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Odisho v Bonazzi [2014] VSCA 11 (18 February 2014)

Background

On 17 April 2006, the appellant, Graxilda Odisho, was taken to the Royal Melbourne Hospital with symptoms that were subsequently diagnosed as multiple pulmonary emboli. Over the following days, the appellant was admitted to the Royal Women's Hospital where she received treatment for her condition.

The appellant subsequently commenced proceedings for damages against the respondent, Marcia Bonazzi, a specialist gynaecologist that the appellant had consulted on 17 February 2006 and 10 April 2006. The appellant alleged that her pulmonary emboli were caused by the respondent's negligence in failing to provide her with an appropriate warning concerning the side effects of a drug known as tranexamic acid. The drug had been prescribed to the appellant by the respondent to treat the appellant's abnormal heavy bleeding. Specifically, the appellant alleged that the respondent was negligent in failing to warn her of a risk that the drug may cause her to suffer a thromboembolic event.

In the primary decision, the County Court dismissed the appellant's claim concluding that:

- The exercise of reasonable care on the part of the respondent did not require her to warn the appellant that taking the drug carried with it the risk of thromboembolic events.
- The appellant had failed to establish that the drug was a cause of her pulmonary emboli.
- Even if the appellant had been given a warning that the drug carried with it a small risk of suffering a thromboembolic event, the appellant would not have been dissuaded from taking it.

On appeal, it was noted that doctors have a duty to warn patients of material risks inherent in any proposed treatment. As set out in Rogers v Whitaker (1992) 175 CLR 497, a risk is "material" if:

- In the particular circumstances, a reasonable person in the patient's position; or
- The doctor should reasonably be aware that the particular patient, would, if warned of that risk, likely attach significance to that risk.

The issues to be determined on appeal were whether the trial judge was wrong to have concluded that there was no breach of duty by the respondent in failing to give a relevant warning and whether the judge was wrong in failing to conclude that the appellant's consumption of the drug was a cause of her pulmonary emboli and that, given an appropriate warning, the appellant would not have taken the drug and developed pulmonary emboli.

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The Law

The duty to warn: ground 1

Determining whether there is a duty to warn of a material risk requires:

- An analysis as to whether in the circumstances of the particular case, a reasonable person in the patients position if warned of the risk, would be likely to attach significance to it (objective limb); and

- An analysis as to whether the medical practitioner is or should reasonably be aware that "the particular patient", if warned of the risk, would be likely to attach significance to it (subjective limb).

As to the objective limb of the enquiry, his Honour was not satisfied that the appellant had established that the respondent owed her a duty of care to warn her that thromboembolic events were described as being a rare side effect associated with the use of the drug because it could be said that a reasonable person in the appellant's position, if warned of that risk, would be likely to attach significance to it. In reaching this conclusion, his Honour had regard to the following factors:

- The drug was commonly prescribed for the type of symptoms that the appellant had been experiencing and was the drug of choice in managing the condition in a patient whose medical history was such that its prescription was not contraindicated.

- The appellant did not fall into the category of patients for whom the prescription of the drug was contraindicated by reason of her medical history.

- It was not the practice within the gynecological profession to warn patients to whom the drug was being prescribed of the risk of a thromboembolic event developing in association with the use of the drug.

- The appellant had presented to the respondent with a condition which, in no way life threatening, was one which was likely to be associated with considerable inconvenience.

- The methods available to manage the appellant's condition involved the prescription of the drug, the implementation of hormone based therapy, the insertion of an intrauterine device or the performance of a hysterectomy.

- The implementation of hormone replacement therapy carried with it a proven complication, although rare, of the development of thrombosis and pulmonary embolism.

- The appellant's virginity was important to her and for this reason it is unlikely she would have been willing to choose insertion of an intrauterine device as the preferred method of managing her condition.

- The relevant product literature described the drug as involving "a rare side effect" in the form of thromboembolic events, the risk of occurrence being < 1/1000

As to the subjective limb of the enquiry, his Honour again determined this issue against the appellant saying there was nothing in the evidence that suggested the appellant presented to the respondent as someone with "special needs or concerns" who would be likely to attach particular significance to a warning about the risks of thromboembolism.

On appeal, the Court of Appeal agreed with the trial judge's conclusion, with respect to the subjective limb, that the evidence did not disclose circumstances which should reasonably have made the respondent aware that the appellant, if aware of the risk of thromboembolism, would have been likely to attach significance to it.

However, the Court of Appeal observed that there seemed to be reasonable grounds for contending that reasonable care required a warning to be provided by the respondent. That said, given their conclusion with respect to the issue of causation, they did not find it necessary to determine the issue.

The issue of causation: ground 2

On the issue of causation, the trial judge found against the appellant on two bases. Firstly, his Honour was not persuaded that the appellant's consumption of the drug was a cause of her pulmonary emboli. Secondly, his Honour was not persuaded that, had the appellant been given a warning of the rare risk of thromboembolism, the giving of the warning would have made any difference.

On appeal, the Court of Appeal agreed with the trial judge that, on the evidence adduced, the appellant had not established that the drug she consumed was a cause of her pulmonary emboli. On the evidence it was no more than possible that it played some part.

Conclusion

The Court of Appeal went on to determine that when looking at the evidence as a whole, they were unpersuaded that an appropriate warning of the risk of pulmonary emboli would have made any material change to the events that occurred. In reaching this conclusion, the Court of Appeal had specific regard to "the exaggerated nature" of the appellant's answers to the questions put to her on the issue of what she would have done had she received a warning. Accordingly, the appeal was dismissed.

Lessons Learnt

This decision illustrates the difficulty of proving causation in "failure to warn" cases where the risk of a side effect is small. In essence, something more than a bald assertion by a plaintiff that, if warned, they would have declined the treatment, is required. The case also serves as a useful example of the combined objective and subjective approach used by the Courts in determining whether there is a duty to warn of a material risk.

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