# Medical Centre/General Practitioner

# Opinion – Case 99HDC01756/

**Summary**

The Health and Disability Commissioner commenced an investigation into the provision of the third generation oral contraceptive pill, Femodene, to the consumer, Mrs A, by the general practitioner, Dr B, and a central city medical centre. The investigation resulted from concerns the Commissioner was alerted to following the death of Mrs A from a pulmonary embolism on 12 April 1998. Information was gathered and experts were engaged to independently review and report on whether they considered the services were of an acceptable standard.

By July 1996 the Ministry of Health advice to doctors regarding the renewal of prescriptions for third generation oral contraceptives was to review the personal and family history, disclose the new risk information and gain informed consent. My general practitioner advisor stated that prescriptions for oral contraceptives should not be renewed unless the patient's blood pressure had been checked and weight recorded at least once in the previous year.

In my opinion the medical centre and the general practitioner, Dr B, breached Right 4(1), Right 4(2), Right 6(1)(b), Right 6(1)(e), Right 6(2) and Right 7(1) of the Code by renewing Mrs A's prescription for Femodene without taking reasonable care to ensure that:

- Mrs A's ongoing use of Femodene had been properly reviewed and remained clinically appropriate; and
- Mrs A had been provided with sufficient information to enable her to make an informed choice and give informed consent to her ongoing use of Femodene.

Since the tragic death of Mrs A, the medical centre and the general practitioner, Dr B, have taken steps to address the areas of concern identified by my investigation. I have recommended that the medical centre and Dr B further review their policies and practice in light of my opinion. A copy of this report will be sent to the Medical Council of New Zealand.

Some of the concerns identified by my investigation may not be unique to this general practice. To ensure that all general practices and practitioners meet the appropriate standards, and comply with their obligations under the Code, I have decided to forward an anonymised copy of this report to the Royal New Zealand College of General Practitioners, Women's Health Action and the Ministry of Health, for educational purposes.

Continued on next page

# Medical Centre/ General Practitioner

## Opinion – Case 99HDC01756/, continued

**Complaint**

The Health and Disability Commissioner received a complaint from the complainant, Mr A, regarding the services his late wife, Mrs A, received from her general practitioner, Dr B, and a central city medical centre. The complaints are as follows:

- Mrs A's general practitioner, Dr B, prescribed Mrs A with the contraceptive drug Femodene for some years without discussing with Mrs A the known risks associated with taking this drug.

- When continuing to prescribe Femodene for Mrs A, Dr B failed to take into account Mrs A's family history of heart disease.

**Investigation Process**

The complaint was received from Mr A on 4 November 1998 and an investigation was commenced on 11 March 1999. On 3 May 2000 the investigation was extended to include the medical centre. Information was obtained from:

| | |
|---|---|
| Mr A | Complainant/Husband of the consumer |
| Mrs A | Consumer |
| Dr B | Provider/General Practitioner |
| Dr C | Epidemiologist |
| Mrs D | Practice Manager at the medical centre |
| Dr E | Senior Medical Advisor, Medsafe, Ministry of Health |
| Dr F | Chairman of an ethical committee |

Mrs A's medical records from the medical centre were obtained and reviewed as part of this investigation. Advice was obtained from two independent general practitioners.

*Continued on next page*

# Medical Centre/ General Practitioner

## Opinion – Case 99HDC01756/, continued

**Information Gathered During Investigation**

***Background***

Mrs A was a healthy young woman. She was a patient at a central city medical centre from 1979 until her death at age 32 on 12 April 1998. Mrs A transferred to Dr B's care in 1996, soon after her regular general practitioner at the practice retired. Mrs A first consulted Dr B on 3 October 1996 in relation to a viral illness. Dr B stated that at this consultation she advised Mrs A to make an appointment to have a well woman check when she recovered from her illness. The medical records note "smear soon". Mrs A later consulted a locum doctor at the same practice on 22 April and 6 May 1997 about irritable bowel syndrome, as Dr B was on leave. At the consultation on 22 April, Mrs A had a cervical smear.

Mrs A's father received a triple heart bypass in 1987 following a diagnosis of coronary heart disease. In April 1997 Mrs A's father underwent angioplasty to open narrow arteries. He died of a heart attack on 4 January 1998. His family has a history of varicose veins and his sister had trouble with blood clots in about 1998.

***Reproductive health services***

Mrs A started taking the third generation oral contraceptive pill Femodene in 1993 and continued to take it until her death on 12 April 1998. Between April 1995 and April 1998 the medical centre renewed Mrs A's prescription for Femodene nine times by way of a repeat prescription. Numerous doctors at the medical centre signed the prescriptions for Femodene.

Based on the medical records, it appears that a general practitioner signed the repeat prescription on 7 April 1995 and 21 September 1995, and then another general practitioner renewed Mrs A's prescription on 16 February 1996 and 27 July 1996. Mrs A consulted Dr B about a viral illness on 3 October 1996. Her prescription for Femodene was also renewed at this consultation. Mrs A received a further repeat prescription signed by Dr B on 19 December 1996. On 12 March 1997 and 25 August 1997 Mrs A received a repeat prescription signed by a fourth general practitioner. A fifth general practitioner renewed her prescription on 23 January 1998.

*Continued on next page*

# Medical Centre/ General Practitioner

## Opinion – Case 99HDC01756/, continued

**Information Gathered During Investigation *continued***

On 12 April 1998 Mrs A awoke at her home with a sore leg, got out of bed and walked around, and eventually returned to bed, as she continued to feel unwell. Mr A had breakfast with his wife and then left the house. He returned to their house half an hour later and found Mrs A dead in the bathroom. Mrs A was taken to the public hospital, where an autopsy found that she had died of a "*massive pulmonary embolism*".

**[General Practitioner: Dr B]**
As noted above, on 3 October 1996 Mrs A consulted Dr B about a viral illness and was given a repeat prescription for Femodene. Mrs A received a further repeat prescription signed by Dr B on 19 December 1996. Dr B stated:

> *"In reply to* [Mr A's] *first complaint,* [Mrs A] *had no known contraindications to taking this medication throughout that five year period. She was a fit and healthy woman.*
>
> *If this situation had changed and any risk factors arisen, then I would have discussed them with her at that time as I do with any of my patients.*
>
> *It would be an extraordinary thing for any general practitioner to raise the subject of risks and benefits at each renewal of a prescription for a medication that a patient had elected to take, had no risk factors indicating she should not take it, and had in fact taken with no problems for several years.*
>
> *The time when these things are discussed is at the initiation of the medication before the patient first takes it. That is the time I take a full personal and family history looking for contraindications to the medication's use, as well as discussing risks and benefits of the medication. This is a procedure I go through with all of my patients.*
>
> *Further discussion occurs, as said previously, if the patient's risks change. In* [Mrs A's] *case, she never developed any known risk factors to suggest change of medication.*

*Continued on next page*

# Medical Centre/ General Practitioner

## Opinion – Case 99HDC01756/, continued

**Information Gathered During Investigation** *continued*

*In addition to discussions at the time of initiation of oral contraceptive medication, every packet of Femodene opened by a user contains a clear and easily understood written information sheet which specifically states contraindications, precautions and possible risks of the oral contraceptive pill. It also describes the symptoms of a venous thrombosis and pulmonary embolus.*

*With regard to* [Mr A's] *second complaint, a family history of heart disease is not a risk factor for venous thromboembolism.*

*As well, the New Zealand Ministry of Health's 'Advice for Women about Oral Contraceptives' published in July 1996, states 'Pills containing desogestrel or gestodene possibly reduce the risk of heart attack or stroke'. These include Femodene.*

*With this possible added protection provided by third generation pills, I considered continuation of Femodene to be the preferred oral contraceptive pill for* [Mrs A]*, while she chose to continue taking an oral contraceptive.*

*I am sorry that* [Mr A] *feels that I did not act appropriately in this matter. I know that nothing I say can alleviate the loss that he must feel, but I would like to assure him that had his wife developed any of the risk factors, then I would have discussed those with her, with a view to changing her prescription, as I do with all my patients for all medications.*"

**[Medical Centre] –** ***policies and practice***

The medical central practice manager, Ms D, stated:

*"Repeat prescriptions for oral contraception requested by telephone, are received by the nurse on duty who then checks the patient records to ensure the patient has been seen by the doctor in the preceding twelve months. The nurse then checks that the patient's smear is up to date and advises the patient if she is due for a smear.*

*Continued on next page*

# Medical Centre/ General Practitioner

## Opinion – Case 99HDC01756/, continued

**Information Gathered During Investigation** *continued*

*If the patient is overdue for an appointment, the prescription for the contraceptive pill is still given to ensure continuity of contraception is not interrupted with subsequent risk of pregnancy, and the patient is advised to make an appointment with her doctor."*

Mrs D further stated:

*"The repeat prescribing of a contraceptive pill (of any sort) was used as an opportunity to review the woman's cervical smear status. The medical centre had a policy that the nurse taking the prescription over the telephone would take the opportunity to look and see when the last smear was and if it was overdue ask the woman to come and have it done. In the normal course of events this would have prompted a visit and thus review of any prescription on a regular basis. The comments given to the woman would not have been recorded in the notes until late 1996 as at that time we were not using the computerised system to record notes. The nurses didn't use the hand written file to record events (this is a historical anomaly, and is true of most general practices).*

*In the normal course of events it would be expected that a patient would have been appraised of the need for a cervical smear and with this a review of her medication. However as noted above this wouldn't have been recorded.*

*The repeat prescription request has been seen as an important point at which recalls and reviews can be initiated. This has been discussed with the nurses and they will routinely ask patients to make an appointment for review if a patient hasn't been seen for a period of time. The time period is arbitrary depending on the medical condition, however a year is considered the longest time that should be allowed to elapse between reviews. Again though, the final decision rests with the doctor that the patient is registered under (who would normally be the person signing the prescription).*

*Continued on next page*

# Medical Centre/ General Practitioner

## Opinion – Case 99HDC01756/, continued

**Information Gathered During Investigation** *continued*

*It is not uncommon for patients to resist coming in for a review of their medication, indeed patients have been known at extremes to have become abusive and hostile when appraised of the need for review of their medication. This leaves the dilemma of whether to continue prescribing or stopping a medication (both options being unsatisfactory).*

[Mrs A's] *care became fragmented due to the number of different doctors involved in prescribing it. This resulted from the retirement of one* [general practitioner]*, the transfer to another* [general practitioner]*, the then transfer to* [Dr B] *(for preference for a different doctor), the transfer to* a [locum] *(as* [Dr B] *was on leave) and then back to* [Dr B]. *Additionally when a doctor is away, the prescription is signed by another doctor in their place (as occurred with the last prescription for* [Mrs A] *for Femodene). The same occurred for the prescription of 27/7/96 (a Saturday, when the doctor filling in for the Saturday morning shift signed the prescription). NB The last letter erroneously stated that* [the second] *general practitioner signed that prescription.*

*Furthermore, several of her consultations were with a locum doctor whereas if she had seen her 'own' doctor on these occasions, it is more than likely that other health issues would have been opportunistically addressed.*

*At the* [medical centre]*, the majority of consultations of patients are with their 'own' doctor and that doctor signs all their repeat prescriptions. Patients are actively encouraged and expect to see their own doctor. It was an unusual sequence of events that led to so many different doctors being fleetingly involved with* [Mrs A's] *care and medication.*

*It is also relevant to add that on occasions patients make appointments at their own convenience, at times when their registered doctor is not available to attend to them, rather than wait for their own doctor. This has happened here.*

*Continued on next page*

# Medical Centre/ General Practitioner

## Opinion – Case 99HDC01756/, continued

**Information Gathered During Investigation** *continued*

*The* [medical centre] *consists of individual doctor's practices operating under the same roof. Each patient is assigned to an individual doctor and the doctor that they are 'registered' under receives the prescription to sign.*"

Since the death of Mrs A, the medical centre has revised its repeat prescribing policy to ensure that patients have regular review of their medication with their doctor. Now patients on permanent medications may have only one repeat between visits to the doctor. Repeat prescriptions are not to be done by Saturday locums but referred to the patient's doctor on the following Monday. The medical centre has also placed the following message on its prescription line for telephone requests for repeat prescriptions:

> "*You have reached the prescription line for* [the] *medical centre. Prescriptions ordered today will be available after 3pm on the next working day. Please note that only one repeat will be issued between discussions with your doctor or their nurse. Please leave your name and date of birth, your phone number, the name of your doctor and the medication you require. There will be a charge for repeat prescriptions. Thank you."*

The policy also includes sending out a 'pro forma' letter with the prescription if the patient is overdue for a consultation. The letter states:

> *"I am writing your prescription today and noted that you haven't been for some time for review. It is good practice to review most ongoing medications and conditions at least every six months. Could you please make an appointment to check things over in the near future? If you have any queries please contact me at the* [the] *medical centre."*

*Continued on next page*

# Medical Centre/ General Practitioner

## Opinion – Case 99HDC01756/, continued

**Independent Advice to the Commissioner**

Advice was obtained from two independent general practitioners. The first independent general practitioner stated:

> "*The information about the slight increased risk of DV, with implied additional risk of Pulmonary Emboli, with the third generation contraceptive pills (Marvelon, Mercilon, Femodene, Minulet), only became known and published in late 1998.*
>
> *Before that they were reputed to have a better side effect profile than the older pills.*
>
> *The IPPF Medical Bulletin supplied with the complaint material itself is dated December 1998. It would only be after the release of the Ministry of Health statement 'Ministry of Health Reviews Contraceptive Advice' of 22/12/98 that any knowledge of the changed status of 3rd generation pills could be expected of GPs.*
>
> *The risk overall is still small – I attach an attributed graph of the causes of death for women …. The pen marks on the graph are from my previous use of the graph in my DVT-third gen pills information sessions with women. This shows, I believe the relative risk attributable to third generation pills.*
>
> *In 1996 3rd generation progestagen containing COCs* [oral contraceptives] *were thought to be safer than older preparations. One can only act on information available at the time. One cannot foresee future research findings.*
>
> *So quite emphatically I believe* [Dr B] *provided* [Mrs A] *with care that complies with professional standards.*"

*Continued on next page*

# Medical Centre/ General Practitioner

## Opinion – Case 99HDC01756/, continued

**Independent Advice to the Commissioner *continued***

Further clarification was sought from a second independent general practitioner who stated:

1. With the knowledge that Mrs A had been taking Femodene since 1993, should Dr B have discussed with her in 1996 the risks associated with taking the drug?

   *"When the oral contraceptive pill is first prescribed a full discussion needs to take place with the patient regarding the risks and benefits of using this medication. Given the fact that* [Mrs A] *was already on the oral contraceptive pill Femodene when* [Dr B] *took over her care in 1996, then it may not have been necessarily incumbent upon* [Dr B] *to have discussed with her the risks and benefits of taking this drug. It would have been quite reasonable for* [Dr B] *to have assumed that the doctor who first put* [Mrs A] *on this medication would have gone through the exercise of discussing the risks and benefits involved in taking it."*

2. As new information regarding the risks associated with Femodene began circulating in 1995, 1996 onwards, should Dr B and/or the other general practitioners have discussed these issues with Mrs A?

   "*It needs to be made clear that in 1995, 1996 there was, even from the information provided to us from the Department of Health, a widespread feeling that not too much should be made of any risks associated with this. The risks were not well proven and we ran the risk of unnecessarily alarming women about these pills, even to possibly leading them to stop taking the pills and becoming pregnant when they did not intend to. In fact, at a meeting of the Working Party on Oral Contraceptives held on 25 October 1995,* [an] *Epidemiologist professor concluded no further action should be taken regarding this issue until studies had been 'published and subjected to debate and literature'. However, he made the point that it would be advisable to change a pill for women who had high risk of thrombo-embolism. That is the issue really in this situation, namely that the feeling in 1995, 1996 was that women who are at high risk of a thrombo-embolism should not be on the 3rd generation oral contraceptive."*

*Continued on next page*

# Medical Centre/ General Practitioner

## Opinion – Case 99HDC01756/, continued

**Independent Advice to the Commissioner** *continued*

3. What patient checks/tests are general practitioners prescribing Femodene for patients required to do prior to and during the prescribing of this drug? Did Mrs A have these checks/tests?

"*The checks/tests that general practitioners were and are advised to do prior to prescribing any oral contraceptive are, first of all, to take a detailed family and personal history and thereby ascertain from the history whether there are any contraindications to the prescribing of the oral contraceptive pill. Secondly the general practitioner must examine the patient, check her weight, blood pressure, check her breasts, and if she is due to have a cervical smear to have that performed. It would appear that* [Mrs A] *had all these checks/tests done.*"

4. What checks/tests should a general practitioner be doing on a patient using an oral contraceptive?

*"The general practitioner should, on a yearly basis, check the women's blood pressure if she is normotensive* [normal blood pressure]*, check her weight and keep up with the cervical smear protocol that is appropriate for that woman."*

5. Is it reasonable for a general practitioner to assume that patients will read the written information in each pack of Femodene before they take the medication?

*"No, I do not think that it is reasonable for general practitioners to assume that patients will read this information. Some patients do, some patients don't and I think it is incumbent upon the general practitioner to discuss and advise the patient before he or she issues a prescription. I think it is unwise of us to assume that all patients will read the leaflets and understand them."*

6. With the knowledge that Mrs A's father had a triple heart bypass operation in 1987 and died of a heart attack at the beginning of 1998, should this have affected the prescribing of Femodene to Mrs A?

*"The answer to this is very simply no."*

*Continued on next page*

# Medical Centre/ General Practitioner

## Opinion – Case 99HDC01756/, continued

**Independent Advice to the Commissioner** *continued*

7. Is the death of a parent by heart attack a known contraindication to the use of Femodene? Should Mrs A have been advised to stop taking Femodene?

*"The answer to this also is no. There is simply no association with a family member having had a myocardial infarction or coronary artery disease to increase risk in taking the oral contraceptive pill."*

8. Should the repeat prescription for Femodene be given to a patient if she is overdue for a smear test? Is it reasonable for a patient to be left to make her own appointment?

*"Although it is important for us to have a recall register and remind patients when they are due to have a cervical smear, I believe that it is for the patient to ultimately make the decision as to whether she wishes to have a cervical smear or not. We cannot blackmail a patient into having a cervical smear so that they continue to receive a prescription for the oral contraceptive. Some patients will make a conscious decision not to have a cervical smear performed and still may wish to be on the oral contraceptive. This is their wish and it must be respected.*

*I feel it is very unreasonable in today's climate for us to make an appointment with the patient for a cervical smear and it is very important that it be left up to her to make an appropriate appointment. For us to make an appointment, inform the patient and insist that she keep it is tantamount to harassment in my opinion."*

9. What risk factors would a patient require to necessitate looking at changing her oral contraceptive?

*"The only known risk factors are a family history of venous thromboembolism (VTE), a personal history of VTE, raised blood pressure or varicose veins. These are the only risk factors that would necessitate such a change."*

*Continued on next page*

# Medical Centre/ General Practitioner

## Opinion – Case 99HDC01756/, continued

**Independent Advice to the Commissioner** *continued*

10. Are there any other issues that arise from the supporting information?

*"Although this case is undoubtedly a tragedy, the fact nevertheless is that* [Mrs A] *did not have any risk factors that pre-empted her from being on Femodene. Certainly at the time when she was prescribed Femodene by* [Dr B] *in 1996, there was no clear-cut advice from any New Zealand authority that she should not be on Femodene. On the contrary, the advice that was promulgated was that any change should be managed cautiously as the risk of thromboembolism was much greater if in fact the woman was pregnant.*

*Thus the sad fact is that* [Mrs A] *died from a pulmonary embolus which was probably related to her being on Femodene but really it cannot be absolutely and categorically stated that it was due to Femodene. The statistics that have now been quoted many times are that if a women is on 2nd generation oral contraceptive she has a 1:10,000 chance of developing a venous thromboembolism and if she is on a 3rd generation oral contraceptive her chances are 2:10,000 of developing a VTE. Only 1-2% of women who develop a VTE go on to die from it and unfortunately* [Mrs A] *was one of these. Even women who are on no oral contraceptive at all have a chance of dying of pulmonary embolism, although the chances are admittedly very small.*

*I feel that it needs to be remembered that this prescribing and advice was given in 1996, not now. If I am prescribing a 3rd generation pill now for my patients, I certainly do go into in some detail of the risks of using this medication, but the risks back in 1996 were not at all clear and, in fact, even the so-called experts disagreed amongst themselves as to how the situation of a woman who is already on a 3rd generation pill should be best managed.*

*Continued on next page*

# Medical Centre/ General Practitioner

## Opinion – Case 99HDC01756/, continued

**Independent Advice to the Commissioner** *continued*

*The consensus from all the papers published at the time, and in particular those promulgated by the Department of Health, was that probably more evidence needed to be accumulated before a reasonable conclusion could be reached about a woman who did not have any significant risk factors of thromboembolism. For a woman who did have risk factors, then the advice was fairly clear cut – that they should either not be on a 3rd generation oral contraceptive or possibly not be on any oral contraceptives at all.*

*As regrettable as* [Mrs A's] *death is, it is still a fact of life that she simply did not have any risk factors for VTEs. Given the risk factors for VTEs that pregnancy presents, the consequences for* [Mrs A] *had she become pregnant might have been exactly the same.*

*In summary I feel that* [Dr B] *and the medical centre did provide* [Mrs A] *with services that comply with reasonable care and skill at the time they were given."*

Further advice was obtained from the second independent general practitioner, who stated:

"*You are correct in saying that* [Mrs A] *was provided with numerous prescriptions for Femodene between 1995 and 1998 and that her blood pressure was not checked on a yearly basis as it would appear should have been done. Likewise I think it is advantageous for weight to be recorded over that time also. Nevertheless during this period it is clear that she had many prescriptions for Femodene prescribed to her, often by way of repeat prescription.*

*Problems with repeat prescriptions for the pill are quite common because often women do not see the need to make an appointment to see the doctor and so incurring a cost which they do not see as being entirely necessary. Therefore most practices do have a significant amount of trouble with women who feel that a repeat prescription for the pill should be handed over as soon as it is requested.*

*Continued on next page*

# Medical Centre/ General Practitioner

## Opinion – Case 99HDC01756/, continued

**Independent Advice to the Commissioner** *continued*

*However, I do believe there is a significant responsibility in prescribing the oral contraceptive pill and thus I think it is reasonable for the practice to insist that the woman's blood pressure be checked at least once a year and her weight recorded. Often the woman will not need to see the doctor as the practice nurse is quite adequate for performing this service.*

*Where a woman who has not been seen in a practice for more than 12 months rings up for a repeat prescription for the oral contraceptive pill, I believe the practice probably should prescribe a continuation of the contraceptive pill so that cover can be maintained without risk of pregnancy. However, this prescription should only be given for one month so that effectively the woman will be forced to have a check done of her blood pressure and weight within a month.*

*It is also I think very important that the doctor who is responsible for that patient signs the repeat prescription so that he or she can check what has taken place over the past 12 months. Also he or she can check whether it is still suitable that the patient continue to be prescribed the contraceptive pill and that nothing has happened to her health in the interim to indicate that she should not be prescribed the pill.*

*We have found that where the ruling of just one month's prescribing is adhered to the patient very rapidly has a check performed in an appropriate way. It is important that a repeat prescription be written in the notes and if a woman does not heed the advice about coming in to have a check, that information be recorded in the notes also.*

*Under this criteria it would seem that the medical centre did not supply* [Mrs A] *with appropriate services and this can be a problem in a large medical practice where a number of practitioners may be away at a given time and repeat prescriptions are signed by another practitioner. Having said that I think that if there are checks and balances in the system this sort of problem can be prevented from occurring.*

*Continued on next page*

# Medical Centre/ General Practitioner

## Opinion – Case 99HDC01756/, continued

**Independent Advice to the Commissioner** *continued*

*However, in the case of* [Mrs A]*, it is an unfortunate fact of life that even had these checks been done, the outcome for her would not in fact have been any different."*

Advice on the provisional opinion was obtained from an Associate Professor of Eipdemiology, Dr C, who has carried out extensive studies on contraceptive use and safety in New Zealand. Dr C stated in response to my provisional opinion:

"*I understand and agree with your main conclusion that there was a failure to take reasonable care to ensure that the patient was provided with sufficient information to enable her to make an informed choice and give informed consent to her ongoing use of Femodene. From July 1996, when the prescriber update article was published there was an onus on doctors to review prescribing. The second issue, is the failure to review the patient's blood pressure and weight. It is clearly good practice, but high blood pressure is not a risk factor for venous thromboembolism. One of your advisors, the second independent general practitioner, in relation to clarification sought number 9, stated that raised blood pressure was a risk factor for venous thromboembolism. I have recently updated a review I undertook with* [an advisor] *of risk factors for venous thromboembolism for Medsafe, Ministry of Health. This confirmed that high blood pressure is not a risk factor. Severe obesity is, but regular weighing will not be an issue if the patient has clearly not been overweight.*

*I agree that regular recording of blood pressure and weight is good practice but this is a side issue, not related to the outcome. I don't think there should be any implication that failure to record blood pressure was related to this fatal outcome."*

*Continued on next page*

# Medical Centre/ General Practitioner

## Opinion – Case 99HDC01756/, continued

**Independent Advice to the Commissioner** *continued*

**Information from New Zealand Medicines and Medical Devices Safety Authority (Medsafe)**

Information was obtained from Medsafe, Ministry of Health regarding the history of concerns raised about the third generation oral contraceptive pill. The senior medical advisor of Medsafe, Dr E, provided advice and information on publications sent to medical practitioners, consumers and media. The information shows that by mid-1996 the advice to doctors when *renewing* prescriptions for third generation pills was of the need to review the medication, to counsel women as to the risks, and allow women to make an informed choice.

The Ministry of Health prepared an action timeline setting out when the concerns about third generation oral contraceptive pills first became public. The action timeline is as follows:

*"**Timeline for Actions on Oral Contraceptives and Blood Clots***

| ***Date*** | ***Actions*** |
|---|---|
| ***1995*** | |
| *18 Oct* | *UK Committee on Safety of Medicines (CSM) examines the results of 3 unpublished studies which appear to demonstrate a higher risk of developing blood clots for 3rd generation oral contraceptives over 2nd generation. CSM sends letter to UK doctors and pharmacists advising of increased risk and recommends changing to prescribing.* |
| *19 Oct* | *CSM issues press release in the UK informing media and public of its concerns, advice is published before UK GPs receive letter. Media driven pill scare begins. NZ Ministry of Health first becomes aware of CSM decisions and obtains copies of letter and press statement.* |

*Continued on next page*

# Medical Centre/ General Practitioner

## Opinion – Case 99HDC01756/, continued

**Independent Advice to the Commissioner** *continued*

| | |
|---|---|
| *20 Oct* | *Ministry of Health release letter to Doctors and Pharmacists containing CSM documents and advising patients not to stop their pills and that doctors should discuss these studies with patients. In women who are at increased risk the Ministry advises doctors to prescribe older 2nd generation pills. A 0800 number is established to allow women to obtain information. Ministry media conference is held and the advice and information is given wide coverage in the media. Ministry convenes emergency meeting of a number of independent specialists, members of the Medicines Adverse Reaction Committee (MARC) and industry to discuss next steps.* |
| *25 Oct* | *The emergency meeting convenes and endorses Ministry advice. Ministry releases new press release reiterating its earlier position and indicating that it cannot make a firm statement until the studies are published and it has all the available information.* |
| *27 Oct* | *Further advice is issued to all doctors and pharmacists giving history of events to date and background information. Blood Clots are formally made an adverse reaction of concern and GPs are asked to report all blood clots to the Dunedin based Centre for Adverse Reactions Monitoring. 0800 number is updated.* |
| *27 Oct* | *European Agency for the Evaluation of Medicines issues a statement based on the advice of its expert committee called the CPMP. The CPMP do not consider it appropriate to withdraw 3rd generation contraceptives and request further information from the manufacturers of these products. No prescribing information is given by the committee to European GPs or pharmacists.* |

*Continued on next page*

# Medical Centre/ General Practitioner

## Opinion – Case 99HDC01756/, continued

**Independent Advice to the Commissioner** *continued*

| | |
|---|---|
| *31 Oct* | *NZ Ministry issues press release describing the CPMP position and that it endorses the decision made in New Zealand.* |
| *14 Nov* | *US FDA announces that it has reviewed the data and considers that the difference in risk between the 2nd and 3rd generation pills is not great enough to recommend a change in prescribing behaviour. Pills containing either of the hormones under scrutiny account for 15% of the US market.* |
| *Mid-Nov* | *NZ Ministry is made aware that the German authorities had the use of 3rd generation contraceptives contraindicated in first time users and women aged less that 30 years. Decision based on suggestion that 3rd generation pills may lower the risk of heart attack in women, which occurs at a greater frequency than blood clots, and has a higher mortality than blood clots, in women over 35 years.*<br><br>*Norwegian authorities also take regulatory action advising that 3rd generation pills should only be used in women intolerant of the older 2nd generation products. However, where a woman has already been on a 3rd generation for more than 2 years they recommend continuation of the same pill. This decision is based on some evidence, which suggested that the risk of developing a blood clot is highest in the first 12 months.* |
| *21 Nov* | *International Planned Parenthood Federation releases a statement, which recommends no change to prescribing behaviour.* |
| *Mid-Dec* | *Ministry of Health distributes 92,000 copies of the Women's Health Action Fact Sheet on the Pill to all medical practitioners, midwives and pharmacists (attached and marked A).* |

*Continued on next page*

# Medical Centre/ General Practitioner

## Opinion – Case 99HDC01756/, continued

**Independent Advice to the Commissioner** *continued*

| | |
|---|---|
| ***1996*** | |
| *Jan* | *Key studies used by the UK's CSM to make recommendations are published in medical journals in Dec 1995 and Jan 1996.* |
| *Feb* | *NZ Ministry of Health publishes Prescriber Update article, distributed to all doctors, pharmacists and midwives, further reviewing the 3 studies and recommending that: prescribers take a comprehensive history; give unbiased advice about the risks; and if risks are present advise that a change to a 2nd generation pill or some other form of contraception is appropriate. The need for informed consent and respect for the patients informed decisions are reiterated (attached and marked B).* |
| *Mar* | *The NZ Medicines Adverse Reaction Committee (MARC) meet to discuss the studies and the reviews and comments on the studies published in the medical journals and information from industry. Committee recommended that prescribers should be informed that careful consideration be given to the need for prescribing 3rd generation contraceptives for: patients first starting the pill; at prescription review; and that patients should be changed from 3rd generation pills if a relative contraindication for blood clots was present. The Ministry commenced writing a new article for publication in Prescriber Update and patient leaflet.* |
| *14 Apr* | *In Europe, the EMEA issues its new position statement following the CPMP review of the published studies. The CPMP did not endorse any action other than informing doctors and patients of the risk factors and results of the published studies.* |

*Continued on next page*

# Medical Centre/ General Practitioner

## Opinion – Case 99HDC01756/, continued

**Independent Advice to the Commissioner** *continued*

*CPMP asks for further analysis of data to determine if there is any evidence that 3rd generation pills lower risk of heart attack, a condition with a greater morbidity and mortality.*

*May* — *In NZ, MARC reviews and edits several drafts of article for Prescriber Update and leaflet. Faculty of Family Planning and Reproductive Health Care of the UK Royal College of Obstetricians and Gynaecologists send copies of their latest guidelines. These guidelines support the use of 3rd generation pills in conditions where women have particular medical conditions, but generally recommend a change to second generation pills.*

*5 June* — *MARC discuss the 'final version' of article at its meeting and supports its publication.*

*Mid-June* — *Family Planning Association and Royal College of Obstetricians and Gynaecologists express concerns over proposed Ministry of Health position and indicate that they will disassociate their organisations from the proposed advice. Ministry decides to hold a meeting with several representatives from original working party (GPA, FPA, RNZCOG) to resolve this disagreement and reach a consensus position.*

*28 June* — *Ministry meets with representatives and reviews evidence and proposed article. Consensus is reached and Ministry agrees to reprint Prescriber Update article. The only alteration to the prescribing advice is to change 'preferentially prescribe' a second generation pill for new patients to 'consider prescribing' a second generation pill.*

*Continued on next page*

# Medical Centre/ General Practitioner

## Opinion – Case 99HDC01756/, continued

**Independent Advice to the Commissioner** *continued*

*This change was on the basis that it was felt inappropriate by prescribers that the entire decision as to which pill most suited a patient was being driven by the small increase in risk of blood clots which are very rare, rather than an overall assessment of all of the possible benefits and risks for use in a single particular patient.*

*July* — *Prescriber Update article published. The article reviews all of the data available, recommends full disclosure of risks and benefits to patients, contains advice for initiating prescribing, reviewing prescribing. The advice is based on the patient giving informed consent (attached and marked C).*

*A further 90,000 patient information leaflets are distributed to doctors, midwives and pharmacists (attached and marked D). The 0800 number message is changed to reflect the advice given in the Prescriber Update article (attached and marked E). Media coverage is large. Changes are made to the prescribing information for doctors for all 3rd generation products to reflect the differences in risk.*

*8 Nov* — *New Zealand Medical Journal carries leading article on safety of third generation oral contraceptives and Ministry of Health response. Prompting further media interest.*

***1997*** — *Articles published in several medical magazines and journals concerning the risks of 3rd vs 2nd generation pills.*

*June* — *New Zealand Doctor publishes article reviewing Ministry decision. Media interest generated by this article.*

*Continued on next page*

# Medical Centre/ General Practitioner

## Opinion – Case 99HDC01756/, continued

| | | |
|---|---|---|
| **Independent Advice to the Commissioner** *continued* | *Nov* | *Several newspapers and GP Weekly publish report from Reuters that reanalysis of studies have demonstrated that there is no difference in risk of blood clots between 3rd and 2nd generation pills. Ministry publishes its position and its response to these reports in GP Weekly in Feb 1998.*" |

***July 1996 – Prescriber Update***
The article stated that:

> "*The purpose of this article is to assist medical practitioners and midwives to evaluate the relative risk between products and the individual risk for women of venous thromboembolism when prescribing combined oral contraceptives. It may also help prescribers meet their informed consent obligations as outlined in the Health and Disability Commissioner Code.*"

The article outlined the advice of the Medicines Adverse Reaction Committee. This included the statement that:

> "*Women currently taking contraceptives containing desogestrel or gestodene should have their medication reviewed when their prescription is due for renewal*."

The article also stated that:

> "*When reviewing combined oral contraceptive therapy the prescriber should:*
>
> - *review the personal and family history to identify contraindications for the use of combined oral contraceptives and risk factors for venous thromboembolism as for initiation of therapy;*
> - *counsel about the risks and benefits associated with the use of the contraceptive the woman is currently taking compared to the risks and benefits of other forms of contraception;*
> - *if contraindications to the use of combined low dose oral contraceptives present, another form of contraception should be agreed upon.*

*Continued on next page*

# Medical Centre/ General Practitioner

## Opinion – Case 99HDC01756/, continued

**Independent Advice to the Commissioner** *continued*

*For women taking oral contraceptives containing desogestrel or gestodene:*

- *in the presence of thromboembolic risk factors the woman should be advised to change to a preparation that does not contain gestodene or desogestrel, or to another contraceptive method, as appropriate;*
- *offer prescription of other hormonal or non-hormonal contraception if, after counselling, the woman finds the relative risk of venous thromboembolism with combined oral contraceptives containing gestodene or desogestrel unacceptable;*
- *respect the woman's informed choice if she chooses to continue to take her current contraceptive*."

**Response to Provisional Opinion**

**Dr B's response**

Dr B stated in response to my provisional opinion:

"*There are some incorrect assumptions and disturbing issues raised in* [the Commissioner's] *opinion regarding* [Mrs A's] *case.*

*Page 22:*
*'On balance I conclude that it is unlikely that* [Mrs A] *was ever advised to make an appointment to see her doctor to review her medication.* [Mr A] *stated that* [Mrs A] *took her health very seriously. It is my view that if* [Mrs A] *had been advised to see her doctor, she would have followed this up.'*

*Continued on next page*

# Medical Centre/ General Practitioner

## Opinion – Case 99HDC01756/, continued

**Response to Provisional Opinion *continued***

*This is speculation and incorrect. What has been missed in this investigation to date is that on my first meeting with* [Mrs A] *in October 1996, even though I was seeing her for an acute illness, I advised her to come back to see me for a full well woman check when she had recovered (this being the procedure I adopt with any other patient for whom there is no documented recent woman's health check review with the medical centre). This is clearly documented in the notes as 'smear soon', the standard note that I write in all my patients notes when advising them they are due for a well woman health check which includes BP, weight, breast examination, contraception review and where appropriate, smear. The reason this is written as 'smear soon' and not 'well woman check' is that it is also written to alert my nurse to check that the patient is correctly listed on the smear recall.*

*In an ideal world, the well woman check would be done there and then, but as any experienced General Practitioner would agree, not only is this not practical as in this case because* [Mrs A] *was acutely unwell, but also because of the pressure of time. With only fifteen minutes per appointment, a comprehensive well woman check cannot be undertaken after dealing with an acute problem. It is standard practice in this situation to advise the woman to schedule another appointment to be able to give her the appropriate amount of time to do a comprehensive check properly, and I believe that in advising* [Mrs A] *to come back when she had recovered, I had offered the best standard of care appropriate to her individual need at the time.*

[Mrs A] *was then given a prescription of Femodene to tide her over till seen. She elected not to come for this review and I think there has been some misunderstanding regarding the relevance of smear recall here. We are all aware that patient choice regarding actually having a smear is paramount and that to force a patient to attend for one would amount to harassment. However, in our practice as in most others, the smear recall is used as a tool to invite women to attend for their well woman checks. The actual smear is only part of the check up and not mandatory.*

*Continued on next page*

# Medical Centre/ General Practitioner

## Opinion – Case 99HDC01756/, continued

**Response to Provisional Opinion *continued***

*The patients are still advised to attend for the rest of the check. It would seem that the actual process of having a smear was not a barrier to* [Mrs A] *attending as she elected to have one in April the following year as an add on for another acute consultation (with a Locum in my absence) having declined my request to come for her full well woman check with her regular doctor.*

*At the time, I was also routinely giving out copies of the Health Department advice to women dated July '96 when doing their medication reviews. I have not mentioned this in my notes as I just handed them out routinely as we all did and made no mention of it in any of my patient notes, a mistake in hindsight. There is a possibility that* [Mrs A] *may have not got this as I was expecting to see her soon for a full review, but its contents were relevant to her prescription (note the statement on the second page of the handout stating that 'these pills possibly decrease the risk of heart attack and stroke'). This was the relevant risk for* [Mrs A] *and with this advice, I did not think it appropriate to change her pill and still do not according to the information available at the time.*

*In December '96,* [Mrs A] *again phoned for a repeat prescription of Femodene and according to the procedures in place at the time, the nurse would have again advised her that she was due for a check up as activated by my first consultation with her, therefore a further prescription was given. This would have been typical practice for most general practices in New Zealand at that time.*

*The Commissioner's report advised on page 21 that only one month of a medication should be prescribed then more refused until the patient is reviewed. This sounds good in an ideal world but as this case is clearly demonstrative of, we do not live in an ideal world and in the reality of general practice, this course of action raises alarming ethical issues from a medical point of view. Firstly, in the intervening years and particularly in light of this case, we have actually tried this approach with the result of patients shouting abuse at our staff then refusing to take the prescription at all i.e., stopping their medication altogether.*

*Continued on next page*

# Medical Centre/ General Practitioner

## Opinion – Case 99HDC01756/, continued

**Response to Provisional Opinion *continued***

*Compliance with attendance for review of medication is an ongoing dilemma in general practice as has been clearly shown in this particular case. In* [Mrs A's] *case, refusal could have resulted in an unplanned pregnancy with 6 times the risk of DVT. In other cases such as diabetes, hypertensive patients and asthmatics, the potential for disaster is huge.*

*I have discussed this case with the* [chairman of an ethical committee, Dr F]*, and enclosed is his reply, which I believe gives valuable independent input into this matter* [attached and marked F]. *I have also sent it to the RNZCGP committee regarding 'Good Practice', and await their reply.*

*The advice* [the Commissioner] *received regarding this course of action came from a doctor in a central city practice. It should be remembered that the demographics of this type of practice are considerably different to those of a suburban or rural practice and compliance issues likewise, differ substantially. I am sure that a doctor may be within their rights to refuse more medication after the one month with advice to come for a check as discussed, but to practise in such a dogmatic way to retain a doctor's rights and medico legal defence is not always going to be in the patient's best interests and surely the ultimate goal for all of us is the best care available to our patients.*

*I am sure that* [the Commissioner] *would really rather see the more practical and personal approach taken where every patient is treated individually according to their needs. I believe it is a fundamental right of the patient to be given personal consideration according to the individual circumstances and I think* [the Commissioner] *would agree, as would any experienced general practitioner. To lay down hard and fast rules invites disaster and is ethically unsound medical practice.*

*Despite the situation in this case, I believe it is rare for a woman in our practice not to attend for review when requested and we now have good systems in place to ensure that women do always attend as this case has shown that the previous system was not entirely fool proof.*

*Continued on next page*

# Medical Centre/ General Practitioner

## Opinion – Case 99HDC01756/, continued

**Response to Provisional Opinion *continued***

*I believe that* [Mrs A's] *rights were not breached by the medical centre. Two invitations to attend to fulfil our obligations were ignored. As all the expert advisers have stated, the outcome in this particular case is extremely unlikely to have been any different had she attended.*

*The doctors at the* [medical centre] *are ever mindful that a tragedy has occurred, and we collectively express our most sincere condolences to* [Mr A]. *It has impacted on the practice's policies regarding monitoring of regular medications and in 2001, I think it can be said that both the doctors and the public recognise that more formally regulated reviews are expected than in the 1990s. We think that informing the College without identifying individuals or practices, is appropriate and will be beneficial.*

*To this end* [Mr A] *can be assured that changes and improvements in General Practice will occur, based on the Commissioner's report, which arose as a result of* [Mrs A's] *death."*

**Code of Health and Disability Services Consumers' 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 services that comply with legal, professional, ethical, and other relevant standards*

*Continued on next page*

# Medical Centre/ General Practitioner

## Opinion – Case 99HDC01756/, continued

**Code of Health and Disability Services Consumers' Rights *continued***

*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; ...*
*(e) Any other information required by legal, professional, ethical, and other relevant standards; ....*

*2) Before making a choice or giving consent, every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, needs to make an informed choice or give informed consent.*

*RIGHT 7*
*Right to Make an Informed Choice and Give Informed Consent*

*1) Services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent, except where any enactment, or the common law, or any other provision of this Code provides otherwise.*

**Jurisdiction**

The Code of Health and Disability Services Consumers' Rights came into force on 1 July 1996. Therefore, I cannot investigate acts and omissions occurring prior to that date. However, pre-1 July 1996 acts and omissions may be relevant background to a complaint and can be considered in determining whether there has been a breach of the Code post-1 July 1996. Accordingly, it is important to note that the circumstances surrounding the initiation of Femodene, including whether all relevant information was provided, is beyond the scope of my investigation. However, the circumstances surrounding the ongoing prescription of Femodene from 1 July 1996 onwards is part of my investigation, including what, if any, subsequent information about risks was provided.

*Continued on next page*

# Medical Centre/ General Practitioner

## Opinion – Case 99HDC01756/, continued

**Opinion: Breach Medical Centre and Dr B**

**Vicarious liability**

Employers are vicariously liable under s 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 s 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's relevant act or omission.

**Findings**

In my opinion the medical centre and the general practitioner, Dr B, breached Right 4(1), Right 4(2), Right 6(1)(b), Right 6(1)(e), Right 6(2) and Right 7(1) of the Code of Health and Disability Services Consumers' Rights.

**Appropriate standards – Rights 4(1) and 4(2)**

***Review of medication and risk factors***

The consumer, Mrs A, was entitled to have services provided to her with reasonable care and skill in compliance with legal, professional, ethical, and other relevant standards.

The Ministry of Health advice to practitioners since 1996 included advice that women currently taking third generation oral contraceptives such as Femodene should have their medication reviewed when their prescription was due for renewal. The Ministry also advised that when reviewing the contraceptive the prescriber should review the personal and family history to identify contraindications and risk factors of venous thromboembolism, as for initiation of the contraceptive.

My general practitioner advisor stated that women taking oral contraceptives should have their medication reviewed regularly, at least once a year as a minimum, to ensure that nothing has happened in the intervening period that indicates that the medication is no longer clinically appropriate. Before renewing a prescription for an oral contraceptive a practitioner has a responsibility to check whether a patient needs her medication reviewed and that it is still suitable. If the medication needs to be reviewed, in most situations it would be sufficient to inform the patient of the need for a review and allow the patient to arrange this.

*Continued on next page*

# Medical Centre/ General Practitioner

## Opinion – Case 99HDC01756/, continued

**Opinion: Breach Medical Centre and Dr B *continued***

It is good practice to confirm this advice in writing. In some situations it may be appropriate to prescribe a continuation of the contraceptive for one month to ensure that cover is maintained pending a suitable appointment. Such discussions should always be clearly recorded in the medical notes.

My epidemiologist advisor stated that from July 1996 there was an onus on doctors to review prescribing and that regular recording of a patient's blood pressure and weight is good practice.

I accept this advice. In my opinion the services provided by the medical centre and Dr B did not meet these standards. Mrs A commenced taking Femodene in 1993. From 1 July 1996 until Mrs A's death in April 1998 the medical centre and Dr B renewed her prescription without taking reasonable care to ensure that her ongoing use of Femodene had been properly reviewed and remained clinically appropriate.

*Refusal to prescribe medication without the necessary review or checks*
I concur with my expert advisor that a cervical smear is not mandatory before prescribing an oral contraceptive. While smears are not related to the taking of contraceptives, a patient's history, blood pressure and weight are. In my opinion, if a review of the medication is overdue, it is entirely reasonable and appropriate to require it before renewing the prescription. Doctors are not beholden to their patients' demands for clinically inappropriate services. In my opinion, if a patient decides *not* to have her medication reviewed, it is clinically inappropriate to renew the prescription.

Dr B infers that to refuse to renew medication when a patient declines to have the required review is unrealistic and raises "*alarming ethical issues*". She comments that it has resulted in patients shouting abuse at staff then stopping their medication and that "*compliance with attendance for review of medication is an ongoing dilemma in general practice …*".

*Continued on next page*

# Medical Centre/ General Practitioner

## Opinion – Case 99HDC01756/, continued

**Opinion: Breach Medical Centre and Dr B** ***continued***

Dr B later concedes that it is rare for a woman not to attend for review when requested and notes that the Medical Centre now has good systems in place to ensure that women do always attend as this case has shown that the previous system was not entirely foolproof. I do not accept that such an approach is unrealistic or that compliance issues in relation to prescribing oral contraceptives in the medical centre are significantly, if at all, different to those in a central city practice.

I acknowledge that in some circumstances one month's cover may be appropriate to "tide a patient over". I also accept that it may not have been appropriate at the consultation in October 1996 to offer a comprehensive well woman check, in light of the time constraints and the fact that Mrs A was unwell. However, in my opinion, offering to review Mrs A's medication at this consultation, if necessary with the assistance of a practice nurse, would have been reasonable and appropriate in the circumstances.

I have considered the comments from the Chairman of the Ethics Committee, Dr F. Dr F's opinion is based on certain assumptions that have not been substantiated in this case. In my opinion, it was clearly unethical to continue to prescribe Femodene to Mrs A in these circumstances, as she was not fully informed about the relevant risks or the need for a medication check. While I accept that there is a possibility that the refusal to renew a prescription for the oral contraceptive pill may result in an unplanned pregnancy in some cases, most patients in this situation would use other forms of contraception.

Dr B's comment that such a practice is a "*dogmatic way to retain a doctor's rights and medico legal defence* [and] *is not always going to be in the patient's best interests and surely the ultimate goal for all of us is the best care available to our patients…*" is disappointing. It reflects a misunderstanding of my opinion and of the Code of Health and Disability Services Consumers' Rights. Dr B further comments that every patient should be treated individually according to their needs, and be given personal consideration according to the individual circumstances. There is no dispute about that.

*Continued on next page*

# Medical Centre/ General Practitioner

## Opinion – Case 99HDC01756/, continued

**Opinion: Breach Medical Centre and Dr B *continued***

The Code is a means of ensuring the delivery of quality services. The Code sets out ten legally enforceable rights of all health and disability consumers. In general terms, these rights cover basic principles (such as the right to respect), standards of practice, information disclosure, consent, and complaint procedures. Right 4(3) of the Code provides that "*every consumer has the right to have services provided in a manner consistent with his or her needs*". Right 4(4) provides that "e*very consumer has the right to have services provided in a manner that minimises the potential harm to, and optimises the quality of life of, that consumer"*. Each right imposes a corresponding legal duty on health care providers. Under Clause 3 of the Code, a provider will not be in breach of the Code if he or she has taken "reasonable actions in the circumstances" to give effect to a consumer's rights. This takes into account factors such as a consumer's clinical circumstances and a provider's resource constraints. Proof that harm has resulted from a breach of one of the rights is also not necessary. Proof of actual harm to a consumer is not necessary for the Commissioner to find a provider in breach of one of the rights.

The Code does not give consumers the right to have clinically inappropriate services, even if fully informed. While patients cannot be required to undergo prerequisite reviews or checks, patients equally cannot expect to receive medication on demand in these circumstances. Providing services in a manner consistent with patients' needs is not the same as providing inappropriate services in accordance with patients' wishes.

*Advice to review medication*

Having carefully weighed all the information, on balance I conclude that Mrs A did not make an informed choice to refuse a medication review. In my opinion Mrs A was never sufficiently informed of the need to review her medication.

*Continued on next page*

# Medical Centre/ General Practitioner

## Opinion – Case 99HDC01756/, continued

**Opinion: Breach Medical Centre and Dr B** ***continued***

Dr B asserts that Mrs A elected not to have a medication review, despite her advice. I accept that during the consultation with Dr B in October 1996 Mrs A was probably advised to make an appointment to have a smear soon and possibly a "well woman check". And again in December 1996, when renewing her prescription, she was probably advised by the nurse to have a smear in accordance with the procedures in place at the time. It is unfortunate that the medical records do not clearly reflect Dr B's version of events. I concur with the advice of the second general practitioner advisor that:

> *"It is important that a repeat prescription be written in the notes and if a woman does not heed the advice about coming in to have a check, that information be recorded in the notes also."*

I acknowledge that it would now be difficult for Dr B to recall the details of what was discussed at the consultation, which focused mainly on Mrs A's acute problem, owing to the significant lapse of time since the consultation. Even if Mrs A was advised to have a well woman check, this would not be adequate disclosure of the need to have her medication reviewed. A reasonable consumer would not interpret such advice in this way. Accordingly, I am not satisfied that Mrs A was ever clearly advised of the need to have a medication review.

Mr A has stated that Mrs A took her health seriously. Mrs A had a smear in April 1997 in accordance with advice. There is no record of any discussions about a medication review. It is my view that if Mrs A had been advised to have her medication reviewed she would have followed this up. In any event, even if Mrs A was advised to see her doctor for this purpose, and chose not to follow such advice, this would not justify the continued prescription of Femodene without proper review. As noted above, if a patient decides not to have her medication reviewed, it would be clinically inappropriate to continue to renew the prescription.

*Continued on next page*

# Medical Centre/ General Practitioner

## Opinion – Case 99HDC01756/, continued

**Opinion: Breach Medical Centre and Dr B *continued***

*Risk factors*

I accept my general practitioners' and Dr B's advice that Mrs A had no known risk factors or contraindications to her ongoing use of Femodene. I also accept the medical advice that a family history of heart disease is not a contraindication to the use of Femodene. However, there is no record of any reasonable endeavours by the medical practice or Dr B to identify whether Mrs A's situation had changed since 1993. There is no record that Mrs A's personal and family history were reviewed to identify any contraindications and risk factors, nor that her blood pressure and weight were checked. Having said that, I accept the epidemiologist Dr C's advice that high blood pressure is not a risk factor for venous thromboembolism. While severe obesity is a risk factor, it is not an issue in this case. In the absence of evidence of any meaningful review of Mrs A's situation, I am unable to positively conclude that she had no risk factors or contraindications that may have precluded her from using Femodene.

*No adequate procedural safeguards*

I have noted that a number of doctors renewed Mrs A's prescriptions, some of whom were not "her" doctor. I do not accept that this in any way explains or justifies the omissions in this case. Each and every practitioner who signs repeat prescriptions must comply with the relevant standards.

The medical centre policy for renewing the oral contraceptive pill at the time was that if a request for a repeat prescription were received, the nurse would check the patient's records to see if she had seen a doctor within the preceding 12 months. In my opinion, this policy did not meet the relevant standards. The policy fails to clearly differentiate between situations where a patient has been seen by a doctor and where a patient has had her medication reviewed within the preceding 12 months. Although Mrs A was seen by a doctor at the medical centre three times over the three years preceding her death, her medication was not reviewed and she did not receive necessary checks.

*Continued on next page*

# Medical Centre/ General Practitioner

## Opinion – Case 99HDC01756/, continued

**Opinion: Breach Medical Centre and Dr B *continued***

I concur with my general practitioner advisor who stated:

> *"... It would seem that* [the medical centre] *did not supply* [Mrs A] *with appropriate services and this can be a problem in a large medical practice where a number of practitioners may be away at a given time and repeat prescriptions are signed by another practitioner. Having said that I think that if there are checks and balances in the system this sort of problem can be prevented from occurring."*

In my opinion Dr B and the medical centre ought to have known that Mrs A's prescription for Femodene needed to be reviewed and should have taken reasonable steps to review it, to ensure that its ongoing use was clinically appropriate. Reasonable steps would include clearly informing Mrs A about the need for the review of her medication. Such a review would have included seeking an updated history and performing a physical examination, including a blood pressure check, to identify whether Mrs A had any new risk factors or contraindications.

In my opinion, by prescribing Mrs A with medication without taking reasonable steps to ensure that its ongoing use was clinically appropriate, the medical centre and Dr B failed to provide Mrs A with services with reasonable care and skill and in compliance with relevant standards, and therefore breached Right 4(1) and Right 4(2) of the Code.

**Informed consent**

Mrs A commenced taking Femodene in 1993. The medical centre, through its staff, continued to prescribe Femodene to Mrs A until her death in April 1998. As the Code makes clear, the requirements for informed consent are more complex than a one-off action at the initiation of a course of medication. Rather, it involves an ongoing process that is embodied in three essential elements under the Code. These three elements are effective communication (Right 5), provision of all necessary information (Right 6), and the consumer's freely given and competent consent (Right 7).

*Continued on next page*

# Medical Centre/ General Practitioner

## Opinion – Case 99HDC01756/, continued

**Opinion: Breach Medical Centre and Dr B** ***continued***

**Rights 6(1)(b), 6(1)(e) and 6(2)**

A provider has an ongoing responsibility to provide a consumer with information that a reasonable person in that consumer's circumstances would expect to receive. The information that a reasonable person in the consumer's circumstances would expect to receive before deciding to take the oral contraceptive pill is not in issue. What is in issue is the information a reasonable consumer in the consumer's circumstances would expect to receive from a provider when her medication is renewed.

In my opinion, a reasonable consumer in Mrs A's circumstances would expect to receive updated information about risks associated with taking the third generation oral contraceptive. Accordingly, the medical centre and Dr B had a clear duty to inform Mrs A of this when she renewed her prescription and allow her the opportunity to make an informed choice to continue to use Femodene or change her contraceptive.

Dr B stated that she discusses with her patients the risks and benefits associated with taking the pill, and takes a complete personal and family history from the patient at the initiation of prescribing an oral contraceptive pill. She stated that it would be an extraordinary thing for a general practitioner to discuss the risks and benefits each time an oral contraception prescription is renewed, especially if that patient had been on Femodene for a while and had no problems. My general practitioner advisor stated that it would have been reasonable for Dr B to assume that Mrs A's previous general practitioner discussed the risks and benefits associated with taking Femodene. Dr B assumed that Mrs A had been told of the risks and benefits associated with taking Femodene when she first commenced it in 1993.

I concur that it would be reasonable for Dr B to assume that Mrs A had been told of the risks and benefits associated with taking Femodene when she first commenced it in 1993, if such a discussion was documented in the medical file. A reasonable patient would not always expect risk/benefit information to be repeated each time the prescription is renewed. However, a reasonable patient would usually expect to be updated if the situation significantly changed or new information came to light. Dr B acknowledged that further discussion occurs if the patient's risks change.

*Continued on next page*

# Medical Centre/ General Practitioner

## Opinion – Case 99HDC01756/, continued

**Opinion: Breach Medical Centre and Dr B** ***continued***

There is no doubt that the situation did change after Mrs A commenced taking Femodene in 1993. New information about the increased risk of blood clots associated with the third generation pill came to light. I have received conflicting advice as to exactly what and when the information became known, and the relevance of it. While the two independent general practitioners suggest that by mid-1996 there was no clear information about the additional risks from third generation oral contraceptive pills and that this came later, the Ministry of Health advice is that the increased risks had been clearly stated by mid-1996.

My first general practitioner advisor stated that the *"information about the slight increased risk of DV, with implied additional risk of Pulmonary Emboli, with the third generation contraceptive pills (Marvelon, Mercilon, Femodene, Minulet), only became known and published in late 1998".*

My second general practitioner advisor stated:

> *"It needs to be made clear that in 1995, 1996 there was, even from the information provided to us from the Department of Health, a widespread feeling that not too much should be made of any risks associated with this. The risks were not well proven and we ran the risk of unnecessarily alarming women about these pills, even to possibly leading them to stop taking the pills and becoming pregnant when they did not intend to. ...*
>
> *I feel that it needs to be remembered that this prescribing and advice was given in 1996, not now. If I am prescribing a 3rd generation pill now for my patients, I certainly do go into some detail of the risks of using this medication, but the risks back in 1996 were not at all clear and, in fact, even the so-called experts disagreed amongst themselves as to how the situation of a woman who is already on a 3rd generation pill should be best managed."*

*Continued on next page*

# Medical Centre/ General Practitioner

## Opinion – Case 99HDC01756/, continued

**Opinion: Breach Medical Centre and Dr B** ***continued***

I do not accept this advice in light of the available evidence and the definitive Ministry of Health advice. The Medsafe timeline shows that by mid-July 1996 the Ministry of Health had gone to some length to bring the information about the higher risk of venous thromboembolism from third generation pills, such as Femodene, to the attention of prescribers and women. In 'Prescriber Updates' and letters the Ministry of Health advised doctors to "*disclose the new risk information and gain informed consent"* when renewing prescriptions for third generation oral contraceptives. There was significant media coverage and publicity about the increased risks and public interest in it. A helpline was set up, and written patient information was widely distributed to provide risk information to consumers. The information is on the Medsafe website: http://www.medsafe.govt.nz.

I am aware that there is continuing debate about the true extent of the risk of blood clots associated with the third generation oral contraceptive pills. I also accept that a reasonable consumer would not ordinarily expect to be told about absolute risks of a magnitude of 2 in 10,000. However, in circumstances where there had been extensive publicity about the sixfold increase in the risk of blood clots for women using third generation oral contraceptive pills, compared to non-use of every oral contraceptive pill, fuller disclosure by the medical centre and Dr B was required.

In accordance with Ministry of Health (Medsafe) advice, and in keeping with the reasonable expectations of consumers in such circumstances, health professionals in New Zealand were and are required to inform women about the debate and the heightened risk of blood clots from third generation oral contraceptives.

*Continued on next page*

# Medical Centre/ General Practitioner

## Opinion – Case 99HDC01756/, continued

**Opinion: Breach Medical Centre and Dr B** ***continued***

The medical centre and Dr B ought to have been aware of the increased risks associated with the third generation oral contraceptive pill and the Ministry of Health advice in relation to it. There is no evidence that they took reasonable steps to ensure that Mrs A was adequately informed of this. Dr B stated that it would be unusual to discuss risks and benefits at each renewal of a prescription. At the time the medical centre did not have a system in place whereby pamphlets about the increased risks were readily accessible to patients when renewing their prescription. Dr B later stated that she routinely gave out the Health Department advice when doing medication reviews, but accepts that Mrs A may not have received this as Dr B did not review her medication.

In my opinion, by not fully informing Mrs A of the risks and side-effects of Femodene, the medical centre and Dr B breached Right 6(1)(b), Right 6(1)(e) and Right 6(2) of the Code.

**Right 7(1)**

Mrs A had not received sufficient information to enable her to make an informed choice and give informed consent to the ongoing use of Femodene. Without this information she was unable to make an informed choice and give informed consent. In my opinion the medical centre and Dr B breached Right 7(1) of the Code.

I am aware that the Ministry of Health advised prescribers to ensure women taking third generation pills made an informed choice when renewing their prescription, and to respect the woman's informed choice if she chose to continue to take her current contraceptive. The fact that Dr B did not think it was appropriate to change Mrs A's medication or that Mrs A might have continued to take Femodene had she received sufficient information does not justify depriving her of the opportunity to make an informed choice to do so; nor does the fact that the risks of a blood clot are higher if a woman is pregnant than if she is using an oral contraceptive.

*Continued on next page*

# Medical Centre/ General Practitioner

## Opinion – Case 99HDC01756/, continued

**Opinion: Breach Medical Centre and Dr B** ***continued***

Informed consent is at the heart of patients' rights and includes the right to withdraw consent to taking medication in the face of medical advice to continue it. Respect for individual autonomy requires that patients are able to make informed decisions based on their evaluation of the relevant information. It is significant to note that as a result of the new risk information many women changed from using third generation pills to second generation pills.

**Actions**

I recommend Dr B and the medical centre take the following actions:

- Apologise in writing to Mr A for their breach of the Code. Their apologies are to be sent to the Commissioner's Office and will be forwarded to Mr A.
- Review their policy and practice in relation to prescribing oral contraceptives in light of this report.

**Other Actions**

A copy of this opinion will be sent to the Medical Council of New Zealand. A non-identifying copy of this opinion will be sent to the Ministry of Health, Women's Health Action and the Royal New Zealand College of General Practitioners, for educational purposes.