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THE PATIENT INJURY ACT
A COMMENT BY
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BACKGROUND AND HISTORY

The question of how patients, who have been injured in connection with medical treatment, shall be compensated has been discussed for a long time.

Prior to the Tort Damages Act of 1972, it was difficult to receive compensation for treatment injuries. The introduction of the Tort Damages Act did not mean an actual change in this situation. Even after the law went into effect, it has been difficult for patients to prove, in the context of a court proceeding, that an injury has resulted by an error or omission by hospital staff, in connection with treatment. One reason for this is that circumstances in health care often are complicated and difficult to investigate by those without special expertise. It can therefore be a long and costly process for the patient to obtain compensation through tort law.

These circumstances have meant that only few injured persons have obtained damages for health care-related injuries. During the years immediately preceding 1975, damages were awarded in only about ten cases of health care-related personal injuries. In addition to these cases, there were patients who received compensation directly from the care provider's liability insurance, and a few who obtained compensation ex-gratia from the caregiver in extreme cases of hardship. Before 1975, a total of approximately 100 persons per year received some form of compensation for treatment complications.

Special provisions for tort liability for treatment injuries were discussed in connection with drafting of the Tort Damages Act. One proposal was to introduce strict liability for treatment injuries (i.e. liability independent of error or negligence). However, it was felt that the incidence of injuries was not high enough, nor were the injuries of a sufficiently unusual nature, as to warrant a special regime.

Several motions for an expanded right to compensation for treatment injuries were nevertheless introduced in the Parliament, but were rejected, since it was felt that specifying which health care-related injuries would be compensated and which would not, in the wording of the law would be technically too difficult. It should be noted that at that time, as no countries had special regulations regarding the compensation of treatment injuries, no experience of this matter could be learned from other countries.

Nevertheless, the Executive Committee of the Federation of Swedish County Councils was in favour of an expanded right of compensation for the County Councils, and, in February 1971, decided to study this matter. All this occurred during a period of great expansion of health care, when new, advanced methods of treatment enabled the treatment and cure of many more illnesses than before. This meant that many more patients could benefit from health care. However, the increased amount of treatment performed led to more persons sustaining injury (probably not in terms of the number of treatments, but rather, in absolute numbers). The number of complications in health care increased, *inter alia*, due to the advent of more advanced diagnostic methods, that larger and more comprehensive surgical interventions were performed and the increased number of operations performed on patients in high-risk groups.
Instead of legislation, a voluntary collective insurance solution was chosen. On 1 January 1975, the voluntary patient insurance of the county councils went into effect. Subsequently, patient insurance was introduced for almost all public and private health care. Until 31 December 1994, this insurance was administered by an insurance consortium consisting of Folksam, Länsförsäkringsbolagen, Skandia and Trygg-Hansa. By means of this insurance scheme, public and private care providers voluntarily assumed the responsibility for compensating treatment injuries that are directly related to health care.

This insurance meant significantly better opportunities to compensating those who have sustained treatment injuries, as compensation can be paid regardless of error or negligence. The insurance pays compensation on objective grounds. Since the introduction of patient insurance, the liability issue has been separated from the compensation issue. Thus, the insurance is not connected to the Health and Medical Care Liability Board or the National Board of Health Welfare. A patient thus no longer needs to "hang" a doctor in order to be entitled to compensation. The insurance has thus created a basis for increased confidence between the personnel and the patient. Today, if an injury occurs in connection with medical treatment, the medical personnel are usually those who initiate the injury report. In an estimated 60-80% of the reported injury cases, a physician, nurse or social worker has helped the patient report the matter. This is a fact that surprises foreigners, especially Americans. In addition to the issue of compensation, the most important functions of this insurance are the maintenance of confidence and the feeling of redress that patients experience when they receive compensation.

Thus, the introduction of patient insurance has radically improved the opportunities of compensating patients who have sustained a treatment injury. Today, around 9,500 treatment complications are reported annually. In about 45% of the cases (over 4,000

cases per year), compensation is paid. The annual cost of compensation is estimated at over 300 million SEK.

In November 1992, the government commissioned a special investigator to review the patient insurance system. This was known as the Patient Insurance Investigation. The purpose of the investigation was to delineate the care-provider's liability to compensate and the obligation to purchase insurance for treatment injuries. The commission for this study emphasised the fact that the current voluntary insurance system did not require that all care providers purchase patient insurance. This meant that there was a risk that patients did not have uniform financial protection in all care situations, in the event of a patient injury. Approximately 5% of all care providers did not purchase voluntary insurance. However those accounted for less than 1% of all health care treatments. Nevertheless, trends in health care, including a growing number of care providers, increased the risk that certain care providers may be intentionally or unintentionally refraining from purchasing insurance coverage. In addition, insured care providers have no interest in a voluntary system that also guarantees injured patients of uninsured providers the right to compensation.

In 1994, the patient insurance consortium was discontinued, since this type of combination was not considered to comport with the prohibition against restricting competition in the new Competition Act that was enacted in 1993. The discontinuation of the consortium also eliminated one of the foundations in the voluntary system. Until 1994, the insurance had primarily been administered by the consortium, in close co-operation with the public health care system. This co-operation created the basis for a common monitoring and improvement of the compensation provisions, and also led to common efforts to effect changes in the rules and solve practical problems.

By the early 1990s, Sweden was no longer the only country with patient insurance. In 1987 and 1992, Finland and Denmark, respectively, enacted patient insurance laws. Since 1988, Norway has had provisional rules regarding compensation for patient injuries. In 1992, permanent rules regarding objective liability were presented in a proposed law, which has not yet gone into effect. Thus, when the review of the Swedish patient insurance system begun, there were experiences from other countries, as well. Therefore it was no longer considered too technically difficult to define compensable health care-related injuries in the wording of the law.

The government-appointed Patient Insurance Investigation, in its report (SOU 1994:75), proposed that the special right to compensation should be regulated in a special law, and be independent from general tort law.

THE PATIENT INJURY ACT

The law went into force on 1 January 1997, and is primarily based on the compensation rules of the voluntary patient insurance, with certain important changes.

The law contains provisions regarding the right to patient injury compensation, and the care providers' duty to maintain patient insurance that will cover this compensation. Every provider of health care, in any form, is thus required to purchase patient insurance.

The law indicates the requirements with which patient insurance must comply. The provisions are compulsory, to the benefit of the injured party. However, individual insurance companies can supplement their patient insurance policies with terms that are more favourable to the injured party.

The insurer pays the patient injury compensation. In order to protect the interest of a patient in cases in which the care provider has not fulfilled its duty to purchase insurance, all the insurers are jointly and severally liable to pay compensation for injuries related to a care provider who has not purchased patient insurance. These patient injury insurers are required to join the Patient Insurance Association, which is to deal with compensation issues regarding care providers that have not purchased insurance. This is similar to the system that applies to traffic injuries, where The Motor Insurers´ Bureau has a similar role.

One requirement for the payment of patient injury compensation, is that the injury must have arisen in connection with health care in Sweden. Patients that are cared for outside of Sweden may continue to be insured through the voluntary undertakings of the care provider.

The law covers patient injuries caused from 1997, and onward. Injuries that were caused prior to 1997 fall under the prior voluntary insurance scheme, provided the care provider is so insured.

SCOPE OF COVERAGE

Health care

Anyone engaging in health care is thus obligated to purchase patient insurance. The term "health care" shall apply to ambulances and other forms of patient transport.

Patient

One requirement for compensation is that the injury must have occurred to the person in connection with his or her being a patient. The term "patient" means all those who have established contact with health care personnel, regarding the condition of their health. When someone is provided with care or treatment, or undergoes an examination, he or she is considered a patient, regardless of the reason for those procedures. The Patient Injury Act also treats as a patient anyone who voluntarily participates as a subject in medical research, or who donates organs or other biological material for transplants or other medical purposes.

PATIENT INJURY

The definition of personal injury

The definition of injury is largely based on the definition used in the voluntary patient insurance scheme. However, certain important changes have been made. One of the most significant of these is the introduction of a definition of personal injury that includes both physical and mental injuries. The voluntary patient insurance provided compensation only for physical injuries. Compensation for mental injuries was available only if those injuries were caused by a physical injury.

Rule of evidence
In order for an injury to be compensable, there must be a causal relationship between the injury and the health care service. The patient has the burden of proving this causal connection. It is required that a causal relation can be established with preponderant probability.

Patient injuries
Pursuant to § 6, patient injuries can be divided into the following six major categories:

1. Treatment injury
Patient injury compensation is allowed for an injury caused by an examination, care, treatment or similar procedure (e.g. blood donation), provided that the injury could have been avoided by a different manner of performing the procedure in question, or by the choice of some other procedure available (e.g. another treatment technique or method) which could have satisfied the medical requirements in a less risky manner.

The assessment as to whether the injury could have been avoided under the circumstances that existed is done after the fact.

The standard of care used in this assessment is that of an experienced specialist or other experienced professional in the field concerned. The treating physician's actual qualifications, expertise and experience, thus do not enter into this assessment. The specialist standard applies even where no experienced specialist was present during the treatment. If a nerve injury occurs in a hip operation, for example, the standard used is how an experienced orthopaedist would have acted.

The rarity and severity of the injury is not considered in this assessment. The crucial issue is whether it would have been possible to avoid the injury.

The burden of proving whether the injury was avoidable is on the patient.

Lack of resources
Lack of resources can be used as a ground for compensation, only if in the actual case, it would have been possible to use existing resources in another way, or to use additional resources. Thus, the possibility to avoid injuries should not be assessed according to an optimal standard of care. The resources must have been available to the care provider.

2. *Material-related injury*

Patient injury compensation is allowed for an injury caused by a defect in, or the defective use of, a medical-technical product or hospital equipment used in examination, care, treatment or any similar procedure.

3. Diagnostic injury

Patient injury compensation is allowed for an injury caused by an incorrect diagnosis.

One difference between this and other kinds of patient injuries is that the compensation here is for effects of the basic illness, rather than injuries sustained due to health care. The diagnostic injury is based on the fact that the treatment does not occur, is less efficacious or is delayed.

A compensable diagnostic injury is an injury that has been caused because an actual, observable symptom was ignored during diagnosis, or was interpreted in a manner that deviates from the normal standards applicable to an experienced specialist in the field in question.

The diagnostic injury consists of the patient's basic illness progressing differently from what had been the case if that illness had been previously diagnosed. Diagnostic injury delays proper treatment, or results in inappropriate treatment. This type of injury can be described, as an added injury in relation to what would have been had there been an initial diagnosis by an experienced physician followed by treatment appropriate to that diagnosis.

4. Infection injury

Patient injury compensation is allowed for an injury caused by the transmission to a patient of an infectious agent during examination, care, treatment or any similar procedure, which leads to an infection. Injuries caused by infectious agents that are carried by the patient prior to the treatment are thus not compensable on this ground.

There is no right to compensation in those cases where the circumstances are such that the infection must reasonably be tolerated. In this regard, the type and degree of severity of the basic illness, the general condition of the patient's health and the possibility of predicting the infection and its degree of severity should all be taken into account.

5. Accident-related injury

Patient injury compensation is allowed for an injury caused by an accident occurring in conjunction with examination, care, treatment or any similar procedure, during patient transport, or in conjunction with fire, or with any damages to health care premises or equipment.

An important principle of this rule is that coverage applies to accidents that are related to, and are typical of, health care activities. The right to compensation is therefore limited to the special risks related to that field. Normal accidents that can occur regardless of whether in a health care context, are excluded from coverage. A patient who can normally manage on his or her own, for example, should not receive compensation for an

accident that occurs in the normal course of everyday life at the hospital. Thus, a patient who trips in the day room when wanting to watch television, or who falls on the way to the bathroom has not sustained an accident that is dependent on care. However, compensation should be paid for accidents that occur in conjunction with treatment, such as when a patient falls off a stretcher while being examined or if a patient collapses while being mobilised by health care personnel.

The patient need not be in direct contact with the medical personnel; it is sufficient that he or she is being placed in a situation with an increased risk of accidents.

6. *Medication injuries*

Patient injury compensation is allowed for an injury caused by the prescription or administration of medication in conflict with rules or guidelines. The Patient Injury Act excludes other injuries caused by medication, such as medical drug side effects, which are subject to the compensation rules of the pharmaceutical insurance.

EXCEPTIONS TO THE RIGHT TO PATIENT INJURY COMPENSATION

Patient injury compensation is not allowed for injuries that result from a necessary procedure for diagnosing or treating an injury or illness, which, if left untreated, can be life-threatening or lead to severe invalidity.

This exception applies to injuries resulting in emergency situations where the need is so great, that treatment must begin, even when normal preparations cannot be taken. This also applies to situations that call for intentionally taking great risks in order to prevent very serious turns in the patient's injury or illness.

INSUFFICIENT INFORMATION OR LACK OF CONSENT IN CONNECTION WITH TREATMENT

The compensation rules for the voluntary patient insurance scheme do not mention anything about compensation on the grounds of insufficient information to the patient or the failure to obtain the consent of the patient in connection with medical treatment.

Thus, in the voluntary patient insurance system, the issue of information has not had any independent significance as to the right to compensation. Instead, the objective medical course of events is to be investigated, and compensation is to be paid, regardless of whether or not the information about the special risks of the treatment has been communicated.

During the drafting of the law, there was a discussion of whether to expand the right to compensation under the Patient Injury Act to include injuries arising as a result of the provision of insufficient information to, or the failure to obtain the consent of, the patient. Due to the complex nature of this issue, additional analysis was deemed necessary. Injuries due to insufficient information or failure to obtain consent in conjunction with health and medical treatment are therefore not covered by the Patient Injury Act.

A patient who feels that he or she has sustained an injury due to the negligent failure to provide information or obtain consent, can instead assert a claim for compensation under the rules of general tort law.

HOW PATIENT INJURY COMPENSATION IS DETERMINED

Patient injury compensation is determined according to the personal injury compensation rules of the Tort Damages Act. The compensation covers economic losses (i.e. loss of income and costs incurred due to the injury), non-economic losses (i.e. temporary and permanent pain and suffering, loss of amenities, extra strain at work etc).

Nevertheless, there are certain deviations from the rules of the Tort Damages Act. In determining the amount of patient injury compensation, an excess must always be deducted. The excess is equal to one-twentieth of the Basic National Insurance Amount (currently 1,830 SEK). There are also absolute limitations. The amount of the compensation for each injured person may not exceed 200 Basic Amounts (approx. 7.3 million SEK). Compensation is for each injury event limited to a total ceiling of 1000 Basic Amounts (36.6 million SEK). These amounts do not include interest and compensation for legal costs.

REVIEW

The Patient Claims Panel

The Patient Claims Panel was established in 1975. Beginning in 1997, the Panel is part of the organisation of the Patient Insurance Association.

The Panel consists of a chairperson and six other members. The members are chosen for terms of three years. The Chairman must be, or must have served as, a regular judge. Three of the other members represent the interests of the patients, one must be a medical expert, one must be familiar with the personal injury settlement process of the insurers, and one must have special knowledge of health care activities.

The Panel shall issue advisory opinions in compensation cases under the Patient Injury Act that are referred to the Panel by a patient or other claimant, a care provider, an insurer or a court. As the Panel is an advisory body, its opinions are recommendations. However, these have always been followed by the insurer.

Bringing a matter before the Panel is free of charge for the patient, who benefits from being able to have his or her patient injury compensation matter heard by an expert body before the case might be brought to court. The patient is entitled to choose whether to go before the Patient Claims Panel, or to proceed directly to court with his or her compensation claim.

From 1 January 1975 to 31 December 1999, approximately 140,000 treatment complication reports were received by the insurers. Of these, the Panel heard 7,223 cases during the same period. At present, the Panel reaches a conclusion that differs from that of the insurers in approximately 10% of the cases.

Court of general jurisdiction

In the voluntary patient insurance scheme, disputes between insurers and injured parties were resolved through arbitration, pursuant to the Arbitration Act (1929:145). As of December 1999, 101 arbitration decisions had been rendered. Of these, 30 were decided in favour of the injured person.

The opportunity to resolve voluntary patient insurance compensation disputes through arbitration was eliminated with the advent of the new law. A patient who is dissatisfied with the insurer´s final decision can instead commence an action in a court of general jurisdiction.

PERIOD OF LIMITATION

Persons wanting to receive compensation according to the Patient Injury Act will lose the right to this compensation unless they make a claim within three years of learning that a claim could be made, and, in any case, no later than ten years after the injury was caused.

If a person seeking compensation has notified the care provider or the insurer of the injury within the required time, he or she will always have six months from the date of receipt of the insurers final decision in the matter, to commence a court action.