chamber Number One of the Supreme Court, the first of which dates back to 1987.[106] Although this was not the first occasion on which such issues had been addressed, previous decisions had always been given in lower courts or in the General Registry and Notary's Division of the Ministry of Justice. Decisions varied to whether the claimant merely sought a name change or a change of sex to be recorded in the Civil Registry. We will now turn to some of the problems raised by medico-surgical sex changes related to transsexuality.[107]

I. Lawful Medico-Surgical Sex Change Operations: Reconciling Physical Sexuality with Psychological Sexuality

321. The first important issue to clarify is the question of the lawfulness of this type of surgical intervention from the criminal law standpoint. The reform of the Penal Code in 1983 declared these operations lawful under the criminal law:'...the expression of free and explicit consent eliminates criminal liability in cases of organ transplants performed legally and in cases of sterilization and transsexual surgery performed by medically qualified personnel, except where consent has been obtained under false pretences or through offering reward or payment or if the person on whom the operation is performed is a minor or is incompetent, in which case such consent will not be valid nor will that given by the legal representatives' (art. 428.2). A surgeon performing such an operation could not therefore be convicted of castration or mutilation (art. 418 of the Penal Code). In the civil law there is nothing to indicate that these surgical operations are unlawful.

322. Elsewhere — and prior to the 1983 reform of the Penal Code—[108] we have regarded this type of surgery as lawful — and it was, even before the reform — provided that it was carried out for a curative purpose, that is, where the case was clearly one of transsexuality. It is appropriate at this point to dwell briefly on what constitutes transsexuality. Transsexuality implies a lack of correspondence between physical sexuality and psychological sexuality, such that all aspects of the individual's behaviour are affected. For reasons of clarity we have limited

our discussion to two sexual variables, but specialists in the field distinguish a greater number of such factors: the sexual chromosome pattern; gonadial and morphological sexuality; hormonal sexuality and related secondary sex characteristics; morphology of the external genitalia; internal reproductive organs; sex as assigned at birth and throughout childhood; psychological sex and gender role. It is, therefore, necessary to analyse the various dysfunctions that can occur in transsexuals in relation to biological identity from the psychological, social and legal point of view .

A mismatch between the sexual organic and the psychological components entails serious difficulties for transsexuals in the development of their sexual and social lives as well as causing serious disturbances in the development of personality. These individuals in fact play a role (in keeping with their psychological sexuality) that is vastly different to that expected or demanded of them by society (the role dictated by their physical and, therefore, legal gender). It should be borne in mind with regard to this that in these cases the gender that appears in the Civil Register, which determines whether the individual is legally assigned to the masculine or feminine sex (as no third possibility is allowed) is logically the organic sex of the individual at birth, as determined by external sexual characteristics (it is here that errors occur in registering the sex of individuals who are pseudo-hermaphrodites).

When such mismatches occur the treatment of the patient logically involves eliminating the source of the mismatch in an effort to produce a correspondence between the physical and the psychological. A possible option — which would appear to be the less drastic of the two as it involves no surgery — is adjusting the sexual psychology and behaviour of the person to their physical sexuality through psychiatric treatment, together with high dosages of hormones to accentuate the anatomical and physiological characteristics of organic gender. Unfortunately, to date this method has not produced very satisfactory results, due mainly to the length of time needed (several years) and also because the desired results are not always achieved at the end of the day and the patient's situation often becomes even more intolerable. For this reason surgery has become a more and more popular solution in recent years. In these circumstances it is the organism that goes through the process of adjustment or being attuned (at least in terms of outer appearance) to the sexual psychology and behaviour of the patient (it should not be forgotten that this is usually the preferred solution of the individuals concerned, who usually do not wish to come to terms with the sex to which they have been assigned organically and legally and reject their own genital organs which they regard as a deformity). This surgical operation consists primarily in amputating and removing the original genital organs and 'modelling' new artificial external organs (by means of plastic surgery using the genital tissue of the patients themselves) as well as the secondary sex characteristics, which also involves high dosages of hormones. Despite the high level of aesthetic — and functional — success of these operations, once they have been carried out the individual concerned suffers irreversible loss of his/her capacity to reproduce.

323. Thus, by seeing these operations as fundamentally therapeutic we can regard them in a positive light from the juridico-criminal point of view. Transsexuals run serious risks of suffering personality disorders because of this complete rejection of their somatic sexuality. They see their own sexuality as an 'anomaly' and if no solution is found the conflict can lead to extreme sreactions, and even to suicide. If, as we have seen, psychiatric and even hormonal therapy are doomed to failure in most cases, other solutions must be sought. We know that human health is multidimensional, that any disturbance has social repercussions (the person becoming marginal, for example) and that mental health plays a particularly important role in the general health of an individual given that psychological and somatic factors are inextricably linked.

As a result, if the physician believes that the solution lies in a physical — external — sex change so as to achieve harmony with the patient's personality, nothing should stand in the way of such an operation being performed. Clearly the medical indication is necessary (in the first place, a statement from the psychiatrist to the effect that there is a mismatch between physical and psychological gender and that other non-surgical measures have proven to be inadequate or ineffective, and an evaluation of the relative advantages and disadvantages of the

operation for that particular patient) and the requirements of *lex artis* must be met. In such cases the physician has to consider (it goes without saying that the individual's views and wishes are of paramount importance in this respect) whether the patient's capacity to reproduce or a balanced mental state is more important in terms of his/her general behaviour. While the loss of the ability to reproduce clearly affects an important aspect of biology in general and human biology in particular — the potential to have children and the paternal/maternal instinct — being mentally disturbed has implications for the development of the personality of the individual and his/her relationships with others, which would lead one to contend that this psychological aspect is of greater importance.

324. While these arguments are valid in the case of sex change operations with clearly therapeutic purposes, they are not when the purpose of the operation is not so clear, when there are other circumstantial goals or benefits (such as better prospects of employment in the artistic sphere, immature persons' desire to "follow fashion", benefits related to specific sports etc.). Nevertheless, the Penal Code, in permitting these surgical operations, makes no distinction between those that are therapeutic and those that are not, which means that the quality of lawfulness must be extended to all such operations —unless there is some problem with the consent of the individual concerned —regardless of the underlying reason. This lawfulness rests on the principal of individual self-determination. Even so, despite the Legislature's intentions, it would seem to be going too far to allow operations with such serious risks and consequences for the integrity of the individual to be carried out without careful weighing up of the therapeutic value — that is to say, verification that a truly transsexual pathology is involved —and of the thought given to the decision and how far the person is determined that the operation should be carried out. This would avoid hasty decisions that are later deeply regretted once the irreversible operation with all its consequences has been performed.

II. Achieving Harmony between the Sex of the Person and His/her Legal Gender or Legal Identity

325. Once the sex change has been accomplished — at least externally — by means of surgery, a very specific but important legal problem arises which is of particular relevance in the light of the Supreme Court case law that was discussed earlier: we are now confronted with the case of a person who from this point onwards clearly belongs to one sex as a result of their external characteristics, psychology and behaviour, but at the same time genetically and legally (that is to say in the Civil Registry) belongs to the other.

There is no need to emphasise the social and legal problems and other issues that can arise for such a person on a daily basis in the course of ordinary life and the implications for the community. In this sense the operation itself achieves little (aside from harmony on the personal level, which, it should be said, is no small achievement) so long as this discrepancy between the personal and the legal persists.

326. The solution to this is once again to attempt to reconcile the two aspects by amending the entry in the Civil Registry. The first step —and the most limited in that it provides only a partial solution to the problem— is to change the person's name (from masculine to feminine or vice versa) so that it is appropriate to the new identity. This has been allowed on some occasions by the lower courts and the Registry and Notary's Division. A second procedure is to apply for official recognition in the Registry of the change of sex. In fact the regulations that govern the Civil Registry (Law of 8 June 1957 and the Regulations of 14 November 1958) do not explicitly provide for the situation we are examining here and thus we are faced with a true legal lacuna. Nevertheless, a correct interpretation of the current regulations allows for an appropriate solution, as we shall see shortly. The current legal situation is as follows: Spain's Civil Registry legislation does not take as its point of departure the assumption that gender is an invariable or immutable condition, as some authors have claimed, but is based only on the *stability* of the information recorded in the entries in the Civil Registry, which can be rectified by means of various procedures if they can be shown to be incorrect or inaccurate or because

of a change in the facts or circumstances that led to the entry.

It is possible, by means of a simple administrative procedure, to rectify 'the incorrect entry for sex when at the same time there is no doubt as to the identity of the individual in the light of other circumstances' (art 93 nº2 of the Civil Registry Law); in which case, according to the Regulations (art. 294), further investigation of various matters is needed. In fact the situation envisaged by the Law and its Regulations in the articles cited here covers exclusively *errors of registration,* in situations of hermaphroditism (pseudo-hermaphroditism) when the external sex organs lead to one sex being attributed and later, when the individual has developed or as a result of medical treatment, it is discovered that he/she belongs to the other. In such cases the simple administrative procedure referred to above will see that the extract of birth in the Register is altered accordingly. In other cases, such as sex change operations, where there is no real error in the entry in the Registry there remains the possibility of seeking a change in status. The Civil Registry Law allows the rectification of entries 'after a definitive decision has been given in an ordinary hearing'. Nevertheless, the Supreme Court has rejected the notion that changes in the entry for sex can be effected simply under art. 92, and has stated that case law must be constructed to develop the issue further, on the grounds that it is the courts that must decide in new circumstances which were not foreseen by the Legislature. Furthermore, in the first such case in 1987 the Supreme Court relied on an application of analogy and the existence of a putative woman, stating that the Law should protect legal fictions. This decision was rightly criticised by civilists,[109] who countered that only fictions created and envisaged by the law can be protected. Two subsequent decisions of the Supreme Court also followed this line of reasoning, but were based also on arguments relating to the right of transsexuals to freely develop their personality, which is recognised and protected by the Spanish Constitution, art. 10. 1.[110]

III. The Transsexual, Marriage and the Family

327. The only remaining question is whether or not the transsexual can marry[111] when as we saw earlier he/she is clearly incapable of reproduction (if he/she has undergone a sex change operation). The institution of marriage — which should not be confused with the family — has also evolved socially and therefore the law has never sought to prevent marriage even when the two parties (man and woman) have come to an agreement not to have children. No legal obstacle should stand in the way of a transsexual's marrying when his/her new gender is legally recognised: such a situation is not included among the restrictions on marriage in articles 46 and 47 of the Civil Code, in which it is stipulated that the only requirement is that the parties to the marriage are from the legal point of view *a man and a woman* (art. 44) and that they have given their consent to the marriage (art. 45).[112] For such consent to be valid it is necessary for the future spouse to know about his/her partner's situation beforehand. The individual concerned must inform the intended spouse about the legal change of sex and the other organic and personal repercussions of this change, including irreversible infertility and any change in the transsexual's personal qualities. Only in this way can the parties avoid the marriage being null and void 'ab initio' because of irregularities with regard to consent, as stipulated by article 73 number 4 of the Civil Code, which defines as null and void marriages entered into as a result of 'mistaken identity or error as to the personal qualities of the marriage partner, this identity or these qualities having been determining factors in the giving of consent'. It should be said that knowledge of such a circumstance can be obtained from the Civil Registry, which must reflect any rectifications with regard to name and sex. It is true, however, as the Supreme Court states, that the modification of an entry in terms of the name does not in itself imply 'complete equivalence with someone of feminine gender for the purposes of certain legal acts and transactions, since each of these demands full capacity and aptitude in each situation'.[113] It could be said that although in the case in question the court did not explicitly prohibit marriage, which it might wee have done, the above statement is not very coherent given the initial premise involved (acceptance of a legal change of sex). In effect, it is tantamount to acknowledging a third sex category (apart from the two legally recognised sexes). Membership of this third sex would exclude one from marriage with either of the other two sexes, since it

would be even more absurd to allow the person to marry someone of the opposite sex to that which was the former's original sex at birth, but who is now of the same sex legally following the amendment to the registry. This would constitute discrimination on the grounds of sex, which is prohibited by the Spanish Constitution (art. 14), and would be doubly discriminatory since the person is prevented from marrying anybody at all, be they man or woman. This, therefore, reinforces our view that transsexuals should be able to marry in accordance with their current legal sex as amended in the registry (but not in accordance with their previous sex), so long as the precautions governing the principle of consent to marriage between a man and a woman that we discussed above are met.

328. In the situation where the person that has undergone the sex change operation was already married, the person to whom he/she was married may logically be granted a legal separation and/or the dissolution of the marriage (divorce), despite the fact that this circumstance is not explicitly dealt with in the law (arts. 81, 82 and 86 of the Civil Code). It is a different matter if the transsexual had children before the surgical and legal sex change, in which case it should be understood —in the absence of any legal indication to the contrary — that the legal relationships that existed prior to the change and the duties and rights arising from these relationships are maintained (such as those in relation to heirs and parental authority).

329. In conclusion, it would seem appropriate for legislation to be drawn up specifically to regulate transsexual issues, starting with limiting the lawfulness of such surgical operations to sex changes where a proven transsexual syndrome exists. The law should also consider all the other civil repercussions discussed above.

NOTES

1. For a more complete account see. C.M. ROMEO CASABONA, 'La reforma penal del aborto: límite mínimo, figuras delictivas y sistema de las indicaciones', in *Propuestas para la reforma penal* (Centro de Estudios Criminológicos, Universidad de La Laguna, Santa Cruz de Tenerife 1992), pp. 143 and ff.

2. V. J. BUSTOS RAMIREZ, *Manual de Derecho Penal. Parte Especial*, cit., p. 59; G. LANDROVE DIAZ, *Política Criminal del aborto*, (Bosch, Barcelona 1976), p. 15; F. MUÑOZ CONDE, *Derecho Penal. Parte Especial*, (8ª ed. Tirant Lo Blanch, Valencia 1990), p. 81; J.M. RODRIGUEZ DEVESA/ A. SERRANO GOMEZ, *Derecho Penal Español. Parte Especial*, (14ª ed. Dykinson, Madrid 1991), p. 74; L. RODRIGUEZ RAMOS (with M.A. COBOS GOMEZ DE LINARES and J. LOPEZ BARJA DE QUIROGA), *Manual de Derecho Penal. Parte Especial, I*, (Akal, Madrid 1990), p. 140 and f.

3. See references in E. FARRE TREPAT, 'Sobre el concepto de aborto y su delimitación de los delitos contra la vida humana independiente', in *Anuario de Derecho Penal y Ciencias Penales*, 1990, pp. 337 and f.

4. Art. 412 Penal Code: "Abortion occasioned by an act of violence, in the knowledge of the woman's pregnancy, without intention to cause abortion is punishable as a lesser offence". The lesser ofence carries a minimum sentence of six months and one day's imprisonment and a maximum sentence of six years.

5. This is a sentence of between 12 years and one day and twenty years in prison.

6. For a more complete account see R.F. SUAREZ MONTES, 'Aplicación del nuevo art. 1 del Código Penal al aborto con resultdo de muerte en la reciente jurisprudencia del Tribunal Supremo', in *Estudios Penales y Criminológicos, IX*, (Publ. Univ. Santiago de Compostela 1986), pp. 209 and ff. Also Rulings of Supreme Court (2nd Cahmber) of 30 March 1985, 4 April 1985, 19 September 1990.

7. Article 416. "Punishment of "arresto mayor" and a fine of between 100,000 and 200,000 pesetas shall be imposed where a person commits the following acts in relation to substances, objects, instruments, means or procedures capable of causing or facilitating abortion: 1. Holders of medical or health qualifications who indicate the use of any of the above, or unqualified persons who do likewise. 2. Manufacturers or businesses who sell the above to non-medical staff or unauthorised distributors. 3. Any person who offers for sale, sells, issues, provides or advertises in any way or form any of the above".

8. A criterion that corresponds to that adopted in the Rulings of the Supreme Court (2nd Chamber) of 28 April 1946, 14 May 1977.

9.Supreme Court Ruling (2nd Chamber) of 5 December 1986, in the opposite sense to earlier decisions: 20 December 1980, 15 October 1983.

10. S. Constitutional Court 75/1984, 27 June.

11. Art. 416 bis can be translated thus: "Abortion performed by a doctor, or under his supervision, in an accredited health care centre or institution, be it public or private, with the explicit consent of the pregnant woman is not punishable in the following circumstances: 1st When it is necessary to avoid grave danger to the life or physical or psychiatric health of the woman and that this is stated in a certificate issued prior to the operation by an appropriate specialist physician other than the doctor who is to perform the abortion or under whose supervision the abortion is to be performed. In emergency conditions where there is a life-threatening risk to the woman, the requirements for explicit consent and a written certificate are waived. 2nd When the pregnancy is the result of an act that constitutes the crime of rape under art. 429, so long as the abortion is performed in the first 12 weeks of pregnancy and the aforementioned act has been reported to the authorities. 3rd When it is assumed that the foetus will be born with grave physical or psychiatric abnormalities so long as the abortion is performed in the first 22 weeks of pregnancy and the written statement is issued by two specialists from a public or private accredited health care centre or establishment, neither of whom shall perform or supervise the abortion. 2. In the cases envisaged in the previous clause the pregnant woman's actions will not be punishable even if the abortion is not performed in a public or private accredited centre or health care establishment or if the medical certificates not been issued.

12. An exemption that has its origins in one of the Constitutional Court's much criticised 'suggestions' to the Legislature in ruling 53/1985, 11 April (legal principle n. 12).

13.I n this sense J. CEREZO MIR, 'La regulación del estado de necesidad en el Código Penal español', cit., p. 108; D.M. LUZON PEÑA, 'Indicaciones y causas de justificación en el aborto', cit., n. 36, 1988, pp. 659 and f.

14.See ROMEO CASABONA, 'La reforma penal del aborto: límite mínimo, figuras delictivas y sistema de las indicaciones', cit., p.152.

15.Supreme Court Ruling (2nd Chamber) of 11 December 1990, which confirmed the provincial court's decision.

16. See J. CEREZO MIR, 'Noción del estado de necesidad como requisito básico de la eximente del número 7 del art. 8º del Código Penal español. Estado de necesidad y colisión de deberes', in *Revista de la Facultad de Derecho de la Universidad Complutense de Madrid*, monog. n. 11, 1986, pp. 200 and ff., for a fuller account of these consequences.

17. In the same line of argument, LUZON PEÑA, 'Indicaciones y causas de justificación en el

aborto', cit., p. 634. A counter argument is provided by DIEZ RIPOLLES, 'Análisis de los elementos de la causa de justificación del art. 417 bis del Código Penal', cit., pp. 216 and ff and 243 and ff.

18. DIEZ RIPOLLES, 'Análisis de los elementos de la causa de justificación del art. 417 bis del Código Penal', cit., p. 216.

19. R.D. 2409/1986, of 21 November, on accredited health care establishments and relevant regulations for the lawful practice of voluntary termination of pregnancy. The 1st article states that these establishments must provide a specialist in Obstetrics and Gynaecology as well as nursing staff, a health care assistant and a social worker (for abortions that do not entail great risk), or Obstetrics and Gynaecology units (in cases of high risk or pregnancies of more than 12 weeks).

20. A. CUERDA RIEZU, 'El delito de aborto ante la Propuesta de Anteproyecto del Nuevo Código Penal', cit., pp. 376 and f; DIEZ RIPOLLES, 'Análisis de los elementos de la causa de justificación del art. 417 bis del Código Penal', cit., pp. 219 and f; LUZON PEÑA, 'Indicaciones y causas de justificación en el aborto', cit., p. 644.

21. See the fuller account in JORGE BARREIRO, *La imprudencia punible en la actividad médico-quirúrgico*, cit., pp. 113 and ff (with some interesting decisions on medical negligence for unjustified delegation of responsibility to nurses in obstetrics cases, p. 154); ROMEO CASABONA, *El Médico y el Derecho Penal, I,* cit., pp. 247 and ff.

22. As for the previous requirement, the ruling of the Constitutional Court of 11 April 1985 was to this effect, which led to its inclusion in the definitive version of the text of the law.

23. DIEZ RIPOLLES, 'Análisis de los elementos de la causa de justificación del art 417 bis del Código Penal', cit., 227. It should be recalled that the physician must be licensed to prescribe abortive drugs (art. 415.4 of the Penal Code) for home use or administration; the same applies to devices inserted into the uterus in the centre by health care workers the abortive effects of which occur at a later stage when the woman is at home, etc.

24. According to art. 9 of the RD of 21 November 1986, information should be furnished in the following terms: Health care professionals shall inform those seeking an abortion of the medical, psychological and social consequences of the continuance of the pregnancy or its termination. They shall also provide information as to the availability of social welfare services and family assistance that may aid the parties concerned. They shall also furnish information as to the appropriate demands and requirements, such as the date and the centre or establishment in which an abortion may be performed.

It is easy to see that the information requirement goes further, in some aspects, than what would be strictly necessary for valid consent to operate as an excuse under the Penal Code.

25. Art. 10.5 of which refers to the right to information of clients of public and private health services (art. 10 final paragraph). See also the 9th art of the LGS.

26. Thus, BUSTOS RAMIREZ, *Manual de Derecho Penal, Parte Especial*, cit., 65.

27. On the consent of pregnant minors or mentaly deficient womwn, see Part. II, Chapter II, section 1 above.

28. According to art. 3.2 and 3 of Law 42/1988, of 28 December, on the donation and use of human embryos and foetuses or their cells, tissue or organs.

29. DE-VICENTE REMESAL, 'El grave peligro para la salud psíquica de la madre en la nueva ley del aborto', cit., p. 8.

30. Attorney General's Office, Consulta nº 4/1987, of 14 November, on *Algunas cuestiones penales y procesales sobre los requisitos excluyentes de la punibilidad en el aborto por indicación ética* (see text in *Anuario de Derecho Penal y Ciencias Penales*, 1988, 203 and ff).

31. A different view is taken by M. BAJO FERNANDEZ, *Manual de Derecho Penal. (Parte especial), Delitos contra las personas*, cit., p. 139; CUERDA RIEZU, 'El delito de aborto ante las Propuesta de Anteproyecto del nuevo Código Penal', cit., p. 380.

32. J.A. GISBERT CALABUIG, *Medicina Legal y Toxicología*, (4ª ed. Salvat, Barcelona 1991), p. 472 and f.

33. BAJO FERNANDEZ, *Manual de Derecho Penal. (Parte Especial) Delitos contra las personas*, cit., p, 133; CUERDA RIEZU, 'El delito de aborto ante la Propuesta de Anteproyecto del Nuevo Código Penal', cit., p. 378.

34. DIEZ RIPOLLES, 'Análisis de los elementos de la causa de justificación del artículo 417 bis del Código Penal', cit., p. 193.

35. In fact the Spanish Penal Code does not actually define what sterilisation consists of. Art. 419 stipulates that whoever intentionally brings about the mutilation of or the dysfunction of an organ or non-principal member or sterility or deformity shall receive a sentence of "prisión mayor" (imprisonment of between six years and a day and twelve years).

36. Art. 418 states that whoever intentionally mutilates or renders useless an organ or principal member of another, deprives him of his sight or hearing, causes the elimination of or severe limitation to his ability to work, causes him to suffer serious physical or mental illness or incurable mental injury shall be sentenced to "reclusión menor" (imprisonment of between twelve years and one day to twenty years).

37. On this issue see A. GUALLART DE VIALA, *La nueva protección penal de la integridad corporal y la salud*, (Ed. Ceura, Madrid 1992), pp. 73 and f.

38. ROMEO CASABONA, *El Médico y el derecho penal*, I, cit., p. 177.

39. BLENLER, *Tratado de Psiquiatría*, (Espasa Calpa, Madrid 1969), pp. 127 and f.

40. See LGS, art. 10.5 and 6.

41. A similar view is expressed by J. CEREZO MIR, *Curso de Derecho Penal español. Parte General, II*, (Tecnos, Madrid 1990), p. 97.

42. Civil Code, art. 162: "Parents with rights of authority are the legal representatives of their non-emancipated minor children, save in relation to 1. Acts concerning the child's right of personality or other rights which, under the law and bearing in mind his level of maturity, he can perform for himself". Art. 267: "Guardians are the legal representatives of minor or incompetent children, save in relation to acts which they can perform for themselves, either as the result of an explicit legal ruling to that effect or a proviso contained in the court's declaration of the child's incompetence".

43. See on this point L. DIEZ-PICAZO/ A. GULLON BALLESTEROS, *Sistema del Derecho Civil, IV*, (5ª ed. Tecnos, Madrid 1990), p. 362; J.M. LETE DEL-RIO, *Comentarios al Código Civil y Compilaciones forales*, (M. ALBADALEJO, ed.), IV, (2ª ed. EDERSA,

Madrid 1985), p. 368.

44. See Chapter II, section 1.

45. For arguments in favour of banning the sterilisation of minors, see L. ARROYO ZAPATERO, 'Los menores de edad y los incapaces ante el aborto y la esterilización', cit., p. 19.

46. On this see, ROMEO CASABONA, *El Médico y el Derecho Penal, I,* cit., p.316; J. SILVA SANCHEZ, *La esterilización de disminuidos psíquicos,* (PPU, Barcelona 1988), p. 46; J. BOIX REIG, *La reforma penal de 1989,* (Tirant lo Blanch, Valencia 1989), p. 132.

47. The Attorney General, in his Consulta of 3/1985, *sobre la capacidad de los oligofrénicos para prestar el consentimiento previsto en el art. 428.2 del Código Penal* (on the capacity of menatl patients to grant the consent envisaged in article 428.2 of the Penal Code), arrived at a similar conclusion.

48. See C.M. ROMEO CASABONA, 'El diagnóstico antenatal y sus implicaciones jurídico-penales, in *La Ley*, n. 1751, 1987, p. 6.

49. GUALLART DE VIALA, *La nueva protección penal de la integridad corporal y la salud,* cit., p. 131; J. TAMARIT i SUMALLA, *La reforma de los delitos de lesiones*, (PPU, Barcelona 1990), p. 191.

50. Along similar lines, Circular n. 2/ 1990 from the Attorney General's Office, *sobre la aplicación de la Reforma de la Ley Orgánica 3/ 1989, de 21 de junio, de actualización del Código Penal.*

51. Of the same opinion and arguing along the same lines, GUALLART DE VIALA, *La nueva protección penal de la integridad corporal y la salud,* cit., p. 132; and Attorney General's Office, *Memoria elevada al Gobierno de S.M.*, (comments by Prosecutor Compte), Madrid 1990, p. 276.

52. Law 35/1988 of 22 November on Assisted Reproduction Techniques.

53. In the Plenary Session of the Congress of Deputies, 10 April 1986.

54. See for example F. PANTALEON PRIETO. 'Contra la Ley sobre Técnicas de Reproducción Asistida', in *Jueces para la Democracia*, n. 5, 1988.

55. See also F. LLEDO YAGÜE, *Fecundación artificial y derecho*, (Tecnos, Madrid 1988), pp. 114 and ff.

56. The idea of well-being encompasses not only possible psychological repercussions resulting from the lack of a father (in regard to which there is still a lack of specific information), but also being deprived of the aspects of paternal authority such as support, food, education, etc. (see art. 154 of the Civil Code).

57. See objections and arguments in favour of this in A de LEON ARCE, 'La Mujer sola, sin pareja, ante las nuevas técnicas de procreación humana', in *La Filiación a finales del siglo XX. Problemática planteada por los avances cientificos en materia de reproducción humana* (Trivium, Madrid, 1988), pp. 407 and ff, who is personally in favour.

58. See on this, M. PALACIOS, 'Selección del sexo y legislación vigente', in *Hojas de Tecnología*, (Ministerio de Sanidad y Consumo, Dir. Gral. de Planificación Sanitaria, ed.) n.

9002, 1990, p. 1.

59. Edict of 12 November 1990. See the complete text in *Labor Hospitalaria*, n. 218, 1990, pp. 318 and ff.

60. Conditions pertaining to health centres and biomedical teams are regulated in arts. 18 and 19.

61. See J. GIL RODRIGUEZ, 'La reproducción humana asistida como acto médico y el fundamento del anonimato', in *Boletín de Información del Ministerio de Justicia*, n. 1593, 1991, pp. 1600 and ff.

62. If insemination is carried out against the woman's will and gives rise to an offence (e.g. of coercion), consent given later would have no effect in criminal law terms. V. ROMEO CASABONA, *El Médico y el Derecho Penal, I*, cit., pp. 292 and ff.

63. On these issues, which bring us into the area of Civil Law, the vast literature published in Spain may be consulted. See in particular, (various authors), *La filiación a finales del siglo XX. Problemática planteada por los avances científicos en material de reproducción humana*, 'II Congreso Mundial Vasco', (Trivium, Madrid 1988), passim.

64. See E. SERRANO ALONSO, 'El depósito de esperma o de embriones congelados y los problemas de la fecundación "post mortem"' in *La Filiación a finales del siglo XX. problemática planteada por los avances cientificos en material de reproducción humana*, cit., pp. 365 and ff; H. CAMPUZANO TOM, *Reflexión en torno a los derechos de la viuda para ser inseminada artificialmente*, from the same volume, pp. 433 and ff.

65. We have used the expression 'partner' here though the Spanish Law uses no such term nor does it make any reference to such a condition, be it stable or unstable. The Law uses only the terms male and unmarried male.

66. The new draft Penal Code of 1992 does, however, provide for various offences in relation to genetic manipulation ('such that its vital constitution (genotype) is altered') of human embryos and foetuses and to artificial insemination when consent has not been given.

67. A. CUERDA RIEZU, 'Limites jurídicopenales de las nuevas técnicas genéticas', in *Anuario de Derecho Penal y Ciencias Penales*, 1988, p. 428, is of the same opinion.

68. See ROMEO CASABONA, 'El diagnóstico antenatal y sus implicaciones jurídicopenales', cit., p. 6.

69. See ROMEO CASABONA, ibidem.

70. With regard to the embryo or the foetus, the Spanish Penal Code does not include an offence of causing injury to the foetus, though this is envisioned in the new draft Penal Code of 1992, arts. 162 and f.

71. See C.M. ROMEO CASABONA, 'La protección jurídica del concebido. El feto como paciente', in *Revista Jurídica de Castilla-La Mancha*, 1989.

72. Some authors consider that in future all the current indications for abortion will cease to exist because treatment will be possible outside the woman's body. This will even be the case when the pregnancy endangers the woman's life as the foetus would be removed and placed in an artificial placenta. Interrupting a pregnancy will not therefore involve terminating the life of the conceived child. V. L. LOMBARDI VALLAURI, 'Bioetica, potere, diritto', in *Giustitia*,

1984, p. 21.

73. See W. KAPP, 'Der Fötus als Patient?', in *Medizinrecht*, 1986, p. 276.

74. The First Additional Provision d. charges the government with the drawing up of such a list (within six months of the Law's coming into force), although it has sill not been passed. The lack of such a list should not preclude foetal therapy being carried out at the moment, provided that the other legal requirements are met.

75. Along these lines see KAPP, 'Der Fötus als Patient?', cit., p. 280, although he does not dismiss the possibility of intervention by the Court for the Protection of Minors in cases of necessity.

76. 'Current' is here understood in the strict sense of the word as meaning not only that the complaint has already become apparent in the mother but that there is a specific risk that she will sustain some further injury in the near future. This is what can be deduced from the use of the term 'grave danger' in art. 417 bis n 1, 1ª of the Penal Code. The hypothesis put forward in the body of the text, however, is that the conflict only arises from the moment the foetal therapy which endangers the mother's life begins.

77. See CEREZO MIR, *Curso de Derecho Penal Español, Parte General, II,* cit., pp. 17 and f. and 48 and ff. on this issue and on how the conflict should be considered and resolved.

78. Consider the legal problems involved when abortion has been excluded as a possibility and no action is taken. The pregnancy runs its course and the child is born but dies soon after, although this could have been avoided if the mother had agreed to foetal treatment that involved no risk for her.

79. See on this, CEREZO MIR, 'La regulación del estado de necesidad en el Código Penal español', pp. 58 and ff.

80. It is a different case where joint consent covers also treatment of the preembryo *in vitro* since in this case neither the man nor the woman are at risk (until implantation) and it is for this reason that the legal criterion is absolutely correct and justified.

81. See Fundación BBV (ed.), *Human Genome Project: Ethics*, Madrid, 1991. See also on this matter, C.M. ROMEO CASABONA, 'El Prtoyecto Genoma Humano: implicaciones jurídicas', en *Etica y Biotecnología*, (Fundac. Humanismo y Democracia, Fundac. Konrad Adenauer and Univ. Pontif. de Comillas, Madrid 1993), pp 167ff; C.M. ROMEO CASABONA, 'Límites penales de la manipulación genética', *Reunión Internacional sobre el Proyecto Genoma Humano* (FBBV, Madrid-Bilbao 1994, in press).

82. See, for example, the rulings of the Supreme Court (Civil Chamber) of 14 July 1988 and 28 May 1990.

83. See a fuller account in B.A. WEINER, 'Treatment rights', in *The Mentally Disabled and the Law,* (Samuel J. Brakel/John Parry/ Barbara A. Weiner, eds.), (3ª ed. American Bar Foundation. Chicago 1985), pp. 327 and ff. Weiner recognises the current importance of the use of drug therapy (because people can be treated as outpatients) but notes that most people have doubts about electric shock therapy and are still apprehensive given its negative image in the past (it was not used selectively and muscle relaxants were not given to prevent fractures). The future of psychosurgery, she notes, is in some doubt despite new developments in Neurosurgery.

84. Law 30/1979 of 27 October. See C.M. ROMEO CASABONA, 'La Ley de trasplantes y

sus repercusiones sociales', in *La Ley*, 1982, pp. 1 and ff.; C.M. ROMEO CASABONA, 'El Derecho ante los trasplantes de órganos. La ordenación jurídica de los trasplantes de órganos en España: Principios rectores', en *Revista General de Derecho*, nº 582, 1993, pp. 1915 and ff.

85. All the provisions referred to can be found in *Trasplantes, reproducción asistida y hemodonación,* (Insalud, Madrid 1991), pp. 37 and ff.

86. The specific regulations governing the donation of blood would be taken into account: RD 1945/1985, 9 October, Ministerial Order of 4 December 1985, and any specific provisions drawn up by Autonomous Communities.

87. Art. 428 reads as follows: "The penalties stipulated in the previous chapter (on bodily harm offences) shall be imposed in their respective cases even when consent has been given by the injured party. Notwithstanding the provisions of the previous paragraph, explicit and freely given consent removes criminal liability in the case of organ transplants carried out in accordance with the Law, sterilizations and transsexual surgery performed by qualified persons, unless consent has been obtained under false pretences or through pressure or the promise of financial gain or if the person giving consent is a minor or is legally incompetent, in which neither this consent nor that of the legal representatives shall be valid (...). The consent referred to in the previous paragraph does not remove criminal liability in the circumstances envisaged by article 422 of this Code". [This final precept refers to self-mutilation or mutilation to which consent has been given in an effort to avoid compulsory military or social service].

88. See arts. 406, 407, 409 and 489 ter: the crimes of murder, homicide, assisting a suicide and failure to fulfil the duty to answer a call for help, respectively.

89. See C.M. ROMEO CASABONA, *Los trasplantes de órganos,* cit., pp. 61 and ff.

90. The team shall comprise a Neurologist or Neurosurgeon and the Chief Medical Officer of the unit or his substitute (art. 5 of the Law and art. 10 of the RD of 1980). In cases of violent death (for example accident), in which the legal authorities have to intervene, a forensic doctor may also be included, although this is not obligatory and is intended rather to facilitate and speed up the legal process.

91. See a fuller account in ROMEO CASABONA, *Los trasplantes de órganos*, cit., pp. 71 and ff.

92. In fact the Law does not establish exceptions for these last two circumstances. The RD of 1980 states that "where minors or mentally deficient patients are concerned, opposition may be expressed by those with parental authority, legal guardians or legal representatives" (art. 8. 3).

93. According to art. 9. 2 of the 1980 RD :"Circumstances permitting, family members present in the health care centre should be informed of the need, nature and circumstances of the removal as well as of the subsequent restoration, preservation and mortuary practices to be carried out".

94. See World Health Organisation, *Principios rectores sobre trasplante de orgános humanos* (EB87/12), Principio Rector 9: "In keeping with the principles of distributive justice and equity donated organs must be made available to patients according to medical need and not to financial or other considerations".

95. See art. 3 of the Law, art. 1. 6 and art. 12. 4. 4. of the 1980 RD and the Resolution of June 27 1980 which develops further the provisions of the Law on organ transplants.

96. C.M. ROMEO CASABONA, 'Aspectos jurídicos de la experimentación humana', in *Revista de la Facultad de Derecho de la Universidad Complutense de Madrid*, n. 11, 1986, pp. 569 and ff.

97. G.H. KIEFFER, *Bioética*, (Alhambra Universidad, Madrid 1983), p. 287.

98. J. ATAZ LOPEZ, *Los médicos y la responsabilidad civil*, cit., pp. 57-99; ROMEO CASABONA, *El Médico y el Derecho Penal, I*, cit., pp. 311-85.

99. An extremely detailed description of clinical trials in terms of objectives (or phases), number of participating centres, methodology and degree of concealment is given in articles 3, 4, 5 and 6 of the RD 1993.

100. See J. GAFO FERNANDEZ, 'Dilemas éticos de la experimentación humana', in *Razón y Fe*, n. 1042, 1985, pp. 616 and f.

101. Consider the fact that in the United States`prisoners have frequently been experimental subjects because apart from their availability they have objective characteristics (homogeneity, stable, orderly and controllable lifestyles) which make them extremely suitable for research: A. JONSEN (et al.), 'Biomedical experimentation on prisoners. Review of practices and problems and proposal of a new regulatory approach', in *Ethics in Science and Medicine*, 1977, pp. 1-28; KIEFFER, *Bioética*, cit., pp. 272-7.

102. RODRIGUEZ DEVESA/ SERRANO GOMEZ, *Derecho Penal Español. Parte Especial*, cit., p. 134.

103. See ATAZ LOPEZ, *Los Médicos y la responsabilidad civil*, cit., pp. 257 and ff; ROMEO CASABONA, *El Médico ante el Derecho*, cit., pp. 117 and ff. on objective liability in medical practice.

104. On this see GAFO FERNANDEZ, 'Dilemas éticos de la experimentación humana', cit., p. 616.

105. For example, the Law on the Removal and Transplant of Organs, cit., art. 2; RD 9 October 1985 on blood donation and blood banks, art. 3.1 (nevertheless, it continues to allow 'in exceptional circumstances' financial reward in accordance with the relevant rules: final provision 1ª).

106. Ruling of Supreme Court (1st Chamber) of 2 July 1987.

107. See a systematic account in J. DIEZ-DEL-CORRAL RIVAS, 'La transexualidad y el estado civil', in *Anuario de Derecho Civil*., 1981, pp. 1077 and ff; ROMEO CASABONA, *El Médico ante el Derecho*, cit., pp. 22 and ff.

108. ROMEO CASABONA *El Médico ante el Derecho*, cit., p. 23.

109. See R. DE-ANGEL YAGÜEZ, 'Transexualidad y cambio de sexo', in *La Ley*, n 1819, 1987, pp. 1 and ff; J.M. MARTINEZ-PEREDA RODRIGUEZ, 'El transexualismo en el Derecho español', in *Actualidad Civil*, 1989, pp. 1173 and ff; J. VIDAL MARTINEZ, "¿Se incluye el 'cambio de sexo' (transexualidad) el 'libre desarollo' de la personalidad al que se refiere al art. 10. 1 de la Constitución española?", in *Revista General de Derecho*, n 534, 1989, pp. 987 and ff.

110. Rulings of Supreme Court (1st Chamber) of 15 July 1988 and 3 March 1989.

111. Other issues that we have not discussed are the possibility of the transsexual's adopting children or doing military service. See ROMEO CASABONA, *El Médico ante el Derecho*, cit. p. 25.

112. For arguments to the contrary see MARTINEZ-PEREDA RODRIGUEZ, 'El transexualismo en el Derecho español', cit., p. 1324.

113. Ruling of Supreme Court (1st Chamber) of 2 July 1987.

Part III. The Physician and Health Care System

Chapter I. Relation with other Health Care Providers

330. In the field of health care other professionals work alongside doctors and perform an important role in assisting and treating patients. Under the broad term "other health care providers" are included nurses, a category known literally in Spanish as "technical health care assistants" or ATS (a type of nurse), doctors' assistants, midwives and auxiliary nurses. Traditionally these professionals have assisted the physician, but as medicine has become increasingly reliant on technology and more and more specialised, largely because of the advent of new and complex diagnostic and surgical techniques, it is now essential for these individuals to be highly qualified and, in most cases, have university level training.[1] They perform a series of tasks which, although complementary to those of the physician, are sometimes absolutely vital and it is often the case that the doctor cannot or does not know how to perform them.[2] Because of the increasing importance of these health care providers, and the need for greater control over medical activity (applicable here also),[3] more rigorous regulation of these professions is crucial. However, this is an area that has been somewhat neglected in Spain, as we shall see shortly.

Other qualified personnel such as pharmacists, psychologists and opticians also participate in health care. When we say that health care teams are multi-disciplinary it is not only because they comprise participants from the various branches of medicine, but also because such persons perform important functions.

331. A number of different provisions make reference to the relations among the different categories of health care providers. In various Statutes governing the activities of medical personnel and paramedical health care workers, the maintenance of good relations and cooperation among these professionals is demanded. In the particular case of physicians, chapter 7 of the Code of Medical Ethics is devoted to the relationship between the physician and other health care providers:

> Art. 36.1. Physicians must maintain good relations with other health care professionals. They shall treat all auxiliary personnel with respect and take note of their opinions with regard to the care of the sick, even if these opinions are at odds with those of the physician.
>
> 2. The physician should not intrude upon the areas of competence of the staff that work with him, but must not allow these professionals to encroach on his area of responsibility when such action could be detrimental to the patient.

§ 1. Pharmacists

332. Pharmacy as a profession forms part of the community health care system and contributes to the common cause of the other health care professions, namely, the preservation and recuperation of health.[4]

The specific know-how of pharmacists confer on them an important role which consists of the following functions:[5] control over the pharmaceutical products dispensed to the patient; in the case of minor ailments that do not require medical attention, dispensing medicaments for symptom relief; ensuring that medicines are used correctly and patients are warned as to any adverse effects; clinical pharmacy and vigilance in relation to pharmaceutical products in the community; the furnishing of information on medicines; the making up of prescribed medicines; the proper conservation of medicines in the pharmacy; the storage of substances that are subject to special restrictions on their use. As a health care professional, the pharmacist plays an active part in programmes for the promotion of health and health education in the community, and any other activities for which his university education has specially prepared

him, particularly those relating to food and environmental health.

333. The pharmacist cooperates with the physician in the preparation of prescriptions and the dispensing of medicines, and undertakes clinical analyses which provide vital information on which diagnosis may be based.

§ 2. DENTISTS (See Part. I, Chapter I, § 1, n. 30)

§ 3. NURSING PROFESSION

334. Traditionally included within the broad category of "nursing" are a group of professionals who perform a wide range of functions that aid and complement medical practice. A number of such professions were recognised by Spanish health regulations as far back as 1860. In 1952 a distinction between ATS (a type of nurse) and midwife was established. In 1963 recognition was given to a further category, auxiliary nurses, the formal qualification for which is obtained in the vocational training system ('formación professional'). Auxiliary nusrses assist hospital nursing staff with the care of the patient by performing tasks such as bathing, feeding etc.

In 1977, with the establishment of Schools of Nursing, a new professional category requiring three years of university education was created.[6] The previous categories of ATS and midwife were given equal status to the new Diploma in Nursing and began to disappear as professions in their own right.

335.Since then, university education of nurses has allowed the profession to acquire functional independence, albeit as an integral part of the coordinated multi-disciplinary health care teams (working alongside physicians, auxiliary nurses, psychologists, etc.) which are central to hospital care.[7] Nurses are responsible for the care of the patient (particularly in terms of treatment management), attending to the needs of the patient's family and, where relevant, assistance with community health care education (as delegated by physicians or psychologists) as teachers, researchers and administrators. It is important to draw a distinction between nurses and auxiliary nurses, who do not hold university qualifications and who work under the nurse in the primary care of the patient and his environment.

Holders of a nursing qualification may also practise privately in centres primarily concerned with the management of treatment prescribed by the physician, rehabilitation and primary care, in accordance with the entitlement to freely practise a profession which is recognised by art. 89 of the LGS and arts. 35 and 36 of the Constitution.

336. Nevertheless, the lack of clear-cut regulatory guidelines to govern the role of nurses produces a good deal of uncertainty and is frequently a source of friction between nurses and physicians because of the confusion as to where the responsibilities of one end and those of the other begin.

337. There is a possibility that new regulations will be drawn up so as to conform to the requirements of the LGS, which stipulates in art. 84 that the government shall draw up a framework statute for, among others, qualified (auxiliary) health care personnel and auxiliary nurses employed by the Social Security system.

After the LGS was passed the Ministry of Health and Consumer Affairs produced a draft version in 1987 which attracted a great deal of criticism. This led to the preparation of another draft of a National Health Service Statute, which was made public in 1988 but did not go through Parliament. As a result, the Social Security Paramedical Health Care Personnel Statute (published by Order of the Ministry of Employment on 26 April 1973), which contains a statute for qualified (auxiliary) health care personnel and auxiliary nurses, should be understood to be still in force. Another piece of legislation which is still binding is Decree 2319/ 1960 of 17 November on the professional responsibilities of ATS, doctors' assistants, midwives and nurses.

The profession itself has been pushing hard for a specific law to regulate nursing in a manner in keeping with the fact that these professionals are now university-qualified.

338. A consequence of the lack of political will to create the appropriate statutory provisions for the nursing profession is the decision by the European Court of Justice of 7 November 1991. The court condemned Spain's failure to implement within the prescribed time limit the provisions of EC Council Directive 80/155 of 21 January 1980 on the coordination of legal, regulatory and administrative provisions regarding access to the professions of midwife and obstetric assistant and the exercise of these professions (which are now specialist fields included in the diploma in nursing).

339. A Code of Nursing Ethics was drawn up by the Spain's General Council for Nursing and passed by Resolution 32/89. The Code lays down guidelines for nurses in the fulfilment of their obligations under three broad headings: nursing and the human being; nursing and the community; nursing and professional practice. As regards relations with other professionals, chapter 10 of the Code stipulates the following:

> Article 63. In order to provide the best possible service to the patient, nurses shall do their utmost to cooperate with other members of the health care team. They should always respect the areas of responsibility of other professionals, but should not allow these professionals to encroach upon their own professional autonomy.

§ 4. Paramedical Professionals

340. *Physiotherapists* This was originally a branch of the profession of ATS, although since 1980 and the setting up of Physiotherapy Schools training has been taken out of Nursing Schools. Physiotherapy is aimed primarily at the rehabilitation of patients.

341. *Chiropodists*: This profession was established as a specialisation within the broader category of ATS and is primarily concerned with the non-surgical treatment of the feet.

342. Optometrists: Optometry Schools have offered university training since 1974. Optometrists's work involves chiefly the grading and production of lenses. This is a group which often suffers from illegal practice.

Chapter II. Relation with Health Care Provisions

§ 1. Hospitals

343. Hospitals are the foundation of the system of specialised medical care. Historically they were not strictly speaking health care institutions, but charitable hostels for the elderly, the poor and for pilgrims, etc. In the nineteenth century the functions that hospitals perform today were the province of charitable organisations.[8] A major expansion in hospital services took place at the end of the sixties as a result of improved human and material resources, though this was still not sufficient to satisfy the demands of public health due to the lack of a true hospital network. This was in part because specialised medical care was provided by the Social Security System which still lacked the means available in other centres to attend to the needs of public patients.[9] Hospitals belonging to the Provincial Governments, 'Cabildos Insulares' (organs of government in the Balearic and Canary Islands) and city councils were able to offer such services. This meant that there was the danger of duplicating specialised health care services as a result of the 1944 Law establishing the bases of the National Health Service. Aside from other factors, this alone was good reason to claim that the way in which the hospitals functioned was not entirely satisfactory and the idea of a coherent network of hospitals began

to emerge as a means of achieving greater efficiency in hospital care. This was attempted through a number of statutory provisions, the first of which was the Law 37/1962 of 21 July which still constitutes today the basic legislation governing hospitals.[10] This law defines hospitals as follows: "establishments providing medical/clinical care, regardless of the names they bear, without prejudice to the fact that such establishments may provide preventive, convalescent and outpatients' treatment as appropriate."[11] However, neither this law nor any of the subsequent legislation has succeeded in arriving at an efficient specialised health care organisation: "the situation of specialised care in 1982 is characterised by the disorganisation resulting from the multiplicity of public administration hospital management bodies and the failure to set up a satisfactory instrument for hospital coordination".[12]

344. The 1962 Law regulating hospitals was developed further by Decree 575/1966 of March 3 on the classification and regionalisation of hospitals. This was followed by a number of other pieces of legislation on various aspects of the hospital service, including the still operative RD 521/1987 of 15 April on the structure, organization and functioning of hospitals managed by the National Institute of Health ('Instituto Nacional de la Salud', known by its acronym INSALUD) and the reform of our National Health System introduced by the General Health Law (LGS) of 1986. Art. 65. 1 of the LGS states that every Health Area should have at least one General Hospital which should be involved in the promotion of health, disease prevention, research and teaching as well as attending to patients' needs. These hospitals should thus complement the primary care network.

The public hospital infrastructure is still not sufficient on its own to provide health care services to the total population. For this reason the LGS, while still seeking to establish a single hospital network, arrived at a system under which private hospitals participate in public health care in two ways, namely, through association agreements and the linking up of private hospitals to the public system.

With regard to *agreements* with private health care institutions, the Public Administration, having previously given approval to the institutions and evaluated the optimal use that can be made of their health care resources, establishes the requirements and minimum conditions that are applicable to all agreements. The conditions and requirements established must include the reciprocal rights and obligations of both parties, guarantees that the service provided will be of the same quality for all clients and a prohibition against the introduction of services that are complementary to those already provided by public health care centres. Under similar conditions of efficiency, quaity and cost, priority shall be given to institutions belonging to non-profitmaking organisations.[13] The Public Administration is charged with the carrying out of inspections of these private centres as regards health care services, administration and financial matters concerning each patient referred to them for admission (art. 94.2 of the LGS).

The *linking up of* private hospitals to the national health system enables them to enjoy a closer relationship with the public system.[14]

345. Access to hospitals, which is open to all those who are ill regardless of their financial or social position, including prison inmates,[15] is granted once all other avenues of diagnosis and treatment in primary services have been explored, save for emergency cases. Hospital care is provided on in in-patient basis, through admission to hospital, and via outpatient consultancies and Casualty Services.

Outpatient consultancies enable specialised care to be provided without the need for the patient to be admitted to hospital. The physician completes a Referral for Outpatients' Consultation which the Health Care Area Authority sends to the hospital concerned and the patient is given an appointment through the Admissions Service. There is direct access, however, to the Casualty Service in very serious cases. A number of beds for withdrawal from drugs of addiction are set aside in INSALUD network hospitals and associated private hospitals in each Area Authority. Under the terms of INSALUD's involvement in the 1985 National Drug Programme all members of the community have access to these beds whether or not they are covered by Social Security health insurance.

The programme designed to make hospital care more human has aided INSALUD in its efforts to provide more user-oriented treatment in the hospital context by means of easier access to health care services and by providing patients and their families with more personalised treatment during their time in hospital. The programme is based on the Patients' Bill of Rights and Duties ('Carta de Derechos y Deberes del Paciente') which as yet is not legally binding. A series of improvements to the Bill are suggested, such as a Patient Care Service designed to provide patients and their families with information on the hospital organisation, available services, timetables and visiting hours and other activities. Visiting hours have been extended and teachers provided for hospitalised children so that there schooling will not be unduly disrupted. Finally efforts are being made to extend and improve the contact between mothers and hospitalised children in a bid to create a better therapeutic environment.

346. Royal Decree 521/1987 of 15 April passed the Regulations governing the structure, organisation and functioning of hospitals managed by the National Institute of Health. These regulations are aimed at improving the management and quality of care provided by hospitals in accordance with the principles laid down in the LGS. In this way, hospital services and activities are grouped together under the following categories: Hospital Administrator's Division, Medical Division, Nursing Division, Management Services and General Services.

I) The top level of hospital management is the Hospital Administrator ('Director-Gerente') who represents the hospital and is its highest authority, with responsibility for the hospital's human, physical and financial resources. This person plans, manages, controls and evaluates the performance of all the hospital divisions and takes measures to ensure the smooth running of the hospital, especially in times of crisis and emergency. The Administrator produces periodic reports on hospital activities and an annual report (art. 7). The areas of responsibility of the Administrator's Division are patient relations, management, computing services, legal affairs, admissions, reception and information, staffing policy, analysis and planning (art. 9).

II) The Medical Division, which covers the areas of Medicine, Surgery, Obstetrics and Gynaecology, Paediatrics, Central Services, Documentation and Clinical Files, Day Hospitalisation, Home Hospitalisation and any other activity in which medical care is involved, is headed by the Medical Director, whose most important functions are the management, supervision, coordination and evaluation of medical and other health care services in the hospital.

III) The Nursing Division is concerned with coordination of the units and services under its responsibility (wards, operating theatres, special units, outpatient's department, casualty etc.) while the Management Division and General Services Department provide the administrative support and technical assistance necessary for the running of all other hospital divisions (financial management and administration, supplies, catering and maintenance, etc.)

§ 2. Preventive Health Care

347. Originally, public health care in Spain was more preventive than treatment-oriented. During the nineteenth century and up until the middle of this century the Administration took responsibility for public health only within the parameters of disease prevention, particularly the prevention of epidemics, and other health hazards arising from poor hygiene and medical treatment provided by unqualified individuals.[16] The Administration took on this preventive role because epidemics affected a considerable sector of the population. What the Administration was in fact concerned with was protecting collective health rather than individual health, which was primarily treatment-oriented.[17] This preventive focus can be seen in the Law of 28 November 1885, the General Public Health Instructions of 12 January 1904 and the Law establishing the bases of the National Health Service (1944).[18] However, the social and political situation in Spain led to the development in the public arena, and not just in the area of health care, of a greater concern with individual needs and an appreciation of the fact that the person in need of medical treatment could not, in most cases, afford to pay for

treatment. As a result, the public health care service was made available not only to the poor and destitute, but also to those with insufficient means of support. In this way, the original state practice of organising health care from a preventive perspective for the population as a whole was finally abandoned in favour of an approach that took account of the dangers to individual health caused by common and frequent diseases and illnesses. The final stage in this process of evolution was the constitutional recognition of the right to health protection for all citizens resident in Spain.[19] Art. 43. 2 of the Constitution, apart from recognising the right to health protection, states in its second paragraph that the organisation of and responsibility for public health shall be achieved through preventive measures and the provision of the necessary services. Similarly, the LGS states explicitly that the actions of the Public Administration in the area of health care should involve the treatment as well as the prevention of disease and illness (art. 18. 2).

348. The right to protection of health includes, therefore, not only treatment to restore good health in cases of illness, but also the right to protection from possible health hazards that might affect the individual. For this reason the LGS lists in art. 18 —in Chapter II, entitled "public intervention in individual and collective health"— a large number of specific actions in Preventive Medicine, such as:

a) The care of high risk groups in the population and the prevention of both congenital and acquired disabilities.
b) The promotion and improvement of sanitation, water supply, removal of liquid and solid residues, air pollution control, health inspections and the improvement of environmental health in all contexts including the home.
c) Family planning
d)The promotion of mental health and health in the workplace.
e)The control and prevention of food and drug-related health hazards.
f)Informing the public on epidemiology.

Intervention by the public administration can consist of requiring authorisation to be sought for any activity that might imply a risk or danger to health, and may, in cases of imminent and exceptional risk, involve the seizure or impounding of products, the imposition of temporary bans on activities, or the closure of businesses or facilities (art. 23 of the LGS). In short, all this means that, in contrast with the nineteenth century approach to health care, the current view is that the individual, and not just the social group, should be afforded health protection (prevention and treatment), in accordance with his rights as laid down in constitutional principles governing social and economic policy which the authorities are duty-bound to observe.

This has led the Legislature to confer on health the protection which it deserves and which is demanded by the Constitution, by legally regulating the manner in which certain dangerous activities should be carried out and stipulating the administrative sanctions applicable to breaches of these regulations. Moreover, actions that endanger or damage public health are treated as criminal offences.[20]

349. In order to assure the effectiveness of preventive medicine, when the risk to public health is imminent, provision is made for the adoption of government measures, including the curtailment of rights and constitutional freedoms, under Organic Law 3/1986 of 18 March, on Special Preventive Health Measures. This law grants the health authorities the right to impose treatment aimed at protecting the individual or aiding his recovery. These measures may range from a simple medical examination to hospitalisation and may affect the individual or groups of people, or those engaged in a particular activity. In the area of epidemics, the Regulation of 26 July 1945 — which developed the Fourth Foundation of the Law establishing the bases of the National Health Service (1944), completed further by the RD 2050/1982 of 30 July — established special measures for the control of outbreaks of disease, such as the obligation of the public to inform the authorities if they have contracted certain diseases and the drawing up

by the authorities of weekly statistical reports containing specific information on cases of epidemics treated.

350. In certain fields preventive medicine has achieved a greater degree of organisation, specification and stability, thanks to the maintenance of a preventive medical service made up of permanent units and specific types of health care services in certain health care contexts. Specific programmes have been drawn up for primary health care, family planning, mental health and obstetric psycho-prophylaxis. We refer here to the Family Planning Centres and Units, staffed by specialists in various fields (gynaecologists, midwives, psychologists etc.), in which advice is given on sexuality and contraception. Prenatal, genetic and legal abortion counselling is also provided in these centres, as is treatment for sexually transmitted diseases. For their part, Mental Health Units are responsible for more than just treatment and they are involved in promotion, education and prevention through specific programmes related to problems such as alcoholism, drug abuse etc. Lastly, Obstetric Psycho-prophylaxis Units are intended to provide pregnant women with information and health education to prepare them for the birth, puerperium and care of the newborn infant.[21]

In the area of drug abuse, for example, the 1985 National Drug Programme, which concerns the control and reintegration of drug addicts into the community, also lists a range of preventive measures, based primarily on health education at primary and secondary school levels. These take the form of educational programmes to promote health and seek to prevent risks to health in the educational context (this approach is more successful if those involved are properly trained and if teachers are provided with information and enabled to include drug prevention or drug-related health subjects in their courses).

With regard to health in the workplace the LGS once again considers various basic preventive measures aimed at reducing risks to workers' health to a minimum. Art. 21 of the LGS establishes the measures that Health Areas must take in relation to the prevention of risks to workers. They are responsible for monitoring working conditions and the work environment, drawing up guides on dangers in the workplace (including an obligation for companies to inform the health authorities on all substances used in production) as well as the setting up of an epidemiological control system on disease and mortality rates in the workplace, promoting, as far as is possible, the education and training of workers and management in the area of health in the workplace.

§ 3. Health Insurance

351. Historically, health care services were provided by means of private health insurance. The State did not take on responsibility for health care in the same way as it did for other public services. It only catered for those in the terminal stages of an illness and for the destitute, and did not concern itself with the medical profession, which was conducted entirely through private practice. For these reasons it is hardly surprising that at the beginning of this century there was a plethora of private health insurance companies through which physicians offered their services to individuals and families in exchange for regular payment. But this lack of interest on the State's part in community health and the medical profession has gradually become a thing of the past as a result of the fact that most citizens were not in a position to pay for their own medical treatment. This led to the State taking on the role of social protector, using its public resources in the service of community health, initially through obligatory health insurance and later with the establishment of the Social Security System. Today both types of health service (private health care and Social Security) coexist.

352. The Spanish Constitution states in art. 41 that "the public authorities shall maintain a public Social Security system for all citizens that shall ensure a minimum level of care and service in situations of need, especially in cases of unemployment. Care and complementary services shall be free of charge". Although the system was created to cover health risks to a specific group of people, namely wage-earning workers, it has gradually widened its scope to include a larger number and range of beneficiaries and to offer more services.

353. Physicians employed by the Social Security are not strictly speaking employees or civil servants. According to art. 3.2 of the Legal Statutes of Social Security Medical Personnel passed by Decree 3160/1966 of 23 December, "the legal administrative relationship between physicians and the Social Security is based on the general principles governing technical staff..." which means that the relationship is similar to that which exists between civil servants and the Administration, although governed by different legal regulations. The Medical Personnel Statutes alone are applicable to Social Security physicians and leaves room for the individual or collective autonomy of physicians when contracted by the Social Security.[22] The statutory relationship between physicians and the Social Security does not preclude private practice, as the aforementioned article indicates elsewhere.

354. The Social Security system currently covers all citizens resident in Spain, together with certain non-residents and foreigners with work and residence permits. It comprises a General Regime and various Special Regimes, which are reminiscent of the old private health insurance systems. There are also differences in terms of the services which one is entitled to according to whether one is registered under the General Regime or one of the Special ones. The latter are an open list and the Government may at any time include them within the General Regime, although it should be said that they are becoming quite similar to their general counterpart in terms of the cover provided.

I)*The General Regime* of the Social Security system includes wage earners who normally work in Spain and certain specific classes of non-resident Spanish workers (civil servants or employees of international organisations, non-civil servant Spaniards contracted by the Spanish Administration to work overseas), and wage-earning foreigners with residence and work permits in Spain. The employer must register his business with the Social Security must ensure that the company registers the employees also. The employer shall be liable for non-compliance with either of these requirements.[23] As soon as the business activity commences, employer and employee Social Security contributions are payable and are compulsory. These are calculated on the basis of the total remuneration that the worker is entitled to receive. Agreements between the worker and the employer such that the worker assumes the obligation to pay part or all of the employer's contribution are null and void.

Registration with the General Regime automatically gives rise to various entitlements: health care, financial assistance for the unemployed, retirement and widows' pensions, etc.. Health care consists of medical and pharmaceutical services as well as rehabilitation and, in some cases, prostheses and orthopaedic appliances. The services are available not only to the registered worker but to his/her spouse or the person with whom he/she has lived, as man and wife, for at least a year prior to registration. Natural and adopted children are also covered, be they the children of the worker or the spouse, regardless of age or the legal relationship. The parents and grandparents of the worker and his/her spouse are covered provided that they live with the worker and are maintained by him/her and are not gainfully employed, receive no benefits from property or a pension exceeding twice the minimum wage and have no other individual entitlement to Social Security health care services.

Health care service covers common illness, accidents occurring outside the workplace, illness produced as the result of work, accidents in the work place and maternity. Care is provided in the area of residence of the registered worker and outside this area when he/she provides proof of registration with the Social Security. Outpatient services, hospital care and house calls are also available through the system. Medicaments are free of charge when they are dispensed by Social Security health care institutions, and for pensioners, for those in receipt of temporary invalidity benefits or benefit in respect of profession-related sicknesses or accidents in the workplace. Social Security beneficiaries pay 40% of the retail price of drugs and medicines used frequently to treat certain illnesses and other specialist pharmaceutical products.

Free health care services are also provided for those without sufficient means of support (an income lower or equal to the minimum wage).

Financial assistance is provided in situations where the worker is temporarily or permanently unfit to work as a result of common illness, illness brought about by work, or accident, whether in the workplace or elsewhere, and maternity. A worker who is temporarily unfit for work, although he is still obliged to pay his social security contributions, is entitled to receive benefit for a period of twelve months, renewable for another six, in cases of accident or illness, and sixteen weeks for maternity (extendable to eighteen weeks for multiple births). Temporary invalid status is granted on expiry of the period of being temporarily unfit for work and if the worker still requires health care assistance and is unable to return to work. This category is applicable for a maximum period of six years calculated from the date when the worker was certified as being temporarily unfit for work. It is not applicable to cases of permanent illness or incapacity. A worker is certified as being permanently incapacitated when, after having undergone the treatment prescribed, there are still serious anatomical and functional disabilities that can be objectively determined. They should be permanent and should diminish the worker's capacity for work or should make work impossible. There are several levels of incapacitation: permanent partial incapacitation for the person's normal work, permanent total incapacitation for the person's normal work, absolute permanent incapacitation for all types of work and grave disability.

Other types of financial assistance are provided for people with children in their care. The children must be under eighteen years of age or, if they are legally adults, must be totally incapacitated for all types of work. The amount of benefit paid monthly for each child is quite low, although it increases in the case of large families or persons with low income (pensioners).

In most cases working life comes to an end at the age of 65, at which time the person —if he stops work— becomes entitled to receive a retirement pension if he has made social security payments for at least 15 years, two of which must have been in the last eight years. The possibility of early retirement at the age of 60 also exists.

The following benefits are available in cases of the death of the worker, pensioner, person receiving temporary invalidity benefit or benefit while recovering from illness:

A) Funeral benefit to assist with the cost of the burial.

B) Widow's/widower's pension for the widow or widower of the deceased worker, provided that there has been a marital relationship, legal separation or divorce (although in some cases cohabitation is sufficient grounds for entitlement).

C) Orphan's pension for children under eighteen or incapacitated adult children or for the deceased's adopted children, provided that adoption was granted at least two years before the death.

D) Family pension for the deceased's blood relations such as grandchildren, brothers and sisters, mother, grandmothers, father and grandfathers living with the deceased and financially dependent on him/her and who do not receive a pension and have no adequate means of support.

There is also universal Old Age and Invalid Insurance for those over 65 who have no right to a pension under the different Social Security regimes, as long as they paid contributions for 1,800 days between 1940 and 1966.

II) Special regimes within the General System. By virtue of RD 2621/86 of 24 December, special systems for railway workers, professional football players, salesmen, bullfighters and artists are governed by the rules of the general regime, with minor variations in terms of contributions, incapacitation and retirement.

III) Special regimes within the Social Security:

A) *Farmworkers*. This regime is applicable to wage earners and self-employed persons in agriculture, forestry and fishing. They have the same cover as workers under the General Regime, with minor variations (they cannot take early retirement, and are not entitled to temporary invalidity benefit, etc.).

B) *Self-employed persons.* This category comprises persons aged over eighteen who normally work for themselves and are gainfully occupied without being subject to employment contracts. It includes also the spouse and family up until the third generation, authors, self-employed persons who are members of professional colleges or associations, self-employed foreigners. Entitlement includes health care, temporary incapacity for work, permanent total and absolute invalidity pensions and grave disability, funeral benefits, benefits payable to surviving relatives and dependents, and retirement benefits.

C) *Seamen*. This includes both self-employed persons and wage-earners and offers the same entitlements as the General Regime, save for a number of special features.

D) *Coal Miners.* Wage-earners employed in the following fall into this category: underground coal mining, opencast mining, manufacture of coal products, research, detection and extraction of coal from slag heaps,extraction of carbon and residual carbon-bearing water and other complementary activities. There are some special features in comparison to the General Regime.

E) *Domestic staff.* This includes workers over 16 who are exclusively engaged as domestic staff for one or several heads of a family, provided that the work is done in the habitual place of residence of said person and in return for payment is made for this work. The category includes child-minding, gardening, driving and other similar activities. The head of the family's spouse, dependent children, dependent parents and dependent grandparents are excluded. Here again there are special features in relation to the General Regime.

F) Students. Student insurance includes Spaniards below the age of 28 who are enrolled as full-time students or otherwise in secondary education or vocational training, the University Orientation Course, undergraduate university studies and post-graduate university studies leading to a doctorate. Foreign students under 28 who are nationals of countries with tacit or explicit reciprocal agreements are also covered when pursuing the above-mentioned studies. Affiliation to the system is automatic on enrolment. Medical attention is obligatory in cases of tuberculosis, surgery, neuro-psychiatry and tocology. Access is provided, depending on financial circumstances, to radiotherapy, physiotherapy and some other services, as well as the treatment of injuries sustained in the school or university environment.

355. The Social Security also protects those who are wiling and able to work, but who lose their jobs temporarily or permanently or whose hours of work are reduced by at least a third, resulting in loss or reduction of earnings. The Social Security provides two levels of unemployment benefit: contributory and supplementary.

I) Contributory unemployment benefit is paid to wage-earners registered under the General Regime or any of the Special Regimes, to those who are released from prison on completion of their sentence or on parole, returned emigrant workers and armed forces reservists, national reserve, troop classes and professional seamen. In order to be eligible for this benefit it is necessary to be currently registered with a Social Security regime which includes unemployment cover. Furthermore, the worker must be unemployed and have been paying Social Security contributions for a six-month period within the four years prior to becoming unemployed. Benefit is paid by the National Employment Institute ('Instituto Nacional de Empleo'), an autonomous entity dependent on the Ministry for Employment and Social Security.

II) Supplementary benefit comprises a financial benefit and payment of the appropriate Social Security contributions. The duration and amount of payment depends on the class of benefit to which one is entitled. The following have the right to supplementary benefit:

A)Workers who have exhausted their contributory unemployment benefit entitlement and who have family responsibilities.

B)Workers over 45 who have exhausted their unemployment benefit payable over at least the previous twelve months and who have no family responsibilities.

C)Returned emigrant workers.

D)Workers who on becoming unemployed have still not completed the

minimum period of contribution that would entitle them to contributory unemployment benefit.

E)Those released from prison.

F)Workers who have been declared fit or partially fit as a result of a medical examination that shows up an improvement in a case of grave disability or permanent absolute or total incapacity for the person's usual work.

G)Non-permanent full-time workers who have exhausted their contributory benefit or were not eligible for unemployment benefit because they had not paid the minimum number of contributions.

H)Unemployed workers over 52.

I)Casual workers included in the special farmworkers' regime.

III) Unemployment cover includes the provision of health care services for workers who are no longer entitled to unemployment benefit or supplementary benefit or to health care through some other avenue. Conditions are that the worker must not have an income higher than the minimum wage, must have been registered with the Employment Office since the termination of unemployment benefit or supplementary benefit, must not have refused an offer of work and must not have access to health care through another avenue.

IV) Under Law 26/1990 of 20 December, which modifies the Revised Text of the General Social Security Law ('Ley General de Seguridad Social') passed by RD 2065/1074 of 30 May, which sought to achieve a more compassionate system, Social Security financial benefits were made available to all. The right to retirement and invalid pensions and child benefit holds good for all citizens even if they have never contributed or have not contributed for a long enough period of time to be eligible for contibutory benefits. Beneficiaries receive not only periodic financial assistance but also medical, pharmaceutical and social services. Minimum requirements established are residence in Spain, insufficient means of support, and a minimum age requirement of 65 in the case of retirement pensions, and 18 (with the necessary degree of disability) for invalidity pensions.

356. A part from the Social Security, there exist 'Mutualidades libres de Prevision Social' (Mutual Pension Funds), which are governed by Law 33/1984 of 2 August and aim to protect their members in case of death, old age, disability, medical treatment, and other situations where a benefit or pension might normally be paid. Any natural or legal person may set up a Mutual Pension Fund, but any such funds must not be profit making, must have a minimum of fifty members and must be authorised by the government. Fundings comes from members' contributions, which may take the form of fixed or variable premiums. The Funds are governed by Statutes, which must be approved by the Ministry of Economy and must stipulate, among other things, equal rights and obligations for all members, that the administrators shall not receive remuneration and that members' liability for debts is limited to an amount less than a third of the contributions paid in the last three financial years.

Colleges of Physicians' agreements with a number of Mutual Pension Funds mean that these benefits are available to members. Joining a social protection scheme at the minimum level of contribution is a compulsory requirement for college membership and members have a duty not to fall in arrears with their payments (art. 36.4 and 43b of the Statutes of the OMC).

NOTES

1 See C. SEGURA/ L. MARTINEZ-CALCERRADA, 'El médico ante el Derecho Civil', in L. MARTINEZ-CALCERRADA, *Derecho Médico I*, cit., p. 54.

2 LLAMAS POMBO, *La responsabilidad civil del médico*, cit., p. 335.

3 See above.

4 MARTINEZ CAÑIZARES, 'Farmacéutico y Sociedad', in *Revista ACOFAR*, 206 (1983), p. 13, quoted in F. RICO PÉREZ, La responsabilidad del farmacéutico, (Trivium, Madrid 1984).

5 E. LLUCH MARTIN, *Política Farmacéutica del Ministerio de Sanidad y Consumo*, (Servicio de Publicaciones del Ministerio de Sanidad y Consumo, Madrid, 1983), p. 21, quoted in RICO PÉREZ, *La responsabilidad civil del Farmacéutico*, cit., p. 10.

6 See SEGURA/ MARTINEZ-CALCERRADA, *Derecho Médico I*, cit. p. 54.

7 While they work in teams that are organised hierarchically, they are responsible for their own specific tasks; on this issue and for a fuller account of the hierarchical superior/subordinate division of labour, see A. JORGE BARREIRO, *La imprudencia punible en la actividad médico-quirúrgica*, cit., pp. 147-66.

8 See J. ORTIZ DIAZ, 'Hacia una reordenación de la Sanidad Pública española: el problema hospitalario', in *Revista de Administración Pública*, n. 51, 1986, pp. 153-60 on the historical origins fo hospitals.

9 Because of this the Social Security Service established agreements with other private and public hospitals. These hospitals catered for public patients or provided the Social Security system with the material and human means of providing such a service.

10 Art. 4 of the law refers to the setting up of a National Hospital Network. To this end, it establishes a Central Coordinating Committee for Hospital Services which, among other things, is responsible for (art. 7) maintaining information on hospital needs and for building, adding extensions to, modifying or closing hospitals (art. 5).

11 Art. 1 includes a second paragraph that states: "hospitals are also centres for the training of technical and health care personnel, for scientific research so long as the appropriate conditions for such purposes are satisfied in accordance with the nature and aims of each Institution. At the same time there should be adequate coordination between teaching centres". Art. 65.2 of the LGS states that "the hospital is responsible for in-patient care as well as specialised and complementary care as required in its area".

12 ELOLA SOMOZA, *Crisis y Reforma de la asistencia sanitaria pública en España*, cit., p. 155. The author adds "the efforts —efforts that have not been put into practice— to rationalise hospital management can be seen in various areas: the appointment of professional managers who are not necessarily medical professionals, the widely expressed desire to make the budget the responsibility of management, the development of a system to assess the quality of care and efficiency, and finally the drawing up of a list of rights of hospital users".

13 See art. 90 of the LGS.

14 See PEMAN GAVIN, *Derecho a la salud y Administración sanitaria,* cit., p. 213.

15 The new art 147 bis of the Prison Regulations ('Reglamento Penitenciario') brought in by RD 319/1988 of 30 March, envisages that, where necessary, if there are no prison hospitals near the penitentiary in which the person is an inmate, or if the prison hospital cannot provide adequate or appropriate care, treatment or surgery and admission to hospital is essential, a non-prison hospital managed by the Public Administration may be used.

16 See Luis MORELL OCAÑA, 'La evolución y configuración actual de la actividad administrativa sanitaria', in *Revista de Administración Pública*, n. 63, 1970, pp. 136-40.

17 See PEMAN GAVIN, *Derecho a la salud y administración sanitaria*, cit., p. 104, who gives more emphasis to the idea of the protection of collective health than to prevention as the basis on which the traditional health care administration was founded. On the oder hand, the protection of indivicual health lacked a preventive element, and was centred rather on care provided by the Welfare ('Beneficencia') that catered for the needs of the poor.

18 The Law of 1944, still partly operative today, devotes its Fourth Foundation to the fight against infetious diseases, and to disinfection, and fumigation and established preventive measures such as an obligation for the physician to notify the existence of disease or insolation measures; in the Fifth Foundation all matters related to External Health are dealt with, such as inspection and control of health hazards; and in the Thenth Foundations specific measures to fight trachoma, sexually transmitted diseases and lepropsy are stipulated. See COBREROS MENDAZONA, *Los tratamientos obligatorios y el derecho a la salud*, cit., pp. 350-9.

19 This is expressed in art. 1.2 of the LGS as follows: "All Spaniards and foreign nationals resident in Spain have the right to health protection and health care".

20 The second section of Chapter II of Title V of Volume II of the Penal Code lists offences against public health.

21 See the Order of 28 March 1984.

22 M. ALONSO OLEA/ J.L TORTUERO PLAZA, *Instituciones de la Seguridad Social*, (12ª ed. Civitas, Madrid 1990), p. 280.

23 Criminal punishment is a possibility, given that and offence against security in the worlk place is committed if false pretences or coertion have been used to impose on workers conditions that perjudice their statutory rights (art. 499 bis. 1 of the Penal Code). Administrative penalties can also be applied (arts. 13, 14 and 15 of the Law 8/ 1988, of 7 April, on infractions and penalties of a social nature), as well as fines consisting of additional social securitu payments (art. 42.2 of the Worker's Statute). Moreover, an employer who has failed to register workers whith the social security may, after a certain period of time, be forced to give them premanent jobs (art. 15. 4 of the Worker's Statute).

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(provisional, not valid; pending to convert it into new paragraph numbers)

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