DISBURSEMENT OF INDEMNITY FOR INJURIES RELATED TO REPRODUCTIVE DRUGS AND DEVICES: A SWEDISH PERSPECTIVE

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I.
INTRODUCTION

Sweden has Europe's oldest pharmaceutical insurance system. (See Appendix A describing other European domestic pharmaceutical insurance systems.) The Swedish pharmaceutical insurance system was created in 1978 to supplement Sweden's weak tort liability system, which made it very costly for plaintiffs to mount a case and very difficult for them to prove fault. The need for a supplement to the tort liability system was not readily apparent in Sweden. For many years, the necessity of a strong tort liability system in Sweden was hidden because of the country's well developed national social insurance and health care systems. Instead of being compensated through the tort liability system, injured persons could simply turn to either the social insurance or health care program for assistance. Needless to say, this put a strain on those two programs.

The Swedish pharmaceutical insurance system is the result of a voluntary agreement between insurance companies. It is not a statutory scheme. The system is designed to be an easily administered form of protection against personal injury. The system seeks to compensate persons on the basis of need rather than fault. Under the pharmaceutical insurance system, compensation awards never reach the level of compensation commonly found in United States. The pharmaceutical insurance system is not an exclusive remedy in Sweden. If an injured person does not seek relief through the pharmaceutical insurance system, then she is free to pursue a claim in the traditional tort liability system.

II.
THE SWEDISH NATIONAL INSURANCE SYSTEM

A. Development of Social Insurance in Sweden

Since the end of the nineteen century in Sweden, the social and financial security of the individual has been strengthened by a series of insurance reforms. The present-day Swedish insurance system is primarily the consequence of a series of reforms made between 1930 and 1960.

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The basic social insurance system in Sweden is composed of a universal health insurance program, a guaranteed basic pension, a supplementary pension, and various independent payments to families with children, such as child allowances and housing allowances. Over the years, these basic elements of the social insurance system have been augmented by the enactment of additional programs to support the physically challenged, to assist individuals injured on the job, and to provide support to families in which one member is performing her obligatory military service. The National Insurance Act, which came into effect in 1963, coordinates all of these programs.

B. Eligibility for Coverage

Sweden's extensive national insurance system is obligatory. All Swedish citizens and legal residents are obligated to participate in the system. The upshot of this is that all Swedish citizens and legal residents in Sweden have basic insurance. But, although a citizen has basic insurance, she is not necessarily entitled to a particular benefit. Eligibility varies depending on the type of benefit being requested. To receive a pregnancy allowance, for example, a person must comply with all of the registration requirements promulgated by the local social insurance office.

Sweden is divided into 25 county councils, each of which is responsible for ensuring that the county's residents have access to good health care. The county councils, which are governed by political assemblies elected through general elections, levy an income tax on their residents. Under county council tax legislation, generally more than 80 percent of revenue is spent to finance the various health care programs. The county councils own and operate hospitals and health care centers, and employ the great majority of the health care workers and medical staff. Most doctors with independent practices are also remunerated by the county councils.

All county councils partially finance their activities through charges to patients who consult doctors or other medical staff. These patient charges, which vary from county to county, are not reimbursed by health insurance; instead, the individual patient bears the cost. Patients are currently charged from SEK 100-200 ($12.44-$24.88)[1] for a doctor visit. Upon admission to a hospital, a patient currently pays up to SEK 80 ($9.95) a day. Patients who are not residents of the county where they seek treatment are normally charged the full cost of the care provided.

Patients' needs for outpatient prescription drugs and dental care are dealt with through a national insurance program rather than through county council financing. The National Corporation of Swedish Pharmacies (NCSP), which has the sole and exclusive right to retail medicines,

1. All U.S. dollar figures that appear in this article and attached appendices are based on the appropriate exchange rate reported in the Wall Street Journal, April 2, 1998, at C20.

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distributes medicines through over 800 pharmacies. The state owns a majority interest in the NCSP. The costs of certain drugs for people suffering from chronic and severe illnesses are entirely reimbursed by the general national health insurance program. For other pharmaceuticals prescribed by doctors, patients currently pay a maximum of SEK 125 ($15.55) for the first purchase of prescription drugs and SEK 25 ($3.11) for refills. Excess costs are paid directly from national social insurance to the pharmacy concerned. All Swedish residents are entitled to these "pharmaceutical discounts." When a patient with an ongoing need for pharmaceuticals or medical consultations has paid SEK 1,800 ($223.92) in less than a 12-month period, the patient is entitled to free pharmaceuticals and consultations for the remainder of the 12-month period.

Dental care insurance is also part of the general national health insurance and covers all residents in Sweden aged 20 and over. Young people under 20 are entitled to free dental care. Other patients must pay the first SEK 700 ($87.08) for treatment. For costs exceeding this amount, national health insurance normally contributes 25 percent of the costs. When costs of treatment exceed SEK 3,000 ($373.20), the share paid by insurance is 40 percent. For costs in excess of SEK 7,000 ($870.80), insurance will pay 70 percent. The portion of costs borne by national insurance is paid directly from the insurance to the dentist providing care, or where the dentist is employed by a county council, to the county council concerned.

III.

COMPENSATION FOR INJURY UNDER THE SWEDISH SYSTEMS

A. General Comparison of Sweden's Different Indemnification Systems

Swedish tort law remedies are available for both defective pharmaceuticals and injuries resulting from medical malpractice. Tort law remedies have fallen out of favor, however, because it is extremely difficult to prove negligence and causation. A certain tolerance for errors is accepted in the practice of medicine, and no strict liability exists.

In Sweden, most patients with drug-related injuries seek compensation through the pharmaceutical insurance system. The pharmaceutical insurance system provides coverage for any drug-related injury for which a pharmaceutical company would be liable. From July 1, 1978 through January 1, 1996, the system handled approximately 4,400 claims, including 218 contraceptive-related injuries, indemnifying 35 percent of overall claims and 66 percent of contraceptive-related claims.

Compensation through the pharmaceutical insurance program is limited to injuries arising from drugs and does not cover injuries that are consequential to disease and its treatment. The pharmaceutical insurance program is not an exclusive remedy, however. An injured person can pursue compensation through the general social insurance system. In addition, there is a specific insurance program, the patient insurance program, for

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claims involving medical malpractice. The patient insurance program began in 1975 as a voluntary agreement between insurance companies and health care providers. It became mandatory on January 1, 1997, when the Patient's Injury Act went into effect.

Under the patient insurance program, injured persons are compensated through a system of modified tort rules. The patient insurance program operates much like no-fault insurance programs in the United States, under which a plaintiff need not prove that a particular defendant was at fault. Instead, a plaintiff will be entitled to compensation upon showing a causal connection between the injury they received and the action of a medical professional. Since the patient insurance program began in 1975, more than 90,000 claims have been filed. Of these claims, about 45 percent of them have resulted in compensation for the injured party. Under the program, an injured party is compensated for both economic damages, such as loss of income, and indirect injuries, such as pain and suffering, physical defects, and general inconvenience. The system is not intended to be punitive, however, and therefore it does not provide for punitive damages.

While the Swedish patient and pharmaceutical insurance programs are similar in many respects, there are differences between the two programs. The patient insurance program, with some significant exceptions, operates on the assumption that an injury was caused by some action or omission for which the medical or health care sector is responsible. Furthermore, it assumes that a person's injury could have been avoided if treatment of the basic disease had been conducted in a different manner. On the other hand, the right to compensation under the pharmaceutical insurance program depends on whether a pharmaceutical product has caused the injury and on whether it would be reasonable to provide compensation after considering the nature of the disease being treated and how unexpected and serious the injury was.

The patient insurance program covers injuries caused by negligent handling or prescribing of drugs. The pharmaceutical insurance system, on the other hand, covers only injuries caused by the drugs themselves.

B. Pharmaceutical Insurance Coverage

The pharmaceutical insurance program covers drugs marketed and obtained in Sweden, regardless of whether the injured party is Swedish or the injury occurs in Sweden. Drugs acquired outside of Sweden are not covered, even if the drug was manufactured in Sweden. Before a drug may be sold in Sweden, it must first be registered with the Medical Products Agency, a governmental agency responsible for the regulation of pharmaceutical preparations. The pharmaceutical insurance program covers all pharmaceutical companies doing business in the Swedish market, and it

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extends to all products defined as drugs under the Swedish Drug Ordinance. The Drug Ordinance defines a drug as a preparation that is intended to be administered internally or externally for the purpose of preventing, alleviating, or curing illness or symptoms of illness. The National Welfare Board has expanded the Ordinance's field of application to include certain products that are similar to drugs in terms of their characteristics and usage, such as oral contraceptives, certain antidotal treatments for smokers, various diet products, and hormone preparations.

The pharmaceutical insurance system covers only injuries that are of a physical nature. If a psychological injury has no physical symptoms, proving that a pharmaceutical caused the injury is difficult. If one can prove that the mental injury has resulted from a physical injury, the system will provide compensation.

The pharmaceutical insurance system does not compensate for a drug's failure to have its desired effect. For example, if a patient takes medication for an infection, and the infection is not cured, the patient cannot receive compensation. The justification for this principle is obvious: medical care can never guarantee that an illness will be cured.

C. Factors Influencing the Indemnification Systems

The most obvious benefit of the pharmaceutical insurance system accrues to injured persons. The no-fault principle incorporated into the system significantly lowers a claimant's burden of proof from what would otherwise be required under Swedish tort law.

A not so obvious, but perhaps even more significant, benefit of the pharmaceutical system accrues to the public at large. Under the system, a drug may be distributed to the public despite its known, or potential, harm to users. Where the positive effects of the drug outweigh its known or potential dangers, society as a whole benefits. Of course, there will be instances where a newly developed drug will, upon its release, injure people. This is unfortunate, but it does not necessarily mean that the drug should be banned. So long as the introduction of the drug produces a net benefit to society, the drug should be introduced. This is one of the underlying principles of the pharmaceutical insurance system.

When injuries do occur as a result of the introduction of a drug with known or potential harms, the pharmaceutical insurance system establishes that the resulting injuries are not the fault of the manufacturer or the prescribing physician. Therefore, the pharmaceutical insurance system bears the cost of remedying the injury. Compensation is based on the reasonable consideration of the circumstances surrounding the injury. Factors to be considered in determining the amount of compensation include: the drug's known side effects; the seriousness of the underlying illness; the patient's general state of health; the severity of the specific symptom or injury being

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treated; and the development risks associated with introducing the new product to the market.

1. Causal Relation

Due to the considerable difficulties that can arise in proving a causal connection between an injury and the use of a drug, the pharmaceutical insurance system includes a unique rule of evidence regarding causation. To receive compensation under the system, the injured person only needs to prove that there is a preponderate probability that the injury was caused by the drug. In practice, this more lenient evidentiary standard has resulted in the acceptance of what has been widely referred to as a statistical, causal relationship. Causation is accepted if it is not otherwise evident from the investigation that a certain factor or predisposition exists in the individual case that could, in itself, have caused the injury with at least as much probability. In the same manner, a chronological connection can be given substantial weight. If the injury occurs within a relatively short period of time after commencing use of the drug, this is accepted as a relatively strong indication of causality. If, on the other hand, no side effects appear for a long period of time during which the drug is used, this is evidence against causation. (See Appendix B for a sampling of decisions regarding the causal relationship between birth control pills and injuries.)

2. Reasonableness Test

Typically, compensation is paid when serious injuries are sustained while using a drug for health reasons that are not considered risky. For example, since birth control pills are not generally used to save a life or prevent serious injury, many types of injuries resulting from the use of birth control pills are compensable. On the other hand, compensation is not paid in cases where dangerous drugs must be used to save a life or prevent serious injury. So, for example, compensation will not be paid where a patient needs treatment for a fatal infection and the antibiotics administered cause a permanent hearing impairment.

The line between acceptable side effects and unacceptable side effects is difficult to draw. Rather than drawing bright line rules, most cases have been decided using the nebulous standards of fairness and practicality. For example, compensation was paid in a case where sulpha was prescribed in normal doses for a mild urinary infection and the patient sustained serious skin damage. Compensation was not paid in a case involving life-threatening cerebral meningitis where strong doses of sulfa had to be administered. In another case, because the wrong disease was diagnosed and the wrong medicine was used to treat the patient, a patient was compensated for an injury caused by the medicine despite the fact that the medicine had well-known side effects.

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In practice, the severity of the disease meant to be treated and the injury resulting from use of the drug are the most important factors in deciding whether a patient should be compensated. One general principle that has been applied in deciding cases is that in order to receive compensation the injury resulting from the use of the drug must be more severe than the injury that probably would have resulted had the drug not been used. Alternatively, a compensable injury has not occurred if the use of a drug cures the primary disease but gives rise to a secondary injury that is less severe than the one that would have resulted had the primary disease not been treated with the drug.

D. Liability Figures

Liability, according to the drug compensation scheme, is limited to SEK 5 million ($622,000) for each injured person and SEK 100 million ($12,440,000) for each serial injury, up to a maximum of SEK 200 million ($24,880,000) for serial injuries attributed to the same calendar year. The justification behind these limits is that certain widespread injuries with common characteristics stemming from one source (serial injuries) can give rise to extensive cumulative economic consequences. The maximum limit for compensation of serial injuries from a particular drug is considered to be more than sufficient if another catastrophe similar to that caused by thalidomide should occur in Sweden. Injuries that are included within a serial injury shall be attributed to the calendar year during which it first became apparent that a serial injury had occurred.

The discovery of serious, previously unknown side effects will always lead to a review of the product. If, however, the product is found to have such great therapeutic value that it should still be used, despite the risk of injury, injuries that occur as a result of the drug having been dispensed after publication of possible harmful effects shall not be considered part of the serial injury. In such cases, when frequent and possibly serious side effects must be accepted due to the other properties of a drug, compensation may be paid according to the aforementioned reasonableness assessment.

E. Waiver of the Right to Claim Damages

An important provision, especially for foreign drug manufacturers, is that the injured person cannot accept compensation from insurance without first waiving her right to claim compensation from other potentially liable persons. This is achieved by requiring the patient to assign her right to tort damages to the insurer.

F. Limitation Periods

A claim must be made within three years from the time the injured party became aware that their injury was caused by a particular drug. No

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other time limitation exists, which means that it is of no importance when the injury was caused or when the injured person finished using the drug.

G. Compensation

Indemnities are paid in accordance with general principles of tort law for assessing damages for personal injury. This means that during a period of acute illness, full compensation is paid for loss of income and costs of treatment and care, as well as compensation for pain and suffering. In the case of permanent disability, life annuities or lump sums can be paid for expenses and loss of income. Compensation for permanent pain and suffering, loss of amenities, and general inconvenience is paid in lump sums. In case of death, compensation is paid for burial costs as well as for loss of support. Compensation for pain and suffering and other kinds of non-economic losses is standardized with a cap of SEK 819,500 ($101,945).

The indemnity from insurance is subsidiary, as the insurance covers only losses remaining after the claimant has exhausted all other sources of available compensation, such as social insurance, third party vehicle insurance, workers' compensation and employer "no-fault" insurance.

About 71 percent of the compensation paid out relates to pain and suffering or other kinds of non-economic losses. Loss of income equals approximately 10 percent of compensation paid out. Costs for hospitalization or doctors fees amount to about 14 percent. Costs in connection with death are estimated at about 5 percent.

H. Claims Committee and Arbitration

If a person does not wish to accept the insurer's decision about her right to compensation, she can have the case referred to the Drug Injury Committee for an opinion. The Committee's decision in the case is not binding on either the patient or insurer. It is worth noting, however, that an insurer has never appealed a Committee decision. As of December 1991, the Drug Injury Committee had passed judgment in 47 cases out of approximately 4,400 claims. The Committee reversed the insurer's decision in about 15 percent of those cases.

If the injured person is not willing to accept the Committee's decision, she can invoke arbitration proceedings. In such cases, the insurer is obligated to pay for the arbitrators, unless the injured person's claims are totally unfounded. Two cases have been tried by arbitration, and neither of the cases were decided in favor of the injured person.

I. Premiums

In 1991, the premiums for the Swedish pharmaceutical insurance system totaled approximately SEK 14.4 million ($1,791,360). The premiums are paid by the Swedish Pharmaceutical Insurance Association to which all

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Swedish manufacturers and importers belong. Each manufacturer and importer contributes to the premium in an amount proportional to their market share. Of the SEK 14.4 million ($1,791,360) in premiums, SEK 5 million ($622,000) was used to compensate persons injured by known side effects. The remaining SEK 9.4 million ($1,169,360) of the premium was used to compensate for serial injuries caused by unforeseen side effects and to pay for the cost of administering the compensation scheme.

IV.

PRODUCT LIABILITY LAW IMPLEMENTED UNDER THE EUROPEAN UNION PRODUCT LIABILITY DIRECTIVE

The Swedish law on product liability was implemented in coordination with the European Union Product Liability Directive and went into effect on January 1, 1993. Under the 1993 law, liability for product-related injuries included injuries caused by products with safety defects. Because drugs may cause personal injuries, they are included in the law. Under the law, liability ensues independent of negligence. Thus, there is strict liability in situations where the product is not as safe as one has reason to expect.

There are important differences between the Swedish pharmaceutical insurance system and the EU Product Liability Directive. The most fundamental difference lies in the general thrust of the two systems. The Swedish compensation system, unlike the EU Product Liability Directive, does not focus on whether there were mistakes or omissions in the warnings or labeling of a drug. Instead, the Swedish pharmaceutical insurance system simply seeks to decide whether or not it is reasonable to compensate for the injury. It remains to be seen whether the alternative approach embodied in the EU Product Liability Directive will have an effect on the pharmaceutical insurance system.

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APPENDIX A

Other European domestic pharmaceutical insurance systems.

Austria

General: All commercial liability insurance must by law include product liability coverage.

Scope: Includes losses consequential to injury.

Rates: Set by national insurance table.

Liability Cap: 5-10 million A.S. ($384,700 - $769,400) maximum; annual cap (from date of medical diagnosis) not to exceed the per-injury limit by a factor of three. Insurance contracts for higher sums are possible.

Denmark

General: A new compulsory insurance system emulating the Swedish model came into effect in 1995 after negotiations about a voluntary industry-wide agreement failed.

Finland

General: Closely resembles the Swedish voluntary system.

France

General: Voluntary, private insurance system with pharmaceutical liability either subsumed in general liability policies or as separate contracts.

Scope: Coverage may, on a case-by-case basis, include drug trial coverage, pre-approval liability, legal defense and expert witness payments.

Claims: May be filed by the injured party directly against the insurer of risk.

Liability Cap: Per-loss coverage limit is generally F.F. 30-150 million ($4,830,000 - $24,150,000).

Germany

General: The law imposes absolute liability for pharmaceuticals for unreasonable side effects in normal use or where the product is unreasonably dangerous by current standards. Producer/importer must show coverage either through an approved insurer or a domestic bank guaranty. The entire producer market shares in one industry-funded and run pool of insurers and re-insurers administered by a large private re-insurer. Direct insurers must contribute their entire pharmaceutical risk portfolio to be eligible for pool reinsurance coverage beyond the initial DM 10 million ($539,700) deductible.

Scope: Lost income, medical treatment and related cost. Excludes pain and suffering.

Rates: Coverage terms and tariffs are set by the insurance pool for prescription, pharmacy-only and generally available drugs.

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Liability Cap: DM 500,000 ($269,850) annually per product and DM 30,000 ($16,191) annually per person harmed. The single-product cap is DM 200 million ($107,940,000) annually, and the single incident cap is DM 12 million ($6,476,400) annually. There is no overall cap per producer or importer.

Great Britain

General: Voluntary private insurance market. Pharmaceutical risks are subsumed in manufacturer's other product liability coverage, or where separately insured, under one-year contracts. Large contracts may be layered into primary and secondary insurance layers to spread the risk of large losses. The standard of liability is one of reasonableness.

Scope: Negotiated on case-by-case basis to reflect the state of the law. Bodily injury covered while purely financial losses are excluded. Legal fees and expert witness cost are often included in overall coverage.

Rates: Set by insurers based on risk exposure of manufacturer.

Liability Cap: Temporal limitations apply: only injuries occurring within these short contract periods are covered, with annual limits acting as overall caps.

Italy

General: Voluntary system in which availability and scope of coverage and limits varies with firm size (smaller operators may not be insured). The insurance industry association has published a model policy for pharmaceutical industry coverage.

Norway

General: Mandatory no-fault liability insurance scheme for all manufacturers and importers. The current 1989 product liability law is modeled on the corresponding EC directive and applies to pharmaceuticals like any other consumer products.

Scope: Covers injuries in use as well as during product trials. No compensation rendered for drug use contrary to directions or inappropriate use.

Claims: May be made by injured persons directly against insurance funds.

Liability Claim: 80 - 100 million N.O.C. ($10,416,000 - $13,020,000) overall annual compensation cap per firm.

Spain

General: Mandatory system of insurance/guaranty funds replaced an earlier voluntary insurance system.

Claims: May be made directly against the insurer, who may recover excess or not-covered sums from the insured manufacturer.

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Liability Cap: Per-event insurance sums with overall annual limits of double the per-event maximum.

Switzerland

General: All-purpose liability policies implicitly cover pharmaceutical liabilities; otherwise such risks may be specifically or separately insured as well.

Liability Cap: May apply either in the form of a per-event/claims-made cap or as overall loss-caused within such period. The legal requirement is capped at the per-event maximum, multiplied by a factor of three within any five policy years.

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APPENDIX B

A sampling of the Drug Injury Committee's decisions regarding the causal relationship between birth control pills and injuries.

1. A 38-year-old woman who had taken birth control pills for seven months arrived at the hospital emergency room with dyspnoea (shortness of breath) and circulatory failure. She died the same day. The autopsy showed that she had pelvic venous thrombosis and lung emboli. The consortium for the pharmaceutical insurance submitted the case to the Drug Insurance Committee (Committee), which ruled there was a predominant probability her death had been caused by the use of birth control pills. (Diary number (dnr) 1979/02.)

2. A 29-year-old woman who had taken birth control pills for two years, and smoked 15 cigarettes a day experienced breast pain and respiratory failure. Upon arrival at the hospital, her ECG showed signs of a cardiac infarction (heart attack). She lost speaking ability and became tetraplegic. She died half a year later. The autopsy journal supported the presumption that the patient had suffered a cardiac infarction causing ischemia and brain damage. The Committee found a predominant probability that the death was caused by the use of birth control pills. (dnr 1979/03.)

3. A 24-year-old woman had taken birth control pills for six months when she developed a central vein thrombus in the hollow of her right eye. Even though she had always suffered from a reduced visual capacity in the left eye due to an inflammation in early childhood, the injury was found to have been caused by the use of birth control pills. (dnr 1979/04.)

4. A 30-year-old woman who had taken birth control pills for one month due to dysmenhorrea developed several lung emboli after a minor operation. She recovered and was free from pain within three months. She was compensated under the pharmaceutical insurance system since there was a predominant probability that the injury was caused by the use of birth control pills (dnr 1979/05.)

5. A 29-year-old woman developed symptoms of a deep venous thrombosis in one leg on the same day that she fell while skiing. The Committee found a predominant probability of a casual relationship between the use of birth control pills and the thrombosis. Both the type of thrombus and its probable existence at the time of the accident supported the causal relationship. (dnr 1980/01.)

6. A 26-year-old woman who had used birth control pills for three years developed an embolus. She suffered from an impaired fibrinolyse activity (her natural defense system against thrombosis was reduced). The Committee decided that there was a predominant probability that the thrombus was caused by use of birth control pills. The patient's increased

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risk for thrombosis caused by her impaired anticoagulation capacity was further increased by the use of birth control pills. (dnr 1980/11.)

7. A 38-year-old woman, who smoked 40 cigarettes a day, experienced a cerebral infarction (stroke). While the woman had used birth control pills for 13 years, she had stopped using them six months before the stroke. The Committee found there was no predominant probability that the use of birth control had caused the stroke. (dnr 1979/06.)

8. A 45-year-old woman treated with natural estrogen developed a thrombus in her left eye. The Committee decided there was not a predominant probability the thrombus was caused by the treatment. (dnr 1980/10.)

9. A 41-year-old woman who had used birth control pills for 10 years died as a result of a lung embolus. Since the medical investigation showed that the embolus had its origin in her left knee and she had had an operation on her left meniscus one month earlier, the Committee decided there was not a predominant probability that birth control pills had caused the thrombosis. No compensation was paid. (dnr 1981/02.)

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