General Physician/District Health Board

A Report by the

Health and Disability Commissioner

(Case 00/02289)

Health and Disability Commissioner
Te Toihau Hauora, Hauātanga

Parties involved

Ms A	Consumer
Dr B	Provider, General Physician, a public hospital
Ms C	Medicines advisor
Dr D	General Practitioner
Dr E	General Practitioner
Dr F	Gastroenterologist, a second public hospital
Dr G	Head of the Alcohol and Drug Unit, a public hospital
Dr H	Specialist Physician
Ms I	Registered Nurse, Medical Case Manager, a second public hospital

Expert advice was obtained from an independent physician, Dr Kate Bayston.

Complaint

On 1 March 2000 the Commissioner received a complaint from Ms A about Dr B. The complaint is that:

During the first outpatient consultation Ms A had with Dr B on 6 August 1998, while seeking to be accepted onto the interferon alpha-2b injection treatment for hepatitis C, Dr B failed to:

- *Inform Ms A about the side effects of interferon alpha-2b injection treatment.*
- *Pregnancy test Ms A after she informed him she had not had her period, was not on contraception and had put on weight.*
- *Adhere to the accepted protocols of interferon alpha-2b injection treatment.*

Additionally, at subsequent consultations once Ms A had been accepted onto the Interferon Alpha-2B injection treatment programme with Dr B, he failed to:

- *Adhere to accepted protocol requiring Ms A to have treatment visits at weeks 1, 2, 4, 6, 8, 12, 16, 20, 24.*
- *Further pregnancy test Ms A.*

An investigation was commenced on 11 April 2000.

Information reviewed

- Letter of complaint.
- Interferon alpha-2b/ribavirin protocol forwarded by complainant with complaint letter.
- Letter of response from, and other information provided by, Dr B.
- Medical records supplied by Dr B.
- Letter of response from the District Health Board and medical records.

Names have been removed to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.

- Medsafe information about interferon alpha-2b.
- Pharmac pharmaceutical guidelines.
- General practitioner's (Dr D's) records.
- ACC documentation.
- Letter from Dr E.
- Letter from Dr F, the second public hospital.

Information gathered during investigation

Background

In September 1997 Dr D, general practitioner, first referred Ms A, a 28-year-old woman, to a pubic hospital for consideration for interferon alpha-2b following abnormal liver function tests and a diagnosis of hepatitis C. Ms A moved to another area in the interim and was seen by Dr E, general practitioner, who referred her to Dr F, gastroenterologist at a second public hospital, for consideration for interferon alpha-2b. Ms A was not seen at that hospital, having subsequently returned to her previous area. Dr D re-referred her as a semi-urgent case to Dr B, physician, at a public hospital in April 1998.

The interferon alpha-2b programme

The Medsafe "Information for Health Professionals Data Sheet" identifies that interferon alpha-2b can be beneficial in reducing liver necrosis and degeneration in patients with Hepatitis C. Interferon alpha-2b is a recombinant version (DNA has been altered by joining genetic material from two different sources) of a naturally occurring alpha interferon, with both antiviral and immuno-modulating effects. The patient is injected with interferon alpha-2b three times a week for up to four months. Special authority is required before a person can be commenced on the programme and a specialist doctor must make the application.

Consultation with Dr B, 6 August 1998

Ms A first saw Dr B on 6 August 1998. Ms A advised that at this visit she was not given "any data re protocol for the treatment of chronic hepatitis C information using Interferon, I had no idea that you had to be pregnancy tested".

Ms A also stated:

> "During this visit I brought [Dr B] up to date with my medical history and wellbeing for example that I had put on weight and had not had a period."

Dr B stated that he saw Ms A on 6 August 1998 and Ms A said she had put on 21 pounds (9.5kgs) in a few months. Additionally, Dr B stated that Ms A told him her last menstrual period was on 4 July 1998 and that he discussed this "in detail because the use of

Interferon [is] hazardous". Dr B said that Ms A had in her possession a letter from Dr E, a general practitioner in the area she had previously moved to, identifying that "she has been told of the pros and cons of Interferon plus reading on Hepatitis C". Dr E stated that although he could not be sure now whether he provided Ms A with information on interferon alpha-2b, he doubted that he would have discussed side effects as there is often a wait "which may be in excess of a year" before assessment at the hospital liver clinic.

Dr B advised that Ms A was reluctant to administer the injections herself and that as the general practitioner or practice nurse was to administer the injections the responsibility for pregnancy testing lay with that person. Dr B stated that "if she was going to give the injections herself I would have gone through all items in detail, again". Dr B reiterated that Dr E had given Ms A information on interferon and hepatitis C and added, "and I discussed it too".

In response to my provisional opinion Dr B stated that Ms A had come to see him for interferon treatment; she had not come "blindly" but had come for treatment and had raised the issue of side effects of the treatment. Dr B stated that he opened the *New Ethicals* (biannual catalogue of routine prescribing information including contraindications, important precautions, adverse reactions and interactions for all brand name pharmaceuticals in New Zealand) and discussed side effects with her.

Hospital appointments are scheduled to be 40 minutes and Dr B stated that 10 minutes of this time is devoted to discussion. Dr B said that when important medication is given the hospital pharmacy also provides both oral and written information to the patient when they dispense the drug. With his response to my provisional opinion, Dr B enclosed a pamphlet supplied with interferon which provides instructions for self-injection and lists common side effects of weakness/fatigue, low grade fever and muscle aches. Dr B said that he does not write down everything he does; he cannot write down everything he says during a consultation.

The hospital outpatient clinical record completed on 6 August 1998 by Dr B stated that Ms A:

- Weighed 53.3 kgs
- Was not on contraception
- Was on diazepam (a sedative for short-term symptomatic management of mild to moderate degrees of anxiety) prescribed by Dr G, Head of the Alcohol and Drug Unit.

In response to my provisional opinion Dr B stated that a liver ultrasound and liver biopsy are not necessarily carried out by other specialists who prescribe interferon. Dr B said Ms A's father and uncle had died of liver cancer and this "hereditary disposition", in addition to the diagnosis of hepatitis C, necessitated early treatment.

In a letter to Dr D following this consultation, Dr B stated that Ms A's last menstrual period was in July and that "it is currently a little delayed but this is the norm"; she was not on contraception and thought her weight had "increased by one and a half stone (10kgs) during the past few months". Dr B also wrote in the letter that he had questioned Ms A

about sexually transmitted diseases but that she had denied having any and an HIV test done a few months earlier was negative. Additionally, Dr B informed Dr D that Ms A had taken non-prescription drugs in the past, was not currently taking any and noted that she had previously overdosed on amitriptyline. Dr B advised Dr D that he had applied for interferon A injections and that he would see Ms A again in a few weeks. He also advised that Ms A was not prepared to administer the injections and that the practice nurse would have to do this three times a week.

Dr B stated that Ms A was "unreliable" and that she "lied" to him when she "withheld current use of narcotic drugs". In response to my provisional opinion, Dr B reiterated that Ms A was a drug addict injecting herself with morphine. Ms A would not give herself the injection, which he found "very strange for a drug addict".

The public hospital laboratory records identify that Dr B ordered blood tests, including liver function tests, which were taken on 6 August 1998.

Consultation with Dr B 3 September 1998

Ms A next visited Dr B on 3 September 1998. Ms A stated that at that visit her weight had increased by four kilograms and the clinical notes record an increase from 53.3kgs to 57.4kgs. Health Benefits Ltd had approved the request for funding to enable Ms A to commence on the interferon alpha-2b programme and Ms A was advised that she was to have three million units three times a week and monthly blood tests.

The hospital outpatient notes record that Dr B wrote to Dr D advising him that he had seen Ms A. In the letter Dr B stated that he had issued Ms A a three month prescription for "Interferon 3,000,000 units three times a week to be given subcutaneously" and advised that he would see her "at the end of this period" and that she would have monthly liver function tests.

Pregnancy

Ms A stated that on 21 September 1998 she found out she was pregnant so stopped having the interferon alpha-2b injections after discussion with Dr D, her general practitioner. On 3 December 1998 during the scheduled visit to Dr B, Ms A advised Dr B of her pregnancy. She had had five injections before discontinuing them. Dr B advised he would review her in April following the birth.

In response to my provisional opinion, Dr B stated that Ms A did not keep appointments. In regards her menstrual periods, he said that if "you are not on contraception and you don't get a period alarm bells should have been ringing".

Consultation with Dr B 16 September 1999

Ms A did not attend the follow-up appointments with Dr B on 29 April and 5 July 1999 after her daughter was born, but did attend on 16 September 1999 when a new application for interferon alpha-2b was made. Ms A advised that she was not pregnancy-tested or

given the protocol for interferon alpha-2b use at this time. Nor did Dr B advise her in relation to breast-feeding and interferon alpha-2b.

Following Ms A's visit Dr B wrote to Dr H, a specialist physician, asking him to take over Ms A's care as Dr H had an interest in the combination therapy of interferon alpha-2b and ribavirin, which Dr B felt might benefit Ms A. Dr B also requested that Ms A have monthly liver function tests.

Interferon alpha-2b protocols

The protocol submitted by Ms A is for the combination treatment interferon alpha-2b and ribavirin. It is not relevant to this investigation, which relates to the information that should be given prior to stand-alone interferon alpha-2b therapy.

Medsafe issue an "Information for Health Professionals Data Sheet" about interferon alpha-2b. Ms C, medicines advisor, advised me:

> "The information about pregnancy … designates the following:
>
> > 'Drugs which have been taken by only a limited number of pregnant women and women of child-bearing age without an increase in the frequency of malformation or other direct or indirect harmful effects on the human foetus having been observed. Studies in animals have shown evidence of an increased occurrence of foetal damage, the significance of which is considered uncertain in humans.'
>
> For most medicines there is very little information on use in pregnancy, because it is not ethical to conduct studies in pregnant women. Hence, data tends to be limited to animal studies which are often of uncertain relevance, and case reports which are difficult to interpret, because congenital anomalies may occur spontaneously or from other causes.
>
> The Ministry of Health has not put out guidelines as to advice a medical practitioner prescribing Interferon Alpha-2B should give to a woman of child-bearing age."

The Pharmaceutical Schedule issued by Pharmac provides guidelines for use of interferon alpha-2b in the treatment of hepatitis C and these include consultation with a gastroenterologist or infectious disease physician, and careful monitoring for side effects in a patient who is otherwise fit. Criteria for treatment requires the establishment of active chronic liver disease by confirming HCV (hepatitis C virus) infection and serum ALT (alanine transaminase)/AST (aspartate aminotransferase) (liver function tests) levels measured on at least three occasions over six months averaging more than 15 times the upper limit of normal.

The Medsafe information sheet and the Pharmaceutical Schedule for interferon alpha-2b are appended to this report.

ACC

The Accident Compensation Corporation declined Ms A's claim for medical misadventure on the basis that there was no evidence that the interferon alpha-2b she received caused any harm to her pregnancy.

Independent advice to Commissioner

The following independent expert advice was obtained from Dr Kate Bayston, physician:

> "I have read the complaint of [Ms A] dated 28.02.00. In this letter she complains that during her first outpatient consultation with [Dr B] on 6 August 1998 while seeking to be accepted onto the Interferon Alpha-2B injection treatment of her Hepatitis C, [Dr B] failed to:
>
> - Inform her about the side effects of Interferon Alpha-2B treatment.
> - Pregnancy test her.
> - Adhere to a protocol of treatment visits at weeks 1, 2, 4, 6, 8, 12, 16, 20 & 24.
>
> She additionally complains that at subsequent consultations, [Dr B] did not address the issues of her pregnancy, failure to adhere to a protocol, or apologise for these.
>
> In formulating an opinion regarding this complaint, I have read the following documents/information:
>
> 1. A reply from [Dr B] dated 12.06.00.
>
> 2. A further letter from [Dr B] dated 10.10.01 with an enclosed single page photocopy of the hospital outpatient notes – 14.04.99, an obstetric ultrasound report dated 24.04.98, a letter from [the second public hospital] to [Ms A] asking her if she requires an appointment at the hospital, a referral letter from [Dr E] to [the hospital] and finally a report from [Professor J] which addresses an ACC claim by [Ms A].
>
> 3. A letter from [the], Clinical Director of Nursing and Professional Practice at [a public hospital] requesting that [Dr B's] first letter be set aside from the investigation and outlining [Ms A's] health record. She encloses a copy of a patient information sheet which outlines the protocol for the treatment of chronic Hepatitis C with Interferon Alpha-2B and Ribavirin, a copy of which was provided to [Ms A] prior to her receiving the combined treatment in 1999.

4. Photocopies of outpatient letters from [the public hospital] including letters from [Dr B] and [Dr K] and results of laboratory investigations relating to those clinics visits.

5. Letters from [Dr L] at [a public hospital] relating to [Ms A's] baby.

6. Copies of [Dr D's] notes, laboratory results and letters from hospital regarding [Ms A].

7. Copies of the special authority applications for Intron-A.

8. A letter from [Dr E].

9. A response from [Ms I], [the second public hospital] regarding a referral for [Ms A] sent in December 1997.

10. Data on Interferon Alpha-2B and pregnancy supplied by [Ms C], [medicines] Adviser.

In addition to the above supplied documents, I have located the guidelines for the use of Interferon in the treatment of Hepatitis C in the April 1998 New Zealand Pharmaceutical Schedule (a copy of which I enclose with my report).

The sequence of events appears to be as follows:

In July 1997 [Ms A] was first tested for Hepatitis C and was found to have positive serology which was subsequently confirmed in September 1997. At this stage she was Hepatitis C PCR positive and had grossly abnormal liver function tests. It is not clear what prompted these investigations in the first place or whether she had previously had Hepatitis C tests which were negative. On 18 September 1997, [Dr D] referred [Ms A] to [a doctor] at [a public Hospital]. An outpatient clinic appointment was scheduled for 10 December that same year. Prior to this, however, in November, [Ms A] advised the [District Health Board] that she had moved to [another area]. A letter was, therefore, sent to [Ms A] from [a public hospital] advising her to contact a GP in [the area] so that she could be referred for specialist attention to [a second public hospital]. [Ms A] was seen [at a medical centre] and a referral was made to [a second public hospital] on 8 December 1997 referring [Ms A] to the Hepatitis C clinic there. An appointment was made with [Dr F] and the appointment sent to [Ms A]. She did not keep this appointment and on 4 August 1999 when the appointment system was being culled, it was noticed that this appointment was never kept and her name was removed from the data base. [Ms A] did not in fact stay in [the area] very long and returned to [her previous town].

[Dr D] re-referred her to [a public hospital] on this occasion to [Dr B] in April 1998. This was categorised as semi-urgent and she was seen by [Dr B] on 6 August 1998. The letter and hospital notes relating to that clinic visit indicate that [Ms A's] Hepatitis C status was noted and accepted. A history was obtained of reduced energy and tiredness over the previous five months, some irritability and a weight gain of 1½ stone in the few months preceding the clinic visit. Her past history, medications, obstetric and gynaecologic history including last menstrual period and contraceptive history, and social history were obtained. [Dr B] noted that she was not currently taking contraceptives. He elicited a history of drug abuse in the past. He noted she was HIV negative. He examined her noting that she was small, had low blood pressure (80/60) and had no evidence of liver dysfunction. He subsequently stated that he had applied for Interferon A and that he would see her in a few weeks time. He also stated that she was not prepared to give her injections herself and that [Dr D's] nurse would need to do this three times a week.

[Dr B] arranged for [Ms A] to have blood tests performed including liver function tests, full blood count, Hepatitis B serology, syphilis serology, HIV screen, renal function and immunoglobulin levels. [Ms A] had those blood tests taken on the same day as the clinic visit (06.08.98). Her full blood count was essentially normal. Kidney function was normal. Liver function tests were normal apart from a mildly elevated GGT and were not indicative at that time of active liver disease. Hepatitis B, syphilis and HIV serology were all negative. Immunoglobulin levels were normal. Thyroid function was also normal.

Six days later on 12.08.98, [Dr B] received approval for the use of Interferon by Health Benefits Limited. A further appointment was made with [Ms A] for 3 September 1998. The letter from [Dr B] relating to his clinic visits indicates that [Ms A] was reviewed and issued with a script for Interferon Alpha-2B 3 mega units three times a week to be given subcutaneously. She was given a three months prescription and arrangements were made for [Dr B] to see her again at the end of the period. She was advised to have monthly liver function tests with copies to [Dr D]. Liver function tests were in fact repeated on 3 September and on this occasion were significantly abnormal. On 4 September 1998 [Ms A] received her first dose of Interferon. She subsequently received doses on 07.09.98, 09.09.98, 11.09.98 and 18.09.98 having missed two doses. The following week on 21.09.98 [Ms A] found out that she was pregnant and this was confirmed by [Dr D]. [Ms A] therefore, received five injections of Interferon Alpha-2B prior to discovering she was pregnant and stopping the Interferon programme. At that time [Dr D] and [Ms A] had a discussion about the risks of Interferon and she was told that the results of tests in animals showed an increased risk of fetal abnormality. A few days later she had a scan that showed her to be 13½ weeks pregnant and she was advised that it was too late for a termination. Further discussions with [Dr D] who had discussed the issue with [Dr G] indicated that the major risk of Interferon was early abortion

which evidently had not occurred. [Dr D] also noted in September 1998 that [Ms A] was using oral Morphine, Methadone and Valium.

On 3 December 1998, [Ms A] attended her follow up appointment with [Dr B] at which time she informed him that she was pregnant and that she had discontinued her Interferon. She was thought to be of 23 weeks gestation at that time. [Dr B] noted that her liver function tests had considerably improved. He recommended continuing with monthly liver checks and arranged to see her again in April 1999.

[Ms A's] baby was born on 08.04.99. [Dr L] reports that the baby had no abnormalities apart from features of opiate withdrawal which settled within a few days of birth. There was a recommendation from [Dr L] that the baby should have tests for Hepatitis at about the age of six months and then again at about the age of 12 months. There is no evidence to state whether or not these tests have in fact been done.

[Ms A] did not attend her April 1999 or July 1999 appointments with [Dr B], but subsequently attended on 16 September 1999 at which point a new application was made for Interferon to Health Benefits Limited. Further approval was subsequently given and [Ms A] was recommenced on Interferon on 4 October 1999 while [Ms A] was still breastfeeding her daughter. She was also referred by [Dr B] to [Dr H] as he felt that she might benefit from the combined Ribavirin and Interferon protocol which [Dr H] was familiar with. [Dr H] saw [Ms A] in February 2000 and he advised her that the combination of Rivavirin and Interferon would increase the chance of a cure from about 20% to 40%. [Ms A] signed a consent form agreeing on the protocol.

At the time that [Ms A] first received Interferon in September 1998 Pharmac had issued guidelines (see enclosed), but not a formal protocol for the administration of Interferon in the treatment of Hepatitis C. The guidelines suggested patients should be fit and that liver cancer should be excluded by ultrasound examination and alpha fetoprotein levels. It laid out some criteria for treatment including criteria for diagnosis and criteria for establishing active chronic liver disease, HIV positivity, pregnancy, low white cell count and or low platelet count and continuing alcohol abuse or intravenous drug use. The recommended dose of Interferon Alpha-2B was 3 million units three times a week. Monitoring for side effects and efficacy was recommended at 0, 1, 2, 4, 8, 12, 16, 20, 24, 28, 36 and 48 weeks. This included blood tests particularly liver function tests and blood count along with a clinical assessment. It should be noted however that these were guidelines and not a protocol. At that time there was a protocol also available which was for the combined treatment with Interferon and Ribavirin, copies of which have been included as evidence.

Guidelines simply give recommendations and are not prescriptive. Working through the guidelines it appears that [Dr B] did not establish the presence of active chronic liver disease prior to recommending Interferon treatment either

by serial measurements of liver enzymes or by liver biopsy nor did he request an ultrasound or alpha fetoprotein level (although liver cancer would have been very unusual given her short duration of Hepatitis C infection).

He addressed most of the other exclusion criteria including testing for HIV, conducting a full blood count, enquiring about alcohol and drug abuse and eliciting the date of her last menstrual period and asking about contraception. He did not request a pregnancy test, but nor did the guidelines state this is necessary. I am not aware that autoimmune studies were performed although there was no reason to believe that she had concomitant autoimmune disease. In terms of patient monitoring it is clear that [Dr B] did not follow the guidelines. He recommended monthly liver function tests and three monthly clinic assessment. There was no indication to the patient or GP that the full blood count should also be carefully monitored (as Interferon can lower the blood count). Nor does he indicate that she should be seen regularly for assessment of side effects. In fact there is no indication in the hospital notes or either of the two letters of August or September 1998 that side effects of Interferon were discussed with the patient at all. Nor was there any advice to the general practitioner, [Dr D] regarding the possible side effects of Interferon and the type of monitoring that might be required. In particular there was no mention of the likely side effects including new symptoms of depression or worsening of depression and suicidal ideation (relevant in view of [Ms A's] previous Amitriptyline overdose), possible worsening of liver function tests, lowering of the blood count, in particular the white cells and platelets and lowering of the blood pressure (again relevant in view of her initial clinic visit blood pressure recording). Given that [Dr B] asked about contraception and date of her last period, there is no indication that he made a recommendation that she should not become pregnant whilst on Interferon. It is further noted that in [Dr B's] response to the complaint he indicated that the responsibilities for discussing side effects of treatment lay with the GP, [Dr D] as his surgery would be responsible for administering the injections. Whilst that is of course ideal it assumed that [Dr D] and or his nurse was familiar with the side effects of the Interferon. The onus however is on the prescriber to inform the patient of the side effects of prescription medicines either verbally or by providing written information. There is no indication in the notes that this was done. [Dr B] subsequently states that [Ms A] had been appraised of the side effects of Interferon by [Dr E] in December 1997. That was of course nine months prior to commencing Interferon and relies on the patient's memory and also on another doctor to impart the relevant information. [Dr B] does state that he himself discussed the side effects of treatment, but as stated previously there is no written confirmation of this.

In my opinion, [Dr B] was a little hasty in applying for Interferon. He did not have clear evidence at the time of application that she had persistently abnormal liver function tests over a six month period. Given that her liver function tests were normal at that visit, a liver biopsy would have been recommended by me. I would also have repeated her Hepatitis C PCR test.

For completion sake, autoimmune screening could have been requested but I do not think was essential. A full blood count, liver function tests, thyroid function, Hepatitis B serology and HIV testing were all appropriately carried out. A pregnancy test was not performed, however, I did not think this would have been a routine practice and was therefore a reasonable omission. Following the initiation of Interferon, it would be usual to recommend more frequent blood tests initially either at one or two weekly intervals including full blood count and liver function tests. A follow up at one month would have been reasonable given that she was visiting her GP or his nurse for the injections.

[Dr B] appears to have kept an accurate record of [Ms A's] clinic attendances and has also written to the GP when she has failed to attend clinics. My comments with regards to the initial clinic visit letter/notes are as follows:

- The diagnosis of Hepatitis C and current status of liver disease at the time of the clinic appointment were not commented on giving the impression that there was not due consideration given to the eligibility for Interferon treatment.

- There is no history given as to how she contracted Hepatitis C or when this might have been.

- The letter does not indicate what blood tests [Dr B] felt were appropriate or indeed that he had requested any although the laboratory data tell us that he did.

- The letter in the notes fails to show that there was any discussion regarding the side effects of Interferon or that [the] GP was given advice on the side effects and asked to discuss them with the patient.

- The letter indicates that monthly liver function tests and the monthly clinic visits are necessary for follow-up, but does not indicate that the GP needs to keep a closer eye on both the full blood count and liver function tests or that he should be seeing the patient for review of side effects on a more frequent basis.

- [Dr B] does however elicit a very adequate medical history apart from that relating to her presentation with Hepatitis C and documents his clinical examination of her.

[Dr B's] response to the complaint is unfortunate and appears not to address the main issues.

As I indicated earlier on, [Dr B] has not breached any written protocol in the management of [Ms A]. The major issue is whether or not he informed [Ms A]

of the side effects of Interferon and at the end of the day all we have is his word against hers as there is no written documentation. I do not feel any further investigation will help resolve these issues."

Further advice

Dr Bayston reviewed Dr B's response to the provisional opinion and provided the following further advice:

"…

1. A doctor often has more information about a patient than is put down on paper and it seems that this is the case here. I was unaware of the strong family history of liver cancer. It is not known or stated whether hepatitis C was the underlying cause of liver cancer in these close relatives, however, such a family history does change the dynamics of the situation.

2. Given [Dr B's] statements that [Ms A] had requested Interferon treatment, was aware of the side effects (having discussed them with him as well as the Pharmacist) and had documented hepatitis C by serology and given her family history it is probably reasonable that Interferon was provided. Individual preferences, facilities available to doctors in different areas as well as differing circumstances for different patients often alter the way a patient is managed in a way that will veer from guideline recommendations.

3. My initial opinion was that [Dr B] had not breached any written protocol in the management of Ms A. I stick to this opinion. At the time of my initial opinion, I felt that the major issue in [Ms A's] complaint was whether or not [Dr B] informed [Ms A] of the side effects of Interferon.

It appears that [Dr B] was genuinely trying to help the daughter of a close friend of his. It is indeed unfortunate that she became pregnant just as she was starting Interferon treatment. Given [Dr B's] enquiries about her contraceptive history, menstrual history and previous pregnancy history, it would seem that [Dr B] had taken as much care as is reasonable to exclude the possibility of pregnancy. Interferon is not a drug like Ribivarin which can cause serious foetal abnormalities. There are many drugs which are not particularly desirable to be taken in pregnancy, but we do not routinely do pregnancy tests on all patients prior to commencing these drugs. There is also an onus on the patient to inform the doctor if she considers there is a possibility of pregnancy. As it happens the patient discovered she was pregnant after five injections and stopped treatment thereafter. No harm came to the baby or the patient as a

result of this. It is my considered opinion that any further enquiry will undermine [Dr B] with no further gain to the patient."

Code of Health and Disability Services Consumer's Rights

The following Rights in the Code of Health and Disability Services Consumers' Rights are applicable to this complaint:

RIGHT 4
Right to Services of an Appropriate Standard

1) Every consumer has the right to have services provided with reasonable care and skill.
2) Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards.
…
5) Every consumer has the right to co-operation among providers to ensure quality and continuity of services.

RIGHT 6
Right to be Fully Informed

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 expected risks, side effects, benefits, and costs of each option; …

Opinion: Breach – Dr B

Right 4(2)
Dr B did not adhere to the guidelines in terms of monitoring Ms A during her treatment. My expert advised that following the initiation of interferon alpha-2b, it is usual to recommend more frequent blood tests than those ordered by Dr B. According to the Pharmaceutical Schedule for Interferon Alpha-2b, monitoring for side effects and efficacy is recommended at 0, 1, 2, 4, 8, 12, 16, 20, 24, 28, 36 and 48 weeks. This includes blood tests, particularly liver function tests and blood count, together with a clinical assessment. Dr B did not carry out side effect monitoring. My expert adviser noted that a follow-up appointment at one month would have been reasonable given that Ms A was visiting her general practitioner or his nurse for the injections.

In failing to provide care that complied with accepted guidelines, in my opinion Dr B breached Right 4(2) of the Code.

Right 4(5)
My expert advised that Dr B did not alert Ms A's general practitioner, Dr D, to the possible side effects of interferon alpha-2b, such as depression, suicidal thoughts, worsening of liver function, lowering of the blood count and lowering of the blood pressure. This was important information in light of Ms A's previous amitriptyline overdose and her low blood pressure recording at the August 1998 visit.

Dr B stated that he elicited when Ms A's last menstrual period was and discussed this "in detail because the use of Interferon [is] hazardous". Although Dr B asked about contraception and the date of her last period, there is no indication that he made a recommendation that Ms A should not become pregnant while on interferon alpha-2b. Dr B claimed that if Ms A had been going to administer the injections herself, he "would have gone through all items in detail, again" but that as the general practitioner or practice nurse was to administer the injections the responsibility for pregnancy testing was theirs. My physician advisor noted that the guidelines recommended monitoring for side effects and efficacy at 0, 1, 2, 4, 8, 12, 16, 20, 24, 36 and 48 weeks. Such monitoring includes blood tests, particularly liver function tests and blood count, together with a clinical assessment. None of this information was provided to Ms A's general practitioner.

Dr B did not ensure quality and continuity of care to Ms A when he failed to communicate to her general practitioner the risks and side effects of interferon alpha-2b and the need for appropriate monitoring during the administration of the drug. In these circumstances Dr B breached Right 4(5) of the Code.

Opinion: No Breach – Dr B

Right 4(1)
Ms A stated that Dr B did not do a pregnancy test before or during her treatment on the interferon alpha-2b programme.

Dr B did not request a pregnancy test at any point but did attempt to ascertain that Ms A was not pregnant by recording the date of her last menstrual period and asking her about contraception. Dr B's clinical notes and his August 1998 letter to Dr D advising of the outcome of his consultation with Ms A both record the date of the last menstrual period. The letter to Dr D also identifies that although the last menstrual period was late this was not uncommon. Although the Pharmac guidelines identify pregnancy in the exclusion criteria there is no explicit requirement to undertake a pregnancy test and my expert advised me that pregnancy testing would not be common practice. Accordingly, in not undertaking a pregnancy test on Ms A, Dr B did not breach Right 4(1) of the Code.

Right 4(2)
Ms A stated that Dr B did not adhere to accepted protocols before commencing her on the interferon alpha-2b programme.

My expert advised that Pharmac had issued guidelines, but not a formal protocol, for the administration of interferon alpha-2b in the treatment of hepatitis C at the time that Ms A first received interferon alpha-2b in September 1998. Further, my expert noted that guidelines are not prescriptive but provide recommendations and that Dr B did not breach any written protocol even though he did not comply with the guidelines.

The Medical Practitioners Disciplinary Tribunal (MPDT) in *Re John* (MPDT 183/01/71D, 10 December 2001) accepted that guidelines are good evidence of acceptable standards. Dr B did not follow the guidelines in establishing the existence of active chronic liver disease either by a serial measurement of liver enzymes or a biopsy. I accept that measures such as liver biopsy are invasive and for that reason may not always be appropriate. Dr B also did not conduct an ultrasound or an alpha-feto protein level to exclude autoimmune liver disease. In response to my provisional opinion, Dr B identified that his priority was to commence Ms A on treatment as she had been diagnosed with hepatitis C (which can cause liver cancer if untreated) and had a family history of liver cancer. My expert considered that "such a family history does change the dynamics of the situation". I accept that Dr B had appropriate clinical reasons for deviating from the Pharmac guidelines and did not breach right 4(2) of the Code in relation to this aspect of Ms A's care.

Right 6(1)(b)

Ms A stated that Dr B did not inform her about the side effects of interferon alpha-2b before or during her treatment on the interferon alpha-2b programme. Dr B stated that Ms A had received information both from Dr E and from himself. Dr B stated that Dr E had given Ms A information on interferon alpha-2b and hepatitis. Dr E thought it unlikely that he had discussed side effects of interferon alpha-2b at that time and that such a discussion usually took place at the liver clinic.

Dr B stated that Ms A had come to see him for interferon treatment and had raised the issue of side effects of the treatment with him. Ms A stated that she had heard that interferon was a tough programme with side effects and was concerned. Dr B stated that he spent 10 minutes discussing contraindications, important precautions, adverse reactions and side effects with her. Dr B stated that he did not record his discussion with Ms A on interferon alpha-2b in the clinical notes.

Dr B also said that the hospital pharmacy provided both oral and written information when they dispensed the drug and the written information supplied provided instructions for self injection and listed common side effects such as weakness/fatigue, low grade fever and muscle aches.

Dr B claimed that responsibility for discussing the side effects of treatment lay with Ms A's general practitioner, as his surgery would be responsible for administering the injections.

In my opinion it was unreasonable for Dr B to assume that another medical practitioner had informed or would inform Ms A of the risks and side effects of the treatment. A general practitioner cannot prescribe interferon alpha-2b and therefore may not be able to provide advice on the risks and side effects.

The information provided by Dr B to my investigation was not highly persuasive. However, I accept that Ms A went to the appointment with information about interferon alpha-2b, had a discussion with Dr B about side effects and accessed other information via the hospital pharmacy and the interferon alpha-2b user pamphlet.

In these circumstances, I am satisfied that Dr B took reasonable steps to ensure that Ms A had adequate information about the side effects of interferon alpha-2b and did not breach Right 6(1)(b) of the Code.

Opinion: No Breach – District Health Board

Vicarious liability
In addition to any direct liability for a breach of the Code, employers are vicariously liable under section 72(2) of the Health and Disability Commissioner Act 1994 for ensuring that employees comply with the Code of Health and Disability Services Consumers' Rights. Under section 72(5) it is a defence for an employing authority to prove that it took such steps as were reasonably practicable to prevent the employee from doing or omitting to do the thing that breached the Code.

Dr B was an employee of a District Health Board. However, at the time Ms A first received interferon alpha-2b injection treatment in September 1998, Pharmac had issued guidelines for the administration of interferon alpha-2b in the treatment of hepatitis C. The *New Ethicals Catalogue*, which serves as a guide for doctors when prescribing, provided information on interferon alpha-2b, and Medsafe (a unit of the Ministry of Health) also provided comprehensive information to prescribers. Given the availability of national guidelines and data information, it was not reasonable to expect the District Health Board to issue its own guidelines for interferon alpha-2b injection treatment.

Therefore, in my opinion, the District Health Board is not vicariously liable for Dr B's breaches of Rights 4(2) and 4(5) of the Code.

Actions

I recommend that Dr B take the following actions:

- Apologise to Ms A for failing to provide appropriate monitoring during her interferon alpha-2b injection treatment.

- Review his practice in light of this report.

Further Actions

- A copy of this opinion will be sent to the New Zealand Medical Council.

- A copy of this opinion, identifying Dr B only, and of Dr B's letters in response to my investigation (letter dated 12 June 2000) and to my provisional opinion (letter dated 17 April 2002) will be sent to the New Zealand Chair of the Royal Australasian College of Physicians, with a recommendation that a senior member of the College meet with Dr B to discuss issues of professionalism that arise from his correspondence.

- An anonymised copy of this opinion will be sent to Medsafe and to the Royal Australasian College of Physicians, and placed on the Health and Disability Commissioner website, www.hdc.org.nz, for education purposes.