International Journal of Risk & Safety in Medicine 10 (1997) 133–135
IOS Press

Law notes

Medical negligence and the use of estoppel

Stafford v. Neurological Medicine Inc., 811 F.2d 470 (8th Cir. 1987).
1996 Mo. App. LEXIS 366 (Mo. Ct. App. Mar 5, 1996).

In 1984 a Missouri woman with lung cancer underwent a CT scan by a Dr Cohen, who was attached to a private neurological clinic, in order to determine whether or not the condition had yet metastasized to the brain; since no brain deposits were found, the lung cancer was operated upon. Cohen subsequently found that the patient's insurance would not cover a CT scan conducted for preventative purposes; he therefore improperly altered his record of the diagnosis to "brain tumour", and submitted this on a claim form. The patient received a copy of the claim form, concluded that she was suffering from a brain tumour, and committed suicide. An action for wrongful death was brought against Cohen and the clinic by her husband, and in the Court of first instance damages for negligence were awarded.

Thereupon Cohen and the clinic sought to recover the sum from their insurers under a theory of joint liability. The trial court entered a jury verdict for the plaintiff, but the insurers appealed, claiming that the plaintiffs had failed to show how the physician's negligence caused Mrs Stafford's suicide. The appeal court agreed that Missouri law views suicide as an independent act breaking any causal relationship, and that proof would have to be provided that the suicide was a direct consequence of the negligence. Lacking such proof, Cohen and the clinic invoked the doctrine of collateral estoppel, i.e., claiming that in view of the findings in the original case brought by Mr Stafford their negligence in the matter was already established in law and could not be denied. The court of appeal rejected this argument; the insurer was not subject to the earlier findings because there had been no full and fair opportunity to litigate the issue.

It is not yet clear whether this line will be followed in future cases where a physician seeks to recover from his malpractice insurer; if a judgement in a malpractice suit, to the effect that the negligence indeed occurred and was a proximate cause of the damage, is not to be accepted as constituting a sufficient basis for assessing a subsequent insurance claim, physicians will face the curious and difficult challenge of having to establish their own negligence and its relevance. In view of the particular circumstances of this case, with the intervening suicide, there is reason to hope that other US courts will decline to follow it.

Publication of unfavourable drug information

A highly unusual case heard in Belgium in 1997, apparently reported only in the local media, raises questions as to the ethical standards maintained by some drug companies. In January of this year Dr Robert Bourguignon, a physician practising in Brussels wrote to the Lancet presenting certain results of an enquiry which he had conducted, together with a Flemish colleague, among general practitioners to detect possible serious adverse reactions of the antidepressant fluoxetine (Prozac®). Certain of the

physicians approached indeed described having observed severe psychic effects, variously in the form of severe nervousness, a sensation of impending death and attempted suicide; in two cases epileptic attacks had been provoked in susceptible subjects. In the Lancet, these findings were presented cautiously, the possibility being raised that bias in the response rate could have flattered the figures. The manufacturer of the drug however reacted to the enquiry by circularizing Belgian physicians stressing that the drug was safe and that "Questioning, without any scientific evidence, (Prozac's) efficiency and safety is false and dangerous". Thereafter the manufacturer brought an action in the Belgian courts against Dr Bourguignon for "negative publicity" which could injure the company financially. The Court of first instance in Brussels rejected the claim, but the case was at the time of writing due to go to appeal. In the meantime a Kentucky court has found for the same manufacturer in one of a large series of cases brought by US patients claiming to have suffered injury from Prozac®. However, because there was some reason to believe that the manufacturer had in fact arranged a substantial financial settlement with the plaintiff under which the latter would agree to withhold certain evidence and hence lose the case, the State of Kentucky has empowered a judge to conduct an investigation into the possibility that the firm had acted fraudulently. The outcome of both cases merits careful attention. This is not the first time that serious suspicion has arisen regarding the standards maintained by one or another major manufacturer in promoting a highly profitable new drug, in part by seeking to suppress unfavourable information, discourage inconvenient investigation or bar legal judgements which might mar its image. The pharmaceutical industry is entirely within its rights in seeking to counter activities which improperly injure its commercial interests, but there is clearly a risk that in doing so it will sometimes go well beyond the limit of what is ethically permissible.

"Wrongful birth" and the Daubert standard of evidence

Jones v. United States (No. 93-20137, 1996 US Dist. WL 382937 (N.D. Cal. July 3, 1996).

For a considerable period, courts in the US have struggled with claims brought by persons who attribute an unwanted pregnancy to incorrect contraceptive guidance provided by the health services and seek substantial damages; in some cases the sums sought relate to the entire costs of bearing and raising the "wrongfully born" child. Judgements have not been consistent, courts being swayed variously by the facts of each case, by the consideration that contraceptive advice is no more than advice, by the fact that all contraceptive methods (and their users) are fallible, and by the question how far an award of damages can reasonably go; not every unexpected child, after all, remains unwanted.

In mid-January 1992, Mrs Karyn Jones was prescribed contraceptive tablets by a US army gynaecologist, James Murphy; Dr Murphy did not indicate to her that certain drugs, if taken, might interfere with the product's contraceptive efficacy. Three weeks later (on February 7th) an army oral surgeon (Dr Cerbus) examined her for a dental condition for which he prescribed Penicillin-VK. Her medical record showed that she was taking contraceptive tablets but she was not warned of any potential interaction. On February 19th a second surgeon who prepared her for dental surgery did tell her that the drugs might interact, but a routine pregnancy test taken that same day proved positive, and a daughter was subsequently born. Mr and Mrs Jones then sued the Army for malpractice and wrongful life, seeking an award to cover the costs of pregnancy and of raising the child.

The court applied the criteria for acceptance of medical evidence recently set by the US Supreme Court in Daubert v. Merrell Pharmaceuticals, and rejected the claim. In effect the Daubert standard requires that medical evidence must reflect "scientific knowledge" and must be "relevant to the task at

hand". The first of these criteria will be assessed by considering whether the theory advanced by an expert is generally accepted by the scientific community, whether it has been subject to peer review and publication, whether it can be and has been tested, and whether the known (or potential) rate of error is acceptable.

In the Jones case, the court noted that the experts called by the plaintiffs had not conducted independent research on the drug interaction in question, that they had cited articles which did not find a statistically valid link between the use of antibiotics and contraceptive failure and/or had not been based on controlled scientific studies. As far as relevance to the matter at hand was concerned, the Court noted that while evidence had been adduced that antibiotics could interfere with oestrogen metabolism, the contraceptive tablets also contained a progestogen which itself might prevent pregnancy.

As far as the acts and omissions of the physicians were concerned, the court remarked that, when proposing a given form of treatment, the physician must disclose the available choices and the risks of each, but that relatively minor risks need not be discussed; interference caused by Penicillin-VK was considered such a minor risk.

Finally, the court considered that Jones had failed to prove that she had become pregnant during the brief period that she had taken Penicillin-VK before the positive pregnancy test was performed (i.e., 12–13 days), rather than before this time.

Outside the USA, the growth of "wrongful life" and "wrongful birth" actions in North America has long been regarded with some astonishment, and it is not surprising that they should be reined in to some extent. In this particular case, the facts themselves might have led to the failure of the plaintiff's case, especially in view of the timing of the events. However the court chose to rely on the Daubert standards as the basis for its views. This is of some concern; there are undoubtedly some situations in which it is commendable to apply the Daubert principles strictly, e.g., to thwart frivolous litigation and exclude the evidence of "professional witnesses" of poor standard, but there is a considerable risk that these rules may pervert the course of justice in other cases. Knowledge of adverse drug reactions and interactions, but also of other risks in medicine and surgery, accumulates very largely through field experience, and once a serious problem is identified with even a fair degree of probability it is customary to avoid any situation which can give rise to it, without awaiting the performance of controlled, statistically validated studies. Where the fear of a particular risk has arisen, it is even regarded as ethically unacceptable to undertake the controlled studies which might define it further. Even the appalling events relating to thalidomide in 1960/1 were never statistically proven to exist. It may therefore be asking a lot to require that a cause/effect relationship be statistically proven, or that expert witness must have themselves conducted studies relevant to the matter. Interactions between antibiotics and oral contraceptives are well recognized on the basis of case histories and retrospective studies alone and they widely taken into account in prescribing.

Not surprisingly, defendants in drug cases in the US appear to be seizing upon the Daubert standards as a sovereign remedy against unwelcome claims; the rules will have to be interpreted with much wisdom by courts if they are not to deprive legitimate and deserving claimants in cases involving new drugs of an opportunity to recover damages.