Medical Practitioners Disciplinary Tribunal

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DECISION NO: 65/98/33C

IN THE MATTER of the Medical Practitioners Act 1995

NAME OF RESPONDENT

NOT FOR PUBLICATION

-AND-

IN THE MATTER of a charge laid by the Complaints Assessment Committee pursuant to Section 93(1)(b) of the Act against F medical practitioner of xx

BEFORE THE MEDICAL PRACTITIONERS DISCIPLINARY TRIBUNAL

TRIBUNAL: Mrs W N Brandon (Chair)

Mr P Budden, Professor B D Evans, Dr D C Williams,

Dr L F Wilson (Members)

Ms G J Fraser (Secretary)

Ms C Koks (Stenographer)

Hearing held at xx on Monday 15, Tuesday 16 and Wednesday 17 February 1999

APPEARANCES: Ms S D'Ath for the Complaints Assessment Committee ("the CAC")

Mr C W James for F.

1. THE CHARGE:

1.1 THE Complaints Assessment Committee pursuant to Section 93(1)(b) of the Medical Practitioners Act 1995 charges that Dr F, registered medical practitioner of xx;

1. Prior to or at the time of administering a lumbar epidural injection of the steroid drug depo-medrol to his patient A on or about the 27 June 1989 failed to obtain from his patient informed consent in that Dr F was or ought to have been aware of;

   (a) The medical controversy surrounding the use of depo-medrol intraspinally epidurally and within the spinal joints

   and/or

   (b) That the administration of depo-medrol by epidural route was not recommended by the New Zealand agent Upjohn (NZ) Ltd

   and should have adequately informed her of the possible adverse consequences associated with the use of depo-medrol epidurally and obtained her informed consent prior to carrying out the procedure.

2. On or about 14 October 1994 when having been specifically requested by his patient A not to use the same steroid drug used in the previous epidural injection in fact administered

bilateral facet joint injections of the same drug being depo-medrol contrary to her request and failed to obtain her consent to doing so.

3. On or about 14 October 1994 prior to or at the time of administering bilateral facet joint injections of the steroid drug depo-medrol to his patient A failed to obtain from his patient informed consent in that Dr F was or ought to have been aware of;

(a) The medical controversy surrounding the use of depo-medrol intraspinally epidurally or within the spinal joints

and/or

(b) That the administration of depo-medrol by intraspinally was not recommended by the New Zealand agent Upjohn (NZ) Ltd

and should have explained the possible adverse consequences associated with the use of depo-medrol in facet joint injections to his patient A and obtained her informed consent prior to carrying out the procedure.

being professional misconduct.

2. AMENDMENTS TO PARTICULARS OF CHARGE:

2.1 **PURSUANT** to Clause 15 of the First Schedule of the Act, the Tribunal have the power, at any time during the hearing of any charge laid under Section 102 of the Act, to amend the charge in any way.

2.2 **AT** the commencement of the case for the respondent doctor, Mr James made an application for amendment of the charge on the basis that the Complaints Assessment Committee had not produced any evidence to make out a prima case facie case to answer in respect of a number of salient features. After hearing from Mr James in support of the application, and counsel for

the Complaints Assessment Committee, Ms D'Ath, who opposed the application on behalf of the CAC, the Tribunal determined as follows:

2.2.1 **THAT** the particulars contained in paragraph 1 (a) stood;

2.2.2 **THAT** paragraph 1 (b) should be deleted;

2.2.3 **THAT** a prima facie case in support of the general matters contained in paragraph 1 had been made out;

2.2.4 **PARTICULAR** 2 was not challenged;

2.2.5 **PARTICULAR** 3 (a) and 3 (b) were deleted, but the remainder of Particular 3 was to remain.

3. PRIVACY ORDERS:

3.1 **IN** Decision Number 58/98/33C, issued on 16 December 1998 the Tribunal made an Order (following application from Mr James on behalf of Dr F) pursuant to Section 106(2)(d) of the Act that the publication of the name of the respondent be prohibited pending further order of the Tribunal, and that this Decision not be published beyond the Tribunal, the parties or their counsel in a form which contained any reference to the name of the respondent.

4. BACKGROUND:

4.1 **IN** February 1997 the complainant, Mrs A, complained to the Medical Council about the treatment she had received from the respondent on two occasions, June 1989 and October 1994.

4.2 **THE** complainant alleged that the respondent failed to obtain her informed consent either prior to or at the time of administering a lumbar epidural injection of the steroid drug depo-medrol on or about 27 June 1989.

4.3 **THE** complainant further alleged that the respondent was or ought to have been aware of a medical controversy surrounding the use of depo-medrol intraspinally, epidurally and within the spinal joints and that the administration of depo-medrol by epidural route was not recommended by its New Zealand agent. She further alleged that the respondent had failed to adequately inform her of possible adverse consequences associated with the use of depo-medrol epidurally, and therefore had failed to obtain her informed consent prior to carrying out the procedure.

4.4 **IN** relation to the event of October 1994, the complainant alleged that she had specifically requested the respondent not to use the "same steroid drug" used in the 1989 epidural injection, but that the respondent ignored that request.

4.5 **THE** complainant further alleged that the respondent had failed to warn her of any medical controversy surrounding the use of depo-medrol and that he should have explained the possible adverse consequences associated with the use of depo-medrol in facet joint injections, and in proceeding to administer the injections in the absence of any such warnings or information, the respondent also failed to obtain her informed consent on this occasion.

5. EVIDENCE FOR THE CAC:

The Complainant:

5.1 **IN** July 1987 the complainant tripped upon some steps while carrying a container of firewood and immediately developed a pain in her lower back. Her back pain persisted over several days and she consulted her general practitioner. She was referred for physiotherapy and at a later date to a chiropractor and an osteopath. In October 1988 her GP referred her to Mr Lander, an Orthopaedic Surgeon. Mr Lander referred her for first physiotherapy and when her pain persisted, referred her to the respondent in April 1989. In his referral letter Mr Lander noted *"I would be grateful if you would consider an epidural steroid profusion" [perfusion]*. The complainant said that Mr Lander did not explain to her what an epidural steroid perfusion was nor did he provide her with any details of the procedure.

5.2 **THE** complainant duly presented herself to the respondent. He described himself to her as a "pain specialist". In an interview which she estimated lasted approximately 20 minutes, the respondent took her history, read Mr Lander's notes and examined her. The complainant was adamant that the respondent did not tell her *"anything"* about the treatment proposal nor did he provide her with any information about possible adverse effects, consequences or side effects of either the procedure, or the steroid drug which was to be injected epidurally into her spine.

5.3 **THE** complainant asked the respondent if the procedure could be performed under general anaesthetic as she had a fear of needles, and her back was painful. The respondent apparently told her that because of her apprehension he would give her a sedative in theatre to calm and relax her and he also told her that she should feel only a slight sting from the local anaesthetic before the epidural.

5.4 **IN** cross-examination, the complainant agreed that the respondent had explained to her that the procedure could not be carried out under a general anaesthetic because it was necessary for her to be awake for the procedure. She also agreed that the respondent had given her reasons as to why it was necessary for her to be awake for the procedure.

5.5 **IN** giving evidence, the complainant also recalled asking the respondent about the procedure, its safety and effects and common practice. However she stated that she was not given any leaflets or written material explaining the proposed procedure, nor, she said, was she told what drugs would be used in the injection apart from the information that a steroid was to be used; she was not shown any diagrams or pictures from a book of the spine; there was no explanation as to the possible outcome of the procedure other than to say it would relieve her pain; nor was the procedure explained to her by using a model of the spine.

5.6 **THE** complainant attended at the xx Hospital for the procedure on 27 June 1989 and the procedure was carried out later that day. She signed a consent form on admission but said she received no further information or explanation about the procedure she was to undergo either from the respondent, or any of the nursing staff who also attended at the procedure. The complainant saw the respondent on a number of occasions subsequently, in 1990, 1991, 1992 and April 1994.

5.7 **THE** complainant stated that on 4 October 1994, she again consulted the respondent and on this occasion another doctor was present and was introduced to her, but that she was not told what his position was or why he was there. She was under the impression that he was another pain specialist. A nurse was also present on this occasion. At the conclusion of his examination, the

respondent told the complainant that he could help her with facet joint injections. She expressed an objection to receiving any further injections into her spine. She said that the respondent did not provide any explanation of what a "facet joint injection" was and how it differed from the injection she had had previously. However, she was persuaded by the respondent's reassurance, and agreed to have the injections *"but only on condition that a different steroid was used that he had used in the epidural injection I'd had in 1989. I made a point of reminding him that I'd had a bad experience of that injection. Both the nurse and Dr B were in the room when I said this. [The respondent] agreed that he would definitely use a different steroid. There was no mention of the name of the drug which would be used but because he had said he would use a different steroid I presumed that a different steroid was available"*.

5.8 **ON** 14 October 1994 the complainant presented for the facet joint injections, accompanied by her stepmother and her son. Once again she was admitted by a nurse and signed admission papers including a consent form. When she was taken to theatre she said the respondent expressed surprise that she had turned up for the facet joint injections. She understood this to mean that the respondent had understood how doubtful and worried she was about having more injections in her back. The complainant does not recall being given any explanations either prior to or on her arrival in theatre for the injections. As things turned out, the first injection was so painful she pleaded with the respondent to stop but he carried on and she asked that the second injection not be given. However the respondent persuaded her to have the second injection because he said "the worst one" was done and the second would not be as bad. The complainant recalled the second was more painful than the first.

5.9 **FOLLOWING** the injections the complainant said her condition worsened. In October 1995 she decided to check her medical records to ascertain why she was "allergic" to two different steroids. It was at this time that she discovered that the same steroid, depo-medrol, had been used in both procedures.

5.10 **THE** complainant then commenced a series of investigations into the use of depo-medrol and became aware of various publicity and debate regarding its use dating back to the late 1980's.

5.11 **IN** 1997 the Accident Rehabilitation and Compensation Insurance Corporation accepted cover for the complainant's medical misadventure, on the basis of medical mishap. The acceptance of her claim was on the basis that her pain had been made worse following the facet joint injections in 1994 and that the incidence of this occurring was less than 1 in 100. ACC noted that at no stage did the Medical Misadventure Committee consider there would be any question of medical error on the part of the respondent.

Mrs C:

5.12 **MRS C**, the complainant's stepmother, gave evidence of accompanying her to xx Hospital in October 1994 when the facet joint injections were administered by the respondent.

5.13 **MRS** C confirmed the complainant's evidence that she was admitted by a nurse and signed the forms presented to her on admission. Mrs C recalled being told by the complainant that she was going to have another injection but with a different steroid than had been used in June 1989, because the complainant had thought that the steroid administered on that occasion had caused her back to get worse.

5.14 **IN** response to a question from the Tribunal, Mrs C recalled being telephoned by the complainant and asked if she could take her to the hospital:

"... I said yes. I said what for she said an injection and I said not the same one you had before because it didn't do much for you. She said no it's a totally different one. And I said are you sure and she said yes and I said OK. She was positive that it was to be a different steroid than the one she had before."

Mr D:

5.15 **MR** James objected to the calling of this witness on the grounds that he had not previously been advised by the CAC that this witness would be called, and neither he nor his client had either an opportunity to review his evidence or to prepare any rebuttal. The Tribunal heard submissions from both counsel on this point.

5.16 **PURSUANT** to Clause 6 of the First Schedule to the Act, and subject to Clause 5(3) of the First Schedule, the Tribunal may receive as evidence, any statement, document, information or matter that may in its opinion assist it to deal effectively with the matters before it, whether or not it would be admissible in a court of law. Clause 5(3) of the Schedule provides that the Tribunal *"shall observe the rules of natural justice at each hearing"*. Having heard from both counsel, the Tribunal determined that the evidence would be allowed, but the weight in which the Tribunal might place upon it was a matter for the Tribunal and, in the absence of the respondent's ability to challenge the evidence by relying on any documents or other material which might fairly be bought to the Tribunal's attention in this regard, the weight which the Tribunal might place upon the evidence might be diminished.

5.17 **FURTHER**, the CAC's expert witness, Dr Alan Merry, provided an extensive statement of evidence which presented the medical matters at issue in this hearing in a very balanced and

objective fashion. Thus any prejudicial effect of the evidence given by Mr D was able to be considered by the Tribunal within the overall context of the case presented by the CAC.

5.18 **MR** D was also a former patient of the respondent. He had received three epidural spinal injections in 1989 and 1990, all administered by the respondent. He gave evidence of his consultations with the respondent and said that he too had not been shown any model of the spine or diagram by the respondent, nor had he been told what drug would be administered or that the treatment was in any way controversial. He had also not been told that there were possible side effects related to the treatment.

5.19 **FOLLOWING** the last epidural spinal injection given to him on 13 July 1990 he was unable to walk and was admitted to hospital. He had subsequently suffered problems with his legs and was able to walk only with the assistance of walking sticks.

Expert Evidence:

5.20 **DR** A F Merry gave expert evidence on behalf of the CAC. Dr Merry is a specialist anaesthetist and has been involved in the management of chronic pain for many years and in private practice and currently through the Auckland Regional Pain Centre at Auckland Hospital.

5.21 **THE** central issue in this case was whether or not the complainant had given her informed consent to:

(a) The epidural steroid injection in June 1989;

and

(b) The facet joint injection of depo-medrol in October 1994.

5.22 **THERE** are two features to the case for the CAC:

(1) That the respondent was, or ought to have been aware of the safety and efficacy of the steroid used in the 1989 epidural steroid injection- depo-medrol;

and

(2) On neither occasion did the respondent explain to the complainant what the procedures involved either procedurally or in terms of the medication which was to be used.

5.23 **DR** Merry's evidence covered the technical aspects of epidural and facet joint injections; their safety and efficacy, including risks and possible side effects; the condition of arachnoiditis; the extent and chronology of the development of the controversy over epidural steroids, including media publicity about a West Australian patient who claimed that their health had been harmed by epidural injections of depo-medrol; the development of the doctrine of informed consent in New Zealand; and his knowledge and experience of usual professional practice and conduct of a specialist physician seeking to obtain a patient's informed consent for epidural and/or facet joint steroid injections.

5.24 **IN** particular, it was Dr Merry's evidence that the use of epidural steroids was an issue which has been widely debated and about which there is a range of opinions. Epidural steroids have been extensively used for over 40 years in many countries including New Zealand, Australia, the United States of America, Canada, Britain and Europe. They have been the subject of numerous publications in the medical literature and the substantial majority of opinion supports the use of epidural steroids if there are appropriate clinical indications. Dr Merry referred to the *"very important and comprehensive publications"* of the National Medical Research Council of Australia. Whilst bearing in mind that the complainant received only one epidural steroid injection

(in 1989, the second injection being administered into the facet joints of the spine rather than epidurally) the report provides helpful guidance regarding the appropriate standards of practice with respect to obtaining informed consent for patients (Chapter 4). The report, (at paragraph 4.1) sets out a list of principles which it is recommended be adopted. These principles are as follows:

1. Prior to any epidural steroid injection being scheduled, or undertaken, the patient should receive a consultation during which the perceived merits, expectations, risks and possible complications of the procedure are fully explained.
2. At such a consultation, written informed consent should be obtained.
3. The consultation may be undertaken and informed consent obtained, either by the doctor who refers the patient for the procedure or by the doctor who is to perform the procedure.
4. To avoid any risk of actual or inferred coercion, consent should be obtained at a time and in a setting other than that at which and in which the procedure is to be undertaken.
5. If the doctor who is to perform the procedure is not the one who has referred the patient, the doctor who is to perform the procedure must consult with the patient and must be satisfied that the patient has been fully informed, and that consent has been obtained in accordance with recommendations 1 to 4 above. This latter consultation may be undertaken at any time up to and including immediately prior to the procedure being undertaken. This consultation should be recorded by the doctor who is to undertake the procedure countersigning the form for informed consent. The patient should also sign the form a second time to indicate that the confirmatory consultation occurred.
6. Arrangements should be made to monitor the patient's response to the injection. The patient should be reviewed formally within six weeks following the injection, in a manner

suitable and convenient to both patient and doctor either who prescribed or who performed the procedure, although provision must be made to obtain an earlier consultation if so desired by the patient.

5.25 **AS** to the difference between the epidural steroid injection administered in 1989, and the facet joint injections given in October 1994, Dr Merry's evidence was as follows:

(a) *(Paragraph 5) Epidural injections are placed inside the bony canal of the spine but outside the dura, and are separated from the spinal fluid by the dura. The needle is inserted from the back, passes through skin and subcutaneous tissue, and then through ligaments which lie between the spinous processes of the vertebrae. The tip of the needle stops in the epidural or extradural space. A special needle called a Touhy needle, with a blunt bevel is used to achieve this, and a reasonable level of expertise is required.*

and

(b) *(Paragraph 7) Facet joint injections are quite distinct from both epidural and subarachnoid injections.* ***Facet joints or sygo-apophyseal joints*** *connect the bony vertebrae. They are located outside the spinal canal, well away from the spinal cord and its coverings. The small nerves which innervate them enter the spinal cord at the same level as the large nerves which radiate to the limbs. Thus pain arising from the facet joints may also be felt in the leg, for example. Facet joint injections are usually carried out under radiographic control, and they are quite a distance away from the epidural space, so there is little risk of inadvertent epidural injection during these procedures.*

5.26 **DR** Merry provided extensive evidence regarding the extent and chronology of the development of controversy over the use of epidural steroids, especially depo-medrol. The specific allegations giving rise to the controversy are that spinal (often intrathecal) injections of steroids (often depo-medrol) exacerbate back pain. These allegations first arose in the United States in the 1980's. In Australia attention to epidural steroids has occurred at two distinct periods of time - in 1981 following a report published in the Medical Journal of Australia, which report led to review in the same journal in 1982 and in 1985, the conclusions of which were essentially that there is no reliable clinical evidence that any steroid preparations have a deleterious effect on neural tissue

provided they are injected into the epidural space. The matter appears to have been resolved during the intervening period (1981 - 1985).

5.27 **SUBSEQUENTLY**, in approximately 1988/89 a group of West Australian patients alleged that their health had been harmed by epidural injections of depo-medrol and publicity ensued, culminating in a "highly emotive programme" on the topic screened on Channel 9 in Australia on 5 November 1990.

5.28 **REPRESENTATIONS** were made to the Ministry of Health in New Zealand, the Medical Council of New Zealand and other authorities by patients and doctors, the latter seeking guidance and clarification of the issues. Epidural steroids continue to be used by reputable specialists in New Zealand and internationally.

5.29 **DR** Merry's chronology was consistent with a chronology for depo-medrol (Exhibit 5) obtained from the Ministry of Health by the complainant.

6. EVIDENCE FOR THE RESPONDENT:

6.1 **IN** opening the case for the respondent, Mr James reminded the Tribunal that the events at issue went back some ten years and that concept of informed consent had evolved and developed considerably over that time. He submitted that in the context of disciplinary proceedings, the determination as to what constituted informed consent was not so much a legal question as a matter to be determined by reference to standards considered reasonable by the medical profession, at the time of the events at issue, and patient expectations.

The Respondent's Evidence:

6.2 **THE** respondent "emphatically" denied the allegations made against him. In particular, that the respondent gave evidence of the initial consultation he had with the complainant which occurred on 15 June 1989. He had no direct recollections of that consultation, but outlined his customary practice within the context of consultation with a new patient. In corroboration, the respondent submitted his letter reporting the outcome of the consultation to Mr Lander, the Orthopaedic surgeon who referred the complainant to the respondent.

6.3 **THE** respondent also gave evidence regarding each of the consultations which occurred between 1989 and 1994.

6.4 **IN** particular, the respondent gave evidence of his forming the view that the complainant was addicted to benzodiazepines, and the steps he took in this regard.

6.5 **IT** was the respondent's evidence that both in October 1989 and in June 1994, that he explained to the complainant the procedures he proposed to undertake, with the aid of a model of the spine. He is certain that he would have explained to the complainant what the procedures involved, and the risks, consequences and likely outcome of the procedures.

6.6 **HE** described himself as a strong advocate for patient rights and affidavit evidence in this regard was submitted in support. He characterised his relationship with the complainant as "difficult" and he described what he perceived to be the deterioration of their doctor/patient relationship between 1992 and 1994.

Mr R F J Hickey:

6.7 **DR** Hickey, a retired medical practitioner of Auckland, gave evidence of his extensive experience treating patients for pain. Dr Hickey has administered depo-medrol since 1964. By 1989 Dr Hickey estimated he had performed in excess of 10,000 epidural injections epidural steroid injections, plus many intra-thecally. In 1989 he was not aware of any controversy concerning epidural injections. He first became aware of the early stages of controversy which developed in Australia in the early 90's. His first awareness of the controversy was following the screening of the television programme in November 1990.

6.8 **DR** Hickey gave evidence that, in his opinion, there was no indication to advise patients about the chance of adverse reactions to depo-medrol in 1989. It was also Dr Hickey's evidence that he did not see the need to discuss the use of depo-medrol to the patient in respect of facet joint injections and that he did not and would not discuss the Australian controversy with patients because that related to epidural injections only. Dr Hickey gave evidence of his own experience and the poor recall of patients, particularly when given information while in pain and expressed the view that *"patients in pain have very poor memories for what happens and what they are told"*. Having suffered with back pain himself for several years, Dr Hickey related his personal experience and difficulty in recalling details of consultations he had participated in as a patient.

Mr R A Boas:

6.9 **MR** Boas, associate professor in anesthetics at Auckland School of Medicine, also gave evidence regarding the use of epidural steroid injections in the treatment of back pain and sciatica in New Zealand. He confirmed the chronology of the debate regarding the safety and efficacy

of depo-medrol and confirmed that, in his view, there were no concerns with respect to the appropriate list of the epidural steroid injection procedure in mid 1989. He considered that it would have been sufficient and appropriate for the respondent to indicate that the period of any relief obtained might well be short term and it was his practise to indicate to patients that there were no known risk factors although he warned patients that there could be a temporary aggravational irritation causing pain for several days after the injection but that this settles down. He did not consider that there was any evidence of any serious long term risks. It was his conclusion that the only controversy regarding use of depo-medrol for facet joint injections related to the degree and time frame of benefit derived. The efficacy was relatively short lived and his practise was to confine any warnings to this aspect and the chances of short term irritation immediately following the injection.

Mr R O Lander:

6.10 **MR** Lander, an Orthopedic surgeon in Palmerston North, treated the complainant after she was referred to him by her GP in 1988. Mr Lander referred the complainant to the respondent in April 1989. The complainant returned to him in August 1989 and he did not recall her mentioning to him any worries about the effects of the previous epidural steroid injection, though his records did note that she received only partial relief. It was Mr Lander's evidence that he could recall no indication from the complainant that her condition was made worse by the epidural steroid injection in 1989 and he did not record any adverse comment. He stated that it was his practice to record, in the medical records, any adverse comments or patient's concern about procedures. In a letter to the complainant's general practitioner dated 1 August 1989, Mr Lander recorded:

"[the respondent] did this procedure and she got partial relief of her symptoms ... I think she would benefit from a second epidural steroid [perfusion] and she will make arrangements to see [the respondent] when he returns from his overseas trip. She is also planning to trip to Australia and will be away during the second half of September."

In a further letter to the complainant's GP, dated 7 September 1989, Mr Lander has recorded that *"... her pain has been worse following the epidural steroid [perfusion] performed earlier this year by [the respondent] that she is now requesting surgery and I would think that it would be reasonable now to consider surgical decompression of the affected nerve roots...."*. In September 1989 Mr Lander performed a laminectomy. There was some abnormality of the S1 nerve root and a biopsy was taken. Mr Lander again referred the complainant to the respondent following surgery and he has not treated her since that time.

Affidavit Evidence Submitted on Behalf of the Respondent:

6.11 **ON** behalf of the respondent Mr James submitted affidavits from Dr B, Dr E, and from registered nurses who were present at the epidural steroid injection procedure and the subsequent facet joint injection procedure. None of these deponents were able to recall the events at issue, perhaps unsurprisingly given the passage of time that has elapsed. For the CAC, Ms D'Ath asked that the record show that she had requested that these witnesses appear at the hearing and be available for cross-examination. However, for various reasons, none of these witnesses were able to attend. The Tribunal has carefully considered the evidence provided in these affidavits however given the absence of any specific recollections regarding either of the consultations and other subject matter of this hearing, this evidence has been accorded little weight.

7. FINDINGS:

Particular One of the Charge:

7.1 **THIS** charge relates to the administration of the epidural steroid injection in 1989. The Tribunal is satisfied, on the basis of the evidence given by both the CAC's expert witness Dr Merry, and the evidence given by the respondent and his witnesses, Dr Hickey and Dr Boas that the issues

and debate which had arisen in the early 1970's regarding the use of depo-medrol was relatively settled in mid-1989. A further debate regarding the use of depo-medrol arose in late 1989 and 1990 following media publicity in Australia and in particular, the emergence of the West Australia depo-medrol support group in 1990.

7.2 **THE** respondent had no direct recollection of the detail of the initial consultation in April 1989. However it must fairly be noted that the complaint regarding the respondent's care of the complainant, particularly in the context of the issues regarding consent, or the lack of it, did not apparently arise until some six years later, in 1995. It should also fairly be borne in mind that by the time the complainant was first seen by the respondent the pain in the lower part of her spine had persisted for almost two years. It perhaps can reasonably be inferred therefore that the complainant's consultation with the respondent was not a momentous or extraordinary event which might cause the details of what transpired to be fixed in her mind, particularly taking into account that throughout the two years since her accident, the complainant had visited her general practitioner and been referred to physiotherapy, to a chiropractor and an osteopath, as well as to Mr Lander, whom she had seen on a number of occasions before he referred her to the respondent.

7.3 **THE** respondent gave evidence of his usual practice when seeing patients in an initial consultation, and in making recommendations as to a course of treatment, in this case an epidural steroid injection. By way of corroboration, the respondent referred to the letter which he had dictated immediately after the consultation, and forwarded to Mr Lander reporting the outcome. That letter discloses a detailed history taking on the part of the respondent including *"I have offered her a steroid epidural and she has requested that I proceed with this."*

7.4 **THE** respondent gave evidence that he was aware of the debate regarding the safety and efficacy of depo-medrol and said that *"at that stage in 1989 I would have made mention in passing only about the controversy of regarding depo-medrol for this particular steroid, and I pointed out that the drug was the safest and the most effective for the job we hoped to embark on. Recommended by the Health Department in 1978. I would have reassured her that I believe it was a safe drug."*

7.5 **THERE** is clearly confusion on the part of both respondent and complainant regarding the details of this initial consultation. The respondent gave evidence that he *"would have explained in depth what a steroid epidural injection was and I would have used a model to assist the patient's understanding. I am certain about this"*, he said *"because this is how I have always done it, I have always used a model. [of the spine]"* The respondent conceded that he was not certain whether he would have used the words "depo-medrol" instead of steroid.

7.6 **THE** Tribunal is satisfied that it was more likely than not that the respondent used a model to explain the epidural steroid injection procedure. The use of models to explain this procedure was confirmed by all witnesses, all of whom are experienced specialist practitioners who have administered these injections to thousands of patients. The respondent gave evidence of always carrying a small model of the spine with him to use in his consultations. Dr Merry referred to his customary practice in this regard and Dr Hickey also.

7.7 **THE** confusion on the part of both parties is evidenced by disagreement as to the location of the consultation, and who was present. The respondent for his part asking his reference in his written statement that *"I am pretty sure I had Nurse xx in attendance"* be struck from his statement

of evidence because he has since ascertained that Nurse xx was not in fact present at his consultations at that time. The complainant's husband who had also attended the consultation was unavailable to give evidence.

7.8 **PERHAPS** most tellingly, the complainant's position that the respondent *"did not tell me anything about the treatment"* was undermined by the evidence she gave of asking the respondent if the procedure could be done under general anaesthetic as she was not keen on having a needle in her spine, and her back was painful. The complainant's evidence was that the respondent had told her that because she was apprehensive he would give her a sedative in her arm in theatre to calm and relax her. He also told the complainant that she *"would only feel a slight sting from the local anaesthetic before the epidural"*. When cross-examined by Mr James the complainant agreed that the respondent had given her reasons why he could not give her a general anaesthetic for the procedure. When questioned on this point by Mr James, the complainant conceded that she had not remembered that discussion and it had not been included in her statement of evidence because she *"didn't know how much to put in, what I was supposed to do"*.

7.9 **THE** Tribunal is satisfied that both the complainant and the respondent were truthful witnesses, albeit both compromised by the vagaries of memory especially in recalling events which took place ten years ago. The Tribunal is satisfied that, with reference to the principles of informed consent set out at paragraph 5.24 above, and the customary practice at that time, as described by Dr Merry and the other practitioner witnesses, it is more likely than not that the respondent did adequately inform the complainant about:

(a) The fact that there was some debate, if not controversy, about the use of depo-medrol/epidural steroid injections; and

(b) The safety, risks and/or side effects of epidural steroid injections, including the possibility of some short term flare up of pain and the possibility that the complainant might receive no, or only transient pain relief.

7.10 **THE** focus in Particular 1 is on the use of depo-medrol epidurally rather than epidural steroid injections *per se*. The charge alleges that because the respondent did not adequately inform the complainant of the possible adverse consequences associated with the use of depo-medrol epidurally, and the existence of the medical controversy surrounding the use of depo-medrol intra spinally, epidurally, and within the spinal joints, he failed to obtain her informed consent prior to carrying out the procedure.

7.11 **FRAMED** in this way, the charge could only be proven if the CAC was able to establish from the balance of probabilities first, that a "medical controversy" surrounding the use of depo-medrol epidurally existed at part of the consultation, during 1989. On the evidence presented to the Tribunal, that allegation was not established and accordingly, and for the reasons set out above, the Tribunal finds that Particular 1 is not upheld.

Particular 2 of the charge:

7.12 **THE** complainant was adamant that she only agreed to the facet joint injections on the condition that the respondent was not to use the "same steroid drug" used in the previous epidural injection. In proceeding to administer depo-medrol in the face of that instruction the respondent failed to obtain the complainant's informed consent.

7.13 **THE** respondent is equally adamant that the complainant gave no such instruction. The possibility that a misunderstanding, or that the relevant discussion proceeded at cross purposes was raised, but it seemed to the Tribunal (from the demeanor of both the complainant and the respondent) that neither of them accepted that there was any misunderstanding of what was said on this point in their respective minds. The issue turns on the credibility of them both, and in this regard the Tribunal must be guided by the impression it formed from the demeanor of the witnesses, the evidence they gave and their responses to questioning by Counsel and the Tribunal. Once again, the Tribunal is satisfied that both witnesses were truthful witnesses, but impaired in significant respects. With regard to the complainant's evidence, Dr Merry gave persuasive evidence of research which demonstrated that patients vary in the extent to which they recall information given to them within the context of clinical trials designed to investigate this very issue.

7.14 **DR** Merry produced a copy of a study co-ordinated in New Zealand by Dr Garden, Dr Merry and others in which a key finding was that patient's perception of what they have been told changes in the light of information learned subsequently. *"Thus"* said Dr Merry *"a patient may feel satisfied with the information given but later develop a complication. When this happens, inevitably patients become very well informed on that particular complication and generally feel that they should have been given a more detailed and explicit warning about its possibility. Combined with the unreliability of recall discussed above, this creates an almost impossible situation for doctors."*

7.15 **THIS** evidence was supported by anecdotal evidence given by Dr Hickey of his own experience and difficulty recalling details of consultations he had participated in as a patient with back problems.

7.16 **MRS** C's evidence also assists. She recalled that the facet joint injections given in 1994 were to be a "different injection" to the epidural injection administered in 1989.

7.17 **THE** Tribunal is satisfied, on the balance of probabilities, that the complainant did tell the respondent that she did not want him to use the "same steroid drug" used in 1989. However the Tribunal is equally satisfied that the respondent either did not hear that instruction, or that he failed to appreciate the significance of what the complainant was saying to him regarding her concerns.

7.18 **AS** stated above, the Tribunal is satisfied that both witnesses gave truthful evidence, albeit both impaired; the complainant by her lack of medical knowledge and the passage of time, and the respondent by the views he had formed about the complainant, and the strength of his beliefs in the safety and efficacy of depo-medrol.

7.19 **THEREFORE**, on the basis that:

(a) What was stipulated by the complainant cannot now be determined with a degree of certainty sufficient to fairly find the particular to be proven; and

(b) In the event that the complainant did stipulate that a different steroid drug was to be used but the respondent, did not hear that stipulation, then the facet joint injection of depo-medrol was administered inadvertently and as such constitutes "mere inadvertence" or error on the part of the respondent.

7.20 **IT** is well established that "mere inadvertence" is not necessary culpable. The respondent is charged at a level of professional misconduct. Pursuant to Section 109 of the Act the Tribunal may find the charge established at the level of professional misconduct, or at the lesser level of

conduct unbecoming which reflects adversely on the practitioner's fitness to practise. As stated by the Court in *B v The Medical Council* (unreported) HC 11/96, 8/7/96, Elias J the classification requires an assessment of degree.

7.21 *"**THE** question is not whether error was made but whether the practitioner's conduct was an acceptable discharge of his or her professional obligations. The threshold is inevitably one of degree. Negligence may or may not (according to degree) be sufficient to constitute professional misconduct or conduct unbecoming:* ***Doherty v General Dental Council*** *[1988] 1 AC 164;* ***Pillai v Messiter*** *[No: 2] [1989] 16 NSWLR 197;* ***Ongley v Medical Council of New Zealand*** *[1984] 4 NZAR 369 ....the reasonableness of the standards applied must ultimately be for the Court to determine, taking into account all the circumstances including not only usual practice but also patient interest and community expectations, including the expectations that professional standards are not to be permitted to lag. The disciplinary process in part is one of setting standards".*

7.22 **HOWEVER** in support of the respondent's position that he did not understand any such stipulation to be made, it is significant that an alternative steroid drug, Kenacort, was apparently readily available and the respondent would have had no difficulty substituting this for depo-medrol had he understood such a request to have been made.

7.23 **SIMILARLY**, no record of a reported "allergy" to depo-medrol is recorded in the complainant's medical records, and neither is any request for a different steroid drug recorded in the respondent's notes of his consultation at which the facet joint injections were discussed; nor any of the documents completed when the complainant was admitted for the procedure; or on either of the two consent forms signed by the complainant.

7.24 **FOR** all of these reasons therefore the Tribunal finds that Particular 2, is not established.

Particular 3 of the charge:

7.25 **AS** amended, this Particular of the charge alleges that the respondent failed to explain the possible adverse consequences associated with the use of depo-medrol in facet joint injections and thereby failed to obtain the complainant's informed consent to the administration of those injections on 14 October 1994.

7.26 **AS** was the case in relation to Particular 1, the chronology of the debate regarding the safety and efficacy of depo-medrol is relevant. Once again, the medical evidence given to the Tribunal by Dr Merry and Dr Boas in particular, is consistent. Such controversy regarding the use of depo-medrol as did exist related only to its use both epidurally and intrathecally.

7.27 **AS** explained by Dr Merry, (at p 2):

"Facet joint injections are quite distinct from both epidural and subarachnoid injections. The facet joints ... connect the bony vertebrae. They are located outside the spinal canal, well away from the spinal cord and its coverings. The small nerves which innervate them enter the spinal cord at the same level as the large nerves which radiate to the limbs. Thus pain arising from the facet joints may also be felt in the leg, for example. Facet joint injections are usually carried out under radiographic control, and they are quite a distance away from the epidural space, so there is little risk of inadvertent epidural injection during these procedures. As with any medical procedure there are different opinions about the role of facet joint injection, but they are widely performed by reputable specialists internationally. In my opinion there is no basis for extending any controversy in relation to epidural steroids to these facet joint injections. They are a different type of procedure altogether. They may be quite uncomfortable and indeed painful for the patient at the time. Other than that I view these injections as safer than epidural injections, and, in competent hands, I would describe them as a comparatively minor procedure, although the use of radiographic screening may make them seem rather more invasive than they really are."

7.28 **DR** Boas and Dr Hickey, for the respondent, confirmed Dr Merry's evidence in this regard.

7.29 **THE** respondent's report to the complainant's general practitioner following the consultation at which the facet joint injections were discussed confirms that *"we hope to be able to help her with facet joint injections and a lot of reassurance"*. The Tribunal records that the discussion regarding the facet joint injections took place within the context of the consultation attended by Dr B and at a combined clinic for pain and opioid dependence.

7.30 **IN** his evidence, the respondent told the Tribunal of his surprise that the complainant *"managed to come off the large doses of benzodiazepine. I told her I was very impressed with this and therefore would undertake to offer more physiotherapy if we as a group felt this was a good idea and had her agreement... Dr B, who was in attendance, agreed that Mrs A appeared to be coping quite well with the psycho-social and psychological problems of her life but the physical pain, if we could improve on it we should. Hence we discussed facet joint injections"*. The respondent went on to explain the extent of the explanations given to the complainant regarding facet joint injections, and what was involved. He admits that he gave no indication of the controversy regarding the use of depo-medrol in epidurals because the controversy related to different procedure, i.e. epidural administration rather than facet joint injections, and, in any event, the respondent regarded the controversy regarding epidural depo-medrol injections as being settled some years before.

7.31 **THAT** evidence was supported by Dr Merry, Dr Boas and Dr Hickey. None of these specialist practitioners would have raised the controversy regarding the epidural administration of depo-medrol in the context of providing information about its use in facet joint injections.

7.32 **SIMILARLY**, all of the medical witnesses, and the chronology provided by the Ministry of Health (refer to above) confirmed that the body of medical opinion in New Zealand regarded such controversies as had arisen as being settled by October 1994.

7.33 **ON** this basis, the Tribunal finds that Particular 3 has not been established.

7.34 **THE** Tribunal again refers to the Orders made by it on 16 December 1998, and confirms those Orders, sine die.

8. CONCLUSIONS:

8.1 **NONE** of the particulars supporting the charge being upheld, the charge against the respondent is not established. Accordingly, the charge is dismissed. There are no issues as to costs.

DATED at Auckland this 30th day of March 1999

.....

W N Brandon

Deputy Chair

Medical Practitioners Disciplinary Tribunal