NORSTEDTS
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Medical Law

An Introduction

Lotta Westerhäll

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FRITZES

Norstedts Juridik is a part of CE Fritzes AB.

Address:
CE Fritzes AB
Box 6472
S-113 82 Stockholm, Sweden

Orders:
Fritzes
S-106 47 Stockholm, Sweden
Telephone: +46 8 690 90 90, Fax: +46 8 20 50 21

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Lotta Westerhäll
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List of Abbreviations

AFL	*Lag (1962:381) om allmän försäkring* (General Insurance Act)
AT	*Allmäntjänstgöring* (medical residency)
BrB	*Brottsbalken* (The Swedish Penal Code)
FB	*Föräldrabalken* (Swedish Parents and Children Code)
HD	*Högsta domstolen* (Swedish Supreme Court)
HSAN	*Hälso- och sjukvårdens ansvarsnämnd* (Health and Medical Care Liability Board)
HSL	*Hälso- och sjukvårdslagen (1982:763)* (Health and Medical Care Act)
IVF	*in vitro* fertilization
JO	*Justitieombudsman* (Parliamentary Ombudsman)
LVFS	*Läkemedelsverkets författningssamling* (Pharmaceutical Preparations Department Regulations)
MF	*Medicinska författningar* (Medical Regulations)
MFR	*Medicinska forskningsrådet* (Swedish Medical Research Council)
NJA	*Nytt Juridiskt Arkiv*, Avd. I (Swedish Supreme Court Reports)
Prop	*Proposition* (Government Proposition)
PSN	*Patientskadenämnden* (Patient Injury Board)
RF	*Regeringsformen* (Form of Government Law)
RÅ	*Regeringsrättens årsbok* (Annual Report of the Supreme Administrative Court)
SOSFS(M)	*Socialstyrelsens författningssamling* (M) (National Social Welfare Board Regulations concerning Medical Care)
SFS	*Svensk författningssamling* (Collection of Swedish Statutes)
SOU	*Statens offentliga utredningar* (State Public Commissions Series)
SoU	*Socialutskottet* (Social Welfare Committee of the Parliament (Riksdag))
Supervision Act	*Lag (1980:11) om tillsyn över hälso- och sjukvårdspersonalen m. fl. (Tillsynslagen)* (Supervision of Health and Medical Personnel Act)
TF	*Tryckfrihetsförordningen* (Freedom of the Press Law)
WHO	World Health Organization
ÄB	*Ärvdabalken* (Swedish Inheritance Code)

General Introduction

I. The General Background

§1. Geography

1. Sweden is a rather large country in size, but it is a sparsely populated country. Its 8.6 million inhabitants are spread out over 450,000 km^2 – the density of population being 19 inhabitants per km^2, which is the lowest population density in Europe with the exception of Norway and Finland. However, Sweden does have an urban population, with one-third of its inhabitants concentrated around its three largest cities: Stockholm, Göteborg and Malmö.

Sweden is a very long and narrow country with the northernmost part of the country above the polar circle. The Baltic Sea surrounds the country on the east, the narrow Öresund separating the southwestern part from Denmark, followed by the North Sea. This gives Sweden a long coastline, providing the country with possibilities of both fishing and transportation.

Sweden has a wide variety of landscapes, plains in the south, forests in the central part of the country, and steep mountains in the very north. Due to the long coastline of and the Gulf Stream, a substantial part of the country has a rather mild maritime climate, but the north has long and hard winters near darkness.

§2. Cultural Composition

2. Sweden is ethnically a very homogeneous country. Swedish, which is a Germanic language and is very similar to the other two Scandinavian languages Danish and Norwegian, is the official language, and is spoken everywhere. In the very north of the country, there is a small population of indigenous people, the Sámi, who also speak Sámisk, which is quite different from Swedish. Finnish is the first language of the Finnish-Swedes, who make up a substantial minority of the population. English is the second language for the vast majority of the population.

Since World War II the immigration to Sweden has been continuously growing, and today non-Swedish residents make up 5.6 per cent of the population. Most immigrants (about 25 per cent) are from Finland, but the immigrant population of Sweden comes from every continent.

§3. Political System

I. Constitution

3. Sweden is a stable democracy. It is a nation organized along the principles of centralism, and remains so today even though the move towards decentralism has increased to a great extent recently. Sweden has a monarch, but the King does not govern. He is the representative of the people and a respected figure in the country, but is not directly involved in the political affairs of the country.

The dominant political ideology, as clearly illustrated by the Constitution of 1974, requires that every public decision and every public measure involving the citizens' lives and freedom has a basis in the written legislation. The principle of the sovereignty of the people is pronounced in the first sentence of the Constitution: 'All power of the state in Sweden emanates from the people.'[1] It additionally provides that the power of the state shall be exercised under the written laws.

The Swedish Constitution consists of three constitutional statutes. The most important one, the Form of Government Law (*Regeringsformen*, RF), consists of rules with the purpose to protect the individual against illegitimate use of State power by the governmental authorities. RF guarantees the citizens' security and safety in society and it is determinative to this discussion when considering the fundamental concepts of the health care system.[2]

Another constitutional statute of importance for health and medical care is the Freedom of the Press Law (*Tryckfrihetsförordningen*, TF). TF regulates the citizens' right of access to public documents, for example patient journals. However, certain 'restrictions' and exemptions to this right may be found in the Privacy Act (*Sekretesslagen*). There is also a Free Opinion Law (*Yttrande-frihets grandlagen*).

A constitutional statute differs from other legislation in that it is accorded priority in the legal hierarchy. It is a basic law, which cannot be amended as easily as a ordinary statute. A change in a constitutional statute must be enacted by two concurrent *Riksdag* (the Swedish parliament). One of the purposes of this is to ensure that no temporary majorities in the Riksdag will change such fundamental legislation.

1. RF 1:1
2. For a more detailed discussion of the Swedish Constitution see, Nyman, 'Some Basic Features of Swedish Constitutional Law', in *An Introduction to Swedish Law* (Norstedts 1988), 2nd ed. p. 47.

II. Legislation

4. All other legislation is also enacted by the Riksdag. Examples of statutes of special importance to health care are the Health and Medical Care Act,[1] the Supervision of Health and Medical Personnel Act (Supervision Act),[2] the Compulsory Psychiatric Care Act,[3] the Control of Epidemic Diseases Act[4] and the Privacy Act.[5] *Förordninger* (Regulations) are issued by the Government itself. Most commonly, the authority for the regulation is explicitly provided in the statute itself. For example, the Health and Medical Care Act §19 and the Supervision Act

§3 state that the Government is authorized to issue *föreskrifter* (Instructions). The Government may empower the National Social Welfare Board to issue *föreskrifter*, and may consult the Board concerning appointments and qualifications for posts in the health care field. The Board also has the right to issue protection orders, whereby individuals in need of care may have such care rendered even against their wishes. In *Allmänna Råd* (General Advisories) the Board can give recommendations concerning the application of a regulation. They recommend what in their opinion is the best plan of action, but they can not eliminate or prohibit other alternatives.

1. *Hälso- och sjukvårdslagen (1982:763)* (HSL).
2. *Lag (1980:11) om tillsyn över hälso- och sjukvårdspersonalen m. fl. (Tillsynslagen).*
3. *Lag (1991:1128) om psykiatrisk tvångsvård.* See also, *Lag (1991:1129) om rättspsykiatrisk vård* (Judicial Psychiatric Care Act).
4. *Smittskyddslagen (1988:1472).*
5. *Sekretesslagen (1980:100).*

III. Legislative Process

5. The initiative to enact a law usually comes from the Government, in the form of a *proposition* (similar to a Government Bill in the British Parliament). It can also come from an individual member, or a group of members in a political party, in which case it is known as a *motion* (similar to a 'Private Members' Bill' in the British Parliament). The legislative process most commonly starts with a proposal in the Riksdag to form a commission with a specific task. When the investigative commission (or individual 'investigator') is commissioned, the Government sets guidelines and goals by which the commission/individual will operate. These are worked out as a statement of the head of the ministry. Questions concerning medicine are handled by the *Socialdepartement* (Ministry of Health and Social Affairs).

The investigating body has contact with the relevant authorities and solicits comment from those organizations which have an interest in the matter under consideration. For example, trade union organizations are standing 'consultation bodies' (*remiss instans*). The *Landstingsförbundet* (Association of Counties) is an important and influential consultation body for questions concerning health and medical care. Private individuals and any other organizations are also free to express their opinion. All opinions sent to the ministry are open to the public. The commission or the investigator can publish their findings while their investigation is ongoing in the form of a partial report or, more commonly, with one single report when the work has been completed. The reports are published in the *Statens offentliga utredningar* (SOU, State Public Commissions Series).

After the commission submits its report to the Riksdag, it is referred to the appropriate Riksdag committee. Matters concerning health care are assigned to the Social Committee. The proposed legislation will then be discussed in the committee which drafts a Committee Proposal and sends its recommendations to the Riksdag for debate and approval. Unless the Committee Proposal differs greatly from the Proposition, it is usually accepted by the Riksdag. After the Riksdag has

enacted the statute, the Government will without delay, promulgate the law through a governmental decision. The law will then be incorporated into the Swedish Statute Book (*Sveriges Rikes Lag*), which is published annually and known as the 'Law Book' (*lagbok*).

The term *lagförarbetet* (legislative preparatory materials) is used to designate the reports and findings of the investigative commission and the law proposed with its motivations. Consulting the legislative preparatory work is essential in statutory interpretation, and in being able to achieve an understanding of the statute and its application.

IV. Court Structure and Process

6. Several different bodies deal with administrative matters. Most of them are part of a national or local governmental body. Among these there exist two categories: administrative authorities and administrative courts.[1] To some extent there are different procedural rules, depending upon which of these bodies the acting organ belongs to. However, it is not a question of a difference of nature but rather one of degree. The fundamental structure of both bodies is the same, even though the proceedings in administrative courts in some respects are surrounded by somewhat further reaching formal descriptions.

The administrative courts hearing cases in the field of health care are primarily the four *Kammarrätten* (Administrative Courts of Appeals) and the *Regeringsrätten* (Supreme Administrative Court), which is the highest judicial body of the country in the field of administrative law. Cases concerning social insurance are heard by the three *Försäkringsrätten* (Social Insurance Courts) and the *Försäkringsöverdomstolen* (Supreme Social Insurance Court). Because most of the statutes concerning health and medical care are not enforceable in a court, the number of court decisions concerning health care is very limited. Some disciplinary action concerning health care personnel, however, has been taken by the above-mentioned courts.

The courts of general jurisdiction, *tingsrätten* (District Court), *hovrätten* (Court of Appeals) and the *Högsta Domstolen* (Supreme Court), try civil and criminal cases. The medical-professional responsibility of the health care personnel can, of course, be examined as a criminal case. Plaintiffs demanding damages from doctors may also bring their cases to the courts of general jurisdiction.

1. RF 1:8.

V. Sources of Law

7. The Swedish doctrine of sources of law is characterized by a fairly hierarchical structure. After the three constitutional statutes, the acts of the Riksdag constitute the most important source of law. The law in force consists mostly of written rules. Although the fundamental intention is that the written law rules in their legal language will clarify the content of the law, it will in most cases be necessary for

some kind of interpretation in order to clarify the law in force. The legislative preparatory work functions as an important key in such an investigation. These documents mostly consist of the published reports of the commission and committee proposals and bills. They constitute an important source of law.

Case law follows, which means the decisions of the supreme courts, namely the Supreme Court (in criminal and civil cases), the Supreme Administrative Court, and the Social Insurance Supreme Court. Judicial decisions are no doubt an important source of law, but not to the extent that they are in countries that have a common law legal system.

A further source of law is legal doctrine, the consideration of the scientific investigation of the three previously mentioned sources of law. Swedish jurisprudence traditionally deals with abstract analysis. In the recent past years, legal works have been more concrete. One of the reasons for this change in the Swedish jurisprudence is that it has been influenced by Anglo-American jurisprudence and its pragmatism. Today's research concerning the law in force consists mostly of the practical purpose to tell the jurists what the law in force is, in other words, to describe the rules that are considered applicable for the judges/decision-makers and that they have to apply. In the research one will also find recommendations for ways to achieve certain solutions to a particular legal problem in cases where the written law or the customary law does not suffice. A dogmatic method of this type has extensive descriptive elements detailing legal sources.

8. The legal material in the field of health care is somewhat different. Traditional legal sources are used in 'traditional' legal disciplines such as civil or criminal law, or procedural law. But only a small part of the written legal rules consist of civil law, or criminal or procedural law. A considerable part of all written regulations consist of administrative rules (80 per cent – 85 per cent). Health care legislation is a division of the administrative law. Written regulations are only a framework, by which the authorities must abide. At first glance these might seem to be rather detailed and specific, but a closer examination will reveal that there is rather extensive room for adjustment on the level of supervision and application. Legal sources other than the traditional sources of law can be helpful when 'adjustments' need to be made. For example, manuals concerning handling routines, often with computer-technical features and a large number of regulations and instructions may be of assistance. These manuals are distributed by the supervising body, which in this field is the National Social Welfare Board. State supervision and controls are extensive, even though the national government has delegated the management of the health care to the local authorities, the *landstingskommuner*.

§4. Population and Vital Statistics

9. The total population, its structure, and geographical allocation are important factors for the shaping and organization of health and medical care. The population has been increasing, from about 7.7 million inhabitants in the 1960s to almost 8.6 million today. The increase is almost evenly divided between net immigration and an increase in the birth rate.

The demographics of Sweden has been changing, as in all of Europe. The birth rate has been increasing, but the most significant factor is the increasing life expectancy. This increase of the older population, especially the very oldest, and its resulting higher median age, has a significant bearing on the health and medical care especially concerning the needs and demands for health and medical care services.

§5. Social and Cultural Values

10. During the last few years, the importance of health care has been one of the top topics of conversation, especially in industrial countries. In the health care debate, the methods of delivering care have often been connected with the question of physical activity in different forms. The level of education will to some extent influence the demand for care and which forms of care will be demanded. The reason seems to be that the level of education influences the valuations and the attitudes to health and medical care. Better health education means greater knowledge about diseases and how to avoid them, and increased knowledge of the possibilities of treatment and the way to obtain this treatment.

11. The connection between people's lifestyle and their need of and demand for medical care is of importance. A significant amount of the interest is concentrated on the often connected medical, social, and psychological factors in society and on the individual's closest environment. For instance, there is a connection between housing conditions, illness, and consumption of medical care. In Sweden, however, housing problems are a relatively minor consideration compared with the situation in many other countries.

12. Working conditions have a fundamental significance for the individual's state of health and general well-being. In addition, unemployment and underemployment create significant problems in society with enormous damage, not the least concerning health and general well-being of the individual. Sweden has for a long period of time had an unemployment rate that has been much lower than that of most other European countries. In the beginning of the 1980s the unemployment rate has risen, and is presently much higher than normal.

Lately, the development of Swedish working-life has been in the technical side, which means that there has been a great deal of mechanization and automation of the work. The problems in the working environment today are not the same as they were in the recent past. At the same time work has become physically easier, other demands have increased. The focus on the work environment and the health of the employees has developed beyond only the risk of accidents to concerns of injury or illness that may be acquired over a long period of time from such factors as excessive noise, injuries from repetitive tasks, and other concerns of the working environment.

An ordinary consequence of the mechanization is that employees are pushed to a faster pace of work. The conditions of the working-life are shaped through simultaneous influence of different factors in the environment such as physical, chemical,

biological, psychological, and social factors. All these factors have a great importance for the need of health and medical care and for the employer provided health care, which is very well developed in Sweden. The risks in the working-life are well illustrated with statistics concerning on-the-job accidents, job-related illnesses, and absence from work. In addition, the debate concerning the pay system, working-hours, and shift work has been very intense.

13. Other factors of importance for the health care situation are the school environment, the psychological environment (loneliness, difficulties in making social contacts), the use of leisure time, access to commercial, social, and cultural services, the motoring and the traffic conditions. The public social welfare policy that characterizes the country, such as the policy of the labour market, housing, social benefits including social insurance, family policy, and municipal services are factors that have a great effect on the health care system. This care is, of course, one of the most important parts of the social welfare policy.

14. During the last few decades, Sweden has had an intensive debate of the meaning of democratic participation in the society. In recent years the concept of participatory democracy has expanded beyond participation in elections to encompass a broader participation in the community, at work, and in other aspects of daily life. The vehicle for this increased co-determination has occurred partly by legislation covering several different areas, including at the workplace[1] and in the schools,[2] and in hospitals and convalescent hospitals.

The debate has, to a great extent, concerned the citizens' possibilities to influence the shape of the environment in the industrialized society. It is an international trend that has been noticed in a lot of the industrialized countries. The modern society is characterized by rapid changes and by great rearrangement of the population. Research has shown that there is no feeling of solidarity and social contacts in new housing areas to the same extent as they exist in older more mature housing areas. That means that difficulties can arise in regards to the contact between individuals and those with positions of responsibility in the political organs. In this regard, the exhaustive changes in the family situation and the concept of family should be kept in mind. It is now very common that both partners work outside of the home. A significant part of the housework is done during their leisure time. This means that there is often less time for participation in community affairs.

1. *See Lag (1976:58) om medbestämmande i arbetslivet.*
2. *See Skollagen (1985:1100).*

II. General Description of the Health Care System

§1. General Review of the Health Care System

15. The earlier legal regulation in the health and medical care field has mostly been about the activities at the hospitals. In a hospital instruction from 1817, the first general rules about the activities at the hospitals came into being. After some revisions the instruction was replaced by a hospital statute[1] and a local medical care clinic statute in 1901,[2] which in turn were replaced by the 1928 hospital statute.[3] New laws and regulations came into force during the 1940s and the 1950s. They were in effect until the beginning of the 1970s.

1. *Lasarettstadgan (1901:83).*
2. *Sjukstugestadgan (1901:84).*
3. *Sjukhusstadgan (1828:303).*

16. The question of the responsibility of the medical staff was investigated during the 1970s by a governmental commission, the result was legislation that came into force in 1980.[1] The most recent period of reforms has been characterized partly by a desire to bring preventative health care closer to the population, and partly to substantially reduce the detailed state regulation of the activities of the local governments. With the proposal from this commission as a basis, the Health and Medical Care Act[2] came into force. The new legislation, however, did not create any real change in the concept of health and medical care.

1. *Lag (1980:11) om tillsyn över hälso- och sjukvårdspersonalen m. fl.* and *Lag (1980:12) om förtroendenämnder inom hälso- och sjukvården.*
2. *Hälso- och sjukvårdslagen (1982:763)* (HSL).

17. The Health and Medical Care Act defines health and medical care as 'measures to medically prevent, diagnose and treat illnesses and injuries.'[1] Measures pertaining to the physically challenged or other physical handicaps as well as childbirth are included in the concept of health and medical care, even though they are not expressly mentioned in the text of the act. Health and medical care include also the medical transport system and, since 1993, handling with deceased persons.

1. '*Åtgärder för att medicinskt förebygga, utreda och behandla sjukdomar och skador.*' HSL § 1.

18. Abortion and sterilization are also included in the concept of health and medical care. The special regulations for these fields[1] only regulate the conditions for performing the procedure. This is also the case with organ transplantations,[2] medically assisted insemination,[3] and *in vitro* fertilization.[4]

1. *Abortlagen (1974:595)* and *Steriliseringslagen (1975:580).*
2. *Transplantationslagen (1975:190).*
3. *Lag (1984:1140) om insemination.*
4. *Lag (1988:711) om befruktning utanför kroppen.*

19. The concept of health and medical care also includes measures of illness prevention, directed to both the population in general and to the individual. The activities of the local governments concerning the population in general can include efforts to determine how chemical, biological, physical, social and psychological factors influence the health of the population, as well as how living habits affect health. Efforts directed towards the individual, include medical examinations, vaccinations, providing health information, maternity care, and child health care.[1]

1. Sahlin, *Hälso- och sjukvårdslagen med kommentarer*, 3rd ed. (Statens nämnd för utgivande av förvaltningsrättsliga publikationer, Stockholm 1990).

20. The responsibility that the local governments have for providing health care in accordance with the Health and Medical Care Act does not exclude however the possibility of health and medical care being offered by other public authorities (such as health care provided to pupils at their schools), or by private providers. The local governments have, as a rule, no direct responsibility for the medical and health care provided by employers to their employees, or student health care at institutions of higher education.

21. In the field of dental care there is a corresponding statute to *HSL*, the Dental Care Act.[1] According to this statute, every local government must offer good dental care to people living within the boundaries of that local government. The local government must also in other respects work to achieve good dental health for the population. The dental care offered by the local government is called 'Public Dental Care.' The Public Dental Care must offer regular and complete dental care to young people up to the age of twenty, specialist care for adults, and additional dental care to that extent that the local government deems necessary. This dental care is provided without charge to the patient. Private dental care is available to those who do not qualify for public dental care, with the charges to the patient being subsidized by the local government.

1. *Tandvårdlagen (1985:125).*

§2. Regulation of the Health Care System

22. In the Swedish Constitution, there are provisions providing protection for the rights of the individual. Many of these provisions are relevant concerning health and medical care. There are also many other specific provisions in the Swedish social statutes concerning the rights of patients, however they are not very extensive nor explicit.

23. The basic statute concerning health and medical care is the Health and Medical Care Act which provides the basic terms and conditions upon which medical care is rendered, and provides for who is entitled to receive that health care.

24. The Supervision Act is also of great significance, as it contains provisions concerning the duties and responsibilities of the health and medical care personnel, the licensing of medical practitioners, and rules concerning disciplinary measures. There are also some other statutory provisions and regulations concerning, for example, the qualifications and educational standards for various personnel groups. Finally, the Health and Medical Care Advisory Boards Act[1] requires local governments to set up advisory boards to promote contacts between patients and the medical personnel and to provide patients with assistance.

1. *Lag (1992:563) om förtroendenämndsvertesamhet inom hälso- och sjukvården m. m.*

25. The Health and Medical Care Liability Board (HSAN Board) is an independent branch of the National Social Welfare Board. A patient can file a complaint with the HSAN Board if he or she believes malpractice has occurred.[1] The HSAN Board hears cases of disciplinary proceedings concerning the health care personnel. The authority of the HSAN Board is limited, however. The HSAN Board cannot order that the individual must receive other treatment, not even such treatment to compensate for malpractice or other incorrect treatment. Nor can it make an award of financial compensation for treatment injuries. The only possible outcome of a finding by the HSAN Board of malpractice is the punishment of any medical personnel whose actions are found to be negligent or incompetent, and the administration of disciplinary action against the person(s) responsible for the improper treatment.

1. Supervision Act §19 and §24.

26. If a complainant is not satisfied with the decision of the HSAN Board, as she/he is a party to the proceedings, she/he can appeal the decision to the Administrative Court of Appeals, and one step further to the Supreme Administrative Court.

§3. Financing of the Health Care System

This section gives an overview of the structure of the health care system in Sweden, focusing on the financial aspects.

27. The health care system in Sweden may be characterized as being primarily public and part of a universal health insurance system. The costs are financed by revenues from employer charges, with the patients paying a minimal fee for service.[1] Most private practitioners are included in this system, and patients pay substantially the same fee for private medical care as they would for the public care.

Health care services have substantially grown due to the improvement in medical technology, which has resulted in the consequential expansion of medical staff and costs. Services for the elderly, disabled, handicapped,[2] and mentally ill have also considerably increased.

1. At the present, usually 125 kronor (about 17 ECU) per visit.
2. *See Handikapp välfärd rättvisa* – SOU 1991:46.

28. Medical care in Sweden is the responsibility of the public sector. It is provided primarily by 26 regional and local authorities, i.e. 23 *landstingskommuner* (counties) and the 3 kommuner (municipalities) which are not part of a *landstingskommun.*[1] They also operate the public dental service, which provides dental care for young people up to the age of twenty, some special dental care for adults, and dental care for the mentally disabled. All municipalities have a responsibility of certain medical care, especially for elderly people.[2]

1. Göteborg, Malmö and Gotland. This responsibility is regulated in HSL § 3–16.
2. This responsibility is regulated in HSL § 17–25.

29. Every local government must, according to the Health and Medical Care Act, offer health care to all those who are residing within their jurisdiction. The national government, however, is to a great extent responsible for the financing of medical care, for instance, through payments towards psychiatric care, tax revenue equalization and sickness insurance.

30. The national government reimburses the local governments for their health care expenditures for the public medical centers and physician care, hospitals, aid to handicapped people, the public dental service and for certain medical treatment provided by non-physicians in accordance with the General Insurance Act.[1] Even travel connected with treatment is reimbursed under certain circumstances. From a methodical point of view, it may be observed that the General Insurance Act only consists of fundamental rules concerning health care allowance. Rules about, for instance, the basis of calculation and amount of patient's fees are to be found in tables of rates and in other rules.

1. *Lag (1962:381) om allmän försäkring*, chapter 2.

31. These 26 local governments have been the principal providers responsible for almost all health and medical care. While the national government has an overall responsibility for health care, the local governments have a more direct responsibility based on their constitutionally independent position and their tasks according to the Supervision Act. The *landstingskommuner* have a great freedom to decide for themselves how to organize their work. However, important conditions regulating their activities are also shaped through the decisions of the state authorities.

32. Sickness insurance payments are distributed directly to the local governments to pay for a part of the insured person's expenses for in-patient care in a hospital, convalescent care, physician care, dental care, contraceptive counselling, transportation assistance to handicapped persons, and medicine. The payment to the local governments is, as a rule, based on the services rendered. A smaller part of the income of the local governments comes from the fees charged to patients. This standard fee covers the visit to a physician, including any materials used and any lab tests.

33. Lastly, it should be mentioned that in the Dental Care Act[1] it is stated that every local government is required to offer satisfactory dental care to those living

within the boundaries of the local government, or to those visiting and in urgent need of acute dental care. Dental care includes regular and complete care for children and young people up to the age of twenty, special dental care to adult persons and other dental care to adult persons that the local government deems suitable.

1. *Tandvårdslagen (1985:125).*

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Part I. The Medical Profession

Chapter I. Access to the Medical Profession

§1. Medical Personnel – Manpower Planning

34. The Health and Medical Care Act provides that the personnel which are necessary to provide good care shall be found within the health and medical care system.[1] There are special provisions which contain rules regarding the tasks for the medical personnel and about the supervision of the personnel. The local governments have an obligation to have personnel prepared to deliver the good care that is required in accordance with HSL §2a. Precisely how this demand shall be complied with is up to each local government itself. In addition, it should be noted that every patient has the right to a responsible physician at the unit where she/he receives care and treatment.[2]

1. HSL §13 and §23.
2. Ds S 1987:4.

35. Health and medical personnel include the following four categories:

1. Personnel employed at hospitals or other medical centers operated by the public authorities or independently with either financial support or permission from the government.
2. Those who provide care to patients who are professionally licensed, and persons who assist such licensed personnel.
3. Pharmacy personnel and personnel working at a poison information center.
4. Other groups of persons practicing health and medical care who are included in the law according to regulations issued by the government or by the National Social Welfare Board.[1]

According to the Supervision Act, medical personnel are not devoted to the health and medical care *in general*, but rather to *care the individual* – care with the purpose of preventing, diagnosing and treating illness, injury or physical handicap, and the rendering of maternal care. In §1 the patient is mentioned as the object for the care.

1. *Lag (1980:11) om tillsyn över hälso– och sjukvårdspersonalen m. fl*, §1.

36. In the Health and Medical Care Act, the concept 'personnel' is used in a wider sense than in the Supervision Act. In the Health and Medical Care Act every individual who is involved in the care is considered as belonging to the medical

personnel. Even individuals who are not directly concerned with the care of patients are included in the concept of personnel in the Health and Medical Care Act.

37. The primary rule is that there is a duty to give care to a certain individual or group of individuals when the need arises, for instance medical care for young people in school and employer provided medical care. (*See below*, Chapter II. 3.) Thus, tasks of preventive character such as health controls and supervision of the suitability from the health and welfare point of view at places of work and in schools are included in this duty. The same is true in regards to the activity in the social welfare authorities regarding medical care to the clients of the social welfare system, such as physicians at a nursing home for alcoholics. Care according to the Law Concerning Special Care for the Mentally Handicapped[1] is not included in this concept with exceptions for treatment or other medical procedures conducted at a hospital, i.e. special hospitals. Maternity care, abortion counseling, and the work of laboratory personnel who are performing diagnostic tests at the request of a physician are included in the concept of patient care.

1. *Lag (1985:568) om särskilda omsorger om psykiskt utvecklingsstörda m. fl.*

38. The personnel working in the local government's health care agency, the reviewing physician at the local office of the Social Insurance Board, the personnel at the governmental Medico-Legal Expert Stations, personnel at the governmental Legal-Chemical Laboratory, personnel at the National Social Welfare Board and personnel at the administration of health and medical care of the local governments usually have a license to practice as a doctor. When they are practicing their profession, meaning the provision of health or medical care or treatment, their activities are regulated by the Supervision Act; when they are acting in a professional capacity but not providing health or medical care, their activities are not regulated by the Supervision Act. Elected officials, whether in a full-time or part-time position, are not included in the Supervision Act.

39. The status of employee is not a necessary precondition to come under the meaning of medical personnel. The connection to the health and medical care tasks is the deciding factor. The Supervision Act includes everyone whose work is necessary for the provision of the care.

§2. Training and Licensing of Physicians

40. The principle rule in Sweden is that the practice of health and medical care is open to everybody. However, there are of course exceptions to this rule, and many different limitations with the purpose of protecting the public have been placed on certain types of care and treatment.

41. An employee who will serve as a physician must have an evidence of authorization showing that she/he is competent to practice the profession of medical

doctor. A doctors license can by obtained from the National Social Welfare Board upon the fulfillment of the proscribed requirements. The basic requirement is to have satisfactorily complete a university medical education, received a medical degree, and to have completed the so-called general medical duty (*allmäntjänstgöring*). The medical education at a university[1] consists of a minimum of five and a half years of studies (220 points). The student must then complete an internship of one year and nine months, which is divided into the following areas of activity: six months of general surgery, six months of general internal medicine (of which at most two months can be work in chronic invalid medicine), three months of general psychiatry or in child or youth psychiatry, and six months of general medicine.

1. The following Swedish universities offer degrees in medicine: Lund, Stockholm, Göteborg, Linköpping, Umeå and Uppsala.

42. There is also a possibility to obtain a doctor's license without fulfilling the above-mentioned requirements. It can be obtained by a person who is able to show that she/he has reached the competence corresponding to that obtained by the Swedish university medical education and the *allmäntjänstgöring*. This procedure is not unusual, and there are quite a few foreign educated doctors in Sweden, especially from Denmark.

43. A person who has a Swedish medical degree has the legal capacity to obtain employment to complete the medical internship, and a person who has a doctor's license has the legal capacity to be employed as a doctor. A person who has a doctor's license has also the right to open a private practice.

44. To obtain a permanent appointment in the public medical care, there is an additional requirement of having completed a specialist medical education. Thus, doctors with specialist competency have the possibility to apply for permanent appointments in the area of activity corresponding to their specialist competency. In such a case where an area of activity does not fall within the areas for defined specialties, the National Social Welfare Board will give prescriptions about the requirements for licensing that will be required for the medical appointment.

45. The demand of specialist competence to obtain a permanent appointment within the public care has the effect that most doctors choose to continue their education within a specialty after they received their doctor's licenses. The additional education necessary to become a specialist consists primarily of work under guidance within the public care. In addition, the doctor must complete six courses of six weeks each, where every course consists of teaching and extensive self-studies with tests of knowledge. When the appointment and the courses are completed, the doctor can apply for an evidence of specialist competency from the National Social Welfare Board. The total amount of time for the further education varies between 4 years and 5½ years. The variation of time has its basis in the fact that the length of the main and the additional education differs between the different specialties. Today, there are 45 officially established specialties covered in the Regulation concerning Authorization to Perform a Profession within the Health and Medical

Care.[1] Some of these specialties are put together in groups, depending on the specialties having a certain common base of education within the main specialty. For instance, the group of internal medicine has its base of education up to two years' training within the field of general internal medicine.

1. *F (1984:545) om behörighet at utöva yrke inom hälso– och sjukvården m.m.*

46. The rules concerning the license have different legal meanings for different groups of professions. A license is a precondition for midwives, doctors and dentists to practice their profession, and is also evidence of the right to practice. For other groups of professions, a license does not give a right to practice the profession but is rather an acknowledgment by the state of a certain degree of competency. The categories of professions in this second group include opticians, speech therapists, psychologists, psycho-therapists, physiotherapists, nurses, and chiropractors. In addition, there is a possibility for some medical-technical assistants to obtain a license as a nurse.

§3. Delegation of Medical Tasks – Formal Competency and Real Competency

47. The rules concerning delegation of tasks are not contained in the Health and Medical Care Act. They are in a regulation with general advice on delegation of assignments within the medical care[1] This regulation provides for the possibility to distribute medical tasks that, in an international comparison, must be seen as far-reaching and very wide. The rules permit by delegation the medical care personnel to transfer tasks held by an employee with formal competence to an employee who lacks formal competence but who has the real competence for the task in question.

1. National Social Welfare Board's *Kungörelse (SOSFS(M) 1980:100) med allmänna råd om delegering av arbetsuppgifter inom hälso– och sjukvård m.m.*. Concerning psychiatric care see, National Social Welfare Board's *Allmänna räd (SOSFS (M) 1983:7) om delegering av arbetsuppgifter inom psykiatrisk verksamhet.*

48. What is meant by formal competence is someone who has successfully completed the particular vocational training which is required in order to conduct certain medical care. The person in question has by formal education obtained the knowledge which is necessary to competently handle the tasks.

49. What is meant by real competence is someone who has the knowledge and skill to perform certain tasks *without* having obtained such knowledge by formal education; the knowledge has been acquired in some other way, such as practical work experience. The person is considered to have the real competence to carry out the task.

50. A person who has real competence to perform a certain task does not have the authority to perform the task whenever or wherever they wish. They must be formally delegated the legal capacity to perform the task, by means of a so-called

'delegation decision.' Not all tasks may be delegated. In addition, the authority given by a delegation decision is personal; it is restricted to the individual who has been delegated (the authority can not be passed on to another person), and it should be stressed that the person who has been delegated a task or authority must be competent to perform the task.

51. Within the chief physician's medical guidance responsibility (*see below*), he/she has the authority to delegate certain tasks. The delegating physician must carefully use his or her best judgment in determining the delegatee's real competence to execute the task. In addition, the delegating physician remains responsible for the activities of the delegates. The delegatee, on her/his part is responsible for accuracy of the statements and representations she/he gives, or fails to give, concerning her/his competence to perform the tasks, and is responsible to see that the tasks are performed in a professional manner. The person who has the medical guidance responsibility is not liable for the delegatee's performance, except to the extent that the delegatee is carrying out a task that the delegatee is not capable of doing independently.

52. This division of responsibility between the delegating physician and the delegatee can be illustrated by the following two HSAN Board decisions.

> The HSAN Board administered a *varning* (warning) to a physician with medically guidance responsibility and an admonition to an assistant doctor because they had committed an error which was not considered insignificant and led to, among other things, blindness in one eye for the patient.
>
> The patient had sinusitis trouble for many years and his right jaw cavity was closed. The assistant doctor *S* operated on the jaw cavity to release the pain. During the operation *Dr. S* found that the jaw cavity was full of pale polyps. After a discussion on telephone with the physician with the medical guidance responsibility *Dr. S* received advice to make a hole in the jaw cavity wall and after that remove the polyps. When the operation was completed, *Dr. S* noticed that the patient's eye was put out 1.5 cm. The physician with the medically guidance responsibility then increased the hole in the jaw cavity wall finding a hole in of the eyeball. The operation performed by *Dr. S* had been more difficult because of the defects in the area between the jaw cavity and the socket.[1]
>
> The HSAN Board rendered the following decision. The investigation showed that the physician with the medically guidance responsibility delegated the operation to *Dr. S. Dr. S* had, prior to this occasion, acted as an assistant at five operations of the same kind and performed one operation independently. Criticism cannot be given on the fact that the assistant doctor had performed the operation. However, the physician with the medically guidance responsibility had committed an error when she allowed *Dr. S* to, on his own initiative, change the nature of the operation to a removal of polyps. For that measure *Dr. S*, obviously, lacked experience as well as competency. At the operation *Dr. S* had not observed the required standard of care and, therefore, he caused the injury to the eye-ball. As a consequence, both physicians had neglected their duties in the exercise of their profession.

1. HSAN 1985 5:54, 332/84:4.

53. In the following case, the physician with the medically guidance responsibility and the medical student undergoing her internship received an *erinran* (admonition) due to ignorance of their duties.

> A 78-year-old woman entered a hospital complaining of pains in her chest and difficulties breathing. After an examination, the physician ordered a sternale puncture in order to conduct an examination of the bone-marrow. The sternale puncture was performed by an acting assistant physician, *Intern B*, with the assistance of a nurse. At that time, *Intern B* had served at the clinic for five weeks and had earlier been present at only one sternale puncture done by another physician. *Intern B* herself had never performed such a procedure. After the puncture, the condition of the patient suddenly deteriorated with increased difficulties of circulation and breathing, after which she died. Attempts to bring the patient resuscitate the patient were made but without result. The post-mortem showed that the immediate cause of death was a bleeding in the heart-sac caused by a prick injury in the aorta.[1]

1. HSAN 351/81:2.

54. The HSAN Board rendered the following judgment.

> The investigation showed that the patient obtained the injury that led to her death by the sternale puncture, performed by *B*, and that *B* at the time of the procedure had such a limited education and experience that she should not have conducted the puncture herself. The chief physician neglected his duty to assure the safe and appropriate handling of the medical care by allowing such an unexperienced doctor such as *Intern B* perform the puncture without ascertaining her competency.

55. The question of formal and real competency arose also in the following decision:

> A doctor on duty at an eye clinic received a *varning* by the HSAN Board because she, after a telephone call from a nurse at the clinic, had failed to come to the hospital to give adequate treatment to a patient who had gotten a foreign object (a piece of metal) on the cornea of the left eye. The Board had no criticism of the procedures of the clinic, namely that a nurse is permitted in principle to perform a task of care like the one she performed. There is, however, an absolute precondition that the nurse has the education and experience required. According to the HSAN Board, this was not the case in this situation. The investigation showed that the nurse lacked the competency required to assess and treat the injury that the patient had. In her response to the Board, the nurse said that on the night in question, she had told the doctor that she, as newly employed at the clinic, did not consider herself to be competent to handle the cornea microscope sufficiently enough and that she did not

want to remove the foreign object from the eye of the patient. In her statement, she said that the doctor claimed that treatment of such patients could wait until the following day. It had been incumbent upon the doctor to, directly after the telephone call with the nurse, appear at the hospital to give the patient proper treatment. Through her omission to do that the doctor had shown negligence in the exercise of her profession.[1]

1. HSAN 621/81:1.

56. The doctor with the primarily responsibility for the case must form an opinion of the competency of the doctor, or other care giver, who will be delegated the duty of the actual care. If the delegatee does not have sufficient experience or competency, the doctor with the primarily responsibility must perform the diagnosis, care and treatment herself/himself. This responsibility remains with the delegating doctor. Only when the responsibility for the care has been transferred to personnel from other wards will the responsibility be transferred.

§4. The Duty to Write Patient Journals

57. In accordance with the Patient Journal Act,[1] certain categories of persons in the medical care profession have a duty to write patient journals. The categories of professionals with this duty include physicians, licensed midwives, opticians, speech therapists, physiotherapists, nurses, dentists, psychologists and psychotherapists. These individuals rendering health and medical care are obligated to comply with this legislative regulation, and are responsible for any omissions or incorrect information.

1. *Patientjournallagen (1985:562).*

58. What this duty to write a patient journal means for the individual patient is that she/he will be assured a better and more secure care. What the duty to write a patient journal means for those who are obligated to do the writing, is that they must diligently see to it that whatever information is necessary or appropriate for the good and secure care of the patient is included in the patient journal. The information that must be included is information on the identity of the patient, the background of the care, the diagnosis and recommendations for further diagnostic procedures, the care planned to be rendered, and the care rendered including when and who rendered the care. This writing must be consistent with the practices followed in the medical profession, and appropriate for the situation of each individual case (*see below*).

59. Every patient has their own individual written patient journal. This collection of data in the patient journal provides the medical care personnel with the possibility to follow the development of the health status of the patient as well as to render the appropriate care. In addition, it provides documentary evidence of either proper treatment or incorrect treatment in case a complaint is made to the HSAN

Board, which can assist the health care provider as well as the patient in presenting their case.

60. With the increasing interest in patients' rights, including the desire to provide a more humanistic caring treatment, a properly prepared patient journal can assist the health care professionals to efficiently and accurately carry out their tasks. It provides insight into the medical history of the patient as well as documenting the care that has been rendered. In a broader sense it also assists the National Social Welfare Board in its task of issuing prescriptions and instructions, especially in regard to treatment injuries, to minimize the risk of errors being repeated in other hospitals and medical institutions.

Chapter II. The Illegal Practice of Medicine

61. As stated above, the main principle in Sweden is that it is possible for anyone to practice in the health care field. Laymen and others without a formal medical education are, as a general rule, not forbidden to provide health care advice or render medical care. There are exceptions, however, for certain activities which are restricted to those with a proper license.

The reason for this freedom for both laymen and licensed practitioners to operate in the health care field is based on the basis of freedom of trade. However, in order to provide protection to the public, the activities of laypeople have been strictly limited.

62. The Law concerning Prohibition of Certain Activity in the Field of Health Care,[1] also known as the Quackery Act, is directed toward persons who examine another person's state of health or treat another person for illness or other medical condition, including preventive, curing or mitigating care.[2]

The Quackery Act contains the following prohibitions:

1. treatment of infectious diseases which according to the Law concerning Epidemic Diseases are dangerous to the public;
2. treatment of cancer and other serious tumors, diabetes, epilepsy, sickly conditions in connection with pregnancy and delivery;
3. examination or treatment of children under the age of eight;
4. advice in writing for a person's treatment without personal examination of her/him;
5. examination for or dispensing of contact lenses;
6. examination or treatment of a person under general anaesthesia, or under local anaesthesia by injection of anesthetics, or under hypnosis;
7. treatment of a person with radium methods;
8. practice of the work by travelling from one place to another.[3]

1. *Lag (1960:409) om förbud i vissa fall mot verksamhet på hälso- och sjukvårdens område.*
2. A person who is authorized to practice the profession of physician, or who in her/his activity in the health care field is under the supervision of the National Social Welfare Board, is exempted from the regulations contained in the Quackery Act. The activities of such persons are regulated instead by the Supervision Act.
3. Quackery Act §2 - §4.

63. A violation of the law will be considered to be 'health dangerous quackery' and can result in a fine or imprisonment if the person who has been examined or treated has been intentionally injured or by negligence has been injured and the injury is not insignificant. The creation of a risk of such injury can also be punishable. This is the case when either injury or danger is caused by inconvenient treatment or by a break in or delay in treatment by a doctor. It has no importance that the party charged with unlawful practice of medicine, termed 'health dangerous quackery' in the statute, has not realized the true nature of the illness or has not anticipated the injury or risk.

64. If somebody has been sentenced for 'health dangerous quackery,' the National Social Welfare Board may forbid her/him to continue to practice such work either for a prescribed period of time or indefinitely.

65. One of the measures used to control this kind of activity, is the requirement that medical practitioners must report to the National Social Welfare Board any 'health dangerous quackery' in her/his district that she/he becomes aware of.[1]

1. General Physician Instruction §13.

66. The Quackery Act will be replaced in the very near future with a new statute regarding the practice of alternative medicine. In 1984, the Government appointed an investigative commission to study the position of alternative medicine in Swedish society and medical care.[1] The commission's report includes a proposal for new legislation regulating the practice of alternative medicine[2] and suggests that a register be established of persons authorized to practice alternative medicine. A condition for registration would be that the person has completed a special basic medical education consisting of 40 points (1 year) at a university medical faculty. Certain medical care activities would still be prohibited under the new statute and violations would be termed 'illegal practice of medicine' subject to criminal and civil sanctions.

1. Commission on Questions of Alternative Medicine – the Alternative Medicine Commission.
2. Alternative medicine 1: Main report from the Alternative Medicine Commission – SOU 1989:60. *See also*, Alternative medicine 2: Health homes – SOU 1989:61; Alternative medicine 3: Alternative therapies in Sweden – SOU 1989:62; and Alternative medicine 4: Evaluation of alternative medical technology – SOU 1989:63.

67. Alternative medicine has become a significant part of the health care provided in Sweden, with an increasing number of practitioners. In Sweden, there are approximately 500 naprapaths giving 1,000,000 consultations per year, 400 chiropractors, 1,000 homeopaths giving 1,175,000 consultations and 400 zonetherapists giving 24,000 consultations. The Commission has taken the position that it is better to have control over the activity by legalizing it under certain conditions, and in that way create a secure treatment for the individual who will then have the possibility to choose freely between traditional allopathic treatment and alternative medicine.

68. (*See* III.II.2 below, for a further discussion regarding alternative medical care.)

Chapter III. Control over the Practice of Medicine

§1. Professional Liability

I. Generally

69. The provision of health and medical care in Sweden is a societal concern, and therefore is regulated by statutes and regulations. As in other fields, there is a system created in order to ensure that all residents of the country are able to obtain necessary care and treatment when needed. 'Guidance' and 'responsibility' are two concepts in the field of health and medical care which are of great importance. They must be clear because the situation concerns the security of an individual and her/his contact with an institution where treatment injuries can occur. If they do occur, the consequences for the patient can be very significant, even fatal. In addition, a patient and their relatives should always have the right to know who the physician with the responsibility for the treatment is.

70. The responsibility of health and medical care has, by tradition, been divided into a political, a medical and an administrative responsibility.

71. The guidance responsibility in the public medical care has recently taken on a new form. In order to increase the patient's security in the care by giving a collective guidance responsibility to a special physician.[1] This guidance chief physician has both administrative and medical tasks.[2] The National Social Welfare Board decides which tasks shall be combined and given to one individual, such as a chief physician. Some guidance tasks can be delegated.

1. Prop 1989/90:81; see also Ds 1987:4.
2. HSL §14 (1992:567).

72. There are also 'patient-responsible' physicians at these units. They are responsible for the examination of the patient in order to ensure the correct diagnosis and to give the patient the medical care and treatment that her/his condition requires. This physician is also required to coordinate the examination and treatment, keep the patient informed of her/his medical condition, and give her/him the possibility to influence the care and treatment. But first some words about the political responsibility.

II. Political Responsibility

73. The Riksdag by means of legislation and the Government by means of regulations stipulate in legal rules the duties of the local governments as principals for the provision of health and medical care. The local governments have the obligations and responsibility to provide appropriate care to all those living within their jurisdiction.

74. The elected politicians must adjust the supply of medical care in accordance with legal rules in force and the local needs. This is framework under which the political responsibility for health and medical care must operate. The local government must establish *nämnder* (councils) to carry out these functions.

75. The political responsibility for the health and medical care within each local government region is the task of one or more councils, as provided in HSL §10.[1] Such a council can be called a Health and Medical Care Council.

1. See Kommunal lagen (1991:900).

76. Irrespective of the fact that the political guidance is exercised ultimately by the local government at the local government meeting, the Health and Medical Care Council has, to a great extent, become the political guidance authority for the health and medical care within the local government.

77. Under the Health and Medical Care Council, the local government can establish agencies with the responsibility for a particular geographic area or the provision of a particular type of care. That means that the entity with the primary responsibility for the provision of medical care will have a possibility to decentralize some parts of the guidance and the responsibility. By that the organization can be designed so that the local resources can be used in an effective and rational way. The law says, however, that there must be one political board with the overall guidance and responsibility for all health and medical care.

III. The Medical Liability

78. The responsibility within the medical area can be divided in two separate forms of liability. Firstly, there is the medical professional liability which is the fundamental responsibility in this field. Secondly, there is the more overall medical guidance responsibility which only a few employees in the health and medical care have.[1]

1. In this work, the liability of physicians with special regard to new methods of treatment and experimentation will not be examined; only the liability of the physicians in general will be examined.

A. Medical Professional Liability

79. Everyone working in the health and medical care has a personal liability for the way she/he is performing her/his tasks. Thus, it is an independent liability on each person for their own acts. Due to the fact that the tasks within the care vary depending on education and type of care, the extent of the liability is not regulated uniformly for the all different professional categories. The rules that the medical personnel must follow in order to comply with the requirements of professional liability can be seen from what has been said above concerning the patient's claim on care and treatment.

80. All personnel engaged in health and medical care have a duty in the exercise of the profession to give all patients a competent and scrupulous care. The personnel must use the knowledge they have obtained from education and the experience they have obtained from working with patients. For some categories of medical personnel there are rules in special regulations promulgated under the authority of the Supervision Act. These regulations are intended to act as additional guidance on standards of what is regarded as expert care.

81. In the General Instruction for Physicians there is guidance for doctors concerning the extent of their professional liability. It is provided that every medical doctor, whether in the public medical care or in private practice, shall in accordance with scientific knowledge and professional experience give the patient the advice and, if possible, the treatment that the condition of the patient demands. The National Social Welfare Board has stated that the judgment of what is scientific knowledge and professional experience is not static but rather can change. What is thought of here is, for instance, the introduction of a new method of treatment. In such a situation experience is lacking and therefore the scientific knowledge must be decisive. In other situations, extensive clinical experience is available and this will then have a greater weight.

82. Comparable special regulations also exist for nurses and midwives. Both groups of professionals must in the exercise of their professional responsibilities render care conscientiously and to the best of their knowledge and ability. while following the directives which are provided for guidance.

B. Medical Guidance Responsibility

83. In the guidance responsibility there is a general duty to follow the work and an authority to give the subordinate personnel directions and advice on how to perform their tasks in the best and most secure way. The person who receives the direction or advice does not have an absolute obligation to obey the physician with the guidance responsibility. Not only does this person not have a duty to take any measures that would be inappropriate, but they also must not disregard their own professional responsibility. If she/he objects to a particular instruction, or has a different opinion, she/he must inform the person with guidance responsibility what their specific objection is with the direction or advice given. In most instances, they should comply with the directions of the responsible physician if she/he insists. The subordinate can, however, refuse to obey directions she/he feels to be clearly incorrect or inappropriate, as the subordinate still is responsible for her/his own professional acts.

84. In some cases the HSAN Board has said that the physician with the guidance responsibility has a duty to make sure that subordinate personnel do not independently perform tasks for which they lack the necessary competence and experience. It is not possible to come to a general conclusion how far this duty will extend. It is a judgment that must be made for every individual case.

85. In addition to a high level of education, there must be the creation of some uniform routines and rules to provide for the security in the provision of care. The extent of these routines and rules must be determined by the guidance physician. There is one primary restriction though, these routines and rules may not be designed in a way which conflicts with or is contrary to the legislation or other obligatory rules.

86. As mentioned above, the medical activity concerning diagnosis, care and treatment in each individual case belongs to the medical guidance responsibility. Under this responsibility there is also the issue of admission and the discharge of patients. The guidance physician must ensure that the intake and discharging of patients is conducted in a manner that gives the patients a good and secure care, as well as kind treatment. In practice, the responsibility for these decisions is taken by the entity providing the medical care.

87. This medical guidance responsibility also includes the determination of which patients, meaning both which types of patients and which individual patients, shall have priority of care or a medical procedure. This need to prioritize care is due to the divergence between the need of medical care and the available resources to render that care, which is partly due to the fact that new technological achievements in medical care have led to more expensive procedures. This situation is especially acute in the case of transplantation procedures.

88. The fundamental criteria when setting priorities is the medical judgment that a doctor makes. This judgment must be grounded in scientific knowledge and experience. The medical criteria for making a choice can be, for instance, which type of treatment a certain patient needs, how acute the need is, the patient's physical status and likelihood to recover, and the medical risks of a certain care and treatment. The guidance responsibility is to supervise that the medical priority will be in accordance to scientific knowledge and professional experience.

89. Often it is not so simple to prioritize situations rendering of medical care that it can be only a medical judgment which is decisive to determine which of two patients has the most urgent need of care and treatment. If there is a medical need that is identically the same, there must be additional criteria to determine how to make the decision. The patient's age can be such a criterion in some situations. The HSAN Board has dealt with a very special situation of priority in the following case, and the decision expresses the fundamental principle for a just priority between different patients.

> The background is as follows. A patient at an orthopedic ward developed a pain centrally in the chest after an operation of the knee. The patient received nitroglycerine pills, which were without effect. The doctor on duty at the orthopaedic clinic gave the patient 5 mg of morphine intramuscularly and the patient was relieved from the pains after some hours. The doctor on duty at the medical clinic, assistant doctor *C*, was consulted on the question of a possible stroke. After an ECG examination, *Dr. C* found that the patient's pains in the

chest were caused by a severe angina pectoris, alternatively a stroke. In spite of these clear indications the patient was not transported to the heart intensive care ward (HIA) of the medical center, even though there were beds available. Instead *Dr. C* decided that the patient should stay in the orthopaedic ward. The patient died during the night as a consequence of the stroke. The reason for *Dr. C's* decision was the content of a memorandum given by the doctor with the medically guidance responsibility at the medical clinic, chief physician *N*. That memorandum said, patients with stroke symptoms who are under 70 should be placed in the HIA, as should patients with serious heart-rhythm disturbances regardless of age.

The HSAN Board expressed its opinion that the patient after his clear symptoms should have been transferred to the HIA especially since two beds were free. Assistant doctor *C*, who had the responsibility for this, did not act so. She had, by failing to transfer the patient to the HIA acted against the rule in the General Physician Instruction[1] concerning the duty to give patients the advice and, if possible, the treatment that the patient's status requires. Therefore, she could not avoid disciplinary measures. When deciding the sanction, the Board found as an extenuating circumstance that the memorandum with instruction for the stroke care that had been issued by the chief physician *N* as the person with the medical guidance responsibility at the clinic for heart care. The Board was anxious to stress that the legal regulation in the General Physician Instruction must always take precedence over a locally issued memorandum. This memorandum was so poorly formulated that it could be interpreted, with regard to the few beds in the HIA, as if patients over 70 in general should not be placed in the HIA. By issuing such a memorandum *Dr. N* had acted negligently and was guilty of such a mistake in the exercise of professional care for which he was administered a disciplinary sanction. When making the choice of sanction, the Board took into consideration that the reported interpretation was not one that was intended by *Dr. N*. The memorandum had been changed. Both doctors were administered an *erinran*.[2]

1. General Physician Instructions 1963:341 §3 (1).
2. HSAN 524/85:3 and HSAN 471/86:3.

90. When it comes to the medically guidance responsibility for transferred patients, there are two situations of responsibility which can be distinguished; the receiving doctor's responsibility for patients transferred from other doctors, and the transferring doctor's responsibilities. The guidance responsibility includes control of transferring doctors fulfilling the tasks falling on them as receivers of sent patients and as sending doctors.

91. The guidance responsibility also includes the responsibility that a patient's journal is written for every patient. The doctor charged with this responsibility must ensure that the information included in the patient journal is consistent with the legal requirements and the specific situation of the particular patient. A physician working in the compulsory psychiatric care must additionally write in the patient journal information specific for this type of care.

92. Another part of the guidance responsibility is that of the medico-technical equipment and its use in a way that is most appropriate for the patient from a medical point of view. It is important that adequate instructions for the use of this equipment are given to personnel, and that they obtain the requisite knowledge and training. This the same when it comes to the responsibility for the correct and secure administration of medicine. Errors in administering medicine can occur, or the wrong medicine can be administered. The following decision from the HSAN Board illustrates this type of error.

> A male patient came to the emergency room at a hospital complaining of pains in his lower left leg. The X-ray of the leg showed a deep lower leg thrombosis in the vena fibularis. When he was admitted to the hospital, the patient had normal serum calcium and creatinine values. The following day these values were controlled again. His calcium was still normal, but the creatinine was too high. At home the patient had been taking several drugs, among them Dichlotride. A prescription for these drugs was also made at the hospital. When they were going to be dispensed, the personnel found that there was not any Dichlotride in the storeroom of the ward. The treating doctor, an intern, prescribed Moduretic instead as this drug was the only hydrochlortiazid that was available. The patient clinically improved with respect to his thrombosis and a discharge was planned for the fourteenth day of his admission to the hospital. The discharge, however, was delayed due to an accident. On the sixth day, the patient was found in the bathroom without any pulse. He was transferred to intensive care, where it was noticed that the value of serum-calcium had highly increased. The patient died two days later. (It should be mentioned here as background, that the drug Moduretic contains the same quantity hydrochlortiazid as Dichlotride. But Moduretic also contains a calcium-saving component, amilorid, which is why Moduretic may not be given in combination with a drug like Aldactone.)
>
> The HSAN Board rendered the following judgment. *Dr. S* had prescribed Moduretic in combination with Aldactone without any follow up of the patient's calcium and creatinine values. Thereby she had negligently disregarded her duty in the exercise of professional responsibilities. As the physician with the medically guidance responsibility, it fell upon *Dr. L* to insure an appropriate administration of medicine. *Dr. L* had the responsibility to see to it that *Dr. S* prescribed the correct medication and, when he had noticed the inappropriate treatment, he should have corrected it. Both *Dr. S* and *Dr. L* were administered a warning.[1]

1. HSAN 644/84:7 1987 9:88.

93. The National Social Welfare Board has published prescriptions in order to eliminate or at least to reduce problems of confusion.[1] There are detailed rules concerning how the prescription of medicine at the wards will be done, who has the responsibility to take care of record keeping, and other matters concerning the prescriptions; everything must be in order to avoid incomplete and incorrect prescriptions. The physician with the guidance responsibility has a duty to supervise that

the wards have routines in accordance with this regulation. The extent to which the physician with the guidance responsibility must go with her/his duty to control in order to maintain a secure administration of medicine is difficult to say with any precision. The following HSAN decision can give some guidance.

> A pharmacy reported that a buffer stock of the tranquilizers Valium and Sobril was stored at a health centre. During a period of four months, so many pills were dispensed that it would be sufficient for about nine months' consumption. During an inventory of the medical supplies, it was discovered that a large number of tablets were missing. Only two nurses had been administering the medicine and both said that they had not administered more medicine to any patient than what had been prescribed. The one of the two nurses who was liable for the medicine supply was reported by the National Social Welfare Board to the HSAN Board, because she ought to have noticed that the pills started to disappear and then informed the responsible doctor. The lawyer representing the nurse asserted that the physician with the guidance responsibility had the superior responsibility for the handling of the pharmaceutical preparation and that it was him who had not fulfilled this responsibility.[2]

94. The HSAN Board in its decision, however, did not discuss the liability of the guidance responsible doctor, and instead stated that it was the task of the nurse to respond for patients getting their medicines according to the prescriptions. To fulfil this responsibility the person concerned had the duty to regularly follow the withdrawal from the different containers and exercise necessary supervision over the medicine that was stored in the supply.

The silence of the HSAN Board concerning the guidance responsibility cannot be interpreted in any other way than that it is the opinion of the Board that questions of this type are not included in the guidance responsibility.

1. Kungörelse (SOSFS (M) 1980:80) om åtaganden för att förhindra förväxlingar inom sjukvården.
2. HSAN 728/84:7.

95. In the rules concerning the objectives and duties for health care providers in the Health and Medical Care Act, the duty that care will be available even outside normal office hours is included. The principal responsible for this care must decide how the 'Doctor on Call' activities will be arranged.

96. In health and medical care the 'Doctor on Call' duty is divided into primary duty and secondary duty. The doctor with primary duty is often at the hospital (or other medical institution). The doctor with the secondary duty has the overall responsibility and has the most extensive knowledge and experience and will function as a backup resource for the doctor with the primary duty in case difficulties arise. The doctor with the secondary duty does not need to be physically present all the time in the wards but can be at another institution, or can even be at home.

§2. Quality Assurance

I. The Content of the Disciplinary Responsibility

97. The governmental authority with the supervision responsibilities over the professional activities of the health and medical care personnel is the National Social Welfare Board.[1] The supervision is performed partly by inspections of the activity of the health and medical care personnel (§4), and partly by the National Social Welfare Board publishing information concerning problems or situations of general interest with the objective of preventing errors, the National Social Welfare Board's prescriptions and general advise (SOSFS (M)). The most important supervision functions are conducted by the local governments, which have the duty to report to the National Social Welfare Board if a patient in connection with health and medical care has had, or has had a substantial risk of being subject to, a serious injury or illness. The supervision authority of the health care and medical personnel by the National Social Welfare Board can result in a decision of disciplinary sanction, or revocation of one's licence to practice (§12–§19). The procedures of the independent HSAN Board will be discussed in the following section.

1. Supervision Act §2.

98. The disciplinary responsibility for the medical personnel comes into effect when the medical personnel ignore their professional responsibilities. These obligations may be found in several independent regulations, such as rules in the Supervision Act or instructions given with authorization from this act, rules according to the Health and Medical Care Act, the General Physician Instructions, or other prescriptions for the exercise of profession given by the employer, i.e. local government.

99. The medical personnel have legal and ethical responsibilities which are governed by various rules. First, the personnel have a potential criminal liability. The part of the Criminal Code (*Brottsbalken*) concerning crimes against life and health is also applicable to the health and medical care personnel. Secondly, for administrative faults outside the exercise of profession disciplinary sanctions can follow according to the decisions in the collective agreements. Thirdly, there are the rules in the Supervision Act about a special disciplinary responsibility for health and medical care personnel. These rules are applicable to everybody belonging to the category of medical personnel. If it is found that somebody belonging to the medical personnel intentionally or by negligence has neglected their obligations in the exercise of their profession, and the error is not insignificant, a disciplinary sanction may be administered to her/him (§12). The possible disciplinary sanctions are an *erinran* (admonition) which is a reminder of the duty to follow the prescriptions in force, or a *varning* (warning) which has greater consequences. Neither of the sanctions can result in a suspension from the right to practice medicine or work in the health care field. A report of disciplinary responsibility does not give the HSAN Board the right to revoke the authorization; there may be, however, a report made recommending such a revocation (§24 (2)). Only the National Social Welfare

Board has the authority to limit or revoke the person's authorization to practice their profession.

100. Questions about authorization and licenses can also be handled by the HSAN Board after a request from 'the person concerned.' This refers to the situation where a person is seeking to reinstate her/his license or other authorization which has been revoked.

101. In very serious cases, which are rare, the HSAN Board can find that the act was so serious that a disciplinary sanction is not sufficient. Such cases are submitted to the prosecutor to begin an investigation into whether criminal proceedings should be commenced; this is not considered to be 'double punishment.'

II. Organization and Handling of Complaints. The Review Board

102. The HSAN Board is a national authority, independent from the National Social Welfare Board. The HSAN Board consists of a chairman and eight other members (§20). All of them are appointed by the Government for a period of three years. The chairman must be an experienced judge, and the other members must have 'special knowledge of health and medical care.' The meaning of this requirement is not clearly explained in the statute, nor in the legislative preparatory work.

103. The management of the HSAN Board is regulated in the Supervision Act (§24–38). The Board does not have the authority to act on its own initiative; before it can consider a case a complaint must have been filed with the Board, or the case otherwise brought to its attention. The patient who brings a case to the Board has a recognized right to participate in the investigation, in such ways presenting evidence or other information. If a patient is unable to personally bring the case before the Board, such as cases of very serious illness or death, a complaint may be filed by a close relation.

104. The complaints and other information presented to the HSAN Board must be in writing (§25). The Board ordinarily responds in writing with its requests for further information, but there is also the possibility of oral proceedings if it can further the investigation (§28). It is the Board, however, which shall decide if there shall be any oral proceedings or oral presentation of evidence.

105. The HSAN Board is obligated to ensure that the cases brought to its attention are thoroughly investigated (§27). The patient may present whatever evidence he or she so desires, but it is not the *responsibility* of the patient to present the evidence needed. The reports are investigated by a secretariat with help from about fifty specialists from different disciplines. It takes one average one year to reach a decision in a case, but it ranges from six months to three years. There is a 'period of limitation' of two years, meaning that the Board will only investigate a complaint if the act or omission complained of has occurred within the last two years. A decision of the Board may be appealed to the Administrative Court of Appeals (§39). A

further appeal may be made to the Supreme Administrative Court, if the Court agrees to hear the case.

106. The HSAN Board has an increasing number of cases every year. In 1980, there were 768 new cases filed with the Board, 955 cases in 1985, 1,100 cases in 1986 and 1,535 cases in 1991. There are various explanations for this increase. It has been suggested that the care has become worse. Another suggestion is that with increased participation and knowledge about their medical care, individuals have become more assertive about asserting their rights. The health care legislation enacted during the 1980s has contributed to this, particularly in regard to the strengthening the rights of the patient. In addition, the Board and its functions have become more well known. Or it might be simply that expectations have increased at a more rapid pace than the ability of the health care system to meet those expectations.

107. In more than 80 per cent of the cases, the decision of the HSAN Board is that 'neither fault nor negligence is found on the acts of the medical personnel' and that 'what has happened in the case will not lead to any measure by the Board.' Less than one-fifth of the cases leads to any disciplinary measure. But even in these decisions where no disciplinary action is taken, there are often statements made which are of general interest. In cases where the Board finds that fault or negligence has been committed by somebody belonging to the medical personnel, and that 'fault is not insignificant,' the person receives a disciplinary sanction of an *erinran* (admonition) or *varning* (warning).

§3. Biomedical Ethics Committees

108. The primary task of Swedish Medical Research Council (*Medicinska forskningsrådet, MFR*) is to distribute grants for research projects in medical fields. Since the 1960s ethics committees have been established at the faculties of medicine to supervise all research at the faculty from an etihcal point of view. From these committees regional research ethical committees were developed which in turn created a group for coordination of the activity of the committees. MFR then took on much of these coordinating and supervising functions. But the Research Council has also a special Working Team that meets twice a year to exchange experiences and coordinate the work. The Team consisted of the chairman and the secretaries from the regional research ethical committees, one delegate from the National Social Welfare Board, one delegate from the Swedish Pharmaceutical Preparation Society, and one delegate from the Physician Society's Ethical Delegation. In April 1991, the Council shaped a Research Ethics Board. The delegates on the Board are, besides the members in the earlier Working Team, also a member with special knowledge of the relevant legal area, a member with special knowledge of medical ethics and two laypeople.

109. There are six Regional Research Ethical Committees, as mentioned above, each connected to the faculties of medicine and four local committees, three in

Stockholm connected to Karolinska Institutet and one in Örebro under the regional committee in Uppsala.

110. The commitees do not have uniform rules governing their activities. There, however, is a common application form for all committees. When an application has arrived at the committee, the chairman or the secretary examines it and if it is considered as a simple matter presenting no ethical questions, it can be approved without the other delegates reviewing the application.

111. The number of delegates differs from eleven to fourteen. The majority are researchers with medical competence but laymen are also involved. Also the cases that require a meeting differ quite a bit between the committees. Two to five meetings per term are usual. The decisions are usually based on unanimity; but voting can be used.

112. The committees themselves decide if an application concerns research that the committee will make a determination about, or if it is about the ordinary activity in the health and medical care that need not be reviewed. Not infrequently, it is difficult to decide.

113. A researcher applying for a grant from the MFR must have an approval from an ethical committee, as mentioned above. But there are also other sources of funding, primarily private foundations, which do not require an approval from a committee to finance a research project. As an ethical inspection is voluntary and merely advisory, research projects can theoretically obtain grants without undergoing an ethical review. If the research has already begun, a review can be made afterwards. In practice, however, it is very difficult to complete a project without an approval from an ethical committee, because most scientific journals demand such an approval before they will publish the results of the research. The local governments and other health and medical care principals have decided that all research programs related to human beings must be approved by an ethical committee before a researcher may have access to patient contacts and medical material. The committees form an opinion of the risks and the discomfort/inconvenience that the patient/subject of the experiment will be exposed to and the significance of the research project.

114. There are also other ethical organizations. The trade union for the physician is called the Swedish Association of Physicians. The Association has an ethical deputy with the task to analyze ethical questions and create debate. The Swedish Physician Society which is an informal society in order to deal with all kinds of professional questions that can arise. Different specialities of medicine have their interests safeguarded. The society has a delegation for medical ethics giving information and advice in ethical problems, arranging symposia and other professional meetings.

115. Another trade union in the medical field is the Swedish Association of Health and Medical Care Civil Servants. The Association has a workgroup dealing with ethics for both research and care.

Part II. The Physician – Patient Relationship

Chapter I. Rights and Duties of Physicians and Patients

§1. Introduction

116. In many countries, including Sweden, there has been an ideological shift in the direction of making access to medical care a *right* of the individual, available to all regardless of social position, background, or income. No more is health care merely a consumer good or a privilege, but is rather a necessity and a right. It is provided more or less without charge for services and is financed by tax revenue. To actually create a health care system that gives the entire population the right to equal and decent medical care, however, is a very difficult, and perhaps even impossible, task. It should also be mentioned that becoming a patient involves not only the possibility to receive treatment and recover but also the acceptance of a risk of incorrect treatment resulting in injury.

The existence of health care has probably come about, in part, because people experienced a decrease in their ability to take care of their health and get well on their own. Therefore, most people would say that it has become of the utmost importance to be able to receive the social benefits that we call health care. The majority would probably agree that no rights are more important than the right to be cared for when ill or injured, or in need of help because of age or disability.

Regardless of nationality or where one lives, one wants to be diagnosed properly, to be treated competently without unnecessary pain or discomfort, and to avoid avoidable complications or injury from treatment. The insistence upon a just distribution of the benefits of medical care will increase. In Sweden the right to receive care from the health care system is brought forward as a basic human issue. However, does this mean that ill people have legal claim for medical care according to Swedish legislation, or does it mean that the individual only has the *possibility to compete* for scanty resources?

§2. Legislated Goals for the Health Care

117. In the Health and Medical Care Act §2 the basic goal of the health and medical care is stated. The goal is 'good health and care on the same conditions for the entire population.'[1] Health and medical care includes both the patient care carried on by the local government and other providers such as employer provided health care, health care in the schools, and private health care.

This goal is an overall objective; it is not a requirement that must be fulfilled in every individual situation. It focuses instead on a desirable future state of affairs, not qualities or demands for the present. The actual obligations of the local governments are delineated in other sections (§§3–19).

1. *Målet för hälso- och sjukvården är en god hälsa och en vård på lika villkor för hela befolkningen.*

118. The discussion begins with the legislated goal of the health care system: *good health for the entire population.* The definition of the concept of 'health' is not self-evident and a universal definition of this term does not exist. The classic definition used by the World Health Organization is 'health is a state of complete physical, psychological and social well-being and not merely lack of illness or weakness.' The legislative preparatory work of the Health and Medical Care Act states that good health is one of the indicators of the conditions and the qualities under which people live.[1] Morever, it is pointed out that such qualities as meaningful free time, absence of stress in the workplace and overall physical and psychological well-being ought to receive greater attention than they normally do.

1. *Prop.* 1981/82:97, p. 113.

119. According to the legislative preparatory work, health care can be an expression not only for the individual's state of living but also a concept which reflects the health situation of the whole population. The concept of health is relative and dependent on such factors as financial assets, the level and progress of science, environmental conditions, etc.

120. The second part of the objectives for the health care system expressed in the Health and Medical Care Act §2 is *care on the same conditions for the entire population.* This involves, according to the legislative preparatory work, the possibility for everyone – irrespective of where one lives in the country – to use the services offered by the health care system when needed and under the same conditions for all. The possibility of receiving care shall not be dependent on such circumstances as age, gender, ability to take initiative, education, financial means, nationality or cultural differences. Waiting lists, if any, may not be influenced by such circumstances. Even for less acute or serious illness, the possibility to receive treatment must be available within a reasonable time. The society has an obligation, within the framework of available resources and scientific knowledge, to offer care for everyone in need of care. Therefore it is, according to the legislative preparatory work, very important that the society takes care of its especially exposed groups, such as the elderly and handicapped.

According to the general principle of equality under which Swedish local governments operate, is not permissable to give certain residents of the municipality (or groups of residents) special treatment without having an objective and legitimate reason for doing so. It may seem as if the principle of care on the same terms for everyone in the Health and Medical Care Act §2 is an expression of the principle of non-discrimination. This is true except for the fact that the regulation in the

Health and Medical Care Act carries a wider purpose than the principle of equality. The Minister presenting the report stated:

> Various equality demands of general human nature are referred to here. The health care system must strive to even out differences which can lead to inequality in care because of age, gender, income, and education (between different patients), in the meaning of giving everyone equal possibilities to, for example, understand a diagnosis or take part in the planning of the treatment. ... Those responsible for the health and medical care must, as much as possible arrange the activities so that the impact of geographical or language and cultural differences are minimized.... The goal, thus, is more far-reaching than what follows from the municipal principle of equality. Without being seen as conflicting with the latter principle, the courts have accepted that residents are treated differently in certain circumstances. The fundamental basis behind the goal is that efforts made in the health care system must have the aim and direction stated by the goal, even if the individual effort isn't always reached all the way.

121. Thus, it can be seen that the significance of the Health and Medical Care Act §2 is not that it is to be looked upon as a rule of how to solve individual cases, but rather that this goal-oriented paragraph must be kept in mind when interpreting regulations in the statute.

§3. The Right to Become a Patient

I. Equality

122. If the obligations of the state as described here are 'legal rights,' the individual should be able to argue in court, that she/he had been passed by in a waiting list for treatment, had to step aside for a younger and healthier person, not received a necessary yet costly treatment, etc. On the other hand, if it is not a question of legal rights, the above described circumstances for care are nothing more than general objectives which sometimes may be ignored.

II. Equality and the Question of Legal Right in the Application of Law

123. How, then, are the responsibilities of the local governments to give care and treatment characterized?

The responsibility of the local government to provide care includes both institutional and non-institutional care.[1] Patients, however, cannot themselves decide what care will be given; this is dependent on the individual patient's need for treatment and other circumstances, such as the availability of hospital beds at the time and priorities made in relation to others in need of care. According to a HSAN Board decision there is no duty imposed upon medical personnel to comply with the particular treatment or care desired by the patient.

A patient filed a complaint against three dentists claiming that the dentists had refused to carry out a tooth-extraction and a dental plate treatment. All the dentists were of the opinion that such treatment would conflict with scientific knowledge and professional experience. The Board concluded that the duty of the dentists to carry through the treatment as much as possible with the approval of the patient does not force the dentists to comply with the patient's demands which would conflict with scientific knowledge and professional experience. In this case, the opinion of the Board was that the dentists had acceptable reasons for their refusal to perform the requested treatment.[2]

However, just because a report has been made to the HSAN Board, this is not an acceptable reason for the clinic to discontinue treatment of the patient.[3]

1. HSL §5.
2. HSAN 56/85:5.
3. *See* HSAN 672/83:6, 1985 9:107.

124. The patient always has a right to consult a clinic at a public health center, and the clinic, in turn, has a duty to receive the patient, although not always immediately. This can be seen in these two cases considered by the Board.

The issue was whether a nurse at an emergency clinic had acted improperly when one night she had turned away a patient with an ear inflammation. The mother of the seven month old girl with earache phoned the emergency clinic at night and spoke to the nurse. The nurse informed the woman that the physician on duty did not receive patients with ear inflammations at night. The mother then took her daughter to a nearby hospital where the girl was diagnosed as having an ear inflammation. The mother complained about this experience to the Board. She questioned the nurse's right to decide what the patient suffered from and if the physician on duty could refuse to treat ear inflammations at night. The nurse responded by referring to the instructions at the emergency clinic detailing how medical personnel should respond at night to parents of children with an earache. According to these instructions, advice should be given on how to alleviate child's discomfort; from a medical point of view it has no significance if treatment is done immediately or the following day. Cases where the child seems generally ill or shows illness other than an inflammation of the ear, or where the parents wish to speak with a doctor, ought to be referred to the physician on duty, according to the instructions. In its investigation, the Board found that the matter had been handled in accordance with the work routines used at the emergency clinic. Furthermore, it found no reason to criticize these routines.[1]

In this case, a boy who was bitten by a snake was refused treatment at a medical center. Instead, without having been examined by a physician, he was directed to go to another clinic but no transportation was arranged for him. The opinion of the Board was that such an incident was not acceptable and that the nurse who turned him away acted improperly. The nurse admitted that it has been a stressful working situation at the clinic that day, with many patients waiting and therefore she had been under stress. The Board concluded

that the circumstances were such that the errror of the nurse was not so serious that it should lead to disciplinary action.[2]

We can see from these cases that a particular duty does not necessarily create a corresponding right, at least not to a similar extent.

1. HSAN 246/83:7, 1885 2:15.
2. HSAN 214/83:3, 1984 8:71.

125. If the individual finds that she/he has very few possibilities to receive patient status, the question arises: what possibilities are available to that person to have her/his complaints heard? Since 1980, every *landstingskommun* must have a local advisory board where people can turn to with questions or complaints relating to medical treatment. These advisory boards have no formal authority to issue sanctions; instead it is the task of the board to give advice or in other ways assist individuals to resolve a particular problem. In cases of gross negligence, or if an individual has anxiety in reporting their complaints, an alternative is to turn to the HSAN Board.

126. It is therefore arguable whether or not there exists a legal *right* to health care in Swedish law. In §3, the duty is laid upon the local government to take responsibility for all health care in their area. This means not only acute care, but also for other routine care (as stated in §4) the responsibility includes not only for those who are registered as residents, but even for persons who are only temporarily staying there. Thus, in the Health and Medical Care Act it is established who is responsible for supplying the health and medical care for the population. However, no regulations exist concerning the person's right to receive treatment of his or her choice. The right to receive patient status is not explicitly stated in the law. This, combined with the patient's inability to appeal decisions regarding the individual treatment (i.e. no procedural possibilities), leads to the conclusion that no legal right to receive patient status exist. Even considering possibility to complain to the HSAN Board, the local government advisory board or the Parliamentary Ombudsman (JO) does not change this conclusion. The individual hereby cannot receive another treatment, but can merely get a clearer idea whether an error was made. The supposed right is a pseudo-right; it gives the individual a possibility to compete for scarce resources, but not the possibility to make legally enforceable demands.

III. Summary

127. The right to equal treatment is an ethical statement that all people should be treated equally. This belief is profoundly felt in Sweden, where attempts have been made to turn this philosophy into reality. In the Health and Medical Care Act §2, the general goal of the health care system is laid down. The goal is 'good health and care on the same conditions for the entire population.' The second part of the goal deals with the issue of equality. The ability to receive care must not depend on

such circumstances as age, gender, education, financial means, national origin or cultural differences. Irrespective of where one lives in the country, one should have the same ability to utilize when needed the services offerred by the health care system. The person responsible for health care should, as far as possible, institute necessary measures so that geographic and other barriers are reduced. However, for this to be a true 'right,' the individual must have the possibility to be able to go to court and argue that she/he has not received as comprehensive (or costly) treatment as her/his neighbor has received, or that she/he had to travel much further for treatment, etc. This is presently not possible for an individual, which is the same as saying that the principle of equality is not enforceable by the individual. The only conclusion is that no legal right to equality exists. This is what the legislators admit in their legislative work. The conclusion of the preparatory work is that the question of equality is a goal – oriented, service-related issue, not a legal right that the patient may enforce.

Thus, even though there is general agreement in principle on the theoretical equality of access regardless of income, age, gender education and residence, Sweden cannot claim to have transformed this into a legal right for its citizens. However, compared with most non-Nordic countries, Sweden has come much closer to achieving equality. The financial barriers to medical care have been eliminated, which is the most important step towards a health care on equal terms.

§4. The Issue of Patient Rights

I. Good Care

The quality of medical care is often described as 'good care.' It is my intention here to examine how the standards are set in Sweden, and the possibilities of the patient to enforce these standards in their particular case.

A. The Patient's Legitimate Claim on Care and Treatment

128. According to the Health and Medical Care Act §2a, the health and medical care shall be carried out in a manner which complies with the requirements of 'good care,'[1] irrespective of whether it is rendered by the public or private sector. The statute defines good care as being:

1. of good quality and fulfilling the patients need for a sense of security in the care and in the treatment,
2. easily accessible,
3. based on respect for the patients self-determination and personal integrity, and
4. promoting of good relationships between the patient and the medical personnel.

1. §2a *Hälso– och sjukvården shall bedrivas så att den uppfuller kraven på en god vård.*

B. Good Quality and Fulfilling the Patient's Need for a Sense of Security in the Care and in the Treatment

129. It is important that people who visit a health care provider can do so with full assurance of being well taken care of and treated by qualified personnel. It is obviously of great importance for confidence in the health care that the personnel have the prerequisite knowledge and competence. The government is required to provide regulations prescribing the prerequisite qualifications for health care personnel (§16). Additionally, the statute requires that there shall be a specially designated doctor with special competency (called *chefsöverläkare*) at each diagnostic or treatment department to be responsible for the operation of the department, should such a need be seen in consideration of the security of care for the patients (§14; see above).

130. All care, treatment and advice must be in accordance with scientific knowledge and professional experience. According to the Supervision of Health and Medical Care Personnel Act,[1] health care personnel have a duty to give the patient 'competent and appropriate care.'[2] Cases where the question involves whether a particular medical treatment has been performed professionally, i.e. in accordance with scientific knowledge and professional experience, are frequently brought before the HSAN Board. Thus, it is generally the Board, with the help of reports by medical experts, which decides what treatment is or is not in accordance with scientific knowledge and professional experience.

According to the legislative preparatory work of the Health and Medical Care Act, the requirement that the care must be of good quality also includes good material and equipment. Necessary technical equipment, appropriate rooms, and nourishing food for patients in institutionalized care must be available. It is emphasized in the legislative material that this insistence on medical safety and quality does not mean that the care has to take place in large hospitals. Forms of care which do not require so great resources may very well fulfill the quality criteria. Thus, the demand for quality as stated in §5 should not be interpreted as a hindrance for the political aim of a continued decentralization of the public health care system.

1. *Lag (1980:11) om tillsyn över hälso- och sjukvårdspersonalen m. fl.*
2. *§5 Den som tillhör hälso- och sjukvårdspersonalen skall vinnlägga sig om att ge patienten sakkunnig och omsorgsfull vård.*

131. Also of importance for the patient's right to a sense of security in her/his medical care are the provisions in the Patient Journal Act which states that a patient's journal must contain information necessary for the good and secure care of the patient.[1]

Thus, good health care is characterized by good quality and fulfilling the patient's need for a sense of security. Even though not explicitly stated in the Health and Medical Care Act, this includes the requirement that the care is in accordance with scientific knowledge and professional experience.

1. *Patient journallagen (1985:562)* §3 (1).

C. Treatment in Accordance with Scientific Knowledge and Professional Experience

132. The physician has the duty to have a reasonable and competent degree of skill. Skill is a special competence which is the result of aptitude developed by special training and experience. Failure to conduct oneself with this skill and care, to the extent that improper treatment is given or proper treatment is withheld, constitutes negligence. The carrying out of treatment can be *contra legem artis* if it is done without the proper and reasonable standard of skill, care, and competence of the medical profession. The omission of some treatment may be *contra legem artis* if the treatment ought to have taken place according to the proper and reasonable standards of the profession. Thus, both an act of medical treatment on one hand and the omission of such treatment on the other can be *contra legem artis.*

133. The decisive question of what standard of skill and care is to be applied, must be answered according to the knowledge of medical science of the time of the treatment. The physician must keep herself/himself up to date. She/he has not acted negligently if she/he acts in accordance with a practice accepted at the time.

134. There are two classifications of active medical treatment which result in injury, namely cases of conscious deviation from accepted rules and cases of unconscious or negligent deviation from the rules. The second group is clearly the largest. There are many different ways of providing negligent treatment, such as prescribing or administering the wrong medicine, overdosing, failing to properly secure an examination table which subsequently collapses and injures the patient, leaving instruments or other inappropriate objects in the body after an operation, mixing up patients, mistakenly removing a patient's organ or the wrong organ.

135. There is also a large group of cases consisting of omission of an indicated medical treatment, or omission of conducting a specific diagnostic examination. It may also be considered to be malpractice if the physician fails to ensure hygienic conditions in examination rooms, fails to properly examine a patient, fails to make proper notations in the patient's journal after examining a patient, fails to use proper precautions which a colleague of ordinary skill and prudence would take, fails to consult medical reports which she/he had identified as relevant and necessary to the diagnosis of the patient's condition, fails to consult a specialist when she/he finds herself/himself unable to discover the origin of the patient's special condition, fails to test the apparatus used in treatment. Finally, there are the important cases of omitted instructions or incomplete information given to the patient.

136. Where is the doctrine of 'scientific knowledge and professional experience' expressed in the sources of law? According to the General Instructions for Physicians, every medical doctor has a duty to counsel and treat the patient in accordance with scientific knowledge and professional experience.[1] The National Social Welfare Board (*Socialstyrelsen*) has tried to clarify the content of the concept of scientific knowledge and professional experience:

As far as we know, the meaning has not been defined in any *proposition* or parliamentary committee reports. Considering the fast development in the medical sciences, in the progress of scientific knowledge, and the changing experience of the professional medical staff, it is obviously very difficult to define the concept. Therefore the National Social Welfare Board, based on practice up to now, states the following.

From a legal point of view the expression means that the medical doctor in carrying out her/his professional activities has the duty to take into account both scientific knowledge and professional experience. The legal text thus means 'both... and' not 'either... or.' The balance between the two criteria, though, may vary. For example, when a new method of treatment is introduced, obviously experience with this method does not yet exist, and therefore the scientific knowledge becomes the basis for accepting the method together with experience from animal experimentation, if any. In other cases, extensive clinical experience of a method can be the dominating basis for considering whether to accept a certain method of treatment, especially if theoretical and/or experimental scientific evidence are limited.

Sometimes the National Social Welfare Board publishes recommendations for medical personnel as directions in certain concrete situations, for example concerning how a certain state of illness ought to be diagnosed or treated. In cases where special recommendations or instructions are published, these should be followed to fulfil what is thought of as 'scientific knowledge and professional experience.'

The requirement that diagnosis and treatment must be in accordance with scientific knowledge and professional experience ought to result in the doctor's action, treatment, and precautions are based on gained experience and known methods of the medical discipline. This does not mean however, that it is always possible to reach a uniform judgment of what is 'scientific knowledge and professional experience.' Different schools of thought sometimes disagree with each other on what is clearly 'scientific' from their point of view, and in addition what is 'proven experience' may vary between different doctors.

Clinical experiments are an exception from the requirement that treatment be in accordance with scientific knowledge and professional experience. Under ethically approved conditions, new methods of treatment and medicine are tested which do not have proven experience. Such activity is obviously a requirement for the developments in the field of medicine to occur.

In conclusion, it can be said that the purpose of legislative insistence on medical care in accordance with the scientific knowledge and professional experience is to assure the best possible care for the individual patient and to form a framework for the activities of the medical personnel. It does not necessarily require that, for example, new methods are excluded from use, but rather that clinical trials must be conducted in a scientific way so that an evaluation can be made. The requirement of care still allows for medical progress.[2]

1. *Allmänna läkarinstruktionen (1963:341)* §3 (1).
2. Letter to a doctor dated 10 February 1976.

137. In a dentistry dissertation the definition of scientific knowledge and professional experience was rendered in the following way:

> at the present time and for the country's collective bank of collected knowledge, the opinion of the knowledgeable of the practical consequences in the individual case.[1]

1. René, *Odontologiska ansvarsfrågor* 1947–1983 (Odontological malpractice cases 1947–1983) (Malmö 1988), p. 180.

138. In a statement by the Parliamentary Ombudsman, it was said that the concept of scientific knowledge and professional experience ultimately is defined by the HSAN Board and the courts. On one hand, however, it is the science of medicine, in this case science of odontology (often in the form of a report by a scientific committee), which decides the frame of the concept. The possibility that the concept has a specific judicial meaning, which does not correspond with the medical or odontological meaning, is not foreclosed. Solely referring to the technical-legal circumstances would result in the loss of confidence of the concept. Jurists have no medical or odontological professional knowledge concerning what is scientific knowledge and professional experience in the medical or odontological disciplines. It is only representatives of each discipline who can make such determination. However on the other hand, statements from such representatives must be in accordance with the intentions of the legal regulations.

D. Accessibility of the Care

139. Medical care must be easily accessible. This refers primarily to 'geographical conditions.' It may not be possible for everyone to have exactly the same geographical distance to a health care centre, but through a decentralization of the health care system it is possible for most people to have health care available to them within a reasonable distance. Studies have shown that there is a connection between the geographical distance and the frequency of the use.[1] Nearness increases the demand for health care. According to the *proposition*, however, geographical closeness is not the only criterion for easily accessible care. It must be combined with considerations of opening hours of the clinics, availability of acute or emergency care, and any waiting lists for a particular diagnostic examination or treatment. Because an expansion in this connection demands great resources, it is important to weigh the need for easily accessible care against the limited economic resources and personnel available.

1. *See* for instance, *Hälso- och sjukvård inför 90-talet* (Health and Medical Care for the 1990s)– SOU 1984:39 p. 89.

E. Respect for the Patient's Self-determination and Personal Integrity

140. The above section discusses the responsibility of medical personnel to provide the patient with professional and appropriate care, i.e. the responsibility of

the personnel from a purely medical point of view. It is hardly necessary to point out that this responsibility is obviously a very substantial obligation; one mistake on the part of a practitioner can have serious consequences. There is, however, another form of responsibility, that which concerns the self-determination and integrity of the patient. When a patient comes in contact with a care institution, she/he comes up, as an individual, against a system with built-in rules and routines. This may result in the situation where the patient feels that she/he is being treated merely as an object, not as a human being. To be kindly received, to be well-informed about the state of one's health (or illness) and the purpose of the treatment, to have the right to see one's own patient journal, to be protected against treatment without one's consent – all these factors have to do with the integrity of the patient. One goal of the Health and Medical Care Act has been to strengthen the position of the patient. This has been accomplished in the statutory text by stating the requirement (which previously was the practice, although not explicitly stated in any statute) that no measures should be taken without the patient's consent. Similarly, the patient has the right to be fully informed and that the treatment be decided together in discussion with the medical personnel.

141. The purpose of the rule of respect for the self-determination and integrity of the patient is, according to the legislative preparatory work, to emphasize the importance of a human and understanding form of patient care. The right to respect and integrity, which ought to always exist for every individual, must also be present in health and medical care. Furthermore, in the legislative preparatory work, it is stated that even if one can argue that such regulation hardly needs to exist because it ought to be such an obvious rule of human behavior – it is an important point that the objective behind this statute, more than any previous statute, is to emphasize the rights of the patient. It is also essential to procure positive results that medical care be carried out in an environment of cooperation between the personnel and the patient.

142. It should be mentioned that the Health and Medical Care Act §2a has a close connection with the Supervision Act §5, in which the personnel are instructed to show the patient consideration and respect. In addition, the Patient Journal Act §4 requires that all information concerning the patient should be kept in a manner so that the personal integrity of the patient is respected.

143. The respect for the religious integrity of the individual[1] is also of significance in matters of health care. For example, a patient at a hospital has the right to practice her/his religion. Detailed regulations exist about how to provide for this at hospitals and other care institutions. The respect for the religious integrity of the patient also includes protection against undue influence from the health care personnel.[2]

1. *See* RF 2:1 (7) 'Every citizen is guaranteed against the society at large ... freedom of religion: freedom to individually or together with others practice their religion.'
2. HSAN 388/80:1, 1984 10:104.

F. Kind Reception – Promoting a Good Relationship between the Patient and the Medical Personnel

144. Included in the concept and requirement of respect for the self-determination and personal integrity of the patient, there is also the right to be met with kind treatment by the medical personnel and the care provider. The reception of the patient and the way in which the patient is treated may have consequences for the patient.

145. Many cases taken up by the HSAN Board relate to the question of whether the right to kind reception has been infringed upon by the personnel, as illustrated by the following examples. However, as also illustrated by the following cases, the facts concerning the incident are seldom clear, and the HSAN Board is reluctant in such cases to take disciplinary measures.

> In this case in 1983, a woman and her three year old son went to a public dental clinic. The child did not want to lie down in the examination chair, whereupon the dentist uttered (according to the mother): 'I'm the one who decides, so lie down now in the chair and open up your mouth so we can do what has to be done.' When the mother complained to the dentist that such tactics were inappropriate, the dentist responded that if children don't lie down in the chair, he 'pushes them down in the chair and does what has to be done, and that was all there was to it.' In the dentist response to the Board, he said he 'didn't exactly remember' what he had said to the mother and the boy, but he explicitly denied having uttered the latter comment. The HSAN Board concluded that the reception of the boy had been 'inappropriate' but found no cause for disciplinary measures.[1]
>
> When a nurse refused to give her last name to a patient who had threatened to report her to the HSAN Board, the Board found that the nurse had acted improperly, but it was not serious enough for disciplinary measures.[2]
>
> While examining a patient a physician had *snus* (tobacco) in his mouth, and then took it out of his mouth in the presence of the patient. The HSAN Board emphasized the 'importance of physicians and other medical personnel refraining from behavior which may appear to show lack of respect for the patient.'[3]
>
> A patient reported a doctor who, according to this patient, had told her off and ridiculed her age. The doctor, however, firmly denied such behavior and the Board concluded that the investigation did not indicate that the doctor had done anything wrong.[4]

1. HSAN 688/83:3, 1984 10:107.
2. HSAN 110/84:6, 1984 10:105.
3. HSAN 107/83:7, 1985 9:111.
4. HSAN 136/84:3, 1985 9:104.

146. The following cases show the difficulty in deciding where to draw the line between an adequate examination of the patient on the one hand and lack of respect and consideration on the other.

This case concerned 'discrimination and inhuman behavior.' The patient claimed that when she told him about her pain, the doctor had said he did not believe her. Instead he started asking her if she drank alcohol or smoked hash. He wrongly diagnosed the patient as suffering from *anorexia nervosa* (another doctor found later that she was suffering from a gastric ulcer) and gave her the impression of having classified her as a drug addict and mentally ill. The doctor claimed that the questions relating to the use of alcohol and narcotics were a necessary part of the medical examination and he refuted the accusation of having behaved inhumanly towards the patient. The Board stated in its decision that the 'investigation did not find cause' that the questions relating to the patient's lifestyle in this case were inappropriate, and thus there were no grounds for criticism of the doctor.[1]

A patient had many times during a period of about a year visited a medical clinic for some neurological symptoms. Each of the nine times he visited the clinic he was seen by a different doctor. None of the doctors were able to correctly diagnose the patient, and later the illness turned out to be a seldom seen form of syphilis. In the contact with the clinic, the patient experienced an increasingly indifferent attitude towards his pain and he felt that he was being classified as a person with alcoholic problems. Furthermore, he had been asked about his social situation and living habits in a hallway at the clinic 'where patients and personnel ran around,' which he felt was both stressful and disturbing. 'Everything had to be done in no time, *Dr. L* had to stop working at five o'clock'. *Dr. L* admitted that the discussion had to take place in the hallway because all the rooms were occupied. He had no recollection of rushing or classifying the patient as an alcoholic. Concerning *Dr. S*, the patient claimed that the doctor had neglected to write down in his patient journal symptoms that the patient had explained to him on the telephone. *Dr. S*, however, did not recollect having discussed the symptoms on the telephone and he based this on the fact that there were no notes to this effect in the patient's journal. The patient additionally complained about *Dr. H*. At one visit the patient was accompanied by his mother. When she tried to explain how her son behaved at home, the doctor snapped her off. *Dr. H*, refuted that he had behaved impolitely and could not recall cutting off the patients mother. The HSAN Board concluded that there was 'nothing found in the investigation which gave cause for the Board to comment.'[2]

1. HSAN 68/84:1, 1985 1:7; see also HSAN 702/83:3, 1985 9:116.
2. HSAN 281/83:1, 1985 2:17

147. A common feature of the cases discussed above is that no measures were taken against the personnel. The Board generally finds it very difficult to conclude that the behavior of the personnel has been inappropriate. The Board uses the principle that one should always give people the benefit of the doubt: '*hellre fria än fälla*' (better to acquit than to convict). There are, however, examples where a doctor has been criticized because she/he did not show enough consideration and respect for the patient. In one case, the doctor received an '*erinran*' (the mildest form of sanction by the Board) because of his inappropriate comments to three of

his female patients. These three patients complained, at different times, of the doctor's treatment of them as patients.

II. Informed Consent

148. The subject of the patient's right to self-determination can be divided into two parts. First, there is the question of whether or not the patient was sufficiently informed of the procedure. Second, there is the question of whether or not the patient has consented to this medical procedure. A patient cannot give a valid consent if he or she has not received all the necessary information concerning a given medical procedure. Therefore, this section will first examine the right to information, and then the issues relating to the right to self-determination, i.e. consent to medical treatment.

A. Information

149. The Supervision of Health and Medical Personnel Act requires that medical care personnel shall, to the extent possible, cooperate with the patient when planning the treatment and when treating her/him.[1] As a part of this, the person with the responsibility for the care must make sure that the patient receives information about her/his state of illness and the methods of treatment available. If for some reason the information cannot be given to the patient, the information shall be given to someone close to her/him. This is especially the case when the patient is very young, or unconscious. The information, however, may not be given out if there are grounds to believe that providing such information would be in conflict with the restrictions contained in any statute.[2]

1. *Lag (1980:11) om tillsyn över hälso– och sjukvårdspersonalen m. fl* §5.
2. Such as the restrictions in *Sekretesslagen (1980:100)* 7:3 & 7:6, and *Tillsynlagen* §6 & §6a. Such restrictions concern a threat of assault or other serious danger if the information is given out. In addition, the person with overall responsibility of the care has the corresponding responsibility to organize the care so that the medical personnel have the opportunity to fulfil their duty to inform (HSL §2a).

150. The purpose of this regulation is, according to the legislative preparatory work, to give the patient an increased insight into and a more active role in the medical care they receive.[1] The personnel ought to shape and carry out the care in consultation and cooperation with the patient. Furthermore, the patient must be given as precise and detailed information as the situation demands and be stimulated to actively seek information and to critically scrutinise and attempt to adapt this information to her/his situation. The personnel must try to adapt the form of the information so that within the patient's ability she/he can understands the information being provided. When, how, and to what extent the information shall be given to the patient must be judged in each individual case. According to the *proposition*, this cannot be regulated with detailed regulations. When an extensive and risky operation must be performed, it is of importance to give the patient a detailed

account of the situation, while a simple procedure may not demand as much information being given to the patient. No regulations exist which require notations to be made in the patient's journal of what information has been given to the patient. The Patient Journal Act has, however, some general instructions concerning for example the fact that the journal must contain the information which is needed for good and safe care (§3) and that information in the journal be written in a way which respects the personal integrity of the patient (§4). Clearly it is desirable that a notation of information given is made in the patient's journal. In addition, this can give the medical personnel the possibility to prove their innocence in case the patient complains to the HSAN Board that she/he did not receive sufficient or proper information.

1. Prop. 1978/79:220, p. 20.

151. Knowledge that a particular procedure or medicine may cause some pain, discomfort, or other side-effects, is included within the scope of information that should be given out to the patient.

> A woman patient went to a private doctor for *condyloma acuminata*, an infectious verruca illness in the lower abdomen. After the doctor examined the patient, he treated her with podophyllin ointment. To lessen discomfort that may follow this procedure she was given Xylocain viscous. The same evening she had great pain and went to the hospital where she had to stay for six days. She did not completely recover for two weeks. The doctor was reported to the HSAN Board for having neglected to inform the patient that under all circumstances the ointment had to be cleaned off after no more than two hours. In the report it was also noted that the doctor had done a breast examination of the patient without explaining why such a procedure was necessary. The doctor claimed that such examinations are done as a matter of routine on all patients in all ages. The Board was of the opinion that the patient ought to have been informed about the purpose of the examination but did not think it to be so serious as to warrant disciplinary action.
>
> Concerning the information about the care and the cleaning off of the ointment, the doctor denied not having given the patient such information. Furthermore, he insisted that he had referred her to a brochure about the illness, which was available in the waiting room. The Board, however, found that the patient had not understood that the ointment needed to be washed off. By neglecting to be certain that the patient had understood the information, the doctor was responsible for an omission that should not be considered to be insignificant, and therefore received an *erinran.*[1] The doctor appealed to the Administrative Court of Appeals, but the decision was not reversed.

1. HSAN 560/82:3, 1984 8:72.

152. During any visit to a clinic a patient will come in contact with a great number of persons, each with their own responsibilities. Which of them has the responsibility of making certain that the patient receives the information to which she/he is entitled? According to the legislative preparatory work of the

Supervision Act, the duty to inform the patient is placed on the person with the most direct responsibility for the treatment. This does not mean, however, that the responsible person herself/himself must actually provide the information; she/he can delegate this task on to someone else, but it is important to keep in mind that the responsibility for the information reaching the patient stays with her/him.

A fourteen-month old boy, Karl, came to an emergency clinic with his mother who had found a hard lump in his right groin. After an examination, the boy was directly transferred to the surgery clinic where *Dr. A* took over. *Dr. A* found a misplaced right-sided inguinal hernia. The mother was informed that an operation was necessary and that the operation was to be done by *Dr. A* and *Chief Surgeon L.* However, a serious acute operation of another patient was given priority, and therefore they could not say when the operation of Karl was going to take place. Later that night, the hernia was replaced spontaneously. The situation was such that one could chose to carry out the operation that night or wait until the following day. The surgeons chose not to wait but started operating and accidentally removed one of the testicles during this operation. Karl's parents were immediately informed about the accident that had occurred. In their report to the HSAN Board, the parents criticized *Dr. A* and *Dr. L* for the way they had acted in connection with the operation. They claimed that the surgeons had not fulfilled their duty to cooperate with the parents before the operation. The surgeons had not told the parents about the changed condition of their son. The parents commented: 'We had a feeling that everything had to go as fast as possible to get it over with. Our child was doing very well before the operation. There were no reasons for stress. We were told that the doctors had a large operation to do first and that the operation of Karl would take place at 11 p.m. at the earliest. We felt that everyone was very stressed and that we could not talk to the doctors about the changed condition of the hernia. Our son felt well again and the operation could have waited till the following day, when the surgeons were rested and no errors had to be made.'

Both Dr. A and Dr. L denied that the operation was stressful and that they wanted to get it over with as quickly as possible. Neither of them felt tired. Because they had become occupied with another operation and as *Dr. A* had given thorough information to the parents earlier, they did not think that any further discussion was necessary. The parents replied that it ought to be the patient or the next of kin that shall decide when more information is needed. Nor had anybody told them about the risks involved in such a surgical operation. *Dr. L* confirmed that no such information had been given to the parents. He pointed out that such a mistake is very unusual and that it cannot be the duty of the medical staff to tell the patient of all possible complications that can result of a medical procedure.

The HSAN Board criticized the surgeons for the meager information that had been supplied, but stated that the situation had not to a significant extent differed from surgical practice. The point of time of an operation is to be determined by the operating surgeon but it is important that the decision is

conveyed to the patient or the next of kin as soon as possible. No disciplinary measures were taken against the doctors.[1]

1. HSAN 170/83:7, 1985 4:40.

153. In §5 of the Supervision Act, discussed above, it is also stated that there is a duty on the part of the personnel to inform a person close to the patient or the patient's relatives. However, the duty to inform covers only cases where the information cannot be given directly to the patient, for example if she/he is unconscious or, as in the above case, very young.

154. The doctor with primary responsibility for the care also has a duty to inform the relatives or a person close to the patient if the patient's condition seriously worsens, according to the General Instructions for Doctors (§10). Furthermore, in the legislative preparatory work it is stated that the relatives ought to be informed regularly, at least in a case of a more serious illness or if the patient is unable to inform her/his relatives herself/himself. If on the other hand however, the patient does not wish her/his relatives to be informed, this must be respected by the medical personnel.

155. In §5 of the Supervision Act and in the Health and Medical Care Act §2a it is noted that the right to information and the duty to inform the patient or a person close to her/him is restricted by the regulations in the Privacy Act. (Concerning private health care *see below*).

156. The patient has a right not only to receive information orally about the state of her/his health (or illness), but also to read her/his own patient journal. The medical records at public hospitals are public documents, according to the decision of the Supreme Administrative Court in 1951.[1] The right to read public documents is regulated in the Freedom of the Press Law, according to which a public document must, upon request, immediately or as soon as possible and free of charge, be provided (TF 2:12). Thus, a patient journal, which is a public document, must as a rule be made available without delay to a person who wishes to see it. The Privacy Act contains some limitations on this general rule.

1. RÅ 1951 ref 29.

157. The HSAN Board has no jurisdiction over questions of the accessability of patient journals in public health services.[1] It is primarily the head of the clinic who decides whether to provide access to a patient journal or not.[2] It is not permissible to put unreasonable conditions on access, such as a rule which states the patient journal only can be studied in the presence of one of the staff members, or that it may only be read where it is located.[3] The person who wishes to study the patient journal has the right to receive a copy of it for a small charge.[4]

1. *See* HSAN 527/82:6, 1985 9:114. The Board can however hear a complaint of improper behaviour in connection with a request for a patient journal.
2. *See Sekretesslagen (1980:100)* §15:6.
3. JO 1985/86, p. 327 and 331.
4. *See* TF 2:13.

158. Concerning patient journals in private health care, the Patient Journal Act contains some special regulations (§12). The statutory text gives the patient a right to read their patient journal or to obtain a copy of it. However, no one other than the patient herself/himself is entitled to access under this rule, which means that medical records in private health care are not public documents in the meaning of the Freedom of the Press Law. The person in charge of the medical records decides whether to grant the request or not. If she/he is of the opinion that the patient journal ought not to be supplied, she/he is obligated to report the reasons for her/his decision to the National Social Welfare Board, which then will hear the case.

159. The following illustrates the difficulties an individual can come up against when she/he wants to obtain access to her/his medical records.

> In February 1984, HSAN received a complaint from *patient G* concerning the refusal of a company physician to supply *G* with his patient journal. *G* had several times requested to be allowed to study his patient journal but the physician had refused. The physician admitted that the patient several times had requested to see his patient journal, but he had not understood these demands to be of such a serious nature because *G* had refused to give a reason for wanting to see his journal. The Board found that, as the physician had not made the determination that *G's* journal should not be made available, that he ought to have given *G* access to his patient journal. Furthermore, the Board criticized the physician for wrongly having attempted to give the patient the impression that he was required to have a reason for wanting to study his journal. The physician was administered an *erinran.*[1]
>
> In another case concerning a physician's refusal to provide the patient with his patient journal for over a month, the physician claimed he had not supplied the patient with his patient journal because it 'contained some delicate information.' The Board did not find this reason to be an acceptable one for refusing to comply with the request of the patient. However, the patient received the patient journal at the end of the month. The Board concluded that the delay in supplying the patient with the patient journal was long but 'under the circumstances' it could not result in disciplinary measures. The patient appealed to the Administrative Court of Appeals. The court pointed out that the physician had acted incorrectly when he had not turned the question over to the National Social Welfare Board. The error, however, was not seen to be significant and no disciplinary measures were taken.[2]

1. HSAN 153/84:3, 1985 2:13.
2. HSAN 63/83:7, 1985 2:12.

160. A close relationship exists between the requirement of consent and the right to information. This is formulated in the following way in the legislative materials to the Supervision Act: 'That such information be given is a precondition for the requirement of a patient's consent to treatment to have any real significance.' It is further stated that limitations on the right to information may only occur where the information does not concern the care. Even if a rule on the right to consent is not explicitly stated in the statutory text, it clearly follows both from the structure and

the spirit of the law that such is required. In certain detailed regulations of the health care services, there is also an explicitly state requirement for the consent of the patient.

B. Consent and Care without Consent

161. Included in the duty of medical personnel to treat patients with consideration and respect, there is also the general rule that no particular treatment or care may be forced upon a patient. This means in principle that all medical care requires the patient's consent. Medical care without the consent of the patient is permissible only in certain specific situations, which are covered by special statutes. The basic for the requirement of consent is found in the Form of Government Law, which states that all citizens are protected against physical measures being taken against their will.[1] This general principle may only be restricted when explicitly provided by law.[2]

1. RF 2:6.
2. RF 2:12.

162. Care and treatment offered under the Health and Medical Care Act is voluntary. A competent adult has the right to refuse such care and treatment.

163. The rules for 'compulsory care' are contained in a few specific statutes. In the Law concerning Care of Young People,[1] in the Law concerning Care of People who Abuse Drugs,[2] and in the Compulsory Psychiatric Care Act[3] provisions are found that the care of the person may take place even without her/his consent.

1. *Lag (1990:52) med särskilda bestämelser om vård av unga.*
2. *Lag (1988:870) om missbrukare i vissa fall.*
3. *Lag (1991:1128) om psykiatrisk tvångsvård.* See also the Judical Psychiatric Care Act (*Lag (1991:1129) om rättspsykiatrisk vård*).

164. The Control of Epidemic Diseases Act[1] contains provisions of compulsory examination (§36), temporarily taking care (§37) and compulsory isolation (§§38–42) of persons suspected of carrying an epidemic disease or a disease which poses public danger, if measures are not taken on a voluntary basis. Certain provisions also exist concerning limitations of the personal freedom, etc. for a person who is in compulsory isolation (§§44–48). Contrary to the provision of the earlier Control of Epidemic Diseases Act,[2] it is not permissable to treat persons with an epidemic disease against their will. A person who suspects that she/he may have contracted a venereal disease, is obligated to seek medical treatment.

1. *Smittskyddslagen (1988:1472).*
2. *Smittskyddslagen (1968: 231)* §8 and §14.

165. There has been a discussion of whether a patient may be treated against her/his will even for diseases other than that which is the basis for the compulsory treatment. It is generally accepted that medical treatment can be offered against the patient's will if the rejection of treatment is a consequence of her/his mental illness, especially when failing to treat would put the patient's life in danger.

166. It is quite natural that conflicts can arise between the doctor responsible for the care and the patient when the patient rejects the care or proposed treatment that the doctor believes is necessary. This may occur for perhaps religious reasons. According to the Swedish Constitution, every citizen has the freedom to practice their religion.[1] Patients, who reject care and treatment for religious reasons, must have their rejection respected according to both the Health and Medical Care Act and the Supervision Act. The dogma of some religions prohibit blood transfusions. Guidelines concerning this question have been elaborated by the National Social Welfare Board and the Swedish Physician Society's Ethical Delegation.[2] From the statements, it follows that the patient has, in principle, an unrestricted right to waive care and treatment. But this right to self-determination does not lead to a corresponding right for the patients to decide on the content and extent of the care, for instance the choice of treatment methods. Here the resources and the claim on scientific knowledge and professional experience must set the limits. If a patient refuses to have a blood transfusion, her/his will must be respected. The condition is that she/he is not under age or does not suffer from any mental illness, abnormity or other mental impairment. What must be determined is the patient's ability to understand the information and the consequences of her/his standpoint. (In regards to euthanasia, *see below* Chapter II. 3. II.)

1. RF 2:1 (6).
2. The statements were published in the Physician's Bulletin No. 6/1989.

167. In regards to the parents right to consent for medical care for their children, it should be noted that children are under their parents custody until they reach the age of 18, or are married.[1] As a rule, both parents are joint guardians. When only one of the parents is the guardian (such as after a divorce) the other parent usually retains some parental rights (unless restricted by a court), but not guardianship. This is shown in a decision from the HSAN Board.

> A licensed psychologist had conducted an examination of a two year old child on the initiative of the father, who had parental rights but not the guardianship, without consulting the parent who was the guardian. The psychologist had thereby disregarded his duty towards the guardian by not first asking for her opinion and position concerning the examination.[2]

1. *Föräldrabalken* (Parents and Children Code) 6:2.
2. HSAN 639/86:1.

168. The rule in the Supervision Law §5 is of great importance when it comes to consultation with parents. That was stressed in the following case at the HSAN Board.

> The question concerned a vaccination given by the Children's Medical Care. This measure is voluntary and cannot be forced upon children whose parents do not want the child to be vaccinated or who have other viewpoints which must be taken into regard. The actual case was about an extra polio vaccination. The doctor had given the vaccination without ensuring that the parents

were informed and had consented. Even if the action as such did not lead to any risk of injury, the HSAN Board considered that the doctor had negligently had disregarded what was his duty in the exercise of his profession and was administered an *erinran.*[1]

Thus, it is the guardian (s) who shall decide about the care and treatment concerning a minor.

1. HSAN 119/87.

C. The Form of the Consent

169. There are some statutes which contain specific provisions concerning consent. For example, the Law concerning Fertilization Outside the Woman's Body requires the written consent of the husband or cohabitant,[1] and the Law concerning Insemination requires the written consent of the husband or male cohabitant,[2] before such procedure can be performed. The Law on Using some Genethics at General Health Investigations (1991:114) is also of interest in this connection.

1. *Lag (1988:711) om befruktning utanför kroppen* §2.
2. *Lag (1984:1140) om insemination* §2.

170. An abortion procedure requires the consent of the woman according to the law on abortion.[1] According to the law on sterilization, sterilization can only be performed on the request of a person who is at least 25 years old.[2] Sterilization of people of the age between 18 and 25 is only allowed after the approval by the National Social Welfare Board (§3). A circular letter of the National Board contains some instructions concerning the implementation of the law.[3] In the circular it appears that a written application is to be made to the national Board, which must be signed by the applicant (§2).

1. *Abortlagen (1974:595).*
2. *Steriliseringslagen (1975:580)* §2. (It is also a requirement that the person will be a Swedish citizen or resides in Sweden.)
3. MF 1975:115.

171. Transplantation from living human beings may only occur with the written consent of the donor according to the law on transplantation.[1] Further requirements must be fulfilled if the donor is under the age of eighteen or if the donor is not able to fully give her/his consent. Measures may be taken only if: (1) there exists medical reasons for biological tissue to be taken from her/him, (2) the National Social Welfare Board grants permission – which it will do only if special reasons for the measure exists, (3) the guardian, administrator or other protector shall have an opportunity to interfere, (4) and finally the measure must not be allowed without the consent of the donor. The rules concerning measures taken on a deceased person state that as a general rule, the consent should have been given during lifetime (§7). Even without such consent, however, transplantations may be allowed if the deceased during her/his lifetime had orally given permission or if other reasons exist for believing that the measure would have been in accordance with the

person's wishes. If it is doubtful whether the person would have agreed, measures may be allowed if the close relatives agree, however not if the relatives disagree. The Transplantation Commission has recently published its reports recommending a new statute.[2]

1 *Transplantationslagen (1975:190)* §4.
2. *Organdonation och transplantation – psykologiska aspecter* (Donation and Transplantation of Organs – psychological aspects) – SOU 1989:98; *Transplantation – etiska, medicinska och rättsliga aspecter* (Transplantation – ethical, medical and legal aspects) – SOU 1989:99; Kroppen after döden (The Body after the Death) – SOU 1992:16.

III. The Right to Privacy and Access to Medical Records

172. The Privacy Act[1] contains the rules on privacy (or secrecy) which provide that certain 'public documents' may not be released to the public, and confidentiality which means that certain information may not be given out orally either. The Privacy Act contains regulations on the limitations of the right of public access to documents, rules on prohibition of releasing certain information, and the duty to observe confidentiality.

1. *Sekretesslagen (1980:100).*

173. As a rule, the right to privacy is not without limitations. In most cases, a certain condition has to exist for confidentiality to apply, namely that it will cause harm if the information is made public. In health care, confidentiality is the basic rule. The regulations are formulated in the following way: confidentiality remains in force 'if it is not clear that the information may be disclosed without the individual or someone closely related to her/him being harmed.' Thus, the presumption is that the information is confidential until the opposite has been proven.

174. The basic rule in the Privacy Act is that information about 'an individual's state of health or other personal conditions' is confidential (7:1). This refers to information on, for example, what illness the individual suffers from, whether a person is at a particular hospital or on a particular ward. Generally the expression of 'personal conditions' includes all data relating to the individual and includes everything from address and telephone number to information about the individual's (in) ability to work and her/his physical and psychological state. Also information concerning the person's economic situation falls under the expression of personal conditions.

175. One purpose of the privacy regulations is to protect the individual's personal interests. It is not the intention that the information should be kept from the patient (14:4). The principle by which the health care services are to operate under nowadays is characterized by openness on the part of the health care personnel towards the patient. The idea is that the patient shall have the opportunity to influence her/his situation as a patient. Thus, it may seem unreasonable that information may be concealed from the patient.

176. Exceptions to the rule that the individual has the right to information about herself/himself exist when there are sufficient reasons for concealing the information from the patient in a particular instance. According to the Privacy Act 7:3, which applies to both oral and written data, the information is confidential even to the individual herself/himself under certain circumstances. A requirement that must be fulfilled to permit information from being concealed from the patient is that it relates to the state of the patient's illness. Furthermore, it is a requirement of the statute that concealing the information is of utmost importance with regard to the purpose of the care or treatment. This requirement remains even after the patient has been discharged from the hospital, or released from care. However, this possibility of withholding information from a patient must be used very restrictively.

177. Another exception from the rule of allowing the patient to obtain information relating to her/him and her/his health concerns reports or statements made by other people (7:6). They may be kept secret from the patient if it is believed that it might cause danger for this person or to close relatives of her/him if the patient is given the information. The purpose of this provision is to protect those who report or provide information in delicate cases, such as for example child abuse, heavy abuse of drugs or a psychologically ill person.[1] How strong the fear of retaliatory action for the informer must be is not stated in the legislative material and could hardly be specifically described in a statutory text. Instead the interests of the parties and the society must be weighed in every individual case. The legislative preparatory work, however, states that in such cases it must be fear of retaliation of a serious nature.

1. For the provisions covering private health care, see the Supervision Law §6, §6a and §6b.

178. In addition, as a consequence of the right of the patient to obtain information about herself/himself which for others is confidential information, she/he can consent to the release of personal information requested by an individual or company, or by a government agency. However, in case where the person does not give her/his consent, the wishes of this person must be respected. This means that confidentiality is the rule, if the conditions stated in 7:1 are fulfilled. The individual's own interests are given precedence. There are no rules in the statutory text or in the legislative material concerning how consent may be given. In many cases, certain routines have been worked out. A written consent is often attached to the documents, for example an authorization to release medical data to an insurance company or a social welfare agency, and a notation of the consent is most often made in the patient's journal. There are judicial decisions stating that the consent does not always need to be explicitly given. Sometimes consent may be presumed, for example if the patient is unconscious.

179. However, even if the patient has given her/his consent for the release of some information, it is possible that such action may cause harm to a close relative. It is not unusual that patient journals also contain some information about relatives. In such cases, consent must also be given by the relative.

180. According to 14:9 the risk of harm to an individual because some data are released may be eliminated by making a 'reservation' (*förebehåll*). A reservation may only be made when the data are to be given to a private person, not when they are given to a governmental agency. The reservation may stipulate that it is forbidden to pass the information on to anyone else, or that the information only may be used for a stipulated purpose.

181. The statute and the duty of confidentiality applies to *all* personnel within the public health care system, including doctors, dentists, nurses, physical therapists, medical assistants, lab technicians, doctor's secretaries, psychiatrists, social workers, ambulance personnel and building maintenance personnel. It also applies to individuals undergoing practical training such as resident interns or medical students involved in the delivery of medical care.

182. Persons not involved in the provision of health and medical care may also be obligated to maintain the secrecy of a person's state of health. A supervisor at one's place of employment may become informed of the health status of her/his employee, and may not pass on this information to another person who does not have a legitimate need for the information. If she/he does, she/he may be liable under the Penal Code[1] for a violation of the obligation of professional secrecy, and in addition if the person is government employed, under the Public Employment Act.[2] This can be especially important in the case, for example, of a person with AIDS.[3]

1. BrB 20:3.
2. *Lag (1976:600) om offentlig anställning* 10:1.
3. *See*, Saldeen & Westerhäll, 'Some Reflections on HIV/AIDS in Swedish Law,' paper presented at Colloque international 'Droit et Sida: Comparison Internationale,' Paris 24–26 October 1991 (Paris: Centre National de la Recherche Scientifique), p. 21.

IV. The Right to Compensation for Damages

A. Tort Law Liability

183. The Tort Act[1] contains rules about the individual's responsibility for her/his negligence either in form of an act or an omission. This responsibility usually is called a '*culpa*,' responsibility, fault or neglect. It is often not very easy to decide whether negligence exists or not. As a general rule the principle of *bonus pater familias* is applicable. That means that behavior is negligent if it differs from the conduct of 'the good family father.' As it applies to medical care, there is a rule in chapter 3 of the Tort Act concerning superior responsibility, which means that an employer, in this case the *landstingskommun*, is liable for the negligence committed by their medical personnel in the exercise of their professional duties. The rule as such is simple and clear, but there are important difficulties which may be encountered by a patient trying to prove error or negligence on the part of a 'health care employee.' However, it is not necessary to show that a particular individual single has been negligent. It is sufficient to prove that somebody has committed an error and the employer must answer for this 'anonymous' error.

1. *Skadeståndslagen (1972: 207)*, chapter 2.

184. When interpreting the rule of principle responsibility in the field of medicine a certain tolerance against errors and mistakes is to be accepted, as illustrated in the legislative preparatory work. Medical work is performed under such special circumstances that must allow for a certain margin of error. No strict liability exists.

185. This means, of course, that it is very difficult for a patient to receive compensation according to the Tort Act and that the number of such attempts is extremely small. Most people try to get compensation through the Patient Insurance or the Pharmaceutical Insurance, which operates under the principle of no-fault insurance.

186. It can be seen how difficult it is to successfully obtain compensation for medical injuries in tort by examining a fairly recent case, one of the few that exist.

> The *landstingkommun* of Malmö was ordered by an appeals court to pay damages to a patient who had a nerve severed during an operation in an orthopedic clinic. The doctor was found to have not given the patient 'clear information concerning the extent of the operation.' According to the appeals court's opinion 'it must be negligence of not having given clear information in order to base tort liability for the *landstingskommun* for possible injuries as a consequence of the operation....' The appeals court also was of the opinion that the patient 'would not have given permission to the cutting off the *nervous gluteus superior*, if she, before the operation, had received the information that it was possible that the surgeons would cut off this nerve.'[1] The *landstingskommun* was ordered to pay damages and the patient's legal costs.
>
> The case was appealed to the Supreme Court and it attracted a great deal of attention. If the Supreme Court upheld the decision granting compensation to the injured patient, the whole legal field of medical tort law would be changed. The Supreme Court agreed to consider the case in 1987, and rendered its decision on 19 July 1990. Its judgment reversed the decision of the appeals court, and reasoned the case as follows.
>
> According to the Health and Medical Care Act §2a, the care and treatment, as far as possible, must be performed in consultation with the patient, e.g. information provided beforehand to the patient and consent from the patient to the planned treatment. The patient in this case had the right to know that the nerve might be cut off and that complications might arise as a consequence of the measure. But 'the general consent that *KH* had given to her operation... cannot be considered as implicitly having included the undertaken nerve cutting. The fact that the nerve cutting happened without *KH* being informed beforehand about the measure and without her consent, however, does not make the *landstingskommun* liable or responsible for the actions of the doctors concerned.'
>
> It is an incontrovertible fact in this case that the nerve cutting was, from a medical point of view, the appropriate measure considering that the operating had progressed as far as it had without being able to give any explanation for

the patient's suffering. The operation was expected to be helpful for the patient and was not a high-risk procedure. It has also been made clear that it would hardly be possible to cut off the nerve at a later date, because the scar formation in the wound would make it very difficult to find the thin nerve thread again. The doctors' decision to cut off the nerve in this situation must be considered justifiable with regard to what has been said and can not lead to liability for damages for the *landstingskommun*.[2]

1. Hovrätten över Skåne och Blekinge, 861202 case No. T 91/80.
2. NJA 1990 p. 442, *Kerstin H vs. Malmöhus läns landstingskommun*. For commentary on the decision, see Agell, 'Skadeståndsansvaret för operativt ingrepp utan patientens samtycke,' 2 *Juridisk Tidskrift* 439 (1990–91); Rynning, 'Patientens samtycke – rättsligt relevant eller bara medicinsketiskt?' 2 *Juridisk Tidskrift* 630 (1990–91); Löwdahl, 'HD upphävde dom mot läkare i mål om patientens informerade samtycke,' 88 *Läkartidningen* 3154 (1991).

187. From this decision it follows that Swedish tort law still does not acknowledge the doctrine of informed consent. Seeing the operation as appropriate from a medical point of view combined with a low risk of complications, the fact that the operation failed and her pains still remained with increasing intensity had no significance in this case, despite the fact that she had not been informed that she might lose a nerve and for that reason had not been able to give consent to the nerve cutting.

188. If the appeals court decision would have been upheld, this would have had a significant impact on tort law in general and the law of medical malpractice in Sweden. Up to now, the question of medical professional liability has been dealt with quite independently from the issue of compensation in tort law and insurance law. The health care regulations about information and consent have not been taken into consideration when determining the question of the right to compensation. Their only significance has been when the HSAN Board hears a disciplinary case, and at that the number of decisions of the HSAN Board concerning consent are few. On the whole, the topic of consent has not yet developed beyond theory and has never received the attention and significance that it has in some other countries. The concept of informed consent has almost never been used in tort law and it is a very undeveloped question in the legal field of disciplinary responsibility.

B. Patient Insurance

1. Background

189. Prior to 1975, when the Patient Insurance (*Patientförsäkringen*) came into effect, a patient who was injured by medical treatment could only receive compensation for damages in accordance with the general principles of tort law. The patient was required prove that the medical personnel had acted negligently and therefore caused the injury. This was very difficult to prove. Therefore, few people received compensation for injuries caused by improper medical treatment.

Because of this, there were numerous *motions* introduced in the Riksdag to redress this situation.[1]

A workgroup was formed in 1971 to inquire into the question of a collective insurance system for injuries incurred due to medical treatment. The group was composed of representatives from the *Landstingsförbundet* (Association of Swedish Counties) and a number of private insurance companies. The goal of the group was to create a fair compensation system which would reimburse serious injury claims and which would take into consideration the need to compensate the patient from the patient's point of view. The investigation resulted in the proposal of a system for increased protection of the patient. The proposal was greeted very positively and resulted in the creation of Patient Insurance, which came into effect in 1975.

1. *Motionerna* 1967:333, 656, 657, 660, 663, 1185; 1972:1490; 1973:1093, 1166.

190. The insurance is based on a voluntary agreement between a consortium of insurance companies and health care providers (originally only the local government, but now includes almost all health care providers including private practitioners). The result is that almost all medical care patients are covered by this insurance. Claim settlements are controlled by a separate department, which allows for the uniform judgment of claims compensation. The goal of this specially organized settlement procedure is an efficient and just handling of the cases. It usually takes approximately six months to settle a claim, except for more complicated matters. Claim adjustors, who are responsible for doing a medical investigation of the case with the assistance of doctors, handle each claim independently. Any disputes between the Insurance Consortium and the injured party shall be settled by an arbitrator according to the Arbitration Act.[1]

1. *Lag (1929:145) om skiljemän.*

191. The existence of this universal Patient Insurance does not mean, however, that the injured patient is foreclosed from the possibility of going to court with her/his claim. Until the patient has accepted the compensation offered by the claim adjustor, she/he may file a lawsuit in the courts against the medical care provider. In such a case, however, the plaintiff patient can only base her/his demand for compensation upon tort law, and in practice this is a serious obstacle to obtaining compensation.

192. There is the possibility to obtain public legal aid in cases concerning compensation for treatment injuries.[1] In such cases, the individual situation of the person will be considered; in other words, the scope and the degree of seriousness of the injury in question. In addition, the Insurance Organization is available to the injured patient for advice and assistance in such court proceedings. If the injured party is successful with their tort claim in the general courts, the Patient Insurance does not pay the claim; it will be paid by another insurance covering the liability of the *landstingskommun.*

1. *See Rättshjälpslagen (1972:429)* (Legal Aid Act) §8a.

193. The purpose of the Patient Insurance system is to compensate the individual for direct and indirect damages. The starting point for calculating compensation is the rules in the Tort Act (chap. 5). These rules have been somewhat modified, however, for administrative and economic reasons.

194. Compensation can be given for both actual economic loss, such as special care and treatment expenses or loss of future income, and for non-economic injury, such as pain and suffering or permanent injury. Compensation for pain and suffering and for permanent injury is calculated in accordance with tables created by the *Landstingsförbundet* and an advisory board within the Patient Insurance Consortium. The tables are regularly adjusted for inflation. These tables are also used by the courts as well as by other insurance institutions.

195. If the injury had led to permanent invalidity, the injured party is also compensated for general discomfort and future loss of income. Compensation for general discomfort is given only in cases where the person returns to work in spite of her/his disability. There is, of course, a higher level of compensation for permanent disability. Compensation for future loss of income is awarded in cases where the injury has lead to invalidity to such an extent that the person's ability to work has decreased by at least one-fifteenth and yearly income loss due to this inability to work is higher than one-fourth of the 'basis amount' (*basbelopp*). The payment of compensation can be in the form of a one-time payment or monthly payments for life.

196. When the Patient Insurance was established, it was decided that it would be best to make an exception to the right of compensation in the case of minor injuries. It was the view that a minor injury seldom leads to an economic loss which can be distinguished from the loss due to the illness/injury which the patient already has. In view of this, and taking into consideration the basic economic security one has in Sweden due to the social welfare system, there is a so-called 'self-risk' or 'deductible' factor. A governmental commission, the Patient Insurance Commission, has to investigate if the insurance has to be regulated in law (Dir 1992:101).

2. Fundamental conditions

197. Fundamental to the concept of Patient Insurance is the fact that medical negligence does not have to be proven. The Patient Insurance is a 'no-fault' insurance, where the liability for damages does not need to be determined in order to receive compensation. Instead, the right to compensation is based on the fact that the injury is related to a decision or an act for which one of the medical personnel is personally responsible.

198. Patient Insurance compensates individuals for injuries received as a consequence of medical treatment. The ability to collect compensation in any given case is dependent on the fact that the injury in question could have been avoided. Thus,

if the injury was foreseeable and unavoidable, it will not be subject to compensation. When investigating whether the injury is foreseeable and unavoidable, a so-called 'key argumentation' (*facitresonemang*), typical of the Patient Insurance, is used. That means that all known facts are to be used in making the determination.

199. The fundamental limit for the avoiding or not avoiding an injury is drawn at 'underlying illness,' the illness that the person already has. Thus, injuries or complications which are the unavoidable consequences of the underlying illness or the treatment of the underlying illness are not compensable. Health care professionals can not guarantee that a particular treatment will lead to the desired result. Consequently, no compensation is given for unsuccessful treatment. Nor are injuries suffered because of insufficient medical resources reimbursed.

a. Injuries caused by medical treatment

200. A treatment injury according to the Patient Insurance is an injury which results from medical treatment, examination or diagnosis. The injury must be physical. If a psychological injury is incurred as a consequence of a bodily injury which is in turn a result of medical treatment, then the psychological injury is also to be compensated. There is no compensation provided for purely psychological injuries. The reason for setting these limits is that it is extremely difficult to prove the difference between latent psychological illness and illness caused by the treatment.

201. For a claim of compensation to be granted, an examination, treatment or other similar act must have taken place and there must be a direct causal connection between the act and the injury, *and* the injury cannot be an unavoidable complication of a medically motivated measure. Complications caused by the underlying illness and injury occurring as a consequence of the necessary treatment of the underlying illness are excluded from compensation.

202. An assessment will be undertaken from the experienced specialist's level of skill and experience. What is relevant in such a situation is how an experienced specialist would have formed an opinion of the symptoms of the patient and which measures the specialist would have taken as a consequence of this assessment. If the experienced specialist would have acted in another way and the injury could have been avoided, compensation will be paid.

203. Compensation for *incorrect* diagnosis can be paid if a symptom has been observed and not interpreted in a way that a skilled and experienced specialist would have interpreted it.

> This case concerned a woman, 22 years old, with constant pain in the lower part of her abdomen. After the removal of an ovary, the patient still experienced pain. Suspecting endometrics, after serious considerations the physician removed the uterus and the left ovary. A later investigation showed that the patient's suffering was due to an orthopaedic condition. In the consideration of

the suffering displayed at several visits to the women's clinic the woman ought to have been referred to an orthopaedic specialist for excluding an orthopaedic cause to the illness before the uterus and the ovaries were removed. Compensation was paid.[1]

1. PSN 140/1985.

204. Compensation for *delayed* diagnosis can be paid if a symptom has not been noticed and the symptoms should have been observed by an experienced specialist. (If it was not possible to notice the symptom, compensation will not be paid).

This case concerned a women with a dermoid cyst on her right ovary, which was removed in an operation. The cyst was benign. There was a discussion as to whether the delayed diagnosis had resulted in the ovary's removal. Because cysts of this kind are difficult to diagnose and can develop in an short period of time, the obligation to pay compensation did not exist.[1]

1. PSN 31/1984.

b. Necessary risk-taking

205. The concept of necessary risk-taking means that there is always a risk of injury with medical treatment, but such risk is a risk that can not be avoided in that particular patient's situation. An illness, injury or other complication may arise as a consequence of, from a medical point of view, necessary risk-taking in diagnosing or treating an illness/injury which, if left untreated, would be life-threatening or involve a risk of invalidity or great suffering. When a patient has an illness or an injury that is very serious, the risk of complications is extremely great. Medical personnel often work under great time pressure when treating such an illness/injury. There is often no time to discuss what the best method of proceeding is.

The rule of necessary risk-taking is built upon good reasoning. What must be determined is, if it was necessary to take the risks involved. Would the treatment have been performed if the risk of injury was known? If the answer is no, the patient is entitled to compensation. On the other hand, the patient is not entitled to compensation if the treatment would have been performed even if the potential consequence of injury was known. From this it follows that the more serious the illness/injury is, the less likely the patient will be able to obtain compensation for a treatment related injury.

A 40 year old woman was operated on for a tumor on her throat, whereafter paralysis of the tongue and the vocal cords arose. As the tumor was growing close to the nerve of the tongue and the injury on the nerve of the vocal cords probably had arisen when the nerve was put aside during the operation, it was considered to be necessary risk-taking with the treatment of the patient's serious tumor. No compensation was paid.[1]

1. PSN 63/1981.

206.

A 28 year old man suffered from aorta insufficiency. In connection with an operation, he suffered irreversible injuries, such as a lost sense of feeling in the right part of the body and reduced sensibility function on the left side. He also developed spasms, impaired hearing, blurred-vision in the left eye, impaired reactions and partial loss of memory. The patient's lawyer was of the opinion that the patient had not been sufficiently informed about the risks involved in the operation. It could also be questioned, according to the lawyer, if there was such a causation between the operation and the injury, that the injury should be included in necessary risk-taking. The Patient Insurance declined the claim. The Patient Insurance Board found that there was a question of necessary risk-taking in this case and pointed out that 'the risk shall be generally predictable to the physician before he performs the operation.' That means that 'the field' for a necessary risk-taking is very wide. Concerning the patient's consent, the Board wrote in its decision that 'how and to what extent the patient receives information before the treatment was, at the time the insurance was created, not been considered important for the right to compensation. It is the treatment itself and the injuries eventually arising in connection with it that will be judged in the light of an undertaking concerning compensation.[1]

From what is mentioned above, it follows that the opinion not to accept the doctrine of informed consent prevails in the fields of tort law and insurance law.

1. PSN 45/1988.

c. Consequences of the underlying illness

207. An illness, injury or other complication which occurs mainly as a result of an illness or condition that the patient already suffers from, is not considered a treatment injury. The meaning of this exception is, above all, to clarify the fundamental basis of the insurance, namely that illness or injury arising or developing independently of the treatment does not constitute a compensable treatment injury.

A 48 year old woman was treated for a chronic back illness with injections, local anaesthesia and cortisone. Problems with her neck arose. This was not considered to be a resulting injury. The neck problems were a consequence of the chronic back illness.[1]

1. PSN 21/1982.

208. As a rule, an exception is made for diagnostic injuries. In these cases the injury develops independently of the treatment.

d. Injuries caused by pharmaceuticals

209. The Patient Insurance is not applicable to illness, injury or other complications caused by pharmaceuticals or other medicine for which the Pharmaceutical Regulations (*läkemedelsförordningen*)[1] are applicable and when the medicine was used in accordance with the directions provided by the producer. A special insurance is applicable for injuries arising from using such medicine called the Pharmaceutical Insurance (*Läkemedelsförsäkringen*). It came into affect July 1978 through an agreement between the producers and importers of drugs and the Consortium for Pharmaceutical Insurance (*Konsortiet för Läkemedelsförsäkring*).

1. This excludes natural medicine, which is available without a prescription.

210. Injuries arising as a consequence of a defective pharmaceutical are compensated by the Pharmaceutical Insurance. The Patient Insurance reimbursement only pays compensation for injuries caused when the medicine is not used in accordance with the instructions.

> In this case, treatment of asthma with hydrocortonephosphat led to the patient's shortage of breath. The instructions for using the drug had been followed. No compensation was paid.[1]
>
> Another case concerned a 1 year old boy with a large left-sided tumor in his abdomen. In connection with angiography, a severe brain injury arose. The boy who weighed 10.5 kilos, received at least 70 ml contrast liquid during 2.5 hours. This dose had exceeded what is generally allowed. Compensation for treatment injury was paid.[2]

1. PSN 10/1977.
2. PSN 77/1981.

3. Statistics

211. Approximately 4,500 claims are made to the Patient Insurance per year. On average, about 2,300 of these cases result in compensation being paid. The costs for the Patient Insurance are estimated to amount to about 85 million Swedish Kronor per year (1.10 million ECU), which is about 10 Swedish Kronor (1.40 ECU) per inhabitant.

TABLE I. Distribution of injuries by degree of severity

	Number per year
Period of time of compensable illness	
– less than 3 months	250
– more than 3 months	1,150

Permanent invalidity	
– less severe	600
– medium severe	80
– more severe	40
Deaths	30

TABLE II. Average compensation per classification of injury

	SEK
Period of time of compensable illness	
– less than 3 months	2,700
– more than 3 months	8,100
Permanent invalidity	
– less severe	32,100
– medium severe	86,000
– more severe	680,000
Deaths	51,000

TABLE III

The connection between the type of treatment and the injury which occurred

Treatment	Percentage
Operation	46
Narcosis, local anaesthesia	9
Diagnostics	8
Other treatment	16
Accident	17
Remaining	4

The category of 'Other treatment' includes injections, cathetering, blood transfusions, treatment of teeth and orthodontics, physiotherapy, etc. The category of 'Remaining' includes, among other things, injuries caused by defective equipment or materials.

TABLE IV. Types of injury

Type of injury	Percentage
Infection of wounds	14
Injury to nerves	19
Injury to skeleton	11
Injury to teeth	9
Injury to tissue	6
Duration of illness prolonged	7
Injury to internal organs	8
Injury to the circulatory system	5
Follow-up operation required	4
Other	17

The reasons why some reported injuries have not been compensated are shown in Table V.

TABLE V. Causes of injury where compensation was denied

	Percentage
– The illness has no connection with the treatment	19
– The complication could not be avoided	17
– Another insurance has paid the compensation	12
– The injury was reported too late	2
– The injury was too minor	21
– The infection has no connection with the treatment	4
– The accident has no connection with the treatment	15
– The injury was not caused by misdiagnosis	5
– The injury is not compensable due to some other reason	5

TABLE VI. Allocation of compensation

Allocation of compensation	Percentage
Compensation for:	
– loss of income	14
– expenses	10
– pain and suffering	15
– disability and deformity	45
– inconvenience	16

TABLE VII. Compensation for invalidity in the Patient Insurance

Table for calculation of the compensation for disability and deformity

Degree of disability (%)	Total amount (SEK)
10	30,000
20	47,000
50	128,000
75	225,000
100	320,000
100/25	425,000
100/50	560,000
100/100	640,000

Chapter II. The Physician-Patient Relationship in Specific Terms

§1. The Patient who is a Minor

1. The Minor's Right to Self-determination

212. Children are, as a rule, under their parents custody until they reach the age of 18. However, in medical care as with other matters concerning self-determination and personal integrity, the manifestations of a young person's will should always be taken into consideration. When rendering medical care the doctor should attempt to determine if the young person is mature enough to understand her/his own situation and the consequences of a particular medical treatment.

213. No precise age limits are provided for in the legislation, but the development in recent years has been that greater consideration must be accorded to a young person's own desires and opinions, increasing with her/his age and maturity.[1] Guidance may be obtained from other statutes not relating to medical care, or from medical judicial decisions.

1. See the Parents and Children Code (*Föräldrabalken*) 6:11. *Vårdnadshavaren har rätt och skyldighet att bestämma i frågor som rör barnets personliga angelägenheter. Vårdnadshavaren skall därvid i takt med barnets stigande ålder och utveckling ta allt större hänsyn till barnets synpunkter och önskemål.*

214. It is stated in the Social Welfare Act[1] that young people over the age of 15 have the right to file lawsuits and other proceedings under that statute. In addition, those younger than 15 should be heard if it can be useful for the investigation (§56). Similar age limits exist in the Law concerning Care of Young People[2], the Law concerning Special Care of Psychologically Developmentally Disabled[3] and the Compulsory Psychiatric Care Act[4]. Some statutes provide for lower age limits. According to the Parents and Children Code, a youth over 12 cannot, as a rule, be adopted without her/his consent.[5] Decrees concerning custody and parental rights will not be ordered by a court if the child over 12 does not consent (unless it is found to be in the best interests of the child). Even if the child has not reached the age of 12, but shows a certain level of maturity, her/his desire should similarly be taken into consideration.[6]

1. *Socialtjänstslagen (1980:620).*
2. *Lag (1990:52) med särskilda bestämmelser om vård av unga* (§36).
3. *Lag* (1985:568) om särskilda omsorger om psykiskt utvecklingsstörda (§6).
4. Lag (*1991:1128*) on psykiatrisk tvångsvård (§44).
5. FB 4:5.
6. FB 21:5.

215. In regards to the right of privacy, information may withheld from the parent (s)/guardian (s) of a minor if it is reasonably thought that it may result in injury to the young person if such information is released.[1]

1. *Sekretesslagen (1980:100)* 14:4 (2).

216. What this all means is that medical personnel also must take into account the desires and wishes of young patient's when it comes to medical treatment, keeping in mind the young person's maturity and development.

II. Care without Consent and the Right to Refuse Treatment

217. The rules for 'compulsory care' of young people are contained in a few specific statutes. In the Law concerning Care of Young People,[1] in the Law concerning Care of People who Abuse Drugs,[2] and in the Compulsory Psychiatric Care Act[3] provisions are found that the care of the person may take place even without her/his consent. The rules concerning epidemic diseases, the Control of Epidemic Diseases Act,[4] apply to minors as well as to adults.

1. *Lag (1990:52) med särskilda bestämelser om vård av unga.*
2. *Lag (1988:870) om missbrukare i vissa fall.*
3. *Lag (1991:1128) om psykiatrisk tvångsvård.* See also the Judicial Psychiatric Care Act (*Lag (1991:1129) om rättspskiatrisk vård*).
4. *Smittskyddslagen (1988:1472).*

218. The Law concerning Care of Young People has been applied for intervention in the interests of a minor. This has occurred, for example, when the parents of a patient who is a minor have opposed a blood transfusion. The doctor fulfills her/his duty to report according to the Social Welfare Act, and then the young person is taken into custody for 'societal care' by the local social welfare authorities. The statute creates the legal basis for care and medical treatment based upon the community's interest in protecting minors.

219. The National Social Welfare Board announced that a similar, if not acute, situation occurs if the parents refuse to allow a handicapped child to receive such treatment that is necessary for the young person.[1] The local Social Welfare Board has the authority to take the young person into custody in order to make certain that proper care is provided.

1. *See* its General Advice (1981:2) regarding the Law concerning the Care of Young People.

III. Termination of Pregnancy

220. Specifically in regard to termination of pregnancy, the National Social Welfare Board has issued a General Advice concerning the question of abortion when the woman is a minor.[1] If the young woman applies for an abortion, she is considered to have such a degree of legal capacity and maturity, that she can make her own decisions regarding abortion. Most teenage girls seeking an abortion have already discussed the matter with their parents, or another close adult. In addition, youth counselors, family planing counselors, and midwives at health clinics are available. Special attention and support will be given to her if she is unable to

discuss the matter with her parents. The basic rule though is that it is the young woman who shall decide.[2]

1. SOSFS (M) 1989:6.
2. Of course she will be subject to the same rules that she would be if she was an adult. See *Abortlagen (1974:595)* §§1–3.

IV. Other Issues relating to Minors

221. In recognition of the position of young people within the family, the Social Welfare Act[1] provides that anyone who becomes aware a minor is being physically abused in her/his home, or is being otherwise treated in such a way that puts her/his health or development in danger, *should* report this to the local Social Welfare Board. Individuals working for a governmental authority who's activities include responsibilities for children and youth (such as daycare centers) are *obligated* to report to the local Social Welfare Board if they in their official responsibilities become aware of a situation where the social welfare authorities should interfere for the protection of a minor. This applies also to doctors and other health care personnel, including those in private practice. However, this duty to report in regards to those involved in family counseling only applies in the case of physical abuse in the home.

1. *Socialtjänstslagen (1980:620)* §71 (as amended by Lag 1990:53).

§2. The Mental Patient

I. Compulsory Care

222. The legislation concerning compulsory psychiatric care is contained in the Compulsory Psychiatric Care Act.[1] Psychiatric care, and the theories of appropriate psychiatric care, have considerably changed since first version of the Act was adopted in 1966. During the 1970s and 1980s, psychiatric care took on a new direction based upon the idea that mental, social and psychological factors are relevant for the origin of mental disturbances. Psychotherapeutic methods of treatment have continuously been developed, and Sweden has been a leader in the research in this field. It has been realized that to help a person it is necessary to stimulate the activation of their own resources. Care consisting of passive treatment with psychopharmacological drugs is not in the best interests of the patient, except for special situations. Furthermore, it has been realized that a person cannot be institutionalized and thereby isolated from her/his environment and surroundings for a long period of time without negative consequences occurring for the individual.

1. *Lag (1991:1128) om psykiatrisk tvångsvård.*

223. A more nuanced perception of mental disturbances has replaced the former strictly biological concept of disease. This was largely the result of a government commission[1] which proposed that the concept 'serious psychological disturbance'

replace the old thinking of 'psychological illness.' This more modern concept gives a somewhat different and broader formulation of psychiatric problems than was provided by the previous concept directed toward illness of the individual.

1. *Psykiatrin, tvånget och rättssäkerheten* (Psychiatry, compulsion and security in the law) – SOU 1984:64.

224. It is an objective opinion that there is an acute need of care which must be the decisive factor to determine whether psychiatric care and treatment should occur without the full consent of the patient. The goal or purpose of compulsory care is to intervene in a crisis situation in order to put the mentally ill person in a situation so that voluntary treatment is possible.

225. The frequency of use and the extent of compulsory care has a very close relationship with a few related factors – the design of the statute, the organisation of the care, the prevailing opinion regarding mental disturbances and the ideology of care. Recently, there has been a clear decrease in the use of compulsory care. It is interesting that there are considerable regional differences in the extent of compulsory care. There is a clear connection between the number of patients in care and the availability of care; when more beds are available, there is the perceived need to fill them.

226. The legislation concerning compulsory care must regulate and determine which situations are so serious that the person must be taken into custody for psychiatric care. The circumstances in the society and our tolerance threshold towards a divergent conduct should always be taken into account when considering the question of when compulsory care shall be resorted to.

227. The compulsory nature of psychiatric care without the consent of the patient, requires that there are judicial safeguards in place for the protection of the individual. What this means in Swedish law, is that after the individual has been examined by a psychiatric doctor, the actual decision on compulsory care must be taken by a judicial authority with proper legal safeguards for the individual. In addition, if the society has the possibility to deprive a person of her/his freedom with a judgment that she/he is in need of care, the care and treatment must be appropriate and take place in a positive environment giving due respect for the patient.

228. When it comes to the psychiatric disturbed criminals, the Social Drafting Commission found that special rules concerning the care of criminals must be collected in special legislation about legal psychiatric care.

II. Voluntary Care

229. According to the Law concerning the Special Care of Psychologically Developmentally Disabled,[1] a developmentally disabled person who prior to the

age of 16 has suffered an injury or in some other way has a mental deficiency to the extent that makes it vital that she/he receives special assistance in order to be able to participate in the society, shall be given that help. Mental retardation falls into this category and is considered as a lack of development in intellectual capacity, which due to the surroundings or environment creates a challenge for the individual. When estimating the intellectual capacity, one must weigh together the psychological, societal and pedagogical factors. An individual who may be able to manage with the support rendered under the Social Welfare Act[2] and the Health and Medical Care Act and can manage without special care, is not included in the care responsibility of the local government according to these statutes.

1. *Lag (1985:568) om särskilda omsorger om psykiskt utvecklingsstörda m. fl.*
2. *Socialtjänstlagen (1980:620).*

230. Two other groups, who's situation is similar to that of the developmentally disabled, are entitled to special care. The first group are those who after the age of 16 have suffered a brain injury that has resulted in an important and continual reduction of their mental capacity. This can be due to a disease, such as a tumor, cerebral haemorrhage or an accident (e.g. traffic accident). Persons who have a mental handicap as a consequence of physical abuse, mental illness or senility are not included in this category. The second group consists of persons with childhood psychosis. Childhood psychosis begins as a rule before the child starts school and expresses itself in extensive divergences in social and emotional relations and in great disturbances in the ability to speak.

231. The Social Welfare Act and the Health and Medical Care Act regulation of the local governments' responsibility for social services and health and medical care includes care to meet the needs of the mentally challenged.

232. The border between the Law concerning the Special Care of Psychologically Developmentally Disabled, the Social Welfare Act, and the Health and Medical Care Act is not sharply defined. An individual may be in need of care covered by more than one or even all three branches of activity at the same time. It can occur that a difference of opinion arises between the different branches responsible for the care concerning which of them is primarily responsible in a particular case. Both the Social Welfare Act and the Law concerning the Special Care of Psychologically Developmentally Disabled make provisions for the possibility of appeal and administrative court in order to provide some measure of protection of the rights of the individual, particularly as it concerns financial allowances and the right to special care. If the hearing will not take place for some time, it is of the utmost importance and the responsibility of the social welfare authorities to ensure that the individual gets the help and support that they can provide (§2).

233. Special care is characterized by the principles of normalization and integration (§3). The possibility to live a normal life like others means genuine possibilities in reality, taking into consideration the handicap or challenge that the individual has. The goal is to assist the individual with special care so that they can utilize their own resources to the full capacity possible, with the intention of making it possible to live

an independent life as much as possible. Special care can compromise the following: advice, counseling and other personal support by a contact person, daily activity at a day center or other activities for those over school age lacking employment and not in the educational system, short time stay outside one's own home if necessary in a family home (living with a volunteer family), young persons home for teenagers or group-home for adults who cannot live alone (§4).

234. The right to special care is a legal right with the possibilities to appeal the decision. Special care cannot, however, be given against the will of a psychologically disturbed person (§6). A request for special care is the same as an explicit consent to that care. That means also that if and when the psychologically disturbed person explains that she/he does not want the care, it must cease. For those developmentally disabled persons who cannot give a binding manifestation of their will due to their youth or their handicap, the care shall be given on request of their custodian, guardian or administrator. The law provides that young people over the age of 15 who have the capability to form an understanding of their situation and what care is being offered, and who is able to express their will, cannot be given special care without their consent, even if it is contrary to the request of the custodian, guardian or administrator.

235. The National Social Welfare Board has ultimate responsibility over the supervision of special care. An accommodation between the different interests of State supervision and supervisory functions must occur between different interests, for instance of an increased local influence and the demand for legal security.

§3. The Dying Patient

1. Care at the End of Life

236. The primary task of medical care is to save lives. However, when a cure is impossible, it is important to give comfort, relief, help and whatever assistance possible to the dying person, and her/his relatives, and to provide for as good and dignified a death as possible. The personnel must show flexibility to the course of death and to have a readiness (preparedness) to vary the shaping of this very personal care.

237. The main rule is that the patient has the right to decide if he or she wants care or not. She/he may, in principle, determine what treatment she/he wants to expose herself/himself to. The question of a doctor abstaining from undertaking extraordinary measures because the patient is opposed to treatment, must be judged in each individual case. If the medical examination shows that death is near and that there is no possibility of a meaningful life, neither medical ethics nor the law requires treatment to be given.

238. If a patient who is suffering from a terminal illness with no prognosis for recovery, opposes treatment of the illness or injury, her/his will should be respected

under the precondition that she/he after reviewing detailed information and advice, keeps to her/his position. When a patient who is suffering from an incurable illness, which is physically or emotionally trying, but not in itself life-threatening, opposes treatment of a serious but incurable complication, a judgment must be made in each individual case.

239. If a patient after receiving comprehensive information, and despite the influence a doctor through her/his authority and position, remains opposed to treatment, the doctor as a rule shall follow the wishes of the patient as long as the mental abilities of the patient are considered to be intact. The doctor must take the risk of being responsible for not having acted in accordance with scientific knowledge and professional experience.

240. Compulsory treatment of a patient may only be taken in the case of mental illness or another mental abnormality within the provisions of the Compulsory Psychiatric Care Act.[1]

1. *Lag (1991:1128) om psykiatrisk tvångsvård.* See also the Judical Psychiatric Care Act (*Lag (1991:1129) om rättspskiatrisk vård*).

241. As a related issue, there has been a discussion of whether a patient may be treated against her/his will even for other diseases than that which is the basis for the compulsory treatment. It is generally accepted that medical treatment can be offered against the patient's will if the rejection of treatment is a consequence of her/his mental illness, especially when failing to treat would put the patient's life in danger. The National Social Welfare Board is of the opinion that it is impossible to specify under which circumstances it would be well-founded to stop treatment. Treatment will not be given for its own sake. A doctor has the duty to give treatment if she/he can save a life by doing so. It is obvious that exceptions must be made, and occur in real live situations. As there is no legislation explicitly dealing with this matter, the physician herself/himself must shape the norms of acting.[1]

1. *I livets slutskede* – SOU 1979:59.

242. But often the patient's attitude can be learned from oral or written manifestations of her/his will concerning the abandonment of life-sustaining treatment. These written documents are often named 'living will.' Is such a document binding on the responsible doctor? No – it is merely considered to be an indication of the opinion of the ill person and has no legal consequences.[1] That means that there is no hindrance for the doctor responsible for the patient to begin or continue a particular treatment or medical procedure.

1. SoU 1982/83:7.

II. Euthanasia

243. Before discussing euthanasia, the difference between active euthanasia and passive euthanasia should be made clear. Active euthanasia is when somebody by

an act deprives an ill person of life, for instance by giving an injection with the purpose to ending the suffering and allowing this person to have a calm and painless death. Passive euthanasia is the omission or withholding of certain life-sustaining treatment that can postpone the lethal effect of the illness. There is a general consensus, supported by judicial decisions, that active euthanasia is forbidden in Sweden.[1] A patient has no right to be killed and there is no duty for another to take a life in the exercise of her/his profession.

1. NJA 1979 p. 802, *The State vs. Berit Hedeby–Olsson*. See also Prop 1981/82:97, p. 118.

244. Passive euthanasia is allowed as long as further medial treatment would be meaningless, and the patient receives continued good care. If a patient who is suffering from a terminal illness with no prognosis for recovery, opposes treatment of the illness or injury, her/his will should be respected under the precondition that she/he after reviewing detailed information and advice, holds to her/his position. If the medical examination shows that death is near and that there is no possibility of a meaningful life, neither medical ethics nor the law requires treatment to be given. But this does not mean that the doctor may assist in the patient committing suicide.

III. Suicide

245. An act of suicide is often not an expression of a well thought-out wish to take one's life. One can never be certain if the patient actually wanted to take her/his life. Therefore, professional responsibility and medical ethics requires treatment to be given, almost without exception, to save life in this situation.

IV. The Concept of Death

246. Since 1988 Sweden has had a new and statute-regulated concept of death. The Law concerning Criterion for Determination of Human Death[1] gives provisions for statutory rules to assist in the determination of when death has occurred. This statute is applicable for every application of law or other regulation that prescribes the death of a person in the legal meaning. Until the enactment of this statute, there was no precise rules to determine when death had occurred; guidance was obtained from other legal sources.

1. *Lag (1987:269) om kriterier för bestämmande av människans död* (Determination Law).

247. Traditionally a person's death was considered to have occurred when the heart stopped beating or breathing ceased. These heart-related criterion had been applied for a long time without any great problems coming up. In recent years, however, great advances in medicine and other circumstances have resulted in that this criterion is no longer a self-evident definition of death. The improvement in intensive care and the technical equipment available today have given us the result that the cessation of the beating of the heart and breathing functions are no longer the same as death. For ethical and legal reasons a clearer legal definition of death

became necessary. The prospect of cooperating with other countries in Europe in transplantation of organs has also made the need for a modern definition more urgent.

248. According to the Determination Law, a person is dead when all functions of the brain totally and irrevocably cease. Thus, the definition concerns the cessation of all functions in all parts of the brain, whereby death ensues. According to the Determination Law the legal effects of a person's death then arise.[1]

1. See SOSFS (M) 1987:32 'Regulations and general advice concerning application of the *Lag (1987:269) om kriterier för bestämmande av människans död.*'

249. A doctor will decide in accordance with scientific knowledge and professional experience when death has occurred. This may be established by determining if the breathing and blood circulation have ceased and the standstill has been for such a long time that without doubt can be determined that all functions of the brain have totally and irrevocably ceased. By indirect criteria, usually permanent cessation of heartbeat and breathing, almost all deaths are established (over 99 per cent of all deaths according to the preparatory works). Direct criteria are used to establish that death has occurred when breathing and blood circulation are maintained in an artificial way when a person is treated in a respirator. Death shall in such cases be established through an investigation of the brain showing that all the functions of the brain have totally and irrevocably ceased. Two methods of investigation can be used:

(a) Clinical neurological investigation, with an electroencephalogram (EEG);
(b) X-ray investigation of the blood circulation in the brain (cerebral aertocranial angiography).

250. When death is established, all medical measures will immediately be discontinued. However, there are two exceptions: when a woman is pregnant, and when an organ will be removed for transplantation.

Chapter III. Specific Activities

§1. The Unborn Child

251. The ethical issues and legal regulations concerning the unborn child have often been a topic of intense debate. The legal systems in the Western world have historically treated the unborn child, the foetus, as part of the woman carrying it and have given it few rights as an independent entity. In recent years, however, legislatures have increasingly granted foetuses a claim to life similar to those enjoyed by a child after birth, as the medical technology has made possible artificial ways of reproduction and independent life outside the woman's womb at an early stage of development, and also as abortion has become a commonly used method of hindering birth and, finally, as a result of the increasing possibilities of research on foetuses. When viewing the foetus as an independent entity of the pregnant woman, the interest of the foetus sometimes potentially conflicts with the interests of the woman (as in when the woman seeks an abortion). In other areas, such as research on foetuses, the interest of the foetus may hinder a development in society where the child may become a means, rather than an end in itself, to experiment and research.

252. The legal status of the unborn[1] is regulated only to a very limited extent in Swedish law. There are some legal rules contained in family law legislation, such as that giving the unborn the right to inherit,[2] and presumption of paternity to be given to the woman's husband if the child is born within nine months after a divorce or the death of the husband.[3]

1. Andersson, Issues concerning Reproduction in Sweden and the United States, p. 6ff.
2. Ärvdabalken 1:1.
3. Föräldrabalken 1:1.

253. The dividing line between the legal status of 'foetus' and the legal status of 'child' is not defined in the law. When one speaks of human values and human rights, one is usually referring to a human individual, a person. But when does life begin? At what point does the potential individual gain full human 'value'? In a *proposition*,[1] the Genetics Commission outlined three common opinions of when life begins. The first is that human life begins with conception; it is at this point in time that the (potential) child receives its heredity factors, and these are unique. The second opinion is that human life begins with implantation; it is then (approximately 10 days after conception) that the development of the nervous system begins, which is necessary for sustaining life. The third opinion is that human life begins at conception, but because it demands growth and development it is not meaningful at this point to speak of a person, or human life, thus it is a *potential* life which cannot, from the beginning, be compared with actual human life. The Commission agreed with the last opinion.[2] The Swedish Government Medical-Ethical Commission has, in a statement to the National Social Welfare Board, been

unwilling to define in detail the beginning of life, and only states that human zygotes and blastems are 'life in the making.' Thus, there is no one commonly used and shared definition of when life begins in Swedish law and when the foetus gains a claim to life. The difficulty in finding a medical and ethical definition partly explains the lack of a legal definition. Principles which help to formulate the legal rules in issues like these often stem from universal human values and ethical considerations. Without a firm ethical and medical position as to when life begins, it is therefore difficult to have a legal position. As discussed below, some 'practical' definitions have been created in a few areas of law, such as in fertilization. But no one definition exists which could be utilized as starting point for other definitions.

1. Prop 1990/91:52.
2. Prop 1990/91:52, p. 16–17.

254. The National Social Welfare Board has published recommendations on borderline 'born alive – stillborn' cases:

> With a child is meant all born alive, and those stillborn after the 28th week of pregnancy. The child is born alive if it shows signs of independent life, such as breathing movements, heartbeat, ... Stillborn are those who do not show such signs and who have died after the end of the 28th pregnancy week. If uncertainty exists about the duration of the pregnancy, the length of the foetus should provide guidance. If the length of the body amounts to at least 35 cm, the foetus should be considered to be a child.'[1]

1. SOSFS (M) 1987:1.

§2. Termination of Pregnancy

255. According to the first Swedish Law concerning Termination of Pregnancy,[1] which in fact was not a legalization of abortion but rather provided for specific exceptions to the Criminal Code's provisions criminalizing abortion, abortion was in principle not permitted. Pregnancy could be terminated, however, if any of the abortion indications stated in the law were fulfilled: medical, humanitarian, eugenic, and, added in 1946, socio-medical. Thus, the law allowed for abortion if the woman's health was threatened, if she was pregnant because of rape, or if she carried a serious hereditary disease, and later, also if she physically or psychologically may not be able to handle the pregnancy. In 1963, a fifth indication was added to the Law, the *fosterskadeindikationen* or injured foetus indication. The examination to determine if any of the indications were fulfilled was made by two physicians or by the National Social Welfare Board.

1. *Lag 17 juni 1938 om avbrytande av havandeskap.*

256. In the 1960s, the Abortion Commission began its work to investigate the situation and propose a new abortion law.[1] The question of a new abortion law was also a hot topic of debate in the media. The views of women and her role in the society had changed and a reform of the stringent abortion legislation was needed.

After much revision of the Commission's proposal[2] and further work in the Parliament, the Abortion Act[3] was approved by the Parliament in 1974. This law, unlike the former statute which it replaced, was based on the principle that it is the woman's right to decide herself whether to terminate the pregnancy or not, within the framework of certain time limits. In 1980, a new Abortion Commission was appointed to carry out an evaluation of the Abortion Act, and its report showed that the intentions behind the 1974 Abortion Act had substantially been fulfilled.[4] In the final report of the Commission on the Unborn Child late abortions were examined.[5] This issue will be discussed below.

1. *Rätten till abort* (The Right to Abortion) – SOU 1971: 58.
2. Prop 1974: 70.
3. *Abortlagen (1974: 595).*
4. *Familjeplanering och abort* (Family Planning and Abortion) – SOU 1983:31.
5. *Den gravida kvinnan och fostret – två individider. Om fosterdiagnostick. Om sena aborter* (The Pregnant Woman and the Foetus) – SOU 1989: 51.

257. In the past few years, approximately 100,000 children were born and approximately 37,000 abortions were carried out per year in Sweden. More than 90 per cent of these abortions are performed before the 12th week of pregnancy, and only 250 abortions are performed after the 18th week of pregnancy. Approximately 35 per cent of these late abortions are carried out because of the discovery of that the foetus is damaged; otherwise, the reasons are mostly psycho-social.[1]

1. SOU 1989:51, p. 60.

258. According to the Abortion Act, abortion is, as a rule, allowed if the woman, after mature consideration, demands termination of her pregnancy. It may be done before the conclusion of the 12th week of pregnancy, under the condition that it may not seriously risk the woman's life or health (§1). Abortion between the 13th and 18th week requires that the termination of pregnancy is preceded by an investigation of the woman's personal circumstances (a so-called personal investigation) (§2). After the end of the 18th week of pregnancy, termination of pregnancy is allowed only after permission of the National Social Welfare Board (§3). Such approval may be given only if extraordinary reasons exist for the abortion and will not be given if it can be presumed that the foetus is capable of life, except if it can be assumed that the pregnancy may cause serious risk for the woman's health or life because of illness or wrong bodily structure. Pursuant to current practice, abortion is not permitted after the 22nd week of pregnancy.

259. The basis for the Abortion Act is that the foetus in the beginning is a part of the mother's body, but later develops more and more to an human individual with an independent claim to life. At some point a 'conflict of interests' occurs. It is this viewpoint that lies behind the provision that abortion, in principle, may not be carried out after the end of the 18th week of pregnancy. The Commission on the Unborn Child stated that the interpretation of the Abortion Act should be based on the premise that the mother and the prospective child are two separate individuals, both of whom are deserving protection. The developing human life has a great intrinsic value. However, until the pregnancy is advanced, the foetus is completely

dependent on the mother's body for development to an independent individual. If the mother has reasons for not wanting to carry pregnancy to term, her interests have priority up until the 18th week of pregnancy. Thus, here, the Commission states, the Abortion Act allows the interest of the mother to take precedence over the interest of the foetus up until the point of viability. The Commission argues that humanitarian reasons decide the weighing of conflicts of interests between the mother and the foetus, i.e. the woman has greater claim to life than the foetus up until the end of the 18th week of pregnancy. From this reasoning, does it follow that the Commission believes the foetus gains a full claim to life at the end of the 18th week of pregnancy? Have they drawn the line between foetus and human individual – and thus the point where one gains a full claim to life – at the 19th week (or at viability, which is also mentioned in the statutory test as a borderline situation. The Commission report does not discuss this issue as the Commission did not want to give an explicit definition of the borderline between the status of foetus and the status of human individual.

260. One may draw the conclusion that the viable foetus does not in all situations have the same claim to life as the woman, i.e. according to §6. In this paragraph it is stated that the National Social Welfare Board may give permission for abortion even after viability if the pregnancy because of illness or wrong bodily structure of the woman will constitute a serious risk for the woman's health or life. One may conclude from this that the claim of the woman is given priority in certain situations even after the drawn 'line' when the foetus has become an independent human individual, thus explaining why the Commission did not want to create a definition of where the 'full' claim to life begins. Had it found that there was an absolute right to life at the point of viability, it would have been impossible to keep §6 in the statute. It may still seem as if the Commission is unsure where to draw the line, on the basis of ' humanitarian reasons.' Instead of making a clear and definite line, they seem to have drawn a 'practical' line at viability, and then added the exceptions in §6. They may have reached the conclusion that such a practical solution is the best way to solve such a difficult issue as the claim to life; it seems impossible to draw a rigid line in the conflict of the right of the mother versus right of the foetus when no such medical and ethical line exists. A practical solution such as the one in the Swedish Abortion Act then seems appropriate.

§3. Medically Assisted Insemination

261. Medically assisted insemination has been performed in Sweden since the beginning of the 20th century. A Swedish Government Commission in 1953 gave recommendations on donor insemination,[1] but it did not result in any legislation. The reasons for this may have been that there were very few medically assisted inseminations done in Sweden at that time and that a strong resistance to donor insemination existed. In addition, there were plenty of Swedish children available for adoption. The interest in medically assisted insemination did, however, grow – both in Sweden and abroad. In the middle of the 1980s, on average 230 children were born annually in Sweden by donor insemination.[2] For many years, however, both in Sweden as

well as abroad, judicial regulation and public control of this activity was entirely non-existent. In 1981, the government appointed a Commission to examine the matter of medically assisted insemination. In its report, the Commission submitted proposals for statutory provisions with regard to insemination by a husband/partner as well as by a donor.[3] In 1984, the Law concerning Insemination[4] was enacted.

1. *Förslag till lagstiftning om insemination* (Recommendation for Legislation concerning Insemination) – SOU 1953:9.
2. SOU 1983:42 p. 202.
3. *Barn genom insemination* (Children by Insemination) – SOU 1983:42.
4. *Lag (1984:1140) om insemination.*

262. The provisions governing medically assisted insemination in Sweden are contained in the Law concerning Insemination, which came into effect in 1985. 'Insemination' is defined as the introduction of sperm in a woman in an artificial way.

The statute distinguishes between two kinds of insemination, 'husband insemination' and 'donor insemination. Husband insemination is with sperm from the woman's husband or cohabitant, and donor insemination is with sperm from a man who is neither the husband nor cohabitant. Donor insemination may only take place at a hospital under the direction of a doctor with special competence in gynaecology and obstetrics.

263. Thus, the statute makes no provision for insemination for a single woman or two women living together; in fact such medically assisted insemination is prohibited by the statute.[1]

1. *See Barn genom insemination* (Children by Insemination) – SOU 1983:42.

264. The donor must consent to the insemination. The husband/male cohabitant must give written consent for the insemination. The reason is that the consent has decisive weight in placing legal responsibility for the fatherhood on the man. After the insemination has been performed, the husband/male cohabitant who has given consent is irrevocably the legal father of the child.

265. Donor insemination may only be performed at public hospitals under the supervision of a medical doctor with specialist competence in gynaecology and obstetrics. The doctor will conduct a medical and psychosocial examination of the couple. She/he will then examine the physical and psychological health of the woman and the fertility of the husband/cohabitant. Insemination is not considered medically acceptable if, for example, the pregnancy may endanger the woman's health or a genetic defect of the woman may endanger the child's health, or if the couple has good chances of conceiving a child naturally. Insemination should be approved only if it can be assumed that the child will receive a good home and childhood.

266. If a couple are denied insemination, they may ask the National Social Welfare Boards to examine the case, but there is no appeal from a decision of the Board.

267. It is not permitted for frozen sperm to be imported into Sweden without the special permission of the National Social Welfare Board.

268. The rights of the child to know who her/his biological father is are regulated in §4, which provides that a child who is sufficiently mature may obtain the information on the sperm donor. The National Social Welfare Board is obligated to assist the child to obtain the information. The information is to be kept in a special journal, which shall be kept for a minimum of 70 years (§3). This is an exception to the privacy rules in the Privacy Act 7:3. The man must therefore be informed in advance that the child may contact him later in life.

269. The law does not allow medically assisted insemination in other forms than those regulated, under penal of law. Anyone who pursues medically assisted insemination not under public control on a regular basis or for the purpose or profit is subject to penalty of a fine or imprisonment for a maximum of six months.

270. The basis for the legislation is that the activities relating to medically assisted insemination must be carried on only in regulated forms and under strict public control. For example, only some public hospitals are permitted to perform a medically assisted insemination. The meaning of this strict supervision of these activities is to avoid many difficult and unclear situations for the child, the biological father or the social and legal father when no supervision exists to supervise this activity. Thus, the legislation in Sweden is meant to, in advance, secure a well developed family law surrounding the child born after an insemination procedure.

271. The rules have been formulated so as to emphasize the 'best interest of the child.' Therefore, rules have been created to regulate who the parents are, who has custody and the responsibility of support. It was the opinion of the Commission that the child should be able to grow up in a family with a mother and a father, the parents should not be too young (or too old), the child should later in life be able to know who his/her biological father is and obtain information about him, a situation where the child may inherit genetic defects should be avoided, etc. Thus the emphasis is completely on the child's best interest; the parents are strictly examined and controlled. The whole procedure may be compared to the adoption procedure. In sum, the possibility of medically assisted insemination is looked upon as a potential threat to the structure of the family in the society and also as a procedure which may harm the individual, the child, who is the result of the procedure. To avoid an undesirable result of the use of the technology, regulations exist to restrict the use of the technology.

272. Regarding donor insemination, is not easy to provide accurate figures for either inseminations or births. For one thing, there is not diligent follow-up by hospital staff. This is partly due to the Swedish legal rule whereby a man only be a donor in not more than six successful (resulting in birth) inseminations. With the present day lack of donors, hospital staff are not too eager to discourage qualified donors. For another, a woman may desire confidentiality and may not wish to disclose to others that her conception was accomplished by means of medically

assisted insemination. There is also a consideration of privacy of the parties; although *the child* has the right to access to the information, this is otherwise confidential medical information (the fact that one has been conceived by means of medically assisted insemination).

After saying this, however, we can say that there are perhaps between 50 and 100 births by means of donor insemination in Sweden per year presently. However, this is only an estimation, and although it is based on the figures available, may not represent the actual figures. In addition, there may be a significant number of births by means of medically assisted insemination which has taken place outside of Sweden.

§4. Other Reproductive Technologies

273. In addition to medically assisted insemination, a variety of other techniques are available nowadays to medically assist with conception. The underlying theme of these techniques, which are referred to as 'reproductive technologies,' are that the fertilization occurs outside the woman's body.

274. In vitro fertilization (IVF) is used in cases where the woman has defects on her ovaries or when the man has too low a sperm count for fertilization in a natural way; several eggs are taken out from the woman's ovaries, are fertilized, and finally brought back to the ovaries. The only form of *in vitro* fertilization used in practice in Sweden in when the egg and sperm of a married couple or a couple living together are fertilized outside the woman's body.

275. Another form of *in vitro* fertilization is where the egg of a female donor is fertilized with the sperm of the husband (if the wife/cohabitant is infertile) and then brought to the infertile woman's body. This method could be used if the woman is unable to produce eggs or if she carries a serious hereditary disease, which may be carried over to the child. In some countries, including the United States, this method of fertilization is available.

276. A similar form of *in vitro* fertilization is the case when the woman's egg is fertilized outside her body with the sperm of a male donor not her husband/cohabitant and then brought back to the woman's body. This method could be used in cases where the man is infertile or carries on a hereditary disease, and the woman's ovaries are damaged.

277. Another technique of fertilization is using both a donor egg and donor sperm. This is called 'adoption *in vitro*' and may be used when both are infertile. The fertilized egg is then implanted in the body of the woman who has 'ordered' the baby. This method is used in some countries, but it is not permitted in Sweden.

278. Surrogate motherhood should also be mentioned here. This entails a woman being fertilized with a sperm or/and egg from the couple who will receive

the child after its birth. The surrogate mother will give birth to the child and then hand it over to its future parents, often for financial compensation. This method is also practiced in some other countries, but it is not permitted in Sweden.

279. These reproductive technologies were essentially unregulated in Sweden until recently as there was no legislation, nor any need for such legislation. The insemination Commission from 1981 issued a report in 1985.[1] From the legislative proposal[2] followed the enactment the Law concerning In Vitro Fertilization which took effect in 1989.[3]

1. *Barn genom befruktning utanför kroppen mm* (Children by *in vitro* Fertilization) – SOU 1985:5.
2. Prop. 1987/88:160.
3. *Lag (1988:711) om befruktning utanför kroppen.*

280. In vitro fertilization is a technically sophisticated and fairly resource-demanding method. Birth is successful in 15–20 per cent of the cases.[1] Since 1978 – the year when the first 'test tube baby' was born in England – *in vitro* fertilization has become a fairly commonly used method in many countries. It is practiced in more than 500 clinics in the world; so far over 5,000 children have been born after IVF treatment.[2] More than 150 children have been born in Sweden by IVF since 1982 when IVF was first used here.

1. Prop 1987/88:160, p. 6.
2. Prop 1987/88:160, p.6.

281. The Law concerning In Vitro Fertilization[1] is the statute which provides the legal regulation of fertilization of a woman's egg outside her body (§1). The only method allowed in Sweden is the first method described above, i.e. fertilization of the woman's own egg by her husband or cohabitant's sperm (§2). Thus, for IVF neither eggs nor sperm may be donated under Swedish law. The activity is further limited by three prerequisites: (1) the woman must be married or cohabiting with a man, and (2) consent in writing is required from the husband/cohabitant, and (3) the egg must be the woman's own egg and fertilized with her husband's/cohabitant's sperm. According to the preparatory work, written consent is needed also for freezing fertilized eggs or for using the fertilized eggs for methodological research to improve the IVF technique. This written consent may be withdrawn. Thus, similar to the Swedish rules concerning medically assisted insemination, the written consent is a very important and emphasized part of the artificial fertilization procedure.

1. *Lag (1988:711) om befruktning utanför kroppen.*

282. The practice itself is supervised by the National Social Welfare Board. The *in vitro* fertilization procedure may only be done at a public hospital, or another place that has received permission from the National Social Welfare Board (§3).

283. The importance of strict supervision with public control is emphasized. As with medically assisted insemination, anyone who for profit or on a regular basis

engages in *in vitro* fertilization in violation of the statute may be subject to penalty of a fine or imprisonment for a maximum of six months (§4).

284. In looking at the language of the Law concerning In Vitro Fertilization, it is easy to see that the legal rules for *in vitro* fertilization and those for medically assisted insemination are very similar, in fact sometimes identical. The reason for this that the two statutes are regulating very similar questions: two methods of artificial fertilization which bring into question the issues of parental rights and responsibilities, and issues relating the best interests of the child. Both are very important issues for the society.

285. The statutes regulate similar family law questions, those concerning parental rights and responsibilities. For example, it is required that written consent be obtained from the involved parties. Like the Law concerning Insemination, the intention with the Law concerning In Vitro Fertilization is to avoid future family legal conflicts relating to questions of the status of the child, for example, who the biological 'parent' is, who has the responsibility of support, and who the legal parent is. Thus, the legal family issues are regulated identically.

286. In looking at the constitutional and regulatory issues involved, it sometimes becomes an intense discussion of who's interest is being protected and to what extent the Swedish legislature has overly restricted the activities of *in vitro* fertilization. The legislation reflects the same suspiciousness that exist Law concerning Insemination, i.e. the unwillingness of allowing a new technology of reproduction to evolve new family structures in the society. There is a concern that such 'experimentation' will be at the expense of the (potential) child. The statute therefore emphasizes supervision, public control, and a very limited use of *in vitro* fertilization in Sweden, i.e. it limits the availability of such medical procedures to women who are married to or cohabiting with a man, using their own sperm and egg. In addition, certain forms of reproductive technology, surrogate motherhood for instance, are not allowed in Sweden.

287. In the preparatory work of both statutes one may find the emphasis on the 'best interests of the child.' As this phrase is used so frequently, it should be noted that in Sweden as elsewhere, the issue of which family structure is 'best for the child' is controversial. The Swedish legislature has concluded with its legislation that the best interests of the child requires a nuclear family, i.e. a family structure of a man and a woman living together. Reading between the lines in the Commission's report, however, this 'conclusion' may also be viewed as representing an interest of the state to retain and preserve the traditional societal structure of a man and a woman living together with (or without) children.

§5. Prenatal Diagnostics

288. In recent years, many new methods of foetal diagnostics have been developed. These new methods have created ethical, psychological and legal dilemmas.

289. The overwhelming number of foetal diagnostics are carried out routinely at the maternity clinics. They are based on the premise of creating the best possible conditions for the growth of the foetus and can, therefore, be described as concentrating on the foetus, i.e. it is carried out in the interests of the foetus.

290. The form of diagnosis which is based on diagnosing treatable diseases can be described as concentrating on the foetus. Today, the potential for treating diseases during the foetal stage is very limited. The long-term aim is to create, in a more general sense, a situation where it is possible to treat diseases of the foetus in the womb before incurable damage has occured.

291. Foetal diagnostics can furthermore be used as an aid in delivery preparations so that it gives the potential for an improved state of preparedness if the foetus is in some way injured. The diagnostics are of importance for the parents-to-be psychologically as well as for the hospital with regard to suitable treatment in connection with and after the delivery.

292. Foetal diagnostics should also have a generally calming function for women who have, for example, previously given birth to a deformed child, or women above a certain age who are worried that the foetus is deformed and would demand an abortion if reassuring information could not be given.

293. Foetal diagnostics can, in addition, be aimed at discovering diseases and deformities which may motivate the termination of the pregnancy. This may apply to a foetus which is so severely damaged that it could not survive a delivery or would die shortly after the delivery. The diagnostics do, however, also provide information about less serious injury or handicap.

294. As a result of the ever increasing technology with regard to foetal diagnostics, it is has become easier to discover evermore diseases and deformities of the foetus. The parents-to-be, who are informed that the foetus is damaged in some way, are faced with a difficult dilemma with regard to deciding whether or not they want to terminate the pregnancy or not.

295. Foetal diagnostics is, today, not available to all pregnant women. It is offered to women who fall within a so-called risk group, i.e. who run an increased risk of giving birth to a child with some form of deformity or disease the existence of which could be established through foetal diagnostics.

296. In the opinion of the Commission concerning the Unborn Child,[1] foetal diagnostics should only be allowed for the purpose of checking the progression of the pregnancy or in order to determine if the foetus is suffering from any serious injury or disease. Foetal diagnostics should not, however, be permitted to be used for the purpose of determining the gender of the child if this is not – as would be in the case of for example hemophilia – medically motivated.

1. *See* its report, *Den gravida kvinnan och fostret* (The Pregnant Woman and the Foetus) – SOU 1989:51.

297. The Commission proposed that the current prerequisites for foetal diagnostics should be abolished. It shall, in the view of the Commission, to the greatest extent possible be the woman herself who decides whether she wishes to undergo foetal diagnostics. Such a solution tallies well with that which otherwise applies in the matter of early abortions and which is based on the idea that there is no one better qualified than the woman herself to adjudge her situation and her potential for taking care of a child.

298. It is the duty of the responsible physician to determine whether the concern which the woman feels is well grounded, as it is not the patient alone who shall decide. It is the physician, in the end, who determines what medical treatment a patient should receive, although a woman can refuse the offered treatment or procedure. Many pregnant women will probably feel a natural anxiety about the development of the foetus. If there is no substance for such a concern, there shouldn't be a justification for carrying out foetal diagnostics. The woman should, instead, if the physician cannot reassure her, be offered psychological help in order to put this anxiety into the correct proportions.

299. In certain cases, however, a woman's concern may be occasioned by some circumstance which increases the normal risk of serious damage or disease to the foetus, e.g. that the woman has reached a certain age or that she has previously given birth to a child who is deformed. It may also be the case that a woman feels such severe concern during her pregnancy that – despite help being offered – it is affecting her general state of health. These factors may motivate foetal diagnostics.

300. In accordance with the basic principles of public health care, a woman shall, prior to foetal diagnostics, be informed of the diagnostic possibilities available and on what terms they are available. She should be further informed of the limitations and risks of foetal diagnostics, as well as the risks of damage to the foetus which might exist.

301. The examinations which are to be offered are, pursuant to general principles, determined by the treating physician in consultation with the patient. A patient cannot demand an examination which the physician does not consider to be motivated and compatible with science and tried and tested experience. On the other hand, a patient may refuse an examination which she does not desire.

302. In all types of foetal diagnostics examinations it is important, in the view of the Commission, that correct and detailed information be given. In so-called screening examinations, i.e. examinations which are offered on a routine basis to large groups of women, it is particularly important that information is given in such a way that the woman feels that she has freedom of choice.

303. In the view of the Commission, one must operate under the premise that the mother and the prospective child are two separate individuals, both of whom are deserving protection. Even with this viewpoint, it is obvious that one must, sometimes, allow the interests of one to take precedence over the interests of the other.

The developing human life has a great intrinsic value. It cannot be viewed purely as a part of the woman's body. Until the pregnancy is advanced, however, it is totally dependent on the woman's body for its development into a developed human life-form. In the absolutely overwhelming number of cases, the woman happily looks forward to giving birth to her child. However, in the situation where foetal diagnosis discovers a serious defect in the foetus, it is the woman herself who shall decide if she shall abort the foetus or carry it to term. Humanitarian reasons speak in favor, in this case, of her interest in being allowed to weigh more heavily than the interests of the developing human life.

§6. Ethical Issues in Relation to Genetics

304. In 1982, the Swedish Government appointed a commission to make an inquiry into the ethical, humanitarian and social issues, arising from the use of genetic engineering (recombinant DNA techniques, rDNA techniques). The members of the Gene-Ethic Commission represented the various political parties in the Riksdag, and included experts from various fields of science and society. [1]

1. *See* its report, *Genetisk integritet* (Genetic Integrity) – SOU 1984:88.

305. An important task for the Commission was to consider the need of legislation or other regulation of the ethical or social issues, and if necessary to propose measures (laws) to limit certain applications of rDNA techniques on living organisms, including man, animals, plants and microorganisms. The main point, however, concerned the future use of the techniques on man. It was clear from the instruction to the Commission that it should not deal with environmental hazards connected with these techniques.

306. The Commission soon found that questions about the protection of the human genome also lead to questions about the protection of the fertilized human ovum (zygote) and of the early embryo. Accordingly those questions had to be included in the inquiry.

307. The considerations of the Commission on DNA-based diagnosis resulted in the following proposals of ethical norms:

1. Research and experiments on zygotes and embryos are acceptable, provided that they are medically well founded, that they are performed within 14 days after fertilization (freezing time not counted) and that the donor of the eggs or sperm has given her/his free and informed consent. Embryos *in vitro* must not be allowed to develop after 14 days of age.
2. Human zygotes and embryos exposed to experiments must not be implanted and developed *in vivo*.
3. Research and experiments on human somatic cells (in cell or tissue culture *in vitro*) are accepted.
4. Laboratory work with human DNA outside the living cells is accepted.

5. Research and experiments on human germ cells (sperm and unfertilized ova) are accepted.
6. Research and experiments aimed at gene therapy on human somatic cells are accepted.
7. If it is feasible to perform gene therapy on human sperm, ova, zygotes and early cells blastomeres a reliable way, and implantation is to be considered, then the procedure must come under a severe ethical examination which should include full knowledge of all the consequences.
8. Experiments on a live aborted embryo or foetus should be considered in the same way as those on a child.
9. The use of prenatal DNA-based diagnosis should be restricted to severe genetic diseases which threaten the development of the foetus or the child. The doctor, in consultation with the parents (mother), should decide whether or not to use a DNA diagnosis. The decision should be made with respect to the relevant guidelines and regulations.
10. DNA-based diagnosis may be used in public health investigations on genetic diseases if the investigation has a clear medical aim and if the collected genetic information is reliably protected. Participation in such public health investigations is voluntary and requires free and informed consent.
11. Recording, storing and use of genetic information from individuals shall be medically motivated. The individual involved shall give her/his free and informed consent.

In discussing legislation and other regulation, the Commission distinguishes between the application of rDNA techniques in research on man, and the application within medical care.

308. According to the instruction, the task of the Commission was to consider the need for legal restrictions on the genetic manipulation of man. The Commission discussed the necessity of having a special provision in the Constitution to protect the genetic integrity of the individual. Such a rule could be a very effective barrier against genetic manipulation of man. However, the Commission did not find the time ripe for such a measure. The Council of Europe has had the question under consideration and the opinion of the Commission was that any action regarding constitutional rules should wait for the Council of Europe's proposals in this respect.

309. Another legal question is whether the ethical norms proposed by the Commission concerning research should be the basis for a legislation. The Commission, however, preferred to let them remain and function as ethical norms, similar to the norms of the Helsinki declaration concerning biomedical research and experiments on man. The norms proposed by the Commission should, therefore, not be given the status of law.

310. But the opinion in this respect has changed. Now there are statutory regulations concerning measures for the purpose of research or treatment with fertilized human ova[1] and concerning the use of certain genetic techniques in a general health examination.[2] Special permission from the National Social Welfare Board is required for such an investigation. The content of the legal rules are substantially

the same as the above-mentioned ethical norms. Another commission, the Gene-Technic Commission has been appointed by the Swedish government and has recently published a proposal.[3]

1. *Lag (1991:115) om åtgärder i forsknings – eller behandlingssyfte med befruktade ägg från människa.*
2. *Lag (1991:114) om användning av viss genteknik vid allmänna hälsoundersökningar.*
3. Genteknik – utmannig (Genetechnics — a challenge) — SOU 1992: 82.

§7. Sterilization

311. What is meant by sterilization in the Sterilization Act[1] is a medical measure which permanently or temporarily stops the eggs or sperm from reaching their destination without influencing the individual's sexual drive.

1. *Steriliseringslagen (1975:580).*

312. Every method of sterilization is covered by the statute whether it is sterilization by surgery, with chemical measures or by some other method that in the future might replace the present methods of sterilization. The statute does not cover, however, procedures of strictly therapeutic nature, i.e. those that are performed as a part of the treatment of a bodily disease.

313. The main rule of the statute is that a person has in principle the right to decide over her/his body. A precondition for the procedure to be performed is that the person is over 25 and is a Swedish citizen or resides in Sweden (§2). If a request for sterilization is denied, the question will immediately be submitted to the National Social Welfare Board (§2).

314. Sterilization may not be performed until the person requesting the procedure has been carefully informed what the procedure involves and the consequences, and where appropriate, of other possibilities to prevent pregnancy (§5). Information may be given by physicians, midwives and counselors. In order to make it possible for the surgeon to make sure that such information has been given, both the person who has given the information and the person who has received it must sign a confirmation which will be placed in the patient's journal. The National Social Welfare Board has developed a form for this as well as the application form for requesting sterilization.

315. Only licensed medical doctors are authorized to perform a sterilization (§6). If the sterilization is to be done on a woman, the surgery will be performed in a hospital or other medical institution approved by the National Social Welfare Board. There are no statutory provisions requiring a sterilization of a man to be done in a hospital. If someone intentionally performs a sterilization against the law, she/he may be punished with fine or imprisonment for a maximum of six months (§8), if the act is not punishable according to the Penal Code.[1] The rule is applicable for both physicians performing a sterilization complying with the legal requirement, and unlicensed persons performing the procedure.

1. BrB 3:8.

316. If a person between 18 and 25 requests to be sterilized, the National Social Welfare Board may give permission if there is a considerable risk that hereditary characteristics might be transmitted to the descendants, which could result in serious mental illness or abnormity, malignant bodily disease or serious defect of another kind. This is called a genetic indication. For a woman in this age group, sterilization can be approved if the pregnancy as a consequence of illness, defect or 'weakness' would lead to danger for the life or health of the woman. The concept of weakness can cause problems of interpretation. With 'weakness,' the statute intends a divergence of medical character such as weak health, fragile constitution of the body or neuro-asthenic disposition. That means a state of health that clearly diverges from what is considered normal. This is called the medical indication.

§8. Castration

317. What is meant by 'castration' is the removal of the sex glands or in another way to medically disable them with the intent of altering the sex drive of the individual. According to the Law concerning Castration,[1] castration may be performed if there are valid reasons to believe that a person may, due to her/his sex drive, commit a serious crime putting another in danger. The law requires the consent of the person undergoing the castration, but also provides that if someone due to mental abnormity lacks the ability to give an informed consent to castration, he may be castrated if there are special reasons. Castration of persons convicted of sex-crimes is no longer permitted in Sweden.

1. *Lag (1944:133) om kastrering.*

318. Castration is performed for humanitarian reasons, however, upon the request of the individual with a statement from two physicians. No persons under the age of 23 may be castrated except if permission is received which is only given in situation where there are special reasons. The number of permissions granted is small, less than 10 cases per year.

319. The surgery must be performed by an authorized physician in Sweden and the procedure must be done in a hospital or other medical institution approved by the National Social Welfare Board. A person who performs castration against the law may be required to pay a fine or be sentenced to imprisonment for a maximum of six months, unless a provision the the Penal Code[1] is applicable.

1. BrB Chap 3.

§9. Transplantation

320. The legislation in force concerning transplantation, the Transplantation Act[1] regulates the performance of such procedures where organs and other biologi-

cal material are taken from a living or deceased person for treatment of illness or the bodily injury of another person. The statute does not apply to minor and common medical procedures, such as taking blood, removing skin, or taking a cornea from a deceased.

1. *Transplantationslagen (1975:190). A new regulation will propably be in force during 1993.*

321. The fundamental precondition for an organ to be taken from a living person for transplantation is that the individual has in writing and of free will consented to the procedure. A consent once given can be revoked orally or in writing at any time prior to the procedure. It is the responsibility of the doctor who has the primary responsibility for the procedure to ensure that there is a valid and informed consent, which means one that has been given of free will and with knowledge of the risks involved. The prospective recipient must also have information from the responsible doctor, and must give an informed consent.

322. A young person under 18, or a mentally incapacitated person who lacks the ability to give consent, may be a donor only if there are medical reasons and after permission has been obtained from the National Social Welfare Board. Permission is given if there are special circumstances. The custodian, guardian, or administrator must be consulted and under no circumstances may the procedure be performed against the donor's will.

323. If the person is dead the primary task is to determine the opinion of the deceased in this question. If she/he was opposed to donation of her/his organs, it will not occur. If she/he had expressed a positive wish that her/his organs be available for transplantation to another person, this will suffice. When the deceased person's attitude is clearly known, the relatives' attitude has no bearing on the matter. But if the opinion of the deceased person is not known with any reasonable degree of certainty, the donation may occur if a person close to her/him consents. If there are no close relations available, or if they have different views on the position of the deceased, the donation will not be allowed.

324. The Transplantation Commission (*see above*) is of the opinion concerning living donors that in accordance with the legislation in force, the procedure should be performed only on a person who has consented to it in writing.[1] The use of organs from living persons should be strictly limited. The Commission suggests a rule in the Transplantation Act that non-renewable organs and tissue may only be taken from somebody related to the recipient, or who has in some other way a very close connection to her/him. The rules of information will not be changed.[2] A person under 18 or a mentally ill/handicapped person, who is lacking ability to give an informed consent to the donation, may be a donor only if the donation concerns renewable tissue *and* the donor and receiver are genetically related to each other, for instance brothers and sisters.[3] The National Social Welfare Board must determine if there are certain reasons justifying such a procedure; which means the transplantation must be of great necessity for the recipient and no other method of treatment is available. As in the presently applicable rules, the

legal guardian of the child or the mentally ill/handicapped person must give her/his consent. And of course, the procedure may not be performed against the will of the donor.

1. *See* its report, SOU 1989:98.
2. SOU 1989:98, p 170.
3. SOU 1989:98, p 182.

325. The Commission also suggests that the general rules in the Transplantation Act concerning consent should also be applicable to so-called small or minor surgeries. The only exception is that the consent to become a donor of blood does not need to be in writing. According to the Transplantation Commission, voluntary 'donation cards' are to be preferred over a central register of organ donors, primary for economic reasons. The donation card is preferable as it is a very simple way to document one's intention or desire to donate one's organs after death, and by that relieving the relatives from the responsibility of deciding the question. It may also be used to express a limitation on the scope of the donation procedure; either all or only certain specified organs may be taken.

326. The Transplantation Commission also suggests introducing a prohibition against transactions with the purpose of making a financial profit with human biological material in transplantations. The prohibition would cover material taken from both living and deceased persons. A person who intentionally transfers, acquires, acts as an intermediary in transplantations, would be subject to penal sanctions. The Commission was of the opinion that it is ethically wrong to treat the human body as a commercial commodity.

§10. Proceedings with the Dead Body

I. The Legal Position of a Deceased

327. When a person dies, her/his legal entity ceases. What that means is that she/he cannot acquire any legal rights and the rights she/he has are transferred to somebody else. The dead body cannot own something.

328. The legal protection of the dead body is regulated in the Penal Code, which provides that a person who without authorization moves, damages or ignominiously treats a corpse or the ashes of a deceased, opens a grave, urn or other resting place shall be sentenced for a crime against tomb (*brott mot griftefrid*).[1]

1. *Brottsbalken* 16:10.

329. The uses of corpses which are considered acceptable are severely limited. Any measures involving a dead person's body are therefore not allowed unless there is specific legislation allowing such measure.

II. Autopsy

330. Before a funeral may take place, a death certificate must be filed with local central registry office located in the local tax office. The death certificate must contain statements as to the cause of death and it must be issued by a doctor. Autopsies, i.e. outer and inner examination of a dead body in order to make clear the course of illness and the cause of death are performed partly in the pathological wards of hospitals or in mortuaries (clinical post-mortem), and partly at the stations of forensic medicine (medico-legal post-mortem).

331. Rules concerning clinical post-mortems are found in the Autopsy Act.[1] The main rule says that the dead under her/his lifetime must have permitted this in writing (§2). If such a permission is lacking a post-mortem still can be performed if it is necessary to establish the cause of death or if important information of the character of the disease can be obtained (§3). If the cause of death is known, a post-mortem is not permitted if either the deceased was, or somebody close to her/him is, opposed to it. The information obtained in a post-mortem shall be given to a near relative of the deceased if there are no written instructions or no other reasons not to do so. If the cause of death is unknown, there is unconditionally a right to perform a clinical autopsy irrespective of the wishes of the deceased or persons close to her/him.

1. *Obduktionslagen (1975:191)* (Autopsy Act). *See also* the National Board of Health and Welfare rules in connection with the Autopsy Act (MF 1975:123). There will be a new regulation concerning autopsies in 1993 or 1994. *See* SOU 1992:16 (The Body after the Death).

332. The conditions for medico-legal post-mortem are regulated in a special regulation.[1] Decisions on such autopsies are given by a court, the County Government Boards, public prosecutors, or police authorities. In practice, there is a medico-legal examination when the police authorities have ordered an examination of a corpse, which may occur because of suspicion of crime or suicide, the person has died from an accident, or when a death certificate has not been filed with the local tax office within the prescribed period of time. In addition, when a patient has died in a hospital, the chief physician must comply with the rules in the Autopsy Act and perform a clinical post-mortem if a post-mortem is called for.[2] The chief physician also has the duty to immediately report to the police authorities if she/he believes there is a reason for a medico-legal post-mortem or other medico-legal examination.

1. *KK (1973:710) om rättsmedicinsk obduktion. See also* the National Board of Health and Welfare circular with instructions (1975:12).
2. General Physician Instructions (1963:341) §10.

III. Responsibility of the Medical Personnel at Death

333. Within medical care, traditionally there has been a responsibility not only to provide good medical treatment but also in an ethically acceptable way caring for dead persons before and after a possible post-mortem and while awaiting for

removal to the mortuary and the funeral. Even transportation of dead people is effected in the activity of the public health care. Before 1993 there was no legal duty for the entities providing medical care to take such measures at present, but the activities could be viewed as a voluntary undertaking from their side. Treatment in the meaning of the Health and Medical Care Act did not exist concerning dead persons, as only living persons can be treated. This is also the case even when breathing and blood circulation are maintained in a technical way. The duties stipulated in the Health and Medical Care Act ceased when a patient died. The National Social Welfare Board has a duty to supervise measures after an official declaration of death. But this is now changed due to a new regulation in HSL §1. According to the HSAN Board, there is now a possibility of disciplinary sanctions for the medical personnel according to the Supervision Act for possible faults or negligence at the handling of the corpse.

§11. Research with Human Beings

334. The local governments and other authorities responsible for providing health care have decided that every research project concerning the human being must be approved by an Ethical Committee before a researcher has access to contact with patient or information on patients. The Committee decides if the risk and the discomfort that the patient/subject of the experiment will be exposed to, can be justified for the good of the research project. No research grants may be paid out until such approval by the Committee is obtained.

335. Clinical research can be divided into different categories. There are clinical experiments which include factors that are not directly related to a medical care situation. In such studies, measures of experimental nature are involved. All clinical research on healthy persons are to be considered as experiments. However, at a trial, a new method is used that is considered better or equal with the present procedures. The purpose of a trial is to help a patient, and, at the same time, to test (prove) the efficacy of a drug or particular medicine. A physician has the right to test a new method if it is in the interest of the patient; this is considered to be medical care, not research. The presentation of problems at comparative studies are the same as at comparative trials. The ethical questions are not as complicated as they usually are at comparative trials.There is not the same level of uncertainty that can arise when introducing a new diagnostic or therapeutic method.

336. The medical research differs between three groups of research objects that must be ethically examined as research on human beings: namely research on healthy persons, research on patients, and research on patients where the project does not directly concern patient's disease. These individual are regarded as 'subjects of the experiment.'

337. In projects where healthy persons are involved, the main rule is that these persons will never be subjected to a serious health risk, as they have no personal interest, for example the desire to recover from an illness, in taking part in a

research program. But if the research is for the treatment of the patient, higher risks are acceptable, so long as the risk-taking reasonably corresponds to the expected therapeutic result.

338. The individuals participating in medical experiments must have full information in connection with the experiment (nature of risks, etc.) and the chief researcher has the responsibility for ensuring that such information is provided. The information must be given in writing, and must be easily understood. The purpose of the experiment must be clear, and the possible side-effects, inconvenience and risks must be fully explained. The purpose of the particular experiment must also be explained. The patient/subject of the experiment must be informed that the participation is voluntary and she/he must give her/his consent. If a patient for some reason cannot give her/his consent, it must be obtained from a person close to the patient; if no one is available to give such consent, the doctor must take the responsibility for making the decision. There must be a weighing of the risks versus the benefits for the patient, taking into consideration what is in the best interests of the patient.

339. In clinical studies, the subjects participating in the study must give their consent in writing and verify that she/he has read and understood the information. When any study begins, a medical examination is performed on every person participating in the study, and another one is performed after the study is completed. Medical students, health and medical care personnel, and friends and relatives of the researcher are often voluntary subjects of such studies.

340. The most common medical experiments using human beings are clinical trials of pharmaceuticals. Very stringent demands are made for prescription drugs to be allowed to be used in Sweden. Every pharmaceutical must be thoroughly researched and tested.[1] The drug must also be registered with the National Social Welfare Board. The applicant for registration must show that the drug is effective against the disease (effectiveness standard). Reports and other documentation proving the effectiveness and risk of side-effects must be included in the application. In addition, a condition for approval and registration of the drug, is that it must under normal usage not cause any harmful effects that are not unavoidable side-effects considering the nature of the illness which the drug is intended to treat (acceptable risk standard). Such evidence and documentation will be produced at the clinical trials.

1. It is possible, however, for a physician to prescribe or administer a drug that has not been approved yet if special grounds exist – for example, experimental drugs for AIDS patients.

341. Before a drug undergoes clinical trials, both experimental and laboratory tests must have been completed. For ethical reasons the effective mechanisms of a medicine must be proven before it may be tried on human beings. The pharmaceutical preparation producers have the responsibility to conduct such tests. When the laboratory tests have provided satisfactory results, the effects of the drug can be tested on human beings. The responsibility for ensuring that such ethical preconditions have been complied with is on the doctor performing the clinical trials of the pharmaceutical preparation.

§12. Transsexual Procedures

342. Physical change of gender, known as *fastställande av könstillhörighet* in Swedish, is available to individuals who have complied with certain preconditions. All physical changes of gender must be approved in advance by the Swedish Social Welfare Board, which has a special workgroup made up of experts from different fields who will review and decide upon the application in each individual case.[1]

One of the preconditions to approval of a change of gender, is that that person has lived as and assumed the other gender role, and has psychologically adapted himself to that role. There are doctors who are specialists in this procedure.

1. Lag 21 april 1972 om fastställande av könstillhörighet i vissa fall; Instruction 20 oktober 1967 (nr 606) för socialstyrelsen. See also SOU 1968:28. There will be a proposal concerning a new regulation in this area in 1993.

Part III. The Physician in Relation to the Health Care System

Chapter I. Collegial Relationships

343. The Swedish Association of Physicians (*Läkarförbundet*) is the trade union for doctors, to which all doctors both those working for a governmental health care authority or in private practice belong although there is no legal obligation to join the association. The tasks of the Association are to maintain a good and dignified team spirit, to safeguard the professional, social and economic interests of the members and to support their educational and scientific interests as well as to promote the appropriate development of the health and medical care. Within the Association there are sections. These are Professional Societies, Local Societies, Specialist Societies, Interest Societies, and a Society for Younger Members. The Association is connected to the Central Labor Organization SACO/SR. The affairs of the Association are handled of the Delegate Meeting, the Central Board and its Executive Committee, the Representative at Assembly of the Local Societies and the Responsibility Board.[1] The Association publishes the Physician Journal (*Läkartidningen*) as its official newspaper. A person can be member of the Association if she/he is authorized according to regulations in force to work as a physician in Sweden or to have a position as an assistant physician according to a permit from the appropriate authority. In addition, students studying medicine can be members of the Society for Younger Members. A member can be expelled from the Association if she/he disregards the fundamental ethical obligations of the profession.

1. *Central förtroendenämnd* (CSN). The CSN is the forum for the resolution of intercollegial disputes, and improper treatment by a doctor.

344. The above mentioned trade union organization provides legal advice to its members. For example, a doctor who has been reported to the HSAN Board can obtain counseling and legal assistance from the *Läkarförbundet's* Responsibility Board. In addition, each Specialist Society has 'consultation doctors' who assist colleagues in disciplinary cases with discussions, advice and evaluation of the medical issues raised in the complaint, and can provide a medical specialist opinion concerning the circumstances in the report.

Chapter II. Relation with Other Health Care Providers

§1. Pharmacists

345. Few fields in medical care are so strictly regulated as that concerning pharmaceuticals and other medication. There is a considerable amount of legal rules and regulations issued by the National Social Welfare Board. This regulation of medicine consists of, among other things, definitions of concepts and tasks. There are rules about the storage and coordination of the supply of medicine at the unit, the superintendence of the supply, prescribing and dispensing of pharmaceuticals, the storage, dosage, and the administration of medicine to the patients, and also special rules for doctors and nurses.[1]

1. This section is, however, concerned with rather the registration, control and inspection of pharmaceuticals. The handling of medicine by medical personnel is covered in other sections.

346. The State Pharmaceutical Preparations Department is responsible for questions concerning medicine, including registration of pharmaceuticals, evaluation of side-effects, clinical trials, licenses, analytical and biological control, pharmacopoeial cases and inspection of production, laboratories and separate stages of handling. Homeopathic and other natural medicine (*naturmedel*) is also the responsibility of the Department. The Department must follow, initiate and pursue research and development, to inform in its responsibility area and to assist with special knowledge from its professional field.

347. The Pharmaceutical Preparation Department was previously a part of the National Social Welfare Board as a central administrative authority for questions of pharmaceuticals. In July 1990 the Department became an independent authority with responsibility for control and supervision of this field. The regulations within the responsibility of the Department are now contained in the Pharmaceutical Preparations Collection of Statutes.[1]

1. *Läkmedelsverkets författningssamling* (LVFS).

§2. Nurses and Midwives

348. In order to guarantee high quality and safety in public health and medical care, licenses for several groups of professions are required for authorization to provide service to the public. There is a requirement for nurses and midwives to have completed a stipulated education and training before they may work in a health care organization.

349. Additional specialized education and training is necessary for employment in anesthesiology, intensive care, care for accidents and emergency cases, assisting in surgery, district health care and care especially for children. This is also the case

with employment such as a head nurse or care of children at night, psychiatric care or care of mentally ill people and other care of a medical or surgical character. The National Social Welfare Board has established rules stipulating the competency requirements concerning nurses and midwives. The education of nurses in based on a study programme that fulfill the conditions of nurse education in the EC.

350. The education of nurses has a basic part, the so-called health and medical care major, and additional training tracks. The training is built upon the foundation that the student has graduated from a *gymnasium* (high school) with a 'care' major. This high school education provides a fundamental education in care, which is a common base for all students. Successful completion of any track gives one the right to a licence as a nurse.

351. Every work team in medical care must have suitably composed personnel. When recruiting nurses there shall be careful consideration in each case as to the particular competency the work team needs. The National Social Welfare Board can allow an exemption from the requirement of a licence for a nurse for a temporary position. However, the health care provider who questions such a exemption must first try other solutions, for instance to redistribute the tasks or the resources. And even if the possibility of obtaining an exemption exists, the National Social Welfare Board is very restrictive in allowing a person who lacks authorization as a nurse to obtain a temporary appointment as a nurse.

352. Nurses have an important task in dealing with pharmaceuticals. There is a special regulation which applies specifically to nurses concerning medicine. It requires that nurses shall in a secure way keep and distribute the medicine that she/he is responsible for.[1] There is a similar rule applying to midwives.[2]

1. *R (1957:656) för sjuksköterskor* §6.
2. *R (1955:592) för barnmoskor* §9.

353. The main rule concerning the authority to prescribe medicine is that such authority is restricted to persons who are authorized to practice medicine, or dentistry.[1] There is a rule which provides for an exemption for midwives. The State Pharmaceutical Preparations Department has issued rules concerning a midwife's right to prescribe or administer drugs.[2] One of these rules provides that midwives may prescribe medicine which is used in birth control under certain conditions.[3] One of the conditions is that the authority of a midwife to prescribe medicine must be derived from a doctor who has delegated this authority to her, and who remains responsible for the prescribing activities of the midwife.

1. SOSFS (M) 1984:16.
2. LVFS 1990:17.
3. SOSFS (M) 1980:21.

354. The administration of medicine to patients intravenously, or through intravasale catheters or epidural catheters, must be carried out by a licensed nurse and may not be delegated.

355. As an experimental program beginning in 1989, district nurses in the county of Jämtland have had a limited authority to prescribe certain medicine. In addition, they may be delegated by the District Physician the authority to prescribe medicine in a particular case. The condition for this authority is that it must be in writing, and must be for a seriously or terminally ill patient who is being treated in their home. The diagnosis and the prognosis must have been established, and the program for care must be stipulated. The rationale behind the experiment is that patients needing the drugs will have easier access to them.

§3. Alternative Medical Care

356. Natural medicine is medicine that according to experience does not lead to negative health effects for human beings or animals and in which the effective ingredient is vegetable or animal, a naturally occurring bacteria culture, or a mineral or salt.[1] The basic rule is that natural medicine is available without a prescription.

1. Natural medicine is defined in the Pharmaceutical Preparation Ordinance (1962:701, amended 1977:570 (1). The regulation is formulated as an exception to the regulations concerning pharmaceuticals contained in the Pharmaceutical Preparation Ordinance (§1 (3) 2.).

357. Before being allowed to be offered for sale to the public, the producer must file a report with the National Social Welfare Board. Information concerning the contents of the medicine must be provided, representations must be made that it is made up of only natural ingredients and that there are no known negative side effects. There is no control of the medical effects or efficacy claims of the producers.

358. In regard to the delivering of natural medicine by means of an injection, natural medicine for injection will be supplied by a pharmacy only with a written prescription.[1] A patient may request the administration of natural medicine, but the doctor has no obligation to comply with such a request. In cases of serious illness or with special humanitarian reasons, the patient's request should be given greater weight. Injections to patients under the age of 15 are only permitted with the permission of the National Social Welfare Board in that particular case.

1. *See* the National Social Welfare Board rules SOSFS (M) 1986:30 and SOSFS (M) 1986:32.

359. There have been very few reports of serious side effects as a consequence of using natural medicine. If a physician has followed the instructions for the use of a natural medicine for injection, she/he will not be legally responsible even if a secondary effect will appear. The Patient Insurance also covers any potential injuries caused by natural medicine administered by injection, if the treatment has been given in the health and medical care.[1]

1. *See* HSAN 122/87.

360. Acupuncture treatment has recently become more widely available in Sweden, and interest in its use in health care is growing. Acupuncture is defined as

a mechanical, thermal or electrical stimulation by needles that penetrate the skin or mucous membrane.[1] A licensed doctor is permitted to use acupuncture in health and medical care. The National Social Welfare Board is of the opinion that the use of acupuncture for the treatment of pain is in accordance with scientific knowledge and professional experience. In the regulations issued by the Board, there are indications when acupuncture treatment can be used and also information regarding the risks of complications.[2] Any person performing acupuncture treatment must have satisfactory knowledge of the methods of treatment.[3] At the present, most alternative medical treatment, and natural medicine, is not covered by the national health insurance. An exception is a licensed doctor who also practices some form of alternative medical care, such as acupuncture, and is registered with the national health service.

1. SOSFS (M) 1984:33.
2. *See* also Information News No. 39/86 from the National Board of Health and Welfare.
3. *See* SOSFS (M) 1989:2 concerning education in acupuncture.

361. A person who has a degree as a Doctor of Chiropractics at a foreign university, or an equivalent education for chiropractors will, after application, obtain a licence as chiropractor, if she/he meets the following requirements: practical service in Swedish health care corresponding to one year of full-time service, knowledge of the Swedish regulations for the profession, and the necessary knowledge of the Swedish, Danish or Norwegian language to carry out her/his profession. A chiropractor who obtains a licence will in her/his activity no longer be subject to the Quackery Act but instead be under the supervision of the National Social Welfare Board according to the Supervision Act. By this means, the society will have increased its supervision over the practice of chiropractors and practitioners will have the same legal obligations towards their patients as medical doctors, including the obligation to keep patient journals. But a chiropractor who is not also a licensed physician would not be registered with the public health insurance, and therefore she/he does not have the right to issue an illness certificate. A licensed chiropractor can be disciplined by the HSAN Board, and the licence can be revoked by the Board under special circumstances.

362. Naprapaths and osteopaths are groups outside of the health and medical care. As mentioned above in §§66–67, the Alternative Commission has suggested new regulations concerning these professional groups.

Chapter III. Relation with Health Care Provisions

§1. In-patient care

363. The Health and Medical Care Act §5 provides that for health and medical care which requires admission to an institution there must be hospitals. Care given under such admission is called in-patient care (*sluten vård*). Other medical care is called out-patient care (*öppen vård*). A 'hospital' is a medical care institution where in-patient care is given. The concept 'admission' to a hospital requires an explanation. It may be that a patient only stays in the hospital during the daytime (daytime hospital care), only at night (nighttime hospital care), or only during Monday – Friday (five days and nights hospital care). All of these forms of care are usually considered to be in-patient care, i.e. hospital care.

364. The national government is also a health care provider. While the local government is responsible for most medical care, the national government has responsibility for certain specialized care such as strumatic care, military unit care, certain dental and school health care, and medico-legal and forensic psychiatric services. In addition to the responsibilities of the 26 local governments to render primary health care, the municipalities have the primary care responsibility for school health care, health care for their own personnel, and medical care (and supervision) of homes for the aged and service homes (*see above*). These municipalities are also responsible for the general health protection of the population according to the Health and Environmental Protection Act.[1]

1. *Hälsoskyddslagen (1982:1080).*

365. In addition to public health care, care is also available from private providers. Most dental care is performed by private practitioners. All large companies have employer provided health care. Nursing home care is available from private providers. An individual can choose to go to a private general practitioner, and there are also some specialists who have a private practice yet are part of the health insurance system.

366. Health and medical care in Sweden is structured around regional medical care, county medical care, primary care and preventive care. The regional medical care consists of special care in all specializations of medicine, including general medicine. The regional care is built on cooperation between the local governments. According to a decision of the Riksdag, the regional medical care includes the few patients having especially difficult problems which require cooperation between a number of highly trained and experienced specialists or care which requires very expensive equipment for which special training to operate the equipment is necessary. Also included here are such diseases that are so rare that there is no treatment experience on the local level.

367. According to §9 of the Health and Medical Care Act, the local governments must work together with other local governments in their region in questions regarding highly specialized medical care must work together as well inside as between the regions the Government has decided. With this as the basis, a national agreement exists between the local governments for cooperation in health and medical care.[1]

1. *Riksavtalet för hälso-och sjukvård.*

368. The care at the local government hospitals is called county medical care. A concept often used for their activity is a basic unit, i.e. clinics and other corresponding work units, such as medical or clinical service department or care central. The basic unit shall as much as possible be self-governing concerning its activity and development. The unit must therefore have the right to have decision making authority adapted to its responsibilities. Activity plans and budget must be established and a follow-up and control are necessary in the unit. Further, the basic unit must be self-supporting regarding resources of information, decision-making, performance and follow-up of their own activities. The administration must be an integrated part of the activity of the unit.

§2. Out-patient Care

369. The concept primary health and medical care is defined as an organization in medical principal's care system that has a 'primary responsibility for the people's medical care in a geographically limited area – as a rule corresponding to the primary local governments. The primary care has a leading organization of its own that on a local level will cooperate with the social welfare authorities and other local agencies in preventive health care as well as individual treatment. The responsibility of the primary medical care is limited by its resources. When the illness of a patient requires hospital care, the responsibility for the treatment will be transferred there. But the responsibility for the patient's treatment will revert to the primary medical care as soon as the health condition of the patient does not require the resources of the hospital any longer.

370. The preventive health care tasks of the local governments are mainly performed within the primary health and medical care organization. That does not mean that the responsibility for preventive health care is solely with one medical care organization. There are preventive health care tasks that demand the resources of the county medical care, for instance screening examinations using advanced technology, such as X-ray examinations with mammography, cytological cancer screening and foetal diagnostics.

371. It is important to consults the achievements of the primary medical care when designing health investigations and other general programs, such as in the epidemic field. The activity of professional medicine, including support to the employer provided medical care and the primary medical care in their preventive

care, belongs to the county medical care, too. Certain aspects of health care, for instance epidemiological research, are beyond the competency of the basic primary care. The local governments have therefore established special units for the environmental medical activity that must be performed on the county level.

372. There is and must be a close cooperation between the primary medical care and the clinics and laboratories of the county medical care. It is the same state of things for the local governments and the primary municipalities. Despite the existence of an extensive legislation on the different fields of care there are quite obvious problems of limitations between the local governments and the primary municipalities, concerning for instance the home medical care, care for elderly people and efforts for the handicapped. Also in the field of psychiatric care and the care of drug abusers it is difficult to specify what is medical and social need of care, respectively.

373. Considerations concerning the patient's own responsibility of the individual are of significant importance for the preventive tasks of the primary care, e.g. the information of health care. A goal of information in health care is to increase the real knowledge of people and to give guidance to the individual. It is then individuals themselves who makes the decision affecting their own behavior and way of living. Therefore, the primary medical care, in order to fulfil its tasks in the preventive care and create a good foundation of planning, must work with direction of reasons in the daily health and medical care work. As the primary medical care is the first contact with the medical care the individual has, it plays an important role of improving the health condition of the population and counteract differences in state of health between different groups of people, which had not been possible to reach in an organization having its main point in consulting activity and in-patient care.

§3. Social Insurance

374. The legislation concerning health insurance is to be found in the General Insurance Act,[1] namely the health care insurance and the sickness allowance (concerning health care insurance, *see above*). There are also rules concerning basic pension and supplementary pension, which are very important for the sick and disabled person. In the Work-Injury Insurance Act[2] there are legal rules concerning allowance due to a work-related injury. In the case of a short illness, which brings about a reduction in one's ability to work by twenty-five per cent or more, most of the lost income is recompensed (65 per cent, 80 per cent and after 90 days 90 per cent). If the ability to work is reduced permanently by fifty per cent or more, an early retirement pension may be granted. If the ability to work is not reduced permanently but the person is ill for an extended period of time, she/he may receive a sickness cash benefit or temporary disability pension. The pension and the financial assistance may be granted partly from the basic pension fund and partly from the supplemental pension (ATP). Persons who have very low or no ATP can also be granted a pension supplement. Compensation for medical care in the case of illness

or injury – for medical treatment, hospital care, medicine, etc. – will normally be paid directly to the provider while the insured person pays a minimal fee or will receive medical care free of charge.

1. *Lag (1962:381) om allmän försäkring.*
2. *Lag (1976:380) om arbetsskadeförsäkring.*

375. In the case of a reduction of work ability because of a work-related injury, financial assistance will be paid during a 180 day interim period between the sickness allowance and the work injury insurance, whereafter work injury insurance will give full compensation for income loss. After the interim period, the work injury insurance will also compensate for medical care, medicine and other treatment, etc.

376. If the ability to function normally in daily life has been reduced for someone under the age of 65 so that the person needs help and support to live or work, handicap allowance will be granted. The same applies to the extra costs a person may have because of a handicap. If a child under the age of 16, because of illness or handicap etc, needs special care and support, a care allowance may be granted. During rehabilitation in the form of labor market education, financial assistance will be granted under the study period.

377. The current health allowance system is administered by the Social Insurance Organization, i.e. the local Social Insurance Offices and the national Social Insurance Board. The Social Insurance Offices administers social insurance. Every county has a central social insurance office (26) and several local offices (approx. 450). The National Social Insurance Board makes sure that the law on social insurance is implemented, issues advice and instructions, and also has certain service functions, such as computerized data base, and the payment of benefits. During the past few years this organization has taken on more and more functions, so that its area of responsibilities now also includes additional forms of social welfare support, for example, child allowances to families.

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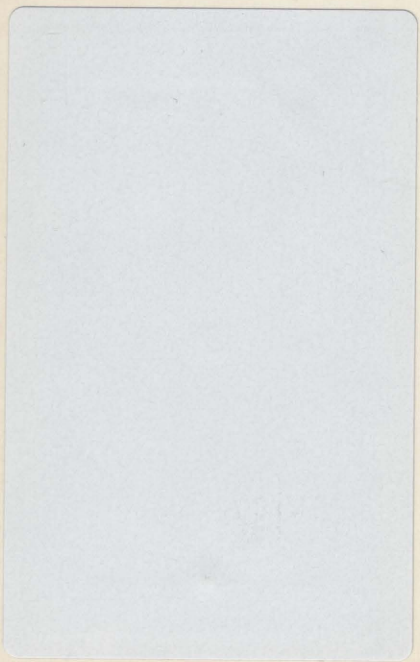

LOTTA WESTERHÄLL

Medical Law

An Introduction

This book deals with important questions concerning the medical profession in Sweden, the physician-patient relationship and the physician in relation to the health care system. That means that access to the medical profession, control over the practice of medicine and the rights and duties of physicians and patients will be discussed. Efforts have been made to explain the concepts of good care, informed consent, privacy and compensation for medical injuries. Focus has been put on special patient categories, such as the minor patient, the mental patient and the dying patient. Specific activities like abortion, insemination, reproductive technologies, prenatal diagnostics, sterilization, castration and transplantation have been examined.

Lotta Westerhäll is Doctor of Law and has a professorship of Social Law at Lund University. She is a wellknown author in the fields of social security law and medical law.

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FRITZES

BESTÄLLNINGAR: FRITZES KUNDTJÄNST 10647 STOCKHOLM
FAX 08-20 50 21 TELEFON 08-690 90 90