DISCLOSURE

THE RIGHT TO BE INFORMED OF THE RISKS INHERENT IN MEDICAL TREATMENT

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CONTENTS

1. INTRODUCTION

Traditionally the doctor – patient relationship has been paternalistic in nature, the physicians knowledge placed him or her in a powerful position with respect to the patient. As the public have become better educated and more knowledgeable, patients are exerting their rights to autonomy and self-determination. To redress the power imbalance and to enable patients to make informed choices about their treatment it is essential that patients receive information about the benefits and risks associated with any course of treatment.

This paper examines the scope and content of a doctor's duty to advise and inform patients of the risks and implications of proposed treatment in New Zealand. It then compares the New Zealand law to the jurisdictions of Australia, Canada and England in relation to the disclosure of the risks associated with third generation oral contraceptive pills.

2. NEW ZEALAND LEGAL POSITION ON DISCLOSURE OF RISKS IN MEDICAL PROCEDURES

A. The Position in New Zealand Prior to the Accident Compensation Act 1972

Prior to the accident compensation legislation *Smith v Auckland Area Health Board*[1] was the leading decision on disclosure of risks in medical treatment in New Zealand. In that case the plaintiff suffered from a suspected aortic anneurysm. A diagnostic procedure known as an aortagram was carried out. This involved the injection of an opaque dye into his aortic artery to allow examination by means of an x-ray. During the procedure the flow of blood to his leg was interrupted necessitating the amputation of the leg. Prior to the aortagram the plaintiff had inquired if there were any risks involved. The doctor glossed over the question and reassured the plaintiff that he would be fine in a few days, neglecting to warn of the slight risks involved.

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[1] [1965] NZLR 191.

The plaintiff brought an action in negligence against the doctor's employer in respect of the conduct of the aortagram procedure and for the failure to warn the plaintiff of the risk of mishap. Despite the jury's finding that the hospital was negligent in respect of its failure, by its employees, to inform the plaintiff adequately of the risks Woodhouse J gave judgment for the hospital. The Court of Appeal reversed the decision and upheld the jury's verdict imposing a duty of care on the doctor in answering the patient's questions as the patient was relying on the answer as the basis of his consent to the procedure. The Court of Appeal restricted their decision to cases where an express inquiry as to the risks involved is made.[2] So where a patient makes a request for information the doctor is obliged to give an honest answer.

B. Disclosure of Risks in Medical Treatment under Accident Compensation Legislation

Negligence for failure to disclose risks in medical treatment is now the subject of the Accident Rehabilitation and Compensation Insurance Act 1992 as section 14 excludes actions for damages arising directly or indirectly out of personal injury covered by the Act. The accident compensation scheme does not however bar civil action where there is no physical injury or actions for exemplary damages.[3]

Early decisions of the Accident Compensation Appeal Authority[4] on claims for medical misadventure restricted the decision in *Smith v Auckland Area Health Board*[5] holding that unless a patient asked specific questions the doctor was not obliged to inform the patient of risks involved in the treatment.[6]

The Accident Compensation Appeal Authority has since recognised an obligation on doctors to adequately advise and inform patients of risks. Inaccurate advice,

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[2] *Smith v Auckland Area Health Board*, above n1, 197.
[3] See *Donselaar v Donselaar* [1982] 1 NZLR 97; *Green v Matheson* [1989] 3 NZLR 564.
[4] See *Re Priestley* ACAA 14/84; *Re McElhinney* ACAA 177/88; *Re P* ACAA 2/89; *Goslingv v ACC* [1990] NZAR 76.
[5] *Smith v Auckland Area Health Board,* above n1.
[6] David B Collins *Medical Law in New Zealand* (Brooker & Friend Ltd, Wellington, 1992) 59-60.

whether in response to a question or not, was held to be medical misadventure in *Re K*[7].

In *H v ACC*[8] a woman became pregnant after her doctor failed to warn her of the risk that her tubal ligation might fail to sterilise her. This was held not to be medical misadventure as the failure to warn of the risk did not cause the pregnancy. However the advice that she could discontinue other contraception was held to be an inadequate answer to her question and therefore constituted medical misadventure.

In the case of *Smith v ACC*[9] it was held that to establish medical misadventure for lack of informed consent the plaintiff must show that the doctor owed a duty of care to inform the plaintiff of the risk, that the doctor breached that duty and that the damage suffered was caused by the breach of the duty.

C. Medical Council of New Zealand's Position on Disclosure of Information

In 1990 the Medical Council of New Zealand resolved to publish a statement on information and consent to offer guidelines to the medical profession. The Medical Council believes that any statutory definition of medical misconduct should include the inadequate transfer of information to a patient deciding on a medical procedure.

> The Medical Council of New Zealand takes the view that (except in an emergency or a related circumstance) the proper sharing of information, and the offering of suitable advice to patients, is a mandatory prerequisite to any medical procedure instituted by a medical practitioner. This applies whether the procedure is a diagnostic one, a medical or pharmacological regimen, an anaesthetic, or any surgical, obstetric, or operative procedure.[10]
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> Information must be conveyed to the patient in such detail and in such a manner, using appropriate language, as to ensure that an informed decision can be made

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[7] [1986] 6 NZAR 231.
[8] [1990] 8 NZAR 289.
[9] [1993] NZAR 490.
[10] Medical Council of New Zealand "A Statement for the Medical Profession on Information and

by that particular patient. The necessary standard for this requirement (that is the extent, specificity and mode of offering the information should be that which would reflect the existing knowledge of the actual patient and the practitioner. More generally, it should also reflect what a prudent patient in similar circumstances might expect.[11]

Thus the Medical Council of New Zealand appears to be in favour of a patient focused standard rather than the doctor focused standard[12] developed by the House of Lords in *Sidaway v Board of Governors of the Bethlem Royal Hospital*[13]

D. Accident Rehabilitation, Compensation and Insurance Act 1992

Personal injury that is the result of a negligent failure to obtain informed consent is covered by the accident compensation legislation.

Section 8 (2) Cover under this Act shall extend to personal injury which-

(c) Is medical misadventure ...

Section 5 Definition of "medical misadventure"

(b) A failure to obtain informed consent to treatment from the person on whom the treatment is performed or that person's parents, legal guardian, or welfare guardian, as the case may be, is medical misadventure only if the registered health professional acted negligently in failing to obtain informed consent.

In the 1997 High Court case of *Doyle v Accident Compensation Corporation*[14] the facts had not been sufficiently established in the Accident Compensation Appeal Authority so Fisher J answered the question of law on assumed facts so as not to further delay the proceedings. The case was destined to fail as the personal injury did not occur in New Zealand, however Fisher J held medical misadventure

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Consent" (Wellington, 1990).

[11] Medical Council of New Zealand "A Statement for the Medical Profession on Information and Consent" (1990).

[12] David B Collins *Medical Law in New Zealand* (Brooker & Friend Ltd, Wellington, 1992) 59-60.

[13] [1985] 1 All ER 643.

[14] [1997] 3 NZLR 160.

includes a mishap flowing from deficient medical advice[15] which can take one of two forms:

- "[a] breach of a doctor's duty to use due care in answering a patient's question where the patient, to the knowledge of the doctor, intends to rely on the answer in making a decision with respect to a potential medical procedure"
- a breach of doctor's "duty to warn a patient of a material risk inherent in proposed treatment. A risk is material:

  (i) if in the circumstances a reasonable person in the patient's position, if warned of the risk, would be likely to attach significance to it; or

  (ii) if the medical practitioner is aware, or reasonably should be aware, that if warned of the risk, the particular patient would be likely to attach significance to it"[16]

> To summarise, in a case of the present kind the claimant must prove three things:
> (a) deficient medical advice, in the sense that the information provided culpably misrepresented the likely outcome or culpably failed to warn of material risks as to the likely outcome;
> (b) physical or mental consequences which were adverse and unforeseen from the claimant's point of view; and
> (c) a causal link between the two.[17]

This case illustrates a shift from the English standards of professional negligence favoured in the earlier Accident Compensation Appeal Authority cases towards the Australian and North American patient focused standards.

E. Health and Disability Commissioner's Code of Health and Disability Services Consumers' Rights 1996

Right six of the Code of Health and Disability Services Consumers' Rights provides the right to be reasonably informed.

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[15] *Doyle v ACC*, above n14, 165.
[16] *Doyle v ACC*, above n14, 165.
[17] *Doyle v ACC*, above n14, 166.

(1) Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including

(b) An explanation of the options available, including an assessment of the risks…

A complaint that any action of any health care provider or disability services provider appears to be in breach of the Code may be made under section 31 of the Health and Disability Commissioner Act 1994. The Commissioner can investigate the complaint, refer the complaint to an advocate for resolution or decline to take any action.

If the complaint is investigated and found to be in breach of the Code section 45 provides that the Commissioner may refer the matter to the Director of Proceedings who may assist the complainant to take proceedings, institute proceedings before the Complaints Review Tribunal or institute disciplinary proceedings. The Complaints Review Tribunal has a discretion as to remedies but can grant declarations, damages and orders as to conduct.

Section 57 provides that the Tribunal may award damages for

(a) pecuniary loss

(b) loss of any benefit

(c) humiliation, loss of dignity, and injury to the feelings of the aggrieved person

(d) any action of the defendant that was in flagrant disregard of the rights of the aggrieved person.

F. New Zealand Bill of Rights Act 1990

In *Simpson v Attorney-General*[18] the Court of Appeal held that a breach of the New Zealand Bill of Rights Act can give rise to a discretionary remedy by way of monetary compensation. The accident compensation scheme bar applies only to proceedings for damages arising out of personal injury covered by the scheme. Thus the bar may not apply to Bill of Rights actions even where there is personal

[18] [1994] 3 NZLR 667 (CA).

injury. The scope of this remedy in medical negligence cases is likely to be narrow as courts will probably take into account the availability of other courses of action and, if accident compensation is available, the court would be unlikely to find it inadequate.[19]

Section 11 provides the right to refuse to undergo medical treatment, inherent in which is the right to be informed of the risks involved in medical treatment so as to be able to make an informed choice whether to undergo or forego the treatment. Theoretically an action could be brought for a breach of the Bill of Rights Act but the outcome of such an action is uncertain especially if there is a personal injury involved.

G. Exemplary Damages

Exemplary damages "... sometimes also called punitive damages are not awarded to compensate the plaintiff (although of course they will be some solace) but to punish the defendant for high-handed disregard of the plaintiff's rights or the like outrageous conduct."[20]

Claims for exemplary damages are not barred by the accident compensation legislation.[21] However exemplary damages should only be awarded where the compensatory damages are insufficient to punish the defendant and any temptation to award exemplary damages merely because the statutory benefits may be felt to be inadequate should be kept under a tight rein.[22]

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[19] Stephen Todd (ed) *The Law of Torts in New Zealand* (2ed, Brookers, Wellington, 1997) 94.
[20] *Green v Matheson* [1989] 3 NZLR 564, 571.
[21] *Donselaar v Donselaar* [1982] 1 NZLR 97.
[22] *Donselaar*, above n21, 104, 107.

3. CASE STUDY: DISCLOSURE OF THE RISKS OF THIRD GENERATION ORAL CONTRACEPTIVE PILLS

A. Background Information

The oral contraceptive pill consists of two hormones – oestrogen and progesterone. It prevents pregnancy by ceasing ovulation, the production of eggs. The third generation of oral contraceptive pills use desogestrel or gestodene as the progesterone. These two progesterones have an increased risk of venous thromboembolism (VTE)[23]. VTE is a condition whereby a blood clot forms in a large vein. When pieces of the clot break off and travel to the lungs, it is known as a pulmonary embolus, which can be life threatening.[24]

A series of studies in 1995[25] revealed that the risk of developing a blood clot was double for women on the third generation pills in comparison to the second generation pills. Instead of one in ten thousand with the older pills the chances are two in ten thousand. In October 1995 British women were advised to change contraceptive pill brands. The result was a 'pill scare' – a rise in unwanted pregnancies and abortions.[26]

In New Zealand the Ministry of Health formulates advice on prescribing drugs for doctors. In July 1996 the Ministry of Health advised medical practitioners to consider prescribing one of the oral contraceptives containing levonorgestrel or norethisterone in preference to one of the third generation pills.[27]

By May 1999 nine New Zealand women had died from blood clots while using a

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[23] Ministry of Health "Prescriber Update" 12 (1996) 2.
[24] Medsafe "Oral Contraceptives and Blood Clots" (Medsafe, Wellington, Feb 1999)
[25] WHO "Collaborative Study of Cardiovascular Diseaese and Steriod Hormone Contraception. Veneous thromboembolism and combined oral contraceotives: results of international multicentre case-control study" Lancet (1995) 346: 1575. WHO "Collaborative Study of Cardiovascular Diseaese and Steriod Hormone Contraception. Effect of different progestagens in low oestrogen oral contraceptives on veneous thromboembolic disease" Lancet (1995) 346: 1582.
[26] W O Spitzer "The 1995 Pill Scare Revisited: Anatomy of a Non-epidemic" 12 (1997) Human Reproduction, 2347-57.
[27] Ministry of Health "Prescriber Update" 12 July (1996) 2.

third generation oral contraceptive pill.[28]

B. Legal Action for Deficient Medical Advice in New Zealand

If a patient has been prescribed third generation oral contraceptive pills without adequate disclosure of the risks involved there are several avenues of legal recourse.

1. Accident Rehabilitation, Compensation and Insurance Act 1992

A patient will be eligible for compensation under the accident compensation scheme if she can establish medical misadventure, to do so requires negligence on behalf of the doctor. A doctor has a duty of care to warn a patient of material risks in proposed treatment.[29] Thus materiality of the risk must be established to found a duty of care.

"The risk of a normal healthy woman developing a blood clot in one year is one in 30,000."[30] Second generation pills have a one in 10,000 risk while third generation pills have a two in 10,000 risk and pregnancy has a six in 10,000 risk.

> Of those who get a blood clot, 1-2 percent will die. One death in about two years would be expected in New Zealand woman using oral contraceptives. Up to the end of 1998, at least seven woman using oral contraceptives died in New Zealand of a blood clot on the lungs....All of those who died were using third generation pills, the first of which became available in 1982. The reason for the higher than expected number of deaths in recent years is unclear. Sometimes natural fluctuations can cause unexpectedly high or low numbers of events.[31]

The risk is therefore quite small but if it eventuates the consequences are very severe. A perfectly healthy woman may not attach any significance to the risk,

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[28] Ministry of Health Press Release 25 May 1999; M Johnston "The Pill: clots kill more women" The New Zealand Herald 26 May 1999, 1.
[29] *Doyle v ACC*, above n14, 165.
[30] Medsafe :Oral Contraceptives and Blood Clots" (Medsafe, Wellington, Feb 1999). See also www.medsafe.govt.nz
[31] Above n30.

however the patient's position may be such that a reasonable person in that position would attach significance to it.

> Some of the risk factors for blood clots are a previous blood clot, a close family member who has had a blood clot, bad varicose veins, being overweight, cancer, recent surgery and being immobilised. Woman who have had a previous blood clot should not take a contraceptive pill containing oestrogen.[32]

If a patient has increased risk factors then a duty to warn of inherent risks exists. Also if a patient asks about the risks involved the doctor is obliged to answer accurately.[33] If the patient does not have any of the increased risk factors and does not ask about the risks involved the doctor may not owe her any duty to disclose the risk. The defendant would argue that as the risk is higher whilst pregnant and the pill prevents pregnancy then the slight risk is in fact protecting the patient from an even higher risk. However as there are other courses of action available to the patient, in order to make an informed choice, she requires all relevant information, so a duty of care may exist.

To receive compensation under the accident compensation scheme it is necessary to have a personal injury – adverse or unforeseen physical or mental consequences from the plaintiff's point of view.[34] If the plaintiff actually suffers from VTE proving damage will be straight forward. If the plaintiff suffers no actual personal injury then despite the deficient medical advice she cannot recover under the accident compensation scheme.

There must be a causal link between the deficient advice and the adverse consequence. This appears to mean that the plaintiff must show that had she received the correct medical advice she would have followed an alternate course of action. In this case that the plaintiff would not have taken the third generation contraceptive pill. This could be difficult to establish as of course with hindsight she would not have taken the pill, so it will be an evidential matter.

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[32] Medsafe "Oral Contraceptives and Blood Clots" (Medsafe, Wellington, 1999).
[33] *Smith v Auckland Area Health Board*, above n1.
[34] *Doyle v ACC*, above n14.

Causation is factually difficult to prove in medical negligence cases due to the complex nature of disease and injury. It is necessary to show that the doctor's conduct could cause the plaintiff harm and that in the particular case the harm did arise from the doctor's conduct.[35] The former depends on expert opinion which can vary widely, whilst the latter requires establishing exactly what the doctor's conduct was.

The House of Lords examined causation in *Hotson v East Berkshire Area Health Authority*[36] In that case the plaintiff fell from a tree injuring his hip. The injury was not correctly diagnosed till five days after the accident, by which time the plaintiff had developed a condition which caused major permanent disability. If the plaintiff had been correctly diagnosed there was still a 75 percent chance of developing the disability, so the trial judge awarded damages for the loss of the 25 percent chance of recovery. Though the decision was affirmed by the Court of Appeal, the House of Lords reversed it on the basis that the fall was the sole cause of the plaintiff's injury so negligence could not be established.

In the case of *Wilsher v Essex Area Health Authority*[37] the House of Lords emphasised that the burden of proving causation rests on the plaintiff and that apart from exceptional cases the plaintiff must show the defendant caused or materially contributed to the injury. Materially increasing the risk of injury does not establish a material contribution but may form the basis of an inference that the defendant did materially contribute to the injury.

Bolitho v City & Hackney Health Authority[38] concerned a two year old boy with respiratory difficulties. When his condition deteriorated the senior paediatric registrar was called, who left a message for her senior house officer to attend. Due to a faulty bleeper the message did not get through and the child suffered a total respiratory collapse and cardiac arrest resulting in severe brain damage. The House of Lords upheld the decision of the Judge and the Court of Appeal that the claim of

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[35] I Kennedy & A Grubb *Medical Law – Text with Materials* (2ed, Butterworths & Co, London, 1994) 468.
[36] [1987] 2 All ER 909 (HL).
[37] [1988] 1 All ER 871.
[38] [1997] 3 WLR 1151 (HL).

negligence failed for want of causation. As even if the doctor had attended, on the symptoms described the child would not have been intubated which was the only procedure that could have prevented the outcome.

As the courts have refused to reverse the burden of proof causation remains a barrier to plaintiffs seeking to establish medical negligence. If the plaintiff suffered VTE and had increased risk factors or had asked questions about the risks involved it should be possible to establish medical misadventure. However if the plaintiff was in perfect health and did not make any inquiry as to the risks she might not be covered by accident compensation.

2. *Health and Disability Commissioner's Code*

The plaintiff would need to establish that her doctor had failed to provide her with the information that a reasonable consumer in the plaintiff's circumstances would expect to receive. This would be the same as establishing a duty of care in negligence. Thus if the plaintiff had increased risk factors then her circumstances would demand a full explanation of the risks involved. If the plaintiff was a healthy woman the defendant would argue that a reasonable consumer would not expect disclosure of the risk.

If the plaintiff established a breach of the Code then the Director of Proceedings may institute proceedings before the Complaints Review Tribunal. The benefit of an action for breach of the Health and Disability Commissioner's Code is that not only can the plaintiff recover pecuniary damages and damages for loss of a benefit but also for any action of the defendant that was in flagrant disregard of the rights of the aggrieved person. An action of this kind does not require personal injury so is available in situations not covered by the Accident Compensation legislation.

Thus it is possible to get both compensatory and exemplary damages in this action, however it is at the discretion of the Health and Disability Commissioner.

3. *New Zealand Bill of Rights Act 1990*

It may be possible to bring an action for a breach of section 11 of the Bill of Rights. However as it is a discretionary remedy the outcome would be uncertain where personal injury is involved.

4. *Exemplary Damages*

Exemplary damages may be recoverable under the Health and Disability Commissioner's Code or where the compensatory damages are insufficient to punish the defendant. Section 57 of the Health and Disability Commissioner's Act allows damages to be awarded against the defendant for a breach of the Code where the defendant's action was in flagrant disregard of the rights of the aggrieved person. The Code gives all consumers the right to the information that a reasonable consumer would expect to receive. The plaintiff would need to establish that a reasonable consumer would expect to be informed of the risks of using third generation oral contraceptive pills. Further the plaintiff would need to establish that the defendant's failure to adequately disclose the risks was a flagrant disregard of her rights.

4. LEGAL POSITION IN OTHER JURISDICTIONS

A. English legal position

In England the law of consent has been developed by the courts rather than Parliament. So the rules have emerged in the context of specific disputes instead of being drafted to deal with general disputes. The English Courts have established one standard of medical negligence for all aspects of medical conduct – treatment, diagnosis and disclosure of risks.

The most important English case on the standard of professional liability is *Bolam v Friern Hospital Management Committee*[39]. In that case Bolam was a voluntary patient being treated for depression by electro-convulsive treatment (ECT) at Friern Hospital. During the ECT he sustained fractures of the pelvis on each side caused by the head of the femur being driven through the acetabulum or cup of the pelvis. Bolam alleged the defendants were negligent for failing to administer relaxant drugs or sufficient manual controls to prevent the fractures and failing to warn him of the risks he was running when he consented to the treatment.

McNair J set out the standard of care of negligent professionals:

> The test is the standard of the ordinary skilled man exercising and professing to have that special skill. A man need not possess the highest expert skill at the risk of being found negligent. It is a well-established law that it is sufficient if he exercises the ordinary skill of an ordinary competent man exercising that particular art.[40]

> a doctor is not guilty of negligence if he has acted in accordance with the practice accepted as proper by a responsible body of medical men skilled in that particular art ... putting it the other way around, a doctor is not negligent, if he is acting in accordance with such a practice, merely because there is a body of opinion which would take a contrary view."

McNair J formulated a two step test to determine if there is a duty to warn:
(1) "does good medical practice require that a warning should be given"?
(2) "if a warning should be given, what difference would it have made?"[41]

The jury found for the defendant, Friern Hospital, so a practitioner need only disclose risks that a responsible body of medical people would disclose. Where there is more than one accepted body of competent opinion it is open to the practitioner to follow either of them.[42] The patient also needs to establish they would have followed an alternate course of conduct had the advice been given.

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[39] [1957] 1 WLR 582.
[40] *Bolam*, above n39, 586.
[41] *Bolam*, above n39, 588.
[42] *Maynard v West Midlands Regional Health Authority* [1985] 1 All ER 635.

The House of Lords modified the professional standard of negligence slightly in *Sidaway v Governors of the Bethlehem Royal & Maudsley Hospital.*[43] The case does not provide a particularly coherent statement of the law as each of the four speeches contain significantly different approaches. However all five Law Lords agreed that Mrs Sidaway could not recover because of the difficulties of proving what was actually said due to the death of the doctor concerned.

The plaintiff suffered from recurrent neck, shoulder and arm pain. She was advised by a surgeon employed by the defendant to undergo an operation on her spinal cord. In the course of the operation the plaintiffs spinal cord was injured resulting in severe disability. The plaintiff alleged the surgeon was negligent in failing to disclose to her the one – two percent risk of damage to the spinal cord and nerve roots.

The majority of the Law Lords agreed that a subjective test for disclosure would be untenable. They rejected the North American concept of informed consent and held that the *Bolam* professional medical standard would prevail so as not to place unwarranted restraints on medical practice and to keep the law simple. However they added a slight modification: in a case involving "a substantial risk of grave adverse consequences"[44]

> ... the judge might in certain circumstances come to the conclusion that disclosure of a particular risk was so obviously necessary to an informed choice on the part of the patient that no reasonably prudent medical man would fail to make it.[45]

Lord Bridge of Harwich also added obiter that if questioned specifically about the risks involved in a particular treatment the doctor is under an obligation to answer both truthfully and as fully as the questioner requires[46]. However in *Blyth v Bloomsbury Health Authority*[47] the Court of Appeal considered the decisions in

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[43] *Sidaway*, above n13.
[44] *Sidaway*, above n13, 663.
[45] *Sidaway*, above n13, 663.
[46] *Sidaway*, above n13, 661.
[47] [1993] 4 Med LR 151.

Sidaway and held that Lord Diplock and Lord Bridge did not lay down any rule of law to the effect that where questions are asked by the patient the doctor is obliged to give all information to the patient. In that case the plaintiff claimed she had asked her doctor about the side effects of her medication and he had failed to warn her of the risks. The Court of Appeal reversed the decision at first instance on the facts as it was found that the plaintiff had not requested the information. The Court held "the question of what a plaintiff should be told in answer to a general enquiry cannot be divorced from the *Bolam* test"[48] even where a specific question has been asked.

In *Sidaway* Lord Scarman dissented, refusing to apply the *Bolam* principle to cases involving the provision of advice or information. Of the *Bolam* test he said "The implications of this view of the law are disturbing. It leaves the determination of a legal duty to the judgment of doctors." He argued that the prudent patient test should be applied in English law.

> ... the merit of the propositions enunciated in Canterbury v Spence is that, without excluding medical evidence, they set a standard and formulate a test of the doctor's duty, the effect of which is that the Court determines the scope of the duty and decides whether the doctor has acted in breach of his duty. This result is achieved, first, by emphasis on the patient's "right of self determination" and second, by the "prudent patient" test. If the doctor omits to warn where the risk is such that, in the Court's view, a prudent person in the patient's situation would have regarded it as significant, the doctor is liable.[49]

The House of Lords affirmation of the *Bolam* test has been critcised primarily because the test allows the standard of care of medical professionals to be determined by medical opinion[50]. This is based on the paternalistic body of thought that 'doctor knows best". In opposition to this view it is believed that "... what constitutes, in law, reasonable medical practice is a matter for judicial determination to be informed by, but not delegated to, medical opinion."[51] In *Reibl*

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[48] *Blyth*, above n47.
[49] *Sidaway*, above n13, 653.
[50] J Keown "Burying Bolam: Informed Consent Down Under" (1994) 53(1) CLJ 16-19.
[51] Above n50, 16.

v Hughes[52] Laskin CJC stated:

> To allow expert medical evidence to determine what risks are material and, hence, should be disclosed and, correlatively, what risks are not material is to hand over to the medical profession the entire question of the scope of the duty of disclosure, including the question whether there has been a breach of that duty.[53]

In *Rogers v Whitaker*[54] it was stated:

> ...even if a patient asks a direct question about the possible risks or complications, the making of that inquiry would logically be of little or no significance; medical opinion determines whether the risk should or should not be disclosed and the express desire of a particular patient for information or advice does not alter that opinion or the legal significance of that opinion.[55]

The test does not require the practice to be accepted by the majority of the medical body so "[t]he courts would appear to view with equanimity the notion that a procedure may be both in and not in a patient's best interests; medical opinion can, it seems, even defy logic."[56]

Sidaway has been criticised for failing to produce a clear *ratio descendi* or statement of law as the four Law Lords took significantly different approaches in their judgments. Apart from Lord Scarman's dissent the Law Lords do not deal with the fundamental human right to control one's destiny by having sufficient information to make an informed choice whether to accept or refuse treatment[57]. A further criticism is the failure to explore why doctors should be in a special position compared to other professionals. A solicitor would not be protected from liability if he or she took an action without their client's permission in order to save the client from the distress of making the decision.[58]

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[52] (1980) 114 DLR (3d) 1.
[53] *Reibl v Hughes*, above n52, 13.
[54] [1992] 175 CLR 479.
[55] *Rogers v Whitaker*, above n54, 486-487.
[56] Above n50, 17.
[57] Health Care Law at 353 referring to I Kennedy *Treat Me Right: Essays in Medical Law and Ethics* (1988, Clarendon, Oxford) at 389.

The test in *Bolam* also places a heavy burden on the plaintiff both in establishing a breach of the duty and causation. However two recent decisions of the High Court suggest that the courts may be easing these burdens[59]. In *Smith v Tunbridge Wells Health Authority*[60] the plaintiff, a 28 year old man, became impotent and lost bladder control after surgery to correct a rectal prolapse. Morland J followed the Australian case of *Rogers v Whitaker*[61] by a 'proper application' rather than a rejection of the *Bolam* test, holding that "although some surgeons may still not have been warning patients similar in situation to the plaintiff of the risk of impotence, that omission was neither reasonable nor responsible."

> *Smith* can claim to be one of the very rare cases in which a doctor has been held liable in negligence even though acting in accordance with a practice accepted by other competent colleagues.[62]

In *McAllister v Lewisham and North Southwark Health Authority & Others*[63] the removal of a vascular deformity in the plaintiff's brain left her leg weaker than before the operation and one of her arms was rendered totally useless. Rougier J held the surgeon was negligent for failing to make a fuller disclosure of the risks. The judge then went on to hypothesize as to what the plaintiff would have done had she known all the risks and held on the balance of probabilities that she would have declined the operation.

These two cases suggest a trend towards a less strict application of the *Bolam* principle. However until it is tested in the appellate courts the correct application of *Bolam* is unclear.

B. Canadian Legal Position

North America has developed a doctrine of informed consent based on the autonomy of each individual patient and the right of self-determination. The classic

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[58] Health Care Law at 353 referring to I Kennedy *Patients, Doctors and Human Rights*
[59] J Keown "Easing the Burdens on Medical Plaintiffs" (1995) 54(1) CLJ 30.
[60] [1994] 5 Med LR 334 (QB).
[61] *Rogers v Whitaker*, above n54.
[62] J Keown "Easing the Burdens on Medical Plaintiffs" (1995) 54(1) CLJ 30, 31.

statement of this comes from the 1914 American case *Schleondorff v Society of New York Hospital*:

> Every human being of adult years and sound mind has a right to determine what shall be done with his own body, and a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable in damages.[64]

Canadian doctors have a duty to their patients to disclose "...the nature of a proposed operation, it's gravity, any material risks and any special or unusual risks attendant upon the performance of the operation."[65]

The leading Canadian case is *Reibl v Hughes*[66] which follows the American case of *Canterbury v Spence*[67] in which it was held that doctors are obliged "to communicate specific information to the patient when the exigencies of due care call for it."[68] "The scope of the physician's communications to the patient, then must measured by the patient's need, and that need is the information material to the decision."[69] "A risk is ... material when a reasonable person, in what the physician knows or should know to be the patient's position, would be likely to attach significance to the risk or cluster of risks in deciding whether to forego the proposed therapy."[70] Causation will be shown if the plaintiff can establish s/he would have declined the treatment if s/he had known of the risks.[71]

Reibl v Hughes involved a neurosurgeon who failed to give adequate information to the plaintiff of the risks involved in an operation to repair an artery in the plaintiff's neck, the purpose of which was to prevent a stroke in the future. The surgeon advised that it was preferable to have the operation but neglected to inform that there was a ten percent risk that a stroke could occur during or immediately

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[63] [1994] 5 Med LR 343.
[64] (1914) 211 NY 125, 105 NE 92, 93.
[65] *Hopp v Lepp* (1980) 13 CCLT 66, 87.
[66] *Reibl v Hughes*, above n52.
[67] (1972) F(2d) 772, 780, 791.
[68] *Canterbury v Spence,* above n67, 781.
[69] *Canterbury v Spence*, above n67, 786.
[70] *Canterbury v Spence*, above n67, 787 referring to Waltz and Scheuneman "Informed Consent to Therapy" (1970) 64 NWUL Rev 628, 639-41.
[71] *Canterbury v Spence*, above n67, 791.

after the operation. The risk eventuated paralyzing the plaintiff down the right side of his body.

Laskin CJC held that lack of 'informed consent' cases should properly by handled under the law of negligence. Battery law applies only where there has been no consent, or the treatment goes beyond the consent, or the consent was obtained by fraud or misrepresentation.[72] A doctor has a duty to disclose all material risks inherent in the proposed treatment because a patient has the "right to know what risks are involved in undergoing or foregoing certain surgery or other treatment."[73] Materiality of risks is "a matter for the trier of fact"[74] and medical evidence will be relevant to findings as to the risks but will not be the sole consideration. It is a question of balancing the likelihood of the risk eventuating with the seriousness of the outcome. Madame Justice McLachlin stated:

> a medical person must disclose those risks to which a reasonable patient would be likely to attach significance in deciding whether or not to undergo the proposed treatment. In making this determination, the degree of probability of the risk and its seriousness are relevant factors. Thus an 'unusual' or improbable risk should be disclosed if its effects are serious. Conversely, a minor result should be disclosed if it is inherent in or a probable result of the process.[75]

The duty to disclose risks does have a qualification:

> ... it may be the case that a particular patient, may because of emotional factors, be unable to cope with facts relevant to recommended surgery or treatment and the doctor may, in such a case be justified in withholding or generalising information as to which he would otherwise be required to be more specific.[76]

On the issue of causation Laskin CJC preferred "to consider objectively how far the balance in the risks of surgery or no surgery is in favour of undergoing surgery."[77] If a reasonable person in the patient's particular position, would still have agreed to

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[72] *Reibl v Hughes*, above n52, 13-14.
[73] *Reibl v Hughes,* above n52, 13.
[74] *Reibl v Hughes,* above n52 , 13.
[75] Rawlings v Lindsay (1982) 20 CCLT 301, 306.
[76] *Reibl v Hughes*, above n52, 13.
[77] *Reibl v Hughes*, above n52, 16.

the treatment, even if all the material risks were disclosed, the failure to inform the patient fully cannot be said to be the cause of the patient's loss.

In a recent case[78] the Supreme Court of Canada refused to believe that the plaintiff would have followed an alternate course had she been fully informed of the risks. The physician failed to warn the plaintiff that her foetus might be injured as a result of the chickenpox she contracted during her pregnancy. She claimed she would have taken steps to terminate the pregnancy however the Supreme Court disbelieved her on the grounds she badly wanted a child.

C. Australian Legal Position

In 1983 the Supreme Court of Australia in *F v R*[79] declined to apply *Bolam* and instead followed the Canadian reasoning in *Reibl v Hughes*. It was held that the duty to disclose risks existed and the determination of that duty was for a court of law not a professional body.[80]

The leading Australian case on disclosure of information is *Rogers v Whitaker*[81]. The plaintiff had been almost totally blind in her right eye since a childhood accident. The defendant, an opthalmic surgeon, recommended an operation on her right eye to remove scar tissue which would improve it's appearance and probably restore significant sight to the eye. Although the plaintiff made clear her great concern that no injury should befall her one good eye the surgeon failed to warn her of a one in 14 000 risk of sympathetic opthalmalia. The surgical procedure did not restore any sight to her right eye and sympathetic opthalmalia left her totally blind in her left eye.

The High Court of Australia, preferring Lord Scarman's dissent, held that the *Bolam* principle was inappropriate.

> While evidence of acceptable medical practice is a useful guide for the courts, it is for the courts to adjudicate on what is the appropriate standard of care after

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[78] *Arndt v Smith* (1997) 148 DLR (4th) 48.
[79] *F v R* (1983) 33 SASR 189.
[80] *F v R*, above n79, 191-194.

giving weight to 'the paramount consideration that a person is entitled to make his own decisions about his life[82]

The Court held that the duty of a medical practitioner to exercise reasonable skill and care is a single comprehensive duty.[83] The standard of care to be observed by a person with some special skill or competence is that of the ordinary skilled person exercising and professing to have that special skill.[84]

The determination of a breach of the standard of care depends on the type of case. If the case involves diagnosis or treatment the standard of care is measured by the practice of a responsible body of medical opinion. If it is a case of the provision of information or advice it will be determined by the materiality of the risks involved.

> The law should recognise that a doctor has a duty to warn a patient of a material risk inherent in the proposed treatment; a risk is material if, in the circumstances of the particular case, a reasonable person in the patient's position, if warned of the risk, would be likely to attach significance to it or if 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. This duty is subject to the therapeutic privilege.[85]

The therapeutic privilege is "an exception to the requirement that a medical practitioner divulge information on material risks viz where doing so would cause great harm to the patient."[86] Thus a doctor must disclose risks of which a prudent patient would take account, but may refrain from disclosing when that might put the patient's health at great risk.

To establish causation the plaintiff must prove he or she would not have consented to the treatment had the proper disclosure been made to him or her. Since *Rogers v Whitaker*[87] there appears to be a trend towards viewing sceptically a patient's

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[81] *Rogers v Whittaker*, above n54.
[82] *Rogers v Whitaker,* above n54, 487 referring to *F v R* (1983) 33 SASR 189, 193.
[83] *Rogers v Whitaker*, above n54, 489.
[84] *Rogers v Whitaker*, above n54, 487.
[85] *Rogers v Whitaker*, above n54, 490.
[86] J Devereux *Medical Law - Text, Cases & Materials* (Cavendish Publishing Ltd, NSW, 1997) 138.
[87] *Rogers v Whitaker*, above n54.

statement, that had he or she known of the risk, he or she would not have consented to the treatment.[88] In *Berger v Mutton*[89] Twigg DCJ found the plaintiff was aware of the risks though she claimed she was not warned. Further his Honour held she would have had the operation even if the defendant had given a more detailed explanation of the risks.

In *Petrunic v Barnes*[90] Justice Tagdell held that even if the plaintiffs had known of the slight risk of failure of the tubal ligation they would not have been dissuaded from the operation. In discussion of this case John Molnar stated "... the case may be read to suggest that the Courts will look closely at the patient's alternatives if they are to argue that they would not have proceeded to surgery had they been adequately advised."[91]

5. CASE STUDY: DISCLOSURE OF THE RISKS OF THIRD GENERATION ORAL CONTRACEPTIVE PILLS IN AUSTRALIA, CANADA AND ENGLAND

In Australia and Canada, like New Zealand, the plaintiff needs to establish a duty of care to disclose *material* risks. New Zealand's test is based on the Australian reasonable patient test whilst the Canadian test looks to the balancing of the size of the risk with the outcome if the risk eventuates. In both cases a duty would be established where the plaintiff had increased risk factors of VTE or where she inquired about the risks involved. In the case of a healthy patient the Australian standard may fail to establish a duty however the Canadian standard may still found a duty as it is an unusual or improbable risk but the outcome, if it eventuates, is serious.

The plaintiff, in both Australia and Canada, then has an evidential burden to establish that the doctor did not warn of the risk and that she suffered damage.

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[88] J Devereux *Medical Law - Text, Cases & Materials* (Cavendish Publishing Ltd, NSW, 1997) 138.
[89] *Berger v Mutton* (22 November 1994) unreported, District Court, NSW 3584/1990, Twigg DCJ.
[90] [1989] VR 927.
[91] J Molnar "Consent in the 90's" (1997) 16 Med Law 567, 575.

In Australia the test for causation is subjective, so the plaintiff must establish she would have foregone the treatment if the risks had been adequately disclosed. While in Canada the test is objective so the plaintiff must establish that a reasonable person in her circumstances would have foregone the treatment. Thus the plaintiff would have a similar likelihood of establishing negligence in New Zealand as she would in Australia or Canada.

However in England, to establish negligence, the plaintiff would need to show that the defendant failed to disclose the risk associated with the treatment and that this was not a practice accepted as proper by any responsible medical body. If the defendant is able to prove that there is a body of medical opinion which would not disclose the risk then there may be no duty upon the doctor to disclose the risk. However *Smith v Tunbridge*[92] may allow a Judge to find for the patient on the basis that although some doctors still were not warning their patients of the risk, that omission was neither reasonable nor responsible.

6. CONCLUSION

The development of the law in New Zealand has been dominated by statutes due to the accident compensation legislation. Whereas in Australia, Canada and England the courts have shaped the law. However this does not appear to have hindered its progress.

The duty to advise and inform patients of the risks and implications of proposed treatment exists in all four jurisdictions examined but the standards of medical negligence differ. A plaintiff, inadequately informed of the risks of third generation oral contraceptive pills, who develops VTE has a strong case for compensation in Australia, Canada and New Zealand. Dogged by the *Bolam* principle, England lags behind, still leaving the medical profession to determine their own standards.

Despite the existence of a duty of care medical negligence remains difficult to establish due to the hurdle of causation. Plaintiffs have the onerous task of

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[92] *Smith v Tunbridge Wells Health Authority* [1994] 5 Med LR 334.

establishing the medical cause and that the doctor's conduct was the cause of the medical outcome. Yet courts have been reluctant to reverse the burden of proof.

The law in New Zealand recognises that patients must be treated as intelligent, mature and rational individuals who require information so as they can make informed choices about their treatment. This may require physicians to spend more time explaining concepts to patients, which could be time consuming and costly, though not as costly as litigation. However communication should improve the doctor – patient relationship and if communications improve then lawsuits should decline.

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