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Law notes

France

Wrongful life: Decisions of the French High Court of Appeal

In a landmark decision on November 17th 2000 (the "Perruche judgement"), France's High Court of Appeal (Cour de Cassation) established the right of a congenitally handicapped child to claim damages against a party responsible for his or her handicap[1]. The case concerned pregnancy in a woman who had in the past insisted that she would only wish to bear a child if she was shown to be immune against rubella. Respecting her request, the treating physician sent three blood samples to a laboratory. Two showed the presence of antibodies against rubella, but the third did not. The physician concluded, incorrectly, that the mother was immune, and she went on to become pregnant. The boy subsequently born manifested serious neurological, mental and ocular defects typical of congenital rubella. In litigation in negligence brought against the physician and laboratory on behalf of both the mother and the child, the Paris Court of Appeal held that only the mother's case could succeed; the injury to the child was not considered a consequence of the medical error. The French High Court of Appeal quashed this decision, holding that the medical fault was to deny the mother the chance to decide for or against an abortion and hence the possibility of avoiding the birth of a handicapped child; it therefore admitted the child's claim for damages associated with the handicap.

The decision was widely debated in legal and medical circles and in the media, while two lower Courts of Appeal subsequently declined to follow it, holding that the particular malformations with which they were concerned were the result of a pathological factor and not the consequence of a medical fault. In one of these cases, heard by the Court of Appeal of Aix en Provence in March 2001[2], a girl was born without a left hand or forearm. An echography had been performed during pregnancy but the echographer had failed to notice the defect. Damages were awarded to the mother for her psychological suffering, but a claim on behalf of the child was rejected since the malformations were spontaneous and were not the consequence of the echographer's fault. In a second case, heard by the Court of Appeal of Orleans in October 2001[3], the physician in charge during the pregnancy had not even requested that echography be performed. The child was born with spina bifida. An expert report to the Court noted that morphological examination between the 20th and 24th week would have been required by standards of good medical practice, and would have detected some two-third of the abnormalities present. Again damages were awarded to the mother (to the extent of two-third of those claimed) but not to the child, since the child's injury was not a consequence of the diagnostic failure.

Both these cases were subsequently heard in the High Court of Appeal, the appellants pointing to the Perruche precedent. The appeals however failed, since the High Court considered that its Perruche judgement, essentially allowing a child's claim for wrongful life, was only applicable where legal therapeutic

[1]The case law of the High Court of Appeal is accessible on www.courdecassation.fr.

[2]Bloch C.: La reparation du prejudice de l'enfant né handicapé. La resistance de la Court d'Appel d'Aix a la jurisprudence Perruche. Semaine Juridique II 10 600, No. 40, 3 Octobre 2001, p. 1829.

[3]Defaut de prescription du diagnostic prenatal non obligatoire. Un arrèt de la Cour d'Appel d'Orleans dui 21 octobre 2001 illustre un nouveau cas de résistance á l'arret Perruche. Dictionnaire permanent Bioéthique et biotechnologies. 21 dec 2001, 7363.

abortion was an option. Some months later the High Court of Appeal once more applied its Perruche ruling in two cases where this criterion for legalized abortion was held to be satisfied (birth of trisomic children)[4].

These French cases have been discussed at greater length by Duguet[5], and relate to the "wrongful life" issue with which Courts in many countries have struggled, nowhere more so than in the U.S.A. Such claims may arise in various situations ranging from the irresponsible supply or prescription of a teratogenic drug (where the act itself actually induces the congenital defect) to a failure to diagnose a teratogenic influence (such as rubella) or to recognize in good time that an unborn child is developing abnormally. The restrictions which the French High Court of Appeal imposed on its own Perruche judgement undoubtedly reflect the limited scope of legalized abortion in France. French Law specifies that abortion can be permitted only where two physicians have certified ". . .after examination and discussion, that allowing pregnancy to continue seriously endangers the health of the mother, or that there is a high probability that the child will be born with a disease of a particular gravity regarded as incurable at the time of diagnosis". Even within the scope of French law, however, the defects observed in the Orleans and Aix cases cited above might well have been classified as grave and incurable, and there seems little doubt that in some other legislations a considerably broader scope will be given to the mother to choose whether or not to bear a handicapped child. Since the above cases were heard there has been a further modification of the law in France which, whilst firmly rejecting claims for "wrongful birth"[6] clearly does allow claims by handicapped children for "wrongful life"[7].

Norway

Failure to maintain adequate patient records

In the course of an operation for diaphragmatic hernia, a haemorrhagic complication occurred as a consequence of which it became necessary to perform splenectomy. In the course of the latter the pancreas was damaged The surgeon entered into the patient's record a very superficial account of the events, which failed *inter alia* to state how the spleen had become detached from the rear wall of the abdomen.

Shortly after the operation the patient developed respiratory problems but was not moved to a referral hospital until more than two days had elapsed. The only entry in the case records during this period related to the patient's transfer to the referral hospital; there was no information on the evaluation which had been performed or the conclusions which had been drawn. Laparotomy at the major hospital showed injury and perforation of the oesophagus. Because the perforation failed to heal and the patient was by now seriously ill a further operation had to be performed. At follow-up the patient was declared to have sustained a permanent 25% disability. Expert reassessment concluded that the disability was due to the deficient manner in which the original surgery had been carried out.

The documentary aspect of the case was referred to the National Health Inspectorate which found that the incompleteness of the surgical record amounted to a failure to comply with meet accepted standards of practice, and was "such as to endanger safety standards in health care". The surgeon in question had

[4] http://www.courdecassation.fr/agenda/arrets/00-11197acc.htm.

[5] Duguet A.M.: Wrongful life: the recent French Cour de Cassation decisions. Eur. J. Hlth Law 9: 139–163 (2002).

[6] A claim for "wrongful birth" alleges that the claimant should not have been born at all: a claim for "wrongful life" seeks to recover damages for the handicap with which the claimant is obliged to go through life.

[7] Law 2002–2003, March 2002, 4th metre ref.

the duty to provide proper care and follow-up, including the maintenance of an adequate record. To cite the Inspectorate's report: "Since life-threatening complications can occur both during and after an operation it is essential that a record be maintained throughout which provides adequate information to the other health personnel involved in the care and 24-hour nursing of the patient". In this case, it was clear that the incompleteness of the surgical record was such as to obscure the correct diagnosis of the ensuing complication.

The surgeon was issued with a "warning" under Article 56 of the Law on Health Personnel.

> Notable in this case is the firm ruling that a surgeon performing an operation assumes responsibility for the patient's care both during surgery and the immediate follow-up period and for maintaining a complete record of events, including both surgical acts and whatever complications may occur.

Source: Helserett-Info (Oslo), 2/01, December 2001, 1–2.

Vascular surgery and patients' rights

In January 2001, a new Law on Patients' Rights came into effect in Norway. In order to examine the extent to which modern legislation of this type modifies existing standards of good practice rather than merely confirming them, a series of cases seen or treated in a University department of vascular surgery were re-evaluated in retrospect.

(1) The right to immediate medical assistance: Section 2/1 of the Law establishes the right of any individual to immediate and necessary help both from general municipal and specialized health services but on certain conditions; the right applies only if it can reasonably be expected that such help will benefit the patient, and if the costs of providing it are not disproportionate to the benefit which is likely to be obtained.

> In the case of a man of 64 in whom intermittent claudication limited the walking distance to 100 metres, the clinic provided an appropriate operation within two months of referral. This was considered to be consistent with the standards set by the new law as regards severity, the improvement to be expected, and the waiting time involved.

(2) Right to chose treatment: In its Section 3/1 the Law gives the patient the right to participate in the choice between those alternative treatment which are both available and medically justifiable.

> A man of 65 with an infrarenal aortic aneurism was asked to express a preference between alternative operative approaches and between immediate surgery and an expectant approach. He was mentally capable ot understanding the issues and was fully informed. Though he ultimate left the choice to the physician it was considered that the requirements of the law had been met by his being put in a position where he could choose if he wished to do so.

(3) Right to information: Under Section 3/2 of the Law, a patient must receive the information which he needs to understand his state of health and the nature of the treatment proposed.

> A man of 66 who had already undergone coronary, carotid and other vascular operations now had severe intermittent claudication. In view of his overall condition it was proposed to admit him for conservative treatment only. Prior to admission he wrote to the senior physician requesting written answers to a series of detailed questions, including the reasons not to operate or to transfer him to the National Hospital for further assessment. The letter was not answered but he was in due course admitted for the agreed conservative treatment and to provide an opportunity to discuss the issues he

had raised. It is noted that the law does not create a right to receive information in writing and that he had been dealt with in the spirit of the legislation.

(4) Right to information regarding complications of treatment: According to the Law's Section 3/2, patients who suffer therapeutic injury or serious complications should be informed of this fact and familiarized with the possibility of seeking compensation under the national patient compensation scheme.

A man of 70 with serious aortic and peripheral arterioscleroris was being treated for intermittent claudication; during treatment dissection of the left iliac artery occurred and demanded grafting, but the graft collapsed and further occlusions followed. Although the clinic provided information as now required by law, it was considered that the degree and nature of the complications which occurred were not unexpected in this type of surgery and the clinic felt it improper to raise excessive expectations as regards the chance of compensation.

(5) Form of information: Section 3-5 of the Law requires that information be provided ina form and manner appropriate to the patients ability to understand, comprehend and interpret it.

A woman of 70 with severe ischaemia of the left foot was referred by the general practitioner for immediate treatment. There was evidence of early gangrene. She was mentally retarded but had not been classified as legally imcompetent. Immediate angiography seemed indicated and the left leg appeared to be endangered. This was explained to her in very simple terms but she firmly refused admission. The staff doubted whether the patient understood the gravity of the situation. She was nevertheless discharged to her family home and the general practitioner was informed. It was considered that the terms of the law had been met.

(6) Patient's consent to treatment: This is required under Section 4/1 of the Law except where certain legal exceptions pertain. An explanatory memorandum points to such exceptions, e.g., where suspension of treatment could lead to very serious consequences for the patient, where a patient requiring immediate treatment is not capable of giving consent, or where there is mental incompetence or senile dementia. The case of the 70 year-old women considered under (5) above was not felt to fall within these exceptional situations.

(7) Right to refuse treatment: Section 4/9 of the Law entitles a patient to refuse even necessary treatment, e.g., blood transfusions; the section applies both to refusal on grounds of conscience and to the situation of the dying.

A man of 79 with severe cardiac and pulmonary complications developed occlusion of the common femoral artery. Surgery was considered feasible but was likely to demand blood transfusion. The patient was a Jehovah's Witness and had in advance refused blood. Despite the risk, surgery was carried out successfully without transfusion, thus respecting the patient's desires and legal rights.
Another man of 79 in poor condition and with an aortic aneurism which threatened to rupture was operated on successfully, but he subsequently developed severe respiratory and metabolic complications and was mentally confused. The family were fully informed as to the situation and very poor prognosis and they agreed that he should not receive aided respiration or haemodialysis.

The reviewers conclude that in the University Department concerned, the Law essentially confirmed the standards which were already being maintained as part of good medical and ethical practice.

It is likely that a similar conclusion will hold good for many clinics and practitioners worldwide as legislation on patients' rights is introduced and put into practice. Such a Law basically serves to

confirm the best existing standards and to apply these universally, even where conditions are less favourable than they are likely to be in a University clinic.

Source: Hanoa R. (2003): Karkirugisske pasienter og pasientrettighetsloven. Tidsskr Nor Laegeforen nr 3; 290–292.

United States

Malpractice claims against Health Management Organizations

A Pennsylvanian patient, Basile Pappas, was referred urgently by his physician to the emergency room at Haverford Hospital because of evidence that he had a spinal (epidural) abscess. He remained in the emergency room, untreated, for a period of three hours while his doctor argued with his Health Management Organization (U.S. Healthcare) over where to send him for further treatment. The practitioner maintained that he should be transported to the Thomas Jefferson University Hospital, but the HMO argued that this was an "out-of-network" facility, and proposed three alternative hospitals (Hahnemann, Temple or MCP). Hahnemann was contacted but could not offer immediate admission. MCP agreed to admit the patient at once. By the time he arrived there, however, the prolonged compression of his spine by the expanding abscess had resulted in permanent quadriplegia.

Pappas sued his general practitioner for malpractice and Haverford Hospital for negligence resulting in delay. Haverford then filed a third-party complaint against the HMO (U.S. Healthcare) alleging that it was responsible for the delay in his transfer to an appropriate facility. The general practitioner also filed a crossclaim against the HMO.

After conflicting decisions in lower courts, the Pennsylvania Supreme Court, applied principles to the case which had been developed earlier by the US Supreme Court in litigation involving Health Maintenance Organizations. It was held there that HMO physicians play roles both as administrators and as providers of health care. Some of the decisions they are called upon to make involve only treatment, others only eligibility issues, and yet others (as in this case) both treatment and eligiblity. Claims against them – and thus against the Health Maintenance Organizations themselves – can be brought under state medical malpractice law. It rejected – as it had rejected in an earlier case – an argument that medical negligence claims against HMO's were pre-empted by other legislation, notable the Employee Retirement Income Security Act ("ERISA") of 1974.

Since the above decision – here reported only in outline – was handed down in April 2001, it has had marked repercussions on litigation in the United States where claims against HMO's are concerned. Clearly such claims commonly will, like that summarized above, involve contesting actions and omissions by HMO's and their physicians which involve both therapeutic and eligibility issues, and it is important that - provided other States follow the lead given by Pennsylvania – they are not able to find legal refuge from medical negligence claims.

Source: Pappas v, Asbel. No. 98 E.D. Appeal Docket 1996, 2001 Pa LEXIS 687 (April 3rd 2001).

Doctor's duty to the unborn child

A Kansas women, Mrs Bonnie Nold, was cared for during her pregnancy by six physicians attached to Wesley Medical Center. During the first trimester of her pregnancy she tested positive for hepatitis B,

a serious infective condition which can be transferred to the unborn child. Mrs Nold was not informed of the positive test. Further, failure to follow strictly the prescribed hospital procedures resulted in her medical chart being incomplete. As a result of this, her newborn daughter Audra did not receive the gamma globulin injection which can be given to young infants to prevent their developing hepatitis B. Only two years after the birth, in connection with other treatment, was Mrs Nold made aware of the fact that both her daughter and herself were infected. Mr and Mrs Nold brought an action for medical negligence against the Wesley Medical Center and the physicians concerned.

In the Court of first instance, the case failed largely because of a judgement to the effect that expert evidence was not required with respect to the standard of care (including obstetric care and the maintenance of patient records). On appeal to the Kansas Supreme Court the judgement was overruled. Quite apart from finding the expert evidence on such matters was relevant and necessary (since the standard of care that is to be applied is not a rule of law), the Supreme Court went on to consider the entire issue of the various duties owed by an obstetric clinic and its staff to mother and (unborn) child. Essentially, it found that a physician who establishes a doctor–patient relationship with a pregnant woman, who intends to carry her pregnancy to term and deliver a health infant, also maintains a doctor–patient relationship with the foetus. The duty to the mother and the duty to the unborn child are intertwined. As regards the specific facts of this case, it went on to state that "...Where a communicable disease has been diagnosed in a pregnant woman who desires to continue her pregnancy to term and deliver a healthy baby" the treating physician has "an obligation as a matter of law to inform the woman of the diagnosis"... A woman's interest in preventing the spread of a disease is intertwined with any interest of her fetus" and thus entirely "consistent with a physician's tandem duty to the fetus..."

> In the US the physician has no statutory duty to his patient's unborn child, but this important decision creates a duty in case law. That duty is certainly incumbent upon the physician who has assumed the direct care of a pregnant woman. There may however be some difficulty in defining with whom the duty lies where a physician participating in a managed care scheme has merely referred the pregnant woman to a specialized centre or practitioner and has little more than diagnose the existence of the pregnancy.

Source: Nold v. Binyon and others. 31 P.3d 274 (Kan. 2001).

Surgery: Abandonment of a patient

On July 10th 2002, Dr David C. Arndt, an orthopaedic surgeon licensed in Massachusetts, commenced an operation for spinal fusion at Mount Auburn Hospital. At unspecified periods after the induction of anaesthesia and the start of surgery he made several telephone calls to an unspecified number to ask whether "his check was there yet". Later, and apparently several hours into the operation, he left the operating theatre without informing the staff where he was going or why and how long he would be away. He requested a second orthopaedic surgeon, who chanced to be present, to take over from him while he "took a break". The second surgeon, who was not experienced in this type of operation and did not have the credentials to perform it, agreed to do so despite the resultant disruption to his own operating schedule, in the belief that Arndt was simply going to the toilet. In fact after leaving the theatre, Arndt asked the sales representative of a medical device company to drive him to his bank and back. After he had been gone for some time, and efforts to contact him through his pager had been unsuccessful, the theatre staff called in the departmental heads of orthopaedics, surgery and anaesthesiology to decide what should be done. In fact Arndt returned after some 35 minutes and completed the operation.

The day after the operation, Arndt was suspended by the hospital, and the incident was notified to the State Medical Board which heard the case on August 8th. Evidence was given that the patient had not been harmed, but an investigator for the Board of Registration in Medicine stated that the patient's safety had been jeopardized. An anaesthesiologist who had told Arndt that his act constituted abandonment of his patient stated that the surgeon had expressed surprise at the accusation. There was evidence that he had told another physician that was having a financial crisis. In his defence, Arndt stated that the operation had taken more time than expected and that he had to go to the bank to cash a cheque. He admitted however that he had exercised serious misjudgement. The State Medical Board suspended his licence since he was considered to pose "an immediate threat to public health".

> It is universally recognized that a surgeon who undertakes an operation assumes direct responsibility for the care of the patient throughout, except insofar as he may need to delegate certain specialized tasks to other members of the team, namely the theatre nurses and the anaesthetist. He can only require others to take on his primary task if he is acutely incapacitated (e.g., by a migraine attack) during the operation, and he should not absence himself at any time except very briefly, e.g., for necessary refreshment or to visit the toilet. In all such instances he should explain the reasons for his leaving the theatre and ensure that the patient is maintained in a safe condition during his absence. The present case appears to represent an unusual instance of abandonment of surgical duties without sufficient reason.

Source: Lasalandra M. (2002): Doc Abandoned Surgery Patient to Cash Check. Boston Herald. 8 August.

The state of the "Learned Intermediary" doctrine

For many years, a common defence to injury cases brought by patients against the manufacturers of drugs or devices has been that the defendant owes no direct duty to the claimant since the product in question has been selected and prescribed by a "learned intermediary", i.e., the physician [1]. While such a defence is unlikely to be successful where the product is clearly defective (e.g., because of a manufacturing fault in a particular batch) it has often been employed with success in instances where the patient's claim is based on failure to warn of a known side effect or other risk. According to the "learned intermediary" doctrine, as concisely expressed in a 1974 case [2], the manufacturer's duty to warn extends only as far as the physician or other health care provider, who must be expected to weigh up the benefits and risk of the product before using it in a particular patient. As the Court put it in 1974: "The limitation of the warning duty to physicians . . . serves to reduce drug-related injuries while acknowledging the reality of patient reliance on physicians and the practical difficulties that would confront a drug manufacturer if it was required to warn the drug consuming public at large."

Most states of the U.S. and some Canadian courts as well have applied the doctrine. It has however become clear that it is not absolute, and that changes in practice could limit its application substantially. One such change is the widespread introduction of "patient package inserts" with prescription drugs which give information and warnings directly to an increasingly vocal public; another is the development in the U.S.A, New Zealand and some other countries of direct persuasive advertising to the public, the intention of which is to influence the public to develop its own preferences for particular drugs and to persuade the individual to request that his health care provider prescribe them.

The matter has been carried on further by massive litigation brought by women in the United States, either federally or within individual states, who claimed to have been injured by their use of the implantable contraceptive "Norplant". This hormonal product is reported to cause a series of adverse reactions associated especially with its particular form of subcutanous administration which involves placing six capsules

under the skin of the upper arm. While primary advertised to physicians in many countries, the firm had in the United States also engaged in direct-to-consumer advertising. It was alleged by claimants that the firm had failed to provide adequate warning to consumers, prescribing physicians or other relevant health care prescribers as to the risks posed by this type of contraceptive.

Although the federal claims originated in many States, a judicial panel had in the interests of efficient pre-trial handling of the matter entrusted the initial hearings to the District Court for the Eastern District Court of Texas. The defendants moved for summary judgement, pleading the learned intermediary doctrine; the plaintiffs argued that because of the direct-consumer advertising the decision to use the product was essentially taken by the woman herself, and that the learned intermediary doctrine would therefore not apply. In 1997, giving summary judgement, the Court found that the long list of possible side effects listed in the firm's material for physicians satisfied its duty to warn, and the "learned intermediary" doctrine was therefore applied to reject the claims [3]. The District Court's judgement was upheld by the Fifth Circuit in January 1999 [4].

By this time the total number of women seeking damages had risen to some 30,000. The bulk of these entered into financial settlements with the defendants, but 2970 women failed to settle in time or explicitly refused to do so, and a further motion for partial summary judgement was filed on their behalf. These claims were the subject of a judgement of the Federal District Court in question which was handed down on August 14th 2002 [5]. The Court dismissed the claims of 2960 claimants, applying the "learned intermediary" doctrine and finding that the side-effects listed in the manufacturer's information to physicians satisfied the company's duty to provide appropriate warnings. In the remaining ten cases, the claims could be accepted for further judgement, since the ten claims in question had substantial links to the State of New Jersey (e.g., because the women concerned were domiciled there and/or had filed their claims in that state). This was relevant in that New Jersey had in its case-law created an exception to the "learned intermediary" rule, applicable where products are sold with direct-to-consumer promotion.

Although the judgement also dealt with other issues related to causation and proof, its interest in the present connection lies in its application of this special rule relating to direct-to-consumer advertising. The New Jersey exception had its origins in the case of *Perez v. Wyeth Laboratories Inc.*, heard by the State's Supreme Court in 1999 [6]. Reversing the summary judgement of a lower court, the Supreme Court had reasoned that direct-to-consumer advertising allows doctors to participate themselves in the choice of a drug; such advertising also encroaches on the doctor-patient relationship by encouraging the lay user to request prescription of a particular product. In that Court's view, "The direct marketing of drugs to consumers generates a corresponding duty requiring manufacturers to warn of defects in their product."

As Wong [7] has commented in an expert commentary on this litigation, ". . .The dismissal of almost all the claims in *In re Norplant* based on the learned intermediary doctrine suggests that the doctrine remains intact. . . It remains to be seen whether *Perez*, only 3 years old, represents an anomaly or the beginning of a judicial response to changes in the roles of pharmaceutical companies, doctors and patients. . . The rise of direct-to-consumer advertising for pharmaceutical and other medical products may lead courts in various jurisdictions to make a *Perez*-style exception. Nonetheless, as the Fifth Circuit in *In re Norplant* suggests, the significant role that physicians play in prescribing prescription drugs supports the prevailing refusal to create a direct-to-consumer advertising exception to the learned intermediary doctrine."

> While these developments primarily affect the United States (and possibly New Zealand where direct-to-consumer advertising is similarly permitted) they could have repercussions in any country where the pharmaceutical industry in some way exerts an influence on prescribing patterns by a direct approach to potential patients. It may be noted that, after considerable controversy, a proposal to

introduce limited direct-to-consumer advertising in Europe was rejected by the European Union in 2002. An essential consideration for Courts will surely be the extent to which direct-to-consumer advertising indeed results in a change in prescribing practices, as it is clearly intended to do, rather than merely equipping the lay patient to engage in discussion with his or her physician regarding the latter's prescribing choices.

Sources:

[1] G. Dukes, M. Mildred and B. Swartz, The "learned intermediary" principle, in: *Responsibility for Drug-Induced Injury*, 2nd edn, M.N.G. Dukes et al. (eds), IOS Press, Amsterdam, Berlin and Oxford, 1998, pp. 317–319.
[2] Reyes v. Wyeth Laboratories: 498 F 2d 1264 (1974).
[3] In re Norplant Contraceptive Products Liability Litigation, 955 F.Supp. 700, 702-3 (E.D.Tex. 1997).
[4] In re Norplant Contraceptive Products Liability Litigation, 165 F.3d 374, 379 (5th Circ. 1999).
[5] In re Norplant Contraceptive Products Liability Litigation, 215 F.Supp.2d 795 (E.D.Tex. 2002).
[6] Perez v. Wyeth Laboratories Inc., 161 N.J. 1. 734 A.2d 1245 (1999).
[7] A. Wong, Products liability: The fate of the learned intermediary doctrine, *J. Law. Med. Ethics* **30**(3) (2002), 471–474.

Pathological findings on routine screening: Duty to inform patient (New Jersey)

Reed, an operator of heavy equipment, aged 27, was due to commence new employment, prior to which he was required to pass a physical examination. His employer contracted with a private medical agency (EMR) to carry out the examination, and EMR subcontracted the task to another firm ("Life Care"). The examination was carried out by Bojarski, an employee of Life Care, and included a chest X-ray. Bojarski consulted the radiologist DePersia on the interpretation of the films, and noted his conclusion that there was a widening of the mediastinum, which could point to the presence of Hodgkin's diseases or some other form of lymphoma. Bojarski reported to EMR that the chest X-ray was "abnormal" but provided no details.

Six months later, Reed sought medical help because of "flu-like" symptoms and severe loss of weight. Advanced Hodgkin's disease was diagnosed and he died ten months later. His wife brought an action for damages against the various parties involved; the cases against Bojarski and Life Care survived summary judgement. Bojarski argued, firstly, that there was no doctor-patient between Reed and himself, and that he therefore owed Reed no duty to inform him of the fact that he might be suffering from a dangerous condition. Secondly, he argued that he had acted reasonably in advising EMR that Reed's X-ray was "abnormal". In the Court of first instance, the jury unanimously found that Bojarski had met accepted standards of care, and the Appelate Division affirmed the judgement for the defendant. The New Jersey Supreme Court however reversed the judgement and remanded for a new trial [1].

The Supreme Court noted that, while other courts and jurisdictions had indeed tended to hold that an examining doctor had no duty, in the absence of a doctor–patient relationship, to disclose abnormalities to the patient, some courts had begun to shift away from this absolute rule. In its view, "New Jersey has long recognized that a physician owes a duty of reasonable care to the non-traditional patient" and it pointed to two earlier cases in the State where a doctor–patient relationship had been held to exist in pre-employment physical examinations. It also found a basis for this view in the State's public policy, as reflected in a regulation issued by the Board of Medical Examiners, and in an opinion of the American Medical Association's Council on Ethical and Judicial Affairs. The Supreme Court therefore concluded that a doctor conducting a pre-employment examination has a duty, which he cannot delegate to other parties, to inform the examinee of any potentially serious problems identified during the examination.

This judgement is of significance far beyond New Jersey, the Court having found a basis for its view in public policy and medical-judicial authority. However it is at least as important that the judgement is founded in common sense. A great many individuals go through life without undergoing. regular medical check-ups, and the need to pass a medical test in connection with a change of employment is likely to provide one of the few opportunities to detect early signs of a disorder which may need treatment. It is entirely proper that the medical examiner should communicate any such findings to the patient concerned. A more difficult consideration is whether the contractual arrangements under which medical examiners currently work will permit information to be given to any party other than that requiring the examination to be performed; it is likely that some contracts of this type will need to be amended.

Source:

[1] Reed v Bojarski. No. A-63, 2001 N.J. LEXIS 8 (Jan 23, 2001).

United Kingdom

Dentistry: Retained root; transfer of dental records

A dentist ("A") was consulted by a woman who had been experiencing symptoms from the lower right third molar tooth for some ten months. Extraction was advised and was carried out under local anaesthesia; three weeks later the socket was found to be healing satisfactorily.

However, four months after the extraction the patient returned to another dentist (B) at the same practice, complaining of pain, swelling and bad taste from the lower right quadrant. On clinical examination a bony spicule/tooth fragment was found, and a radiograph of the area showed a retained root. Dentist "B" referred the patient to hospital, and in the referral letter made the natural assumption that the root remnant was that of the third molar previously extracted by "A". The hospital undertook surgical removal of the retained root, and the discharge summary letter stated that a root fragment of the lower right third molar had been removed. The patient then brought a claim against "A", alleging that when she returned for follow-up of the original extraction she had indeed complained of a remaining fragment but that he had carried out only a cursory examination before reassuring her. According to her statement, she had continued to endure discomfort on a daily basis from then until the root was removed at the hospital. She claimed that "A" 's failure to perform an adequate examination at follow-up had led to unnecessary and protracted pain.

In his defence, the dentist claimed that at the follow-up visit the clinical appearance was that of a normal healing socket, that the whole of the lower right third molar had been removed, and that the retained root must have been the remnant of an adjacent molar tooth extracted years before by another dentist ("C"). However, he had not taken a preoperative radiograph of the tooth, and the limited previous dental records which were available did not assist.

Consulted by "A", the Dental Defence Union sought the opinion of an expert. The latter advised that if a retained root is to cause problems following an extraction, these will usually be represented by failure of the socket to heal, and that the symptoms will be reported rather sooner than 4 months after the extraction. The expert further expressed the opinion that if there was a pre-existing retained root in the position of the adjacent second molar tooth, it may have become uncovered with recession of the gingiva and bone tissue around the third molar region following the extraction of that tooth. This was

considered to be the most likely explanation of the course of events, particularly in view of the position of the retained fragment.

With the agreement of "A" the Dental Defence Union issued a denial of liability to the solicitors acting for the patient, accompanied by disclosure of the expert report. The solicitors later confirmed that their client would not be pursing the claim.

> In publishing this case, the Dental Defence Union comments that, while it is not an absolute requirement to take a preoperative radiograph prior to any dental extraction, in this case and with hindsight it would have been beneficial.
>
> One might add that this is particularly desirable in cases where the dental record is incomplete. Many patients do change dentists several times in the course of their lives and remarkably few individuals have a complete record of their dental treatment. Dentists commonly fail to seek transfer of patient records from a previous practitioner; this can result in subsequent problems, both for the patient and for the dentist himself

Source: Medical Defence Union (Website) Case report published 20 December 2002.

Gynaecology: Failure to diagnose a vesico-vaginal fistula after hysterectomy

A gynaecologist carried out a vaginal hysterectomy on a married woman. The recovery was complicated by various events: drainage flow through a suprapubic catheter was initially limited and heavily blood stained; there was initially a heavy loss of blood vaginally; the haemoglobin level dropped on the second day two to 6.8 g/dl and the patient developed abdominal pain and distension and pyrexia, with tachycardia at times.

Treatment in the first four postoperative days included catheter washouts and intravenous fluids, transfusion of four units of whole blood and a course of antibiotics. On day six the suprapubic catheter was clamped and she began to pass urine normally, though with severe spasms of pain. By day ten the temperature and urine flow were normal but the urine remained bloodstained. Shortly before removal of the suprapubic catheter that evening, the patient developed rectal and lower abdominal pain and urinary frequency and her pyrexia briefly returned; an analgesic was prescribed. Discharged two days later she was readmitted some hours later with pyrexia accompanied by rigor. Blood cultures and urinary sample showed no evidence of infection but a pelvic ultrasound scan showed a 4 cm haematoma in the vaginal vault. She was discharged three days later but shortly afterwards consulted her general practitioner because of heavy vaginal loss of blood; she was advised that this represented drainage of the haematoma. Two days later she returned to see the gynaecologist since she was passing very little urine. A vesico-vaginal fistula was suspected and confirmed by intravenous orography, as was a partial obstruction of the left ureter. A urologist repaired the ureter, which proved to have been occluded by a suture. The patient made a good recovery.

When the patient brought a claim for damages against the gynaecologist the latter sought the advice of the Medical Protection Society, which in turn consulted two experts. Both concluded that the gynaecologist's management of the postoperative care fell below a reasonable standard. In the 24 hours following the operation, the patient had a very low urinary output and haematuria and a catastrophic fall in haemoglobin; these factors should have been sufficient to indicate that a major postoperative haemorrhage had occurred. The persistent postoperative pyrexia and tachycardia did not appear to have been adequately investigated. Given the diminished urinary output following operation, the haematuria and the abdominal distension, a renal and pelvic ultrasound examination and/or intravenous orography

should have been carried out during the first five days after operation. While this patient did not show the classic presentation of an obstructed ureter with flank pain, she had nonetheless abdominal pain, persistent pyrexia and abdominal distension, all of which should have raised the alarm that she had sustained severe postoperative bleeding and injury to the renal tract. The patient's claim was thus considered irrefutable and a financial settlement was negotiated.

> It is striking in this case that all these complications are known risks of vaginal hysterectomy. Though they can usually be avoided the gynaecologist should be aware of them and of their presenting signs, and it is remarkable that in this case they were missed.

Source: Medical Protection Society: Casebook, July 2002.

Eye injury: Delayed treatment

A mother brought her 7-year-old son to the doctor since he had scraped his eye on a toy. The physician did not detect any injury when he examined the eye, and advised the mother to bathe it with a suitable solution and bring the child back if it failed to settle. She returned three days later by which time the eye was inflamed and there was a purulent discharge. The physician diagnosed conjunctivitis and prescribed an antibiotic. A further week later the child was returned to the consulting room in a condition described as sick and drowsy; the physician observe pus in the anterior chamber and arranged an immediate referral to an eye hospital. The eye was examined under anaesthesia by a registrar and a punched out defect in the sclera repaired, but according to the report no swab was taken for culture and no antibiotic was prescribed. When seen by a consultant the next day, the condition had improved but there was still a pupillary haze and a course of glucocorticoids was therefore prescribed. During the next few days the inflammation decreased but a cataract started to develop and the anterior chamber appeared to be reduced in depth. During a further examination under anaesthesia the consultant injected a high viscosity fluid into the anterior chamber, upon which the wound broke down and pus emerged. Despite intensive intravitrial, subconjunctival and intravenous antibiotics, it was too late to save the eye, which became shrunken and effectively blind.

The mother instituted an action against the various physicians concerned who in turn sought the advice of the Medical Protection Society. Several experts who were invited to assess the course of events were critical of all three physicians – the general practitioner for the delay in referral, the registrar for failing to investigate the possibility of an infection, and the consultant for allowing several days to elapse before undertaking a full assessment. An ophthalmologist considered that earlier treatment would have improved the prognosis for retaining an eye with useful vision. The mother's claim was settled out of court.

> Even minor injury to a child's eye merits the most careful examination and immediate treatment if the risk of permanent damage is to be reduced to a minimum or excluded. Referral for specialized examination and therapy is commonly advisable, since penetrating wounds can readily be missed. There should be no hesitation to give antibiotics. It is clear that in this case there were serious errors of judgement at all the three medical levels involved.

Source: Medical Protection Society: Casebook, July 2002.