

**UNDER THE HEALTH AND
DISABILITY SERVICES ACT 1993**

AND

**IN THE MATTER OF THE
MINISTERIAL INQUIRY INTO THE
UNDER-REPORTING OF CERVICAL
SMEAR ABNORMALITIES**

**SUBMISSIONS OF COUNSEL ASSISTING
PART II: TERMS OF REFERENCE 4 TO 7
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Counsel Assisting:

Royden Hindle
Barrister
Level 4, Broker House
14 Vulcan Lane
Auckland
P O Box 141
Shortland Street
Auckland
Telephone: (09) 377 7858
Facsimile: (09) 309 1935

Hanne Janes
Barrister
Level 6, KPMG Centre
9 Princes Street
Auckland
P O Box 272
Shortland Street
Auckland
Telephone: (09) 336 1933
Facsimile: (09) 336 1934

SUBMISSIONS OF COUNSEL ASSISTING
PART II: TERMS OF REFERENCE 4 TO 7

Term of Reference 4: *To identify changes already made to legislation, to laboratory or other processes or to professional practices to address the risks of under – reporting abnormalities in cervical smears*

425. Under this heading the Committee is asked simply to ‘identify’ what has already been done to address risks of under-reporting.
426. We have approached the subject on the basis that it is intended to refer specifically to changes since the time when Dr. Bottrill practiced, ie. since early 1996. We have also inferred that the Term of Reference is directed to the risks of under-reporting at an unacceptable level. It has not been suggested during the Inquiry that even with current state of the art laboratory processes and technology it is yet possible to eliminate all false negative reporting (or false positive reporting, for that matter).
427. Another obvious preliminary point is that changes made to improve the effectiveness of the programme for the future do not address any issue of past under-reporting. This is illustrated by the evidence of the laboratories reviewed by Mr. duRose and his advisers. Even if one puts aside all the difficulties with that review, what emerged is that there are several laboratories around the country where there is a distinct possibility of significant under-reporting in the past. This is important since the programme relies on the cycle of regular repeat smears to reduce the risk of any given woman developing cervical cancer.
428. The change most likely to be effective in reducing the risks of unacceptable under-reporting is the requirement that all laboratories providing services to the screening programme must be TELARC/IANZ accredited.
429. IANZ accreditation has been a requirement of the ethical rules the Association of Community Laboratories since 1993 (although as the experience of GLL shows

the status of member laboratories does not seem to have been checked or the requirement enforced by ACL as it might have been)..

430. It is now a mandatory requirement for reimbursement to laboratories doing cervical cytology: see the 1996 Government Policy for the Programme at **GRB/MOH/1**
431. The Regional Health Authorities made TELARC accreditation a contractual condition at different times. It was, for example, a condition in the contract Dr. Teague's laboratory signed with the Central RHA in 1995 (**Teague at para 16.14**). Midland RHA made it a condition of its contracts with laboratories in the contracts for 1997/8, which were signed in March 1997 and backdated to November 1996 (**Mules at para 138**).
432. It would appear that all laboratories providing services to the NCSP have in fact been TELARC accredited since February 1996 (see eg **JD/HFA/1** and **GDW/IANZ/1**).
433. The proposed HFA standards (**JMP/HFA/40**) will carry the requirement for IANZ accreditation into the future. Indeed the proposed standard requires laboratories to inform the NCSP of the results of their IANZ assessment and accreditation status including any indicators of poor performance, which would trigger a further requirement that an improvement plan be provided and a timeframe for that given. The proposed standards also impose an obligation to notify the NCSP within 5 days of any suspension by IANZ (**JMP/HFA/40 at p 5.8**).
434. Although the draft standards are referred to in the variation of contracts negotiated with laboratories earlier this year (**TM/HFA/89**), the documents are not yet finalised. At the last hearing it was not expected that the proposed HFA standards ('the Peters standards') would be in force until September 2000 at the earliest. (The Committee will no doubt ask for an update on this issue from the HFA.) The practical consequence is that it will not in fact be possible to assess laboratory performance against the Peters standards for some time to come.

Although the work that has been done by the HFA in the comparatively short period that it has had responsibility for the programme must be acknowledged, this is regrettable.

435. In the meantime it is too soon to describe the Peters standards as being a 'change already made'. At present it remains the case that the principal change of direct significance since the mid 1990's is the introduction of the policy/contractual requirement for IANZ accreditation.
436. Of course TELARC accreditation is primarily to do with laboratory processes and practice rather than performance. Accreditation does require participation in an external quality control programme - so that it does address performance to some degree - but simply to have accreditation does not guarantee acceptable performance. For example all of the 6 laboratories identified as giving cause for concern in the duRose review were TEALARC accredited (**JD/HFA/1**). Of these three were of concern because of present reporting issues. When asked what the HFA could do in present circumstances – ie. before the Peters standards are in force - if it were to discover a situation of obvious under-reporting by a laboratory, Mr. duRose did not have a clear answer: see **B 2103 to 2107**.
437. Nevertheless the requirement for accreditation is in our submission the most direct and positive change that has occurred. There can be no doubt that the concomitant requirement for participation in an external quality control programme is likely to assist in avoiding unacceptable under-reporting or at least allow for a possibility of earlier detection of unacceptable under-reporting.
438. The other area of potentially significant change concerns the statutory provisions governing medical practitioners generally. The details are set out in the evidence offered by the Medical Council (see in particular the evidence of **Dr. Baird in chief** and at **B 998 to 1000 and 1002/1003**; and of **Ms Jones in chief especially at para 95 and following** and at **B 1011 to 1016**). In opening for the Medical Council on 12 July Mr. McClelland helpfully summarised the legislative changes brought about by the enactment in 1995 of the new Medical Practitioners

Act that came into force from 1 July 1996. We do not propose to repeat the information in this submission.

439. It is open to debate whether the under-reporting at GLL would have been picked up earlier (or at all) even if the 1995 Act had been in force before 1996. As already noted, when Patient One's case came before the ACC, the Medical Practitioner's Disciplinary Committee and then the Medical Council there does not seem to have been any real consideration given to the possibility that the case might be a signal of a serious underlying public health issue. This is notwithstanding that part of the penalty imposed by the MPDC (and later upheld by the Medical Council on appeal) on Dr. Bottrill was that he not practice in reading or reporting cytopathology for a period of three years except under the supervision of a senior cytopathologist. (It should be noted that this issue was not explored with the Medical Council witnesses – see **B 1029**).
440. There is no doubt that the 1995 Act represents a much better regime for ensuring practitioner competence than did the 1968 Act. But general provisions are unlikely to be an adequate substitute for specific standards in cervical cytology for the screening programme (the Medical Council did not suggest otherwise).
441. In addition to changes made since 1995/6, there are changes that were made before Dr. Bottrill retired but which have only more recently begun to be effective – the collection and correlation of histology data onto the screening register is an example (see, eg **Teague at B 1478**).
442. It is not suggested that the foregoing is an exhaustive list. There may well be other things that the parties/ persons entitled to be heard may wish to raise under this heading. Dr. Tie of the Royal College of Pathologists, for example, drew attention to a newly established Cytopathology Advisory Committee which it is hoped will facilitate a closer relationship between the Royal College and the HFA (presumably the Ministry in future): **B 1140**. He recognised, however that it is hard for a body such as the Royal College to set prescriptive rules about pathologists keeping up to date because practices vary widely – **B 1165/17 and following**.

443. The way in which Term of Reference 4 has been worded means that the Committee is not asked to identify changes that have occurred that might increase the risks of under-reporting – to put it colloquially, the Committee has been asked to identify the good news for the programme, but not the bad news. It would, however, be wrong not to recognise that there have also been changes that may operate to the detriment of the programme. An obvious example is the closure of the short-lived training course for cytology. During the Inquiry concerns were also expressed about the increasing difficulty of training and then retaining an adequate number of suitably trained pathologists in New Zealand. The various pathologists who operate laboratories spoke of a shortage of trained cytoscreeners. Another and perhaps more immediate area for concern is the re-organisation of the delivery of health services to 22 District Health Boards, with all the risks of fragmentation and decentralisation that that entails.

444. Given the way Term of Reference 4 is worded it would be inappropriate to focus in detail on the ‘bad news’ for the programme since 1995/6. It suffices to submit that such changes as have already been made are not sufficient to deal with the various issues that this Inquiry has revealed about the screening programme.

Term of Reference 5: To identify other changes agreed to be implemented, either by the Government or by professional organisations, that will further address any risks of under-reporting of abnormalities in cervical smears.

445. It may be argued that the proposed adoption of the Peters standards (JMP/HFA/40) falls into this category. However for reasons given above, in our submission it is too soon to regard these as changes that have been ‘agreed to be implemented’. They are still the subject of debate, principally on the question of whether there should be a minimum number of smears read by individual laboratories to help maintain competence (see Part I of our submissions). They

are if anything better placed under the heading 'Proposals to ameliorate' (Term of Reference 6)

446. Otherwise the evidence at the Inquiry did not reveal any other significant changes that have been agreed to and which have only to be implemented to become effective. There is still a very great scope for the Committee to make recommendations.

Term of Reference 6: *To consider all relevant proposals that could ameliorate any risks of under-reporting of abnormalities in cervical smears and identify whether these are covered by 4 or 5 above and whether further changes are needed*

447. We draw attention to the evidence of Dr Baird and Ms. Jones for the Medical Council which sets out certain further changes that the Medical Council is advocating as amendments to the Medical Practitioners Act 1995. Again there is a useful summary in the **opening by Mr. McClelland** dated 12 July at **paras 22 to 24**.

448. In addition there are the 'Peters standards' mentioned above. For the reasons given we suggest these are better considered as proposals at this stage rather than as anything which has yet been finally agreed to (much less implemented). We stand to be corrected by any updated information the HFA may be able to give the Committee during the resumed hearing.

449. We have already identified the extent to which changes have been made or have been agreed in dealing with Terms of Reference 4 and 5. It will be apparent from what has already been submitted that we do not consider that what has been done to date is enough to cover the issues that have been canvassed in the evidence taken at the Inquiry.

450. With respect to the question of whether further changes are needed, it seems to us that for practical purposes the subject overlaps with the question of what recommendations should be made. We therefore deal with the substance of this part of Term of Reference 6 in what we will submit in connection with Term of Reference 8 – Recommendations.

Term of Reference 7: *To comment on any other issue the Inquiry Team believes to be of particular relevance*

451. Under this Term of Reference we deal with the following matters:

?? The Kaitiaki Regulations.

?? Issues raised in connection with the release of information for audit purposes in connection with the screening programme, including the issues raised by section 74 A of the Health Act 1956.

?? Ethics Committees.

?? The place of cervical cytology in the screening programme, and the place of the smear in the diagnosis of cervical cancer.

The Kaitiaki Regulations

452. The Kaitiaki regulations are included in the 1996 Policy for the programme at **GRB/MOH/1**. The purpose of the regulations is to protect aggregated data about Maori women who are enrolled on the register from disclosure without the consent of the Kaitiaki Group that is established under the regulations.

453. Evidence about the Kaitiaki Group was given by Ms. Earp of the MOH in chief and at **A 785/18** and following (28 April) and **A 833/26** and following (1May). Ms Reid was also asked about the matter at **B 710 and following** (Ms. Reid is a current member of the Group). On the penultimate day of the hearings in August, the national convener, Te Miringa Huriwai, gave evidence which is at **B 3852 to 3879**.
454. The Kaitiaki regulations represented a compromise that was reached at the time that the change from opt on to opt off was being considered (see, eg **B 712 Reid**). Maori women were concerned to have special protection for their data because of its significance to them, and the importance of the sanctity of te whare tangata. Their first choice would have been to have an entirely separate register, but ultimately the Kaitiaki regulations were accepted instead. In the literature attached to Ms Earp's evidence the regulations are described as a 'lock out' arrangement.
455. The principal concern about the Kaitiaki group emerged out of the evidence that the Maori statistical report could not be published for almost exactly four years, and that in large part this was because of the need to obtain Kaitiaki Group approval.
456. No one who gave evidence to the Inquiry regarded the delay in publishing the Maori report as acceptable. Nor could anyone sensibly do so – if the purpose of the report was to provide 'baseline information' (**Maori Report, Foreword**) to assess participation of Maori women in the programme then it must obviously be published in a very much more timely fashion.
457. This concern led to questions about the frequency of meetings, the workload of the Group, whether or not the regulations represented the view of Maori women generally or were just the result of lobbying by a vocal minority, the way in which the Group has approached the interpretation of the regulations, the qualifications and experience of the members of the group, what recourse there might be for anyone who is disappointed by a decision of the Group, and so on.

458. Although some time was spent on the subject during the evidence, in the end we submit that the Committee should be slow to recommend fundamental changes to the Kaitiaki regulations. Ultimately the rules which govern any special protection for Maori aggregated data is something that the community of Maori women must find acceptable. The risk of recommending detailed changes is that they may not find favour with that community of women, with a result that Maori women may be less inclined to participate in the programme, or to encourage others in their communities to do so.

459. That said, we submit it would be appropriate for a process to be put in place that would allow Maori women to review the effectiveness of the regulations in light of the experience of the Kaitiaki group to date. One cannot help but have an impression that the regulations may have operated to the detriment of Maori women's health because they plainly create a disincentive to research that would address Maori health issues. Given the high incidence of cervical cancer in the Maori population that seems to be unfortunate.

460. One possibility that might be considered by Maori women is that there be an exception to the Regulations, such that where research is being done under the auspices of the programme or for the benefit of the programme (for example, the sort of evaluative research proposed in the Cox/ Richardson national study, or an audit of the type suggested by Professor Skegg, or even simply the compilation of statistical reports for the programme) then Kaitiaki Group approval would not be necessary. This approach would mean that the Group would be concerned with applications for release of data to 'outsiders' where the need for protection is probably at its greatest, rather than to those who have an obvious and legitimate need of the information to ensure the effective running of the programme.

Release of information for audit/evaluation purposes

461. When Professor Skegg suggested the audit of cases in Tairāwhiti there were at least two sources of information that one would have expected to be available to him – the information on the Cancer Register and the information on the

Screening Register. In particular one would not have expected that there would be any great obstacle to his ability to get the information and then link it so as to be able to start with the full set of information about each case from the two registers.

462. It has been a surprise to many at the Inquiry just what difficulties stand in the way of this.
463. Because of the difficulties – particularly in relation to section 74A of the Health Act – attention has been paid to the possibility of using the Committee’s powers under the Commissions of Inquiry Act 1908 to assist Professor Skegg. On 4 August a subpoena was issued to the Director General of Health requiring that named information from both registers be made available to the Committee. On 23 August the Director General provided the information from the Cancer Register but not the Screening register.
464. Professor Skegg has conducted a preliminary analysis of the data now available and his initial conclusions are as set out in his report of 7 September. The question of what can be done to facilitate the suggested study of cases where there has been one or more normal smears within 5 years of a diagnosis of cervical cancer is being considered by the Ministry of Health. Whether or not there will be issues to go to the High Court for determination remains to be seen.
465. In the meantime this submission deals with the effect of the relevant legislation in the absence of any Committee of Inquiry to assist someone like Professor Skegg (in respect of the Tairawhiti study) or Drs. Cox and Richardson (in respect of the national audit).
466. In our submission the position in respect of the Cancer Register is clear. The purposes for which information is collected onto that register are set out in section 4 of the Cancer Registry Act 1993. To the extent that the Health and Information Privacy Code applies, Rule 11 (2) (c) makes it clear that patient consent to the release of health information is not required where the information is to be used for one of the purposes for which it was obtained. In our submission the sort of studies being contemplated for audit and evaluation of the programme are clearly

within the purposes for which the information was collected. It follows that Professor Skegg (or Drs. Cox and Richardson or anyone else wanting to do a clinical audit of the programme for the benefit of the programme) is entitled to have the information from the Cancer Register, including identifying information – so long as it is used for a purpose for which it was collected.

467. Apparently it is a requirement of the procedure adopted by the New Zealand Health Information Service (Cohen affidavit and exhibit 2) that release of identifying data from the Cancer Register can only occur if approval by an Ethics Committee is first obtained. It is not at all clear what the basis for this restriction is. It may be that a given study requires ethics committee approval to proceed, but it does not follow that the NZHIS is entitled to require proof of approval before releasing the data. Furthermore the 1996 National Standard for Ethics Committees contemplates that ethics committee approval is not required for an audit – see page 34 which sets out the position in appendix 5. If it is accepted that a study of the sort Professor Skegg suggested is an audit in the sense contemplated by the Guidelines then he would not need ethics committee approval, and therefore would not have it to pass to the NZHIS with his request for data.

468. The situation in respect of the screening register is more restrictive. The release of information from that register is governed by section 74 A of the Health Act, which is set out in the 1996 Policy document at **GRB/MOH/1**. Subsection 5 prohibits the release of information unless it comes within any one of the exceptions set out. For reasons set out in the submissions already presented on section 74 A, it does not seem to us that any of the exceptions apply to the sort of study under consideration. In the absence of any regulations to allow release of the data to someone such as Professor Skegg the position seems to us to be that the information cannot be released to him.

469. Thus there is the surprising position that a researcher such as Professor Skegg can (or should be able to) get named data about women from the Cancer Register but he cannot find out from the screening register what information it holds about those women.

470. Professor Skegg explained that once he had the names of women with a diagnosis of cervical cancer it would be possible for him to do an effective clinical audit if he were able to access their medical records (for which he would in the ordinary course have to obtain consent, but with the Cancer Register names he would at least have some idea about how to make contact with the women concerned). However there can be no doubt that it would greatly assist such an audit if he were able to begin by matching Cancer Register and Screening register data.
471. We submit that the present situation is unacceptable. It makes no sense that the information on the screening register is not available for studies of the sort proposed by Professor Skegg and Drs. Cox and Richardson, when the purpose of the studies is to promote the effectiveness of the screening programme.
472. The situation should be remedied by an appropriate legislative amendment or by the making of regulations under section 74A(7)(a).
473. We are aware that there is a Crown Law Office opinion of 23 August 2000 that suggests it may not be possible to make regulations since they would be against the purpose of the section. We do not agree with that view, but in the end we suggest that it should not matter how the change is achieved – ie. whether by amending legislation or by regulations - as long as it is achieved without delay.
474. The question which then remains is as to whether there should be some provision that would allow access to individual patient records as part of a clinical audit exercise for the programme without requiring the consent of the women concerned. This is a more difficult issue, because it would involve an intrusion into personal records and not just the analysis of data already entered on a register.
475. We incline to the view that ensuring the effectiveness of the programme is sufficiently important to justify access to relevance personal medical records when that is necessary. We emphasise that such access could only be allowed under appropriately strict conditions of confidentiality and requiring absolute anonymity in the way in which any such data is reported by the researchers.

476. A study that involves access to personal health information without consent of the women affected is properly a subject for scrutiny by an Ethics Committee. However we have reservations about leaving decisions on these matters to Ethics Committees. Experience to date suggests that the ethics committees that have been approached for consent have not fully understood what is at stake, and have refused to allow access without apparently appreciating that the balancing of privacy and public health interests does not always have to result in a decision in favour of privacy.

Ethics Committees

477. We therefore turn to deal with concerns about the practice of Ethics Committees, particularly in connection with approval of a studies such as that proposed by Professor Skegg in the case of Tairawhiti women who have suffered a diagnosis of cervical cancer ('the Skegg audit') and Drs. Cox and Richardson (the national evaluation).

478. Professor Skegg proposed the study as a way of dealing with Term of Reference 1. The protocol (**DCS/CA/1**) was submitted to the Tairawhiti Regional Ethics Committee. Late in April that committee gave consent for the study to proceed, but on condition that the consent of all the women first be obtained. That was not the basis on which consent had been sought because of the need to have as complete a sample of cases as possible (also see discussion by Professor Skegg in his **second brief** and eg. at **B 2425**). A meeting between Professor Skegg and Dr. Richardson and the Committee took place on 3 May 2000, and there was also some subsequent correspondence (**Second brief of Professor Skegg and exhibits**).

479. The Tairawhiti Committee would not be moved. Amongst other things the Committee relied on advice from a Professor Seedhouse. This was not disclosed to Professor Skegg for his comment before the decision was made. That was unfortunate; the advice showed that Professor Seedhouse did not understand the

role of the proposed researchers. There is room for doubt whether he understood what the proposed research involved.

480. In his second brief of evidence and when under examination in July Professor Skegg offered a number of observations about the role and approach of ethics committees. The comments were those of someone who has been engaged in research and has had to deal with Ethics committees on a number of occasions. He was careful to point out that he saw the attitude of the Tairawhiti Ethics Committee as reflecting a pro-privacy mood amongst ethics committees generally; he did not think that the Tairawhiti decision was surprising (**see, eg. B 2393/4**).

481. Although Professor Skegg had some criticisms to make, it is important to note that he considers Ethics Committees to be very worthwhile. In view of the evidence which Professor Evans later purported to give on behalf of all Regional Ethics Committees, it is only fair to Professor Skegg to note that at no stage has he ever advocated the abolishment of the ethics committee system or anything of that sort; to the contrary, he is a strong supporter of ethics committees – **B 2399**.

482. On the other hand he did express concerns that:

?? Ethics committees have suffered from a lack of oversight – they have been left to their own devices and have not been evaluated – **B 2753/4**

?? The system has given rise to a fragmented approach across committees around the country; he saw it as anomalous that local committees can have an impact on a study of national importance - **B 3221**

?? Committees tend, in his experience, not to see the cost of not doing things – for example the cost in terms of lives lost because of failure to do a proper audit /evaluation of the cervical screening programme – **B 2324** and also **B 2397/1**

- ?? He expressed concern about the way in which committees have approached the Health Information Privacy Code, which allows for a balancing of interests but does not seem to be interpreted in that way by ethics committees – **B 2326**. He said that what he was advocating in this respect was that there should be changes in the guidance given to ethics committees and that members should be well informed about the difference between experimental studies and observational studies – **B 2399**. At **B 2402 /3** he discussed the balancing of risk and benefit, and referred to the National Standards for Ethics Committees (**DCS/CA/29**).
- ?? He made the point that if the current concerns about protection of privacy had prevailed the article that ultimately gave rise to the Cartwright Inquiry might well not have been written - **B 2407/16**
- ?? He pointed to the absence on the Tairawhiti Committee of anyone with public health experience – **B 2396** and **2398**.
483. Dr. Cox expressed similar sentiments – see **B 2489** (first statistical report omitted Wellington data because the local ethics committee would not agree); **B 2524** (not against ethics committees but would prefer to deal with a national committee for a national study) **B 2525/26** (have been a barrier to research), **B 2528** (discussion about the national evaluation; not the only audit type of study that has run into ethics committee difficulties) and **B 2610** (with ethics committees privacy concerns and section 74A there is a log jam).
484. This evidence (or, more accurately, the way in which it was published) provoked a response from Professor Evans. Professor Evans is a professor of bioethics at Otago University, and is on the Otago Regional Ethics Committee. He is not medically qualified, and therefore has no clinical experience.
485. The Otago Committee has had the lead role in co-ordinating the response to the application by Dr. Cox and others for consent to proceed with the national Evaluation of the programme.

486. The Committee will no doubt have formed its own impression of the evidence given by Professor Evans. In our submission his evidence only served to confirm all of the concerns that Professor Skegg and Dr. Cox had raised:

?? Professor Evans purported to represent all ethics committees (**brief para 14 and B 3988/8**) when plainly in our submission he did no such thing (**see B 4003 to 4004**, although note that Professor Evans stuck to his assertion of authority despite the difficulties he faced explaining it – **B 4006/1 - 5**);

?? He was questioned on documents such as the Helsinki Declaration and the CIOMS guidelines and the National Guidelines for Ethics Committees in New Zealand (**DME/REC/009**) but when taken to them he was unable to explain in any uncomplicated way how they provided the propositions he was drawing from them: **B 4014 to 4024**.

?? Semantics seemed to be important to outcomes. When asked, for example about the national evaluation it seemed to be significant that the applicants had called it ‘research’ rather than an audit – one would have thought that the substance of what was being proposed would have been more important than a word used in the application (**B 4023/22 and following**. Also see **B 4022/27 to 4023/6**).

?? When attempting to justify his stance that the article written before the Cartwright Inquiry would have been possible today he did not know the facts **B 4062 and following, esp at 4066/7**

?? He plainly did not understand the way the register works. In his brief and at **B 4013/9, B 4015/27 and B 4039/5 and following to B 4041/23** he suggested that the real fault lay in the fact that the register had not been set up properly at the outset. His thesis was that if all the necessary information were abstracted at the start then there would be no problem researching the data. He seemed

unprepared for the proposition that to do that would involve getting information from GP's: **B 4041/23**.

?? At the same time he felt able to say with authority that the requirement that had been suggested by the committee for the first contact with women to come from the Cancer Register would 'improve' (**B 4001/15**) the protocol. One can only wonder what he really understood of the practicalities of what his committee had suggested in this respect, or why anyone would think that a first approach to a woman for consent from a Cancer Registry officer (assuming that were possible to arrange) would be better than allowing the researchers to try to make first contact through GP's or smertakers (see Dr. Cox' letter of 30 March 2000 at **DME/REC/11**).

?? Professor Evans spoke of the letter from the Ethics Committee requiring that the first approach to women be from the Cancer Register (**DME/REC/10**) in the following terms: '*...it was an entirely constructive letter, aiming to improve the protocol so that not only would the very worthy objectives of the study be achieved, but the risks of harm to the participants would be minimised. That was the point of the letter.*' (**B 4009/20 – 23**). Later he asserted that '*...our hope was that this study would go ahead in the most acceptable way to the participants in the study (B 4010/ 10)...the best possible manner was a manner in which the interests of the research participants were best protected...*' (**B 4010/ 15 – 16**). It did not shake his confidence in defending his position that an experienced epidemiologist like Dr. Cox – who has done studies requiring patient consent in the past – disagreed with him. It also emerged that committees try to 'improve' almost all protocols submitted to them: **B 4030/3**.

?? The Otago Committee which he claimed to represent had entered into correspondence with the Minister about its interpretation of the Cancer Registry Act (**DME/REC/12 – 14**). The correspondence showed that the Committee did not agree with the view of the Minister of Health that those were issues for the custodian of the information not the Committee. We

submit that neither Professor Evans nor his committee have any business to raise these issues; the legality or otherwise of releasing the information is not something ethics committees are responsible for (see **B 4041/24 to B 4042/17**). In addition the legal position adopted by the Ethics Committee is in our submission manifestly wrong – see, eg **B 4001/13 to 4002/10**;

?? The evidence tended to highlight Professor Skegg's concern that ethics committees do not see the cost of not doing things.

487. Professor Evans was asked whether the Committee dealing with the national evaluation had had regard to appendix 5 of the National Standards for Ethics Committees particularly at page 34 which indicates that ethics approval for audit is not required. He said no, because it was assumed that members of the committee would be aware of the guidelines (**B 4026/7**). Based on the evidence that Professor Evans gave it is far from clear that the members of the committee understood they were talking about something in the nature of an audit, much less that they were even aware that appendix 5 of the National Standard might apply.
488. What emerges out of all the evidence is that there is a need for a full review of the composition and decision making procedures of ethics committees, the functioning of ethics committees generally, and the training and qualifications of those who serve on them.
489. The success or failure of a project should not depend on where the application is filed in the country. Committees are entitled to have a clear understanding of what they are expected to do and what is beyond the scope of their decision making responsibility. Their procedure should be open (so that, for example, if the Tairawhiti Committee wished to rely on Professor Seedhouse's advice or any other information they would have been obliged to give Professor Skegg a chance to comment first). Committees should be constituted in such a way as to ensure that they are able to balance different interests from a position of some real understanding of the study being considered. There should be a national ethics committee which can deal with studies of a nationwide kind rather than the cumbersome process of having one committee act as a clearing house for opinions

from all other ethics committees. There needs to be a recognition that there will be differences of opinion amongst committee members from time to time. Some clarification about the different considerations applying to observational studies as against experimental studies may be timely. The extent to which recourse to the Health Research Council for a second opinion is adequate as a right of appeal also needs to be re-considered.

The place of cervical cytology in the screening programme, and the place of the smear in the diagnosis of cervical cancer.

490. While we appreciate that what follows will be obvious to the Committee and to everyone who has followed the evidence in the Inquiry, we suggest that there may be merit in drawing attention to the following propositions in the Report:

?? The task of reading cervical smears is only a part of the screening pathway. For the programme to function effectively all parts of the programme must be considered, monitored and evaluated regularly. This includes the process of educating women about the programme, the taking of smears, the reading of smears and follow up in the case of abnormality.

?? The Inquiry has necessarily focussed on the issue of laboratory performance. But as the evidence of women affected showed, there is no reason to be complacent about delivery of the other steps in the pathway.

?? One of the compelling reasons for completion of the national audit (and for regular audits thereafter) is that it should throw some light on the effectiveness or otherwise of all aspects of the programme.

491. Another matter which will seem obvious but which warrants explanation in the Report is that the pap smear is not a diagnostic test. It is a screening test designed to separate that group of women who probably do not have the disease or its precursors from that group of women who probably do have the disease or its precursors. The test is far from infallible. This is something that should be

reflected in all aspects of the programme – from the preparation of educative materials to the reliance placed on a smear result for purposes of follow up and treatment.

492. We say this because there was some evidence which suggested that in some of the patient cases a smear result had been allowed to influence a diagnostic decision when clinical signs of invasive cancer were also present. It should be understood by all who participate in delivering the programme that a normal smear result should never be relied on as any assurance that the disease is not present if there is anything else to indicate that the cervical cancer may be present despite the smear.

The final Part of our submissions dealing with recommendations that the Committee might consider (Term of Reference 8) will be filed as soon as practicable.

DATED this 14th day of September 2000

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Royden Hindle/ Hanne Janes

Counsel Assisting