

## Chapter 4

### *EXPRESSIONS OF CONCERN*

The 1966 Proposal discussed and approved by members of the Senior Medical Staff and Hospital Medical Committee contained a bold hypothesis: that carcinoma in situ does not progress to invasive cancer. Not only did it have obvious implications for the women included in the group to be observed, but medical, ethical, scientific and human ramifications also. From 1966 right down to the present day it has had significance for the health of patients, and will have significance for the practice of gynaecology and the design and review of research in this country. Because these effects are so wide ranging it was important to establish whether or not the Proposal and its hypothesis were questioned, and if so, what if any action was taken in response.

I have been drawn inexorably to the conclusion that although there was increasing opposition to the 1966 trial, both internationally and at National Women's Hospital, there was no will to confront and resolve the difficult issues that emerged. For 20 years there was criticism, yet no special effort was made to ensure that patients' health did not suffer as a result of Dr Green's attempt to prove his hypothesis. Until the Auckland Hospital Board recommended the current Inquiry, no person or body with the power or responsibility to intervene took steps to deal decisively with its consequences. The medical profession failed in its basic duty to its patients.

This chapter traces the attempts of a few concerned health professionals to make the medical establishment aware of the reasons for their disquiet and so provoke a reassessment of the basis and ethics of the trial.

#### **DR MCINDOE'S INTERVENTIONS**

Dr McIndoe died about a year before this Inquiry began. He has been both praised and criticised during the hearing of evidence. Frequently he was blamed subtly for events quite beyond his control. On occasions it seemed that, now dead, he became a convenient scapegoat for much that has gone wrong at National Women's Hospital as a result of the 1966 trial. His presence has been powerfully felt throughout the hearings and yet for 20 years his mounting concern about the dangers of the Proposal was disregarded or treated lightly.

##### **1. June 20, 1966**

Among Dr McIndoe's papers was a memorandum which, in later correspondence and memoranda, he claimed to have tabled at the meeting of Senior Medical Staff on the evening of 20 June 1966. It said:

"Again, I believe Professor Green has made a useful contribution in insisting that progression from in-situ to Invasive Carcinoma of the cervix is not invariable. I do, however, find it difficult to accept his statement that Carcinoma-in-Situ and Invasive Carcinoma of the cervix, are not related conditions.

"On morphological grounds: the appearance of the cells, in dysplasia, carcinoma-in-situ and Invasive Carcinoma of the cervix, there does seem to be a relationship.

"I accept at present, that there is a relationship between these conditions, but that the so-called progression from one to the other, may be uncommon.... If it is accepted that such progression does occur then the attitude to treatment and follow-up will be tempered somewhat by the frequency of this occurrence.

"At our present state of knowledge rather than swing to an extremely conservative position with respect to treatment, I feel the correct measure would be to aim to remove tissue responsible for the positive smear and to follow up patients conservatively thereafter who show no further significant cytological or colposcopic abnormality.

"Furthermore, I believe an authoritative approach to any problem in medicine can be unfortunate unless it is quite obvious that alternative methods of care are either dangerous or unsound.

"In the present case, inadequate tissue diagnosis, which can be the only description of the type of biopsy I at present perform (if this is to be the only biopsy done), and follow-up, only taking further steps if there is clinical or colposcopic evidence of invasion, would seem to me the type of care that should not be followed. Conservative excision of the lesion is in my view the treatment of choice."

There was a final sentence in the memorandum :

"If Professor Green's proposal is accepted, I would feel it very difficult to take seriously any cytology reporting or colposcopic assessment."

When asked in evidence about this memorandum, neither Dr Green, Professor Bonham, Mr Grieve nor Mr Faris recalled Dr McIndoe tabling or speaking to it. Some as corroboration, pointed to the fact that it was not included in the record of the Minutes. However, Dr Warren recalled the incident in some detail. As chairman of the meeting he had good reason to remember Dr McIndoe's concern when he received his copy of that night's Agenda.

On the afternoon of 20 June 1966 Dr McIndoe had called to see Dr Warren and asked if it would be in order for him to prepare and table a memorandum setting out his views on Dr Green's proposal. Dr Warren even recalled asking Dr McIndoe to remove that final sentence from the memorandum. His reason for this request, as far as he can recall 21 years later, was that he felt the sentence might have been seen as "letting down cytology and colposcopy". Dr McIndoe came to see him again the following day. This time he was concerned that he had not expressed his opposition to the Proposal forcefully enough.

Dr McIndoe referred to his 1966 memorandum in two memoranda in the early 1970s. On 13 July 1971, in a memorandum which records his thoughts at the time but which may not have been sent to anyone, he wrote:

**"Carcinoma in situ:**

In June 1966 Professor Green circulated a memorandum in which he noted that 503 cases of Ca. in Situ up to December 1965 had been treated in this hospital – 68.2% of these had been treated by cone biopsy or lesser procedure. 'One case is alleged to have progressed to invasion etc....'

"This memorandum was considered at Senior Staff meeting on 20/6/66 and is recorded in the Minutes (folio 193 and 201) – a copy of this memorandum is attached.

"I wrote some comments on Professor Green's proposals which was cyclostyled and available at the Staff Meeting (20/6/66) and spoke re my statement but this was not recorded in the Minutes (a copy of my statement is attached with last sentence deleted at Dr Warren's request).

"Professor Green was allowed to proceed with his views to a limited extent as noted in Senior Staff Minutes (folio 201) and also Hospital Medical Committee Minutes."

The 1966 memorandum is referred to again in another sent to Dr Warren and dated 14

December 1973. These two papers and Dr Warren's evidence convinced me that the memorandum with the handwritten date, 20.6.66, was tabled at the Senior Staff meeting and that Dr McIndoe also voiced his concerns. It is just as obvious from the evidence that other doctors who attended had no recollection at all of his oral or written comments. It is entirely possible that although he tabled his memorandum, it was not physically circulated amongst those present.

During the course of the Inquiry Dr McIndoe was revealed as a quiet man. Within the hierarchy of medical specialists at the Hospital at that time he was, as counsel representing his Estate put it, "equivalent to the office boy trying to tell the Managing Director how to run the firm". While there was "lengthy discussion during which Professor Green answered many questions", and although Dr Green in his evidence said that he expected some senior staff to oppose the Proposal "because some of them believed that hysterectomy was still the correct treatment", Dr McIndoe's views do not seem to have registered with his colleagues and they were disregarded by those members of the Senior Medical Staff who formed the Hospital Medical Committee and approved the Proposal.

## 2. Action after 1966

Almost three years after the 1966 Proposal was tabled and accepted, Dr McIndoe addressed a memorandum to Dr Green with the handwritten date 15.4.69. It read:

"Your raising with me on Monday 14th April of my comments concerning regrading patients originally diagnosed and classified as Carcinoma in Situ – regrading to Invasive Carcinoma and thus making them ineligible for inclusion in the Ca. in Situ follow up series, gives me the opportunity of raising with you a number of the issues involved.

"I understand you now to say that if there is no unequivocal evidence of invasion after one year of observation by all methods available: cytology, colposcopy, histology and clinical, then the case will firmly be classified as **Non Invasive**, no matter what the initial histology assessment.

"I have accepted up to now, three months between initial histology diagnosis and radical treatment as the evidence that the initial lesion was considered Non Invasive. On this basis I have noted a number of patients who have fulfilled my criteria of Non invasive Initially – Now Invasive. I have tried to avoid the use of the word 'progression' because it introduces a concept not helpful to these discussions.

[Here Dr McIndoe lists and comments on seven cases.]

"I understand further from you that a number of cases originally classified as invasive you now classify as Carcinoma in Situ. If these patients have had radical treatment, the fact of their reclassification should certainly be noted and considered parallel with other non invasive cases which have not had radical treatment.

"I find myself in a difficult position in this study. Increasing pressure is coming from the so called pundits in cytology, Wied, Koss, Frost, Von Hamm, in particular, to make a histological prediction on the basis of the cytology findings. Numbers of people are going away from the Papanicolaou 1-5 Grade report and instead replacing the report with such terms as:

'Probable Dysplasia'

'Findings consistent with Carcinoma in Situ'

'Findings of Invasive Carcinoma' or

'Invasive Adenocarcinoma'

"Frost spoke at Chicago and Koss at Rio de Janeiro in this manner.

"Afterwards at Koss' laboratory in New York, I was critical of this dogmatism

displayed by Koss to another member of his staff. I have noted in my report my concern at this type of cytology reporting. I was informed in Koss' department that it is understood what he means by these reports in his own hospital — the hospital staff do not take too seriously his dogmatic utterances.

"JJ Sullivan on the local scene has continued for a number of years to add the phrase at times to reports, 'Invasive Carcinoma', meaning he believes there is a highly significant chance of this being a case of invasive carcinoma. I can also do this, but I believe this opinion is of little value when it will be shown incorrect in perhaps 50% of cases. Regrettably, however, our local experience has no influence on the continuing pressure in particular from the United States to dispense with what is called the 'number game' in cytology reporting and come down with a written report.

"I have wondered for some time whether there is not a place for some open correspondence perhaps in the Red Journal between various people in Australasia on the various concepts involved in diagnosis and treatment of carcinoma of the cervix.

"From my reading and findings during my study tour last year I am convinced that some of the patients treated here successfully by local excision and classified Non invasive are treated in many places radically and classified INVASIVE. I know you have the same view.

"I wonder whether it can be claimed that if a patient is ever successfully treated then this is evidence that she was not suffering from cancer.

"I understood from remarks Harry Jamieson made to me at the dinner on Thursday 10th, that Malcolm Coppleson was keen to come over here and see some of our material. If you agree and this could be arranged, we could all benefit and I believe it would be possible to convince him that conservative care is a valid concept.

"In addition we would need sufficient notice to get up representative cases for him to see — the post hysterectomy cases for example, Mrs L..., and so on."

Dr Green denied having seen that memorandum until reading the evidence of Sandra Coney, another party to the Inquiry. It was referred to in a subsequent memorandum dated 14 December 1973 which was sent to the Medical Superintendent, Dr Warren, in which Dr McIndoe wrote:

"...I have endeavoured by all means possible in a mature and dignified manner to make my feelings plain [to Dr Green] and so note down specific instances of my attempts.... (b) in personal memorandum to him, dated 15.4.69."

The April memorandum had also been mentioned in another memorandum to the Medical Superintendent dated 10 October 1973 when Dr McIndoe wrote:

**"Criticism of my attitudes by Professor Green —**

Following some criticism of my attitudes in 1969 I presented Professor Green with a memorandum on 15.4.69 (attached 8) noting several patients about whom I was concerned. I received no satisfactory comments in reply. On five occasions in the last two years, I have been 'vigorously interrogated' by Professor Green, twice in Ward 9 and on the last three occasions have been invited to his room and subjected to further 'vigorous examination'. On the last occasion, approximately one year ago, I was goaded into calling him irresponsible in his attitudes and management of patients."

Dr McIndoe also referred to his memorandum to the Senior Staff meeting which he noted he had tabled and spoken to at length. He went on to enumerate other occasions when he had tried to make plain his feelings:

"c) In private, on three occasions in his room in 1972. Professor Liggins interrupted one of these occasions when he came into the room and made a comment such as, 'Are you two still at it?'.

d) In private, on two occasions in early 1972 in Ward 9, following the ward round when he saw fit to 'rebuke' me for comments I had made during the round.

e) In private in commenting on management of [Patient CODE 3Q], towards the end of February 1971.

f) Letter to NZ Medical Journal in name of Dr S E Williams and myself, dated August 1972 (p129)."

This record of incidents, together with the memorandum of 15 April 1969, leads me to conclude that from 1969 at least, Dr McIndoe continued to voice and record his concerns about the implications of the 1966 Proposal. While Dr McIndoe recorded a variety of heated discussions with Dr Green in some detail, in giving evidence Dr Green responded to the suggestion that the two of them "were in fact at odds on it [the 1966 Proposal] right from the start" by saying:

*"I didn't believe so. I didn't see his memorandum of 66 or of 69 and I certainly don't ever remember having three, what he suggests is three occasions of his, in private on three occasions in his room and Professor Liggins saying, 'Are you still at it?'.... I certainly wasn't aware of it, and I still thought I was friendly with Dr McIndoe until 1975 when he refused to speak to me further. Now Dr McIndoe may keep these things to himself. He certainly never made plain to me his feelings other than through those letters about patients that I replied to."*

**Summary and conclusions:** Dr McIndoe's concerns were recorded repeatedly at times when he could have had no possible suspicion that they would be aired so publicly. After so many years it is entirely possible that Dr Green does not recall reading the memorandum dated 15 April 1969. Nonetheless I am satisfied that it was sent to him. I also accept that the 20 June 1966 memorandum was tabled at the Senior Medical Staff meeting and spoken to by Dr McIndoe. And finally, I accept Dr McIndoe's record of their verbal exchanges, and the manner in which they were expressed in the memoranda of 10 October and 14 December 1973 addressed to the Medical Superintendent of National Women's Hospital.

Some parties to the Inquiry obviously considered that Dr Green lied to me. I do not believe that was the case. I think there are two other possibilities.

The first is that he simply does not recall receiving the memoranda or holding any heated discussions with Dr McIndoe. Although Dr McIndoe died before the Inquiry started, his memoranda and descriptions of his personality suggest that what he might have considered a vigorous or heated debate, might simply be overlooked by a far more forceful personality such as Dr Green, in the way that a wasp is brushed from one's sleeve before it has stung.

The second possibility was one suggested by several parties. It is that Dr Green held a theory which he was determined to prove, namely that CIS was a benign lesion which did not progress to invasive cancer. Any viewpoint contrary to his was simply ignored.

I prefer a combination of these alternative possibilities. Although Dr McIndoe was concerned from the start about the 1966 trial and its repercussions on the patients involved as the study developed, he did not begin to express his views strongly and publicly until 1973.

The 15 April 1969 memorandum, while touching on Dr Green's regrading of patients from

an original diagnosis of carcinoma in situ to one of invasive cancer, is so understated and deferential in discussing this important issue that his concern is masked and the points he strove to make obscured. Nonetheless, this memorandum represented an attempt to conduct an intelligent debate on the issue. An attempt which failed.

I have been left with the eerie impression that Dr McIndoe's various memoranda and notes were almost prophetic. The documentation of what he saw first as a debate and later as a matter needing urgent action, demonstrates how closely he watched the development of the 1966 trial and his mounting concern for its consequences.

### THE 1975 WORKING PARTY

It is true to say that after 20 June 1966, Dr McIndoe acquiesced in and even supported Dr Green's Proposal for a period. But as his apprehensions increased and he remained unable to have his point of view seriously considered, he embarked on a more telling line of action. The 10 October 1973 memorandum he wrote to the Medical Superintendent of NWH began:

"I have not been entirely happy, for a number of years, with the management of many patients who have had abnormal cytology and colposcopy findings."

After noting that he had expressed his disagreement with the 1966 trial from the outset, he went on to say:

"For a time following this meeting, I began to wonder whether I had been unnecessarily concerned. However, the subsequent clinical course of a number of patients having varying forms of conservative care, leads me to believe that a reappraisal of policy towards management of patients with abnormal cytology and colposcopy findings is called for. Brief notes on some of these patients are attached. A longer list of patients who should be carefully reviewed is available."

He also noted that there was a further list of patients with continuing positive cytology whom he believed might, if adequately biopsied, demonstrate invasive carcinoma. Attached to his memorandum were the names and brief details of seven patients whose condition, following conservative care, had led Dr McIndoe to seek a reappraisal of the management of patients with abnormal cytology and colposcopy findings.

By this time Dr McIndoe, although not a member of the Hospital Medical Committee, was a sufficiently senior member of the Hospital staff for the memorandum to be taken extremely seriously. Nor was he alone in his concern. Dr Malcolm McLean, the Pathologist in Charge at National Women's Hospital, was also worried. In 1966 he did not oppose Dr Green's Proposal believing that if a Senior Medical Staff member demonstrated adequate reason, the patient whose condition had aroused their concern would be definitively diagnosed and given conventional treatment. But by the late 1960s he had discussed several patients with Dr Green who were later found to have invasive carcinoma. Dr McLean said:

*"He would not accept my views, my concerns."*

On 18 October 1973 Dr McLean forwarded his own memorandum to the Medical Superintendent on the diagnosis and management of carcinoma in situ of the cervix.

"The group of patients I am referring to were considered to be cases of carcinoma in situ of the cervix and were treated conservatively for reasons I consider not soundly based. These patients, in the course of follow-up, have turned out to have invasive carcinoma of the cervix.

"The point for concern is the fact that a diagnosis of carcinoma in situ was made on inadequate biopsies, usually a punch biopsy, and despite positive cervical cytology smears during follow-up, and sometimes my warning of

possible invasive carcinoma nearby. These patients were managed conservatively and adequate biopsies to exclude invasive carcinoma were not taken until after varying periods of delay. In every case these patients were subsequently shown to have invasive carcinoma of the cervix.

"We have insufficient knowledge of carcinoma in situ of the cervix and its relationship to early invasive carcinoma of the cervix except in the broadest terms and **we are not justified in managing cases of supposed carcinoma in situ conservatively unless adequate efforts have been made to exclude invasive carcinoma** [my emphasis].

"My experience has been that the majority of cases of early invasive carcinoma are associated with a carcinoma in situ component and that an inadequate biopsy may show only the latter lesion. We cannot say for certain, but it is likely that in most of these cases causing concern, invasive carcinoma was present when the patient was first seen.

"In my opinion, these patients have had what can be termed varying degrees of delayed and inadequate treatment for a disease (invasive carcinoma) that is generally considered to warrant urgent hospital admission for adequate diagnosis and definitive treatment. I believe that the present mode of management of this type of patient needs to be reappraised.

"A list of patients causing this concern, with details of their histology and my brief comments, is attached. In these lists, the site and nature of each biopsy as indicated in the request form appears in capital letters and the histological diagnosis follows in small letters."

Dr Warren, the Medical Superintendent to whom these memoranda were addressed, had in fact invited the two doctors to document their concerns. He had been aware that there were differences of opinion. Both doctors had already talked to him about it. He obviously took them sufficiently seriously to consult Dr Moody, the Superintendent-in-Chief of the Auckland Hospital Board. In any hospital the opinions of two senior specialists, supported by carefully documented evidence, should result in an immediate and thorough management review of the cases in question at the very least.

Dr Moody, although medically qualified, considered his role first and foremost as that of an administrator. In reply to Dr Warren he set out the managerial steps to be followed when responding to Drs McIndoe and McLean. His memorandum is that of the efficient administrator, but there is a hint of concern when he says,

"After long and careful consideration of these papers [Drs McIndoe and McLean's of October 1973], I conclude that there appears to be evidence to suggest that there is misinterpretation of histological and clinical findings – possibly to the detriment of patients."

However, the steps he advocated, although entirely proper, do not suggest that he regarded the issue as urgent. And, as events transpired, all three memoranda were considered with anything but urgency. In setting out the guidelines Dr Warren was to follow, Dr Moody wrote:

"4. In your management and handling of this difficult problem, involving as it does professional judgement and individual opinion, I must remind you that there are formal administrative and constitutional steps you must take at the Hospital level.

5. Bearing in mind both the meaning and effect of what I have already said, I suggest to you:

- 1) That copies of both Dr McIndoe's and Dr McLean's memoranda should be sent to Associate Professor Green, through the

Professor of Obstetrics and Gynaecology, for his consideration and comments.

Professor Green, as a clinician with care of patients, has a right to know the reasons for the statement '**...that a reappraisal of policy towards management of patients with abnormal cytology and colposcopy findings is called for**' and is entitled to give his comments about it.

[The emphasis is Dr Moody's but he may just have been drawing attention to the fact that he was quoting from Dr McIndoe's letter to Dr Warren.]

2) As soon as Professor Green has supplied his comments, all the papers relating to this topic – ie Dr McIndoe's memorandum, Dr McLean's memorandum and Professor Green's comments should be forwarded to the Secretary of the Hospital Medical Committee for inclusion on the agenda of its next meeting.

The Hospital Medical Committee has already, on 20 June 1966, agreed to a proposal by Associate Professor Green that women under the age of 35 years be followed up without active treatment – outpatient biopsy only.

3) If the result of the meeting of the Hospital Medical Committee is inconclusive or does not satisfy you as Medical Superintendent in all material respects, then the whole subject should be referred to the full Hospital Staff meeting for its consideration.

4) If, after this course of action, the matter is still unresolved to your satisfaction, it should then be referred through the Superintendent in Chief to the Board."

Given the history of this debate, the only adverse comment I would make about Dr Moody's memorandum (and it is made with the wisdom of hindsight) is that he ought to have retained a direct interest or control in the matter. It was asking a great deal of Dr Warren to try and control this dispute, considering the long standing difficulties between members of the Hospital's academic and clinical units. (This issue is discussed more fully in Chapter 8, The Relationship Between the Clinical and Academic Units.)

If the Superintendent-in-Chief had indeed retained control of the problems raised by Drs McIndoe and McLean, then it is to be hoped that the Working Party would have been established with greater alacrity, and would have dealt with the heart of the issue: the health of certain patients included in the 1966 trial.

Dr Warren spoke of his admiration for the clear guidelines laid out in this memorandum. He followed the suggested procedure and having given copies of Dr McIndoe's and Dr McLean's memoranda to Dr Green, received in reply a memorandum dated 7 November 1973. It is set out here in full, excepting those parts that refer to specific patients.

"I have received your memo of 31.10.73 through Professor Bonham. I am prepared to comment on this despite my astonishment at the manner in which two staff members have chosen to approach the matter.

"A. **Background to comments.**

(a) The policy of a conservative approach to the management of this condition was approved at a staff meeting in 1966.

"(b) It is generally recognised that invasive cancer cannot be **entirely** excluded unless the whole uterus and vagina is removed for histology and that anything less can miss invasion. It is also



recognised that what constitutes histological invasion or not, particularly just the possibility of it, is a very personal and subjective opinion that may vary greatly from one pathologist to another.

"In 1965 a survey (Green, 1965) showed that 5 pathologists, including Dr McLean, could agree on the diagnosis of invasion in only 3 of 22 cases previously treated at National Women's Hospital for Stage I cervical cancer. It is therefore apparent that there is a good chance of over-diagnosing and treating unnecessarily radically many women who do not have true 'early' cancers, and conversely, of under-diagnosing invasive cancer.

"(c) It was to find out something of the natural history of carcinoma in situ, and to avoid unnecessarily radical treatment of young women with lesions merely suspected to be cancer, that the study was designed for. It was always a calculated risk that invasive cancer could be overlooked, although it was hoped that colposcopy, clinical examination, and repeated directed biopsies would minimise, if not actually avoid, this. This had been advocated repeatedly by Dr J V M Coppleson in Australia and is now urged by American authorities (eg Stafl and Mattingly, Ostergard and Gondos, Selim et al, all 1973).

"(d) A survey in this hospital (Green, 1971) shows that the length of disease time (as judged by symptoms) before treatment affects the survival rates not at all (except that possibly the **longer** the symptoms in Stage I the **better** the survival rate).

"Also an analysis of 1384 cases in 1972 showed that for the Stage IA (histological diagnosis only) type, into which almost all the cases detailed by Drs McLean and McIndoe fall, the 10-year survival rate is  $96 \pm 2$  percent. It could reasonably be anticipated that even if some 'early' cases were overlooked and treatment delayed, or if some progressed to Stage IA invasion, that such patients would not be put at a disadvantage.

"(e) The ethicality of such a trial has since been urged by Professor A L Cochrane, Head of the British MRC Epidemiology Unit (1971).

"(f) Ever since 1949, when I wrote my MRCOG commentary on 'The Early Diagnosis of Cervical Cancer', and discussed carcinoma in situ with the National Women's Hospital pathologist (Dr Lindsay Brown), I have been studying the histology of in situ and invasive cervical cancer. Since September 1956 I have been personally involved in the histology of approximately 1050 cases of invasive cervical cancer.

"B. **General comments on Dr McLean's letter of 18.10.73 to you.**

"Dr McLean is entitled to his opinion, even on clinical matters if he so chooses (and he has so chosen), but similarly I must be allowed my opinion on histological matters. Dr McLean hardly ever sees the patients before treatment and never in their follow-up career; on the other hand I am intimately concerned with the history and clinical findings in many patients, their histologic sections, their treatment, and their follow-up — so that I am in a better position to say what might or might not happen to a given patient.

"In his letter Dr McLean pin-points a central problem in the diagnosis of

pre-clinical cancer – it is likely that in most of those cases causing concern, invasive carcinoma was present when the patient was first seen. The fact that such things may happen because both clinical and histological assessments can be inexact does not alter the fact that they are made in good faith and are not therefore culpable as implied by Dr McLean.

"In any case, the present population and pathological data do not suggest that any reappraisal of the present management, possibly towards the aggressive ablative attitude seen in some North American centres, will do anything to lower incidence, morbidity, and mortality from cervical cancer in either Auckland province or New Zealand. Sir Richard Doll has recently supported me in this opinion.

"If Dr McIndoe has been unhappy about the policy approved by the HMC in 1966 he has never made plain his feelings – either at that time or since in a staff meeting, in any case notes, or openly to me – about the general principles involved or about individual patients he and I have followed colposcopically and clinically.

"Also his comments are not in line with what his teacher and mentor, Dr J V M Coppleson has taught for many years or what is currently being advocated by North American authorities (see previous reference) – that it is possible to distinguish invasive cancer by careful clinical and colposcopically-directed biopsy studies.

"I have shown in our results (paper in MRC's recent Symposium on Epidemiology) that the numbers of patients apparently progressing to invasion is small (at most 10 in 750, including 6 with positive cytological but negative clinical and colposcopic findings), is influenced undoubtedly by the underdiagnosis of invasion initially and overdiagnosis later (possibly 4 examples of each in the above 10), and that the patients have not suffered – since the lesions which may be overlooked or into which they may progress are all of the Stage IA type with close to a 100 percent probability of a 10-year survival.

"It is regrettable therefore that Dr McIndoe's indecision and doubt could cost us a long lead in the elucidation of the problem of the natural history of in situ cancer. As I tried to bring out at the MRC Symposium there is increasing weight of opinion to the effect that it is unlikely to be the simple spectrum of progression which is implicit in both Dr McIndoe's and Dr McLean's comments. With others, I am convinced that the successful management of invasive cancer lies in its correct diagnosis in the first place, and that many patients will suffer unnecessarily if we are prepared to accept only one aspect of the diagnosis and down-grade equally important historical, clinical, colposcopic and cytological aspects.

"In view of what is now being written and the question of whether the diagnosis of large numbers of in situ cancers can influence favourably incidence and mortality rates (it has certainly not done so for Auckland province or New Zealand) I consider it is not unethical to continue with what we are doing. This opinion has been supported by Professor A L Cochrane, the leading British epidemiologist concerned with population data relative to the history of in situ cancer, and strongly by Sir Richard Doll in the recent symposium.

"E.           **Comments on cases nominated by Dr McIndoe  
as being a cause for concern.**

I have commented quite sufficiently on all these (Section C) but consider that I should do so further in the case of [Patient code 6H] in Section C. I suggest

that you peruse carefully the case-notes (especially the Cancer Clinic follow-up record) of this patient.

"Nowhere does Dr McIndoe express any concern in his repeated opinions in the 8 months during which he was the only person to see her, and even when I was clinically suspicious of invasive cancer, he was still of the opinion that only an in situ lesion existed. I do not consider him blameworthy in this respect – only that it demonstrates the essential limitations of the practice of the technique, and that such cases will continue to occur, albeit rarely, no matter how careful we are about diagnosis and even if we use more than direct-punch biopsies.

"Dr McIndoe does not comment on many other cases which he has followed colposcopically and which should equally be the subject of his concern if we take his comments and his graph at their face value. For examples, I refer to [Patient code 4D], and [Patient code 10L], [Patient code 5Q] and similar long-term cases; to [Patient code 7Y] who was treated as invasive and still has positive smears and a colposcopically significant lesion; [Patient code 3V1] who was called invasive cancer but not treated as such; [Patient code 4M] whom nobody but Dr McIndoe has seen for 3 years on account of her cervical lesion and yet she has continuing positive cytology; [Patient code 8A1] (same remarks); [Patient code 8C1] a patient whom, since Dr McIndoe (on my request) took over the follow-up, I have not seen until recently despite her positive cytology; [Patient code 4M1] whom nobody but Dr McIndoe has followed until she was referred to me recently. This still does not include about [blank] of 405 cases (up to 1967) with a histological diagnosis of dysplasia made only by colposcopy and/or simple biopsy who have not yet had what Dr McIndoe calls 'more adequate biopsy'.

"His graph shows that the peak of usage (by number of new patients) of cytology smears at National Women's Hospital was reached in 1964 and with it a peak for the diagnosis of dysplasia, carcinoma in situ, invasive cancer Stage 1A and all other invasive stages. (The pronounced peak for Stage 1A lesions suggests a certain amount of difficulty in decision between invasive and in situ lesions).

"Exactly the same peak is seen for New Zealand as a whole for in situ and invasive cancer (Cancer Data, 1970 Edition).

"This was the time of the greatest relative number of new patients being smeared and merely revealed increased prevalence figures for these lesions. Dr McIndoe has therefore made an unjustified assumption that it was the increased number of cone biopsies that was responsible for an increased number of invasive cancers discovered in the 1963-4 period at National Women's Hospital.

#### "F. General Comments

(a) In my opinion, and without my wishing to appear derogatory, both Dr McIndoe's and Dr McLean's comments demonstrate what Sir Richard Doll (2.11.73) at the MRC Symposium described as 'the evil power of words to constrain thought', whereby the labelling of a case with a name like 'carcinoma in situ' (possibly he might have included '? invasive cancer nearby') is synonymous in our minds with 'cancer' and all the implied necessity of radical treatment.

"(b) Dr McLean's and my comments illustrate the difficulty of

getting other opinions on histological material. I have never been able to get Dr McLean to ask for a second opinion from Dr JJ Sullivan, a pathologist whose opinion I and many others value highly (for me he is ahead of Dr Kirkland, who is a very good personal friend) and I have been forced to consult almost surreptitiously with Dr Sullivan on occasions about cases in which I have had histological doubts.

"One problem here is that standards change — I am fairly confident that the histology of the cone from the 1958 case [Patient Code 3F] who apparently progressed to invasion after 8 years of negative clinical and cytological findings would not now be described by too many pathologists as carcinoma in situ, but rather moderately severe dysplasia.

"Another problem here is that Dr McLean keeps the best diagnostic slides from many cases in his own private collection **under a disease index only**; these are not always made available to me and if Dr McLean changes his classification later these special slides become as good as lost for that patient.

"(c) I am concerned that our record on the colposcopically-directed biopsy method of exclusion of invasive cancer, as advocated by the authorities mentioned previously, may not be perhaps so good as these others suggest is possible. I propose to extend my own personal skill and experience in this direction as much as possible.

"(d) I will be interested to hear from you what you intend to do with these comments. Will they be considered by you alone, an ad hoc staff committee, or by the HMC? Will other staff concerned in the management of the above patients and therefore in the delays in diagnosis and treatment alleged by Dr McLean, be also asked to comment?

"As Section C shows this would include Mr Grieve, Mr Macfarlane, Mr Harbutt, Dr McIndoe, the assembled 'Tumour Panel', the admissions administrative staff, and Dr McLean and his laboratory administrative staff because of delayed reports. I mention the latter advisedly for I have known the delay to be as long as 4 years in one case of malignancy, despite my repeated requests."

### Comment on Dr Green's Memorandum

1. Any person reading Dr Green's papers and his correspondence to the Medical Superintendent during the 1960s and 1970s will rapidly gain the impression that Dr Green was a person of strong views, impatient with criticism and with total confidence in his own judgement. Having been unprepared to debate questions on the management of patients directly with Dr McIndoe, his reaction to the two memoranda forwarded to him from Dr McIndoe and Dr McLean demonstrates his lack of patience with any system which implies accountability amongst colleagues. His response:

"I am prepared to comment on this, despite my astonishment at the manner in which two staff members have chosen to approach the matter"

and again on 25 June 1974, to Dr Warren:

"The matter of Dr McIndoe's complaints about my handling of certain patients, particularly of his extraordinary attempt to discredit me by the allegations he made behind my back to staff members, and also the questions raised

by me in reply to his written comments have not been settled”  
reveal his indignation. This same sense of outrage comes through again in a letter to Dr Warren on 7 November 1974:

“It is now exactly one year since I replied to your letter about Dr McIndoe’s scurrilous campaign against me.”

It would not have been easy to operate a system of peer review in this emotional climate.

2. “It was always a calculated risk that invasive cancer could be overlooked, although it was hoped that colposcopy, clinical examination, and repeated directed biopsies would minimise, if not actually avoid, this.”

The “repeated directed biopsies” were not specified in the 1966 Proposal itself. The fact that punch biopsies were to be taken was mentioned only as an afterthought during discussion. It seems extraordinary that Dr Green, or the Hospital Medical Committee in approving the 1966 Proposal, would allow there to be a “calculated risk that invasive cancer could be overlooked”.

3. “The ethicality of such a trial has since been urged by Professor A L Cochrane....”

When Dr McLean responded at Dr Warren’s request to this memorandum, he said wryly: “I was under the impression that Professor Green’s application in 1970 to the British Medical Research Council for a Research Grant to aid a project of the type under discussion was declined as being unethical.”

It seems at least possible that Dr McLean knew then what Dr Green ultimately conceded at the Inquiry: that the British Medical Research Council would not approve the trial because it was unethical. Dr Green also knew this in 1973 because he was to have been associated with Professor Cochrane in conducting that trial. Yet the same statement that appeared in Dr Green’s 1973 memorandum was repeated in his evidence to me before this Inquiry. This is one occasion when I cannot accept that there was an oversight or memory loss on Dr Green’s part.

Dr McLean’s comment should have been pursued in order that the ethicality of the Cochrane trial, so similar to the 1966 Proposal, could be evaluated. If the Hospital Medical Committee or the Auckland Hospital Board had confirmed that the British Medical Research Council considered the Cochrane trial unethical, the scientific validity of the 1966 trial would have appeared far more questionable.

4. In commenting on Dr McLean’s memorandum, Dr Green wrote:  
“In any case, the present population and pathological data do not suggest that any reappraisal of the present management, possibly towards the aggressive, ablative attitude seen in some North American centres, will do anything to lower incidence, morbidity, and mortality from cervical cancer in either Auckland province or New Zealand. Sir Richard Doll has recently supported me in this opinion.”

I agree with Dr McIndoe’s comment in his reply when he said:

“It is difficult to follow in the above what Doll has recently supported.

“There is much to be gained by ‘reappraisal of the present management’, excepting that this should be expanded to the ‘present **diagnostic steps** and management’. Exclusion of invasive carcinoma at the outset by more adequate biopsy and further investigation of the continuing positive smear [Patient code 6N1] and abnormal colposcopy findings is clearly required as advocated by Kolstad (1970) and the other authors referred to by Associate Professor Green in his November 7 memorandum.

“The suggestion of an ‘aggressive, ablative attitude’ as the only alternative to adequate diagnostic steps is hardly appropriate.”

In that final sentence Dr McIndoe pinpoints the confusion in Dr Green's comments. Although he had said that the study was designed "to find out something of the natural history of carcinoma in situ, and to avoid unnecessarily radical treatment of young women with lesions merely suspected to be cancer", there was no need to begin a study of non-treatment as a means of moving to more conservative management. National Women's Hospital policy was in line with much of the rest of the world. It was already treating by cone biopsy in the 1960s. The 1966 trial was not a move from hysterectomy to cone biopsy. It involved monitoring positive smears along with under-treatment or no treatment at all.

In accordance with Dr Moody's suggestion to Dr Warren, both Drs McIndoe and McLean were given the right of reply to Dr Green's memorandum. I do not set these out in full in the text but have appended them, again excluding references to particular cases (Appendices 5 & 6).

Although the memoranda from Drs McIndoe and McLean and Dr Green's response were never specifically mentioned in the HMC Minutes, Dr Warren referred the issues arising out of them to the Committee.

The first references in the Minutes to these written concerns put to the Medical Superintendent-in-Chief and the Medical Superintendent are somewhat oblique. In July 1974 Mr Faris moved "that a sub-committee...enquire into all aspects of the diagnosis and treatment of both cancer and pre-malignant conditions...within National Women's Hospital". Although those present felt "some doubt as to what exactly Mr Faris had in mind", the matter was discussed and various names suggested for inclusion in the sub-committee: Professor Bonham, Mr Kyle, Associate Professor Green and Associate Professor Seddon.

The next time the subject was discussed, even indirectly, Professor Bonham is recorded (October 1974) as having discussed with Dr Warren the formation of

"small groups to look at specific projects and problems with the object of providing reports for discussion by the Hospital Medical Committee. These reports would be concerned with such matters as the management of carcinoma of the vulva, carcinoma of the ovary, chemotherapy etc, and alterations to the building...."

In December 1974 a working group comprising Mr Macfarlane (convenor), Mr Kyle and Associate Professor Seddon was recommended. Its task was "to look at the case notes of certain specified cases to assess whether or not they were managed in accordance with the accepted Hospital practice pertaining at the time". When he was first approached, Mr Kyle wrote back to the Medical Superintendent:

"As you are aware, I and many others, have, rightly no doubt, been excluded from all contact with Ca. [cancer] cases for a term in the region of 20 years and my association with, and knowledge of the situation, is minimal as a result.

"As I believe medical progress throughout the centuries has been impeded by people making decisions about subjects on which they know nothing, I beg to decline the opportunity to serve on the Committee in question. I feel, further, that if any aspect of this problem is in the nature of a critical assessment of individuals past performances in this field, such decisions should be made by people who have been accorded seniority by the Board in the past. There then would be less, if any, criticism of the ultimate decision...." (HMC Minutes March, 1975)

The same Minutes record a letter to the Medical Superintendent dated 8 January, 1975, which states:

"In order to resolve the uneasiness which has arisen with the establishment of these committees, the terms of reference under which they will function should be known to all members of the senior staff."

In spite of being asked again to join the working group, Dr Kyle declined once more in writing in 1975.

"...The terms of reference of this Committee are now stated as to look at the case notes of certain specified cases to assess whether or not they were managed in accordance with the accepted hospital practice pertaining at the time.

"I believe that some of the more controversial of these cases are those showing microinvasion and as, in my 25 years in association with this hospital, I am unaware of any directive relating to this particular type of case, I feel that the committee will be unable to act within the terms of reference.

"Furthermore I feel that it is most inappropriate that this matter should be adjudicated upon by members of this hospital staff because of personalities and the fact that local staff have had a long time in which to prejudice the issue.

"While it may be uneconomic of time and money, I feel that this problem would be better assessed by a Gynaecologist, Pathologist and Oncologist from some other institution.

"Alternatively I feel that the present terms of reference of the local committee should be waived and a suitably qualified committee decide on working procedures for such cases in the future, calling upon the lessons of the past where appropriate."

When he gave evidence, Mr Kyle said that in using the word 'personalities' he meant that the three doctors in dispute knew each other. His letter contained some sensible ideas.

- 1) He advocated specialists independent of the Hospital as the appropriate people to resolve the dispute.
- 2) By suggesting that the "present terms of reference of the local committee should be waived", he was, I believe, making the point that the proposed terms of reference would not answer the problem which had arisen.
- 3) He suggested that a treatment protocol be developed for the management of future cases.

The wisdom of these suggestions is proved by the existence of the current Inquiry, held 12 years later, and at a far greater cost in time and money than Mr Kyle would ever have contemplated. In the event, his recommendations were not adopted.

Ultimately, Mr Macfarlane, Mr Faris and Associate Professor Seddon formed the Working Party. Mr Macfarlane is now dead and neither of the other members could recall when giving evidence by what process they selected the patients' files they finally studied. It does appear likely, however, that the 29 cases referred to the Working Party were those attached to Dr McIndoe's memorandum of 14 December 1973, written in response to Dr Green's reply to the two October memoranda sent to Dr Warren. The copy in the Hospital's files has been divided into three groups and Mr Macfarlane's, Associate Professor Seddon's and Mr Faris's names each written against a section.

When the Working Party eventually reported, it was on 14 cases only and one of these was not assessed in detail. The exclusion of the other 15 was not explained by Mr Faris or Professor Seddon. Neither of them could recall why more than half the cases on the list had not been considered. I can only conclude that the review of those 29 cases was perfunctory if 15 were omitted altogether without some recorded reasons for their omission.

### **The Working Party's Report**

It was not until 16 October 1975, two years after the original memoranda were for-

warded to the Medical Superintendent, that the Working Party reported to the Hospital Medical Committee. Given the clarity with which Dr McIndoe and Dr McLean stated their concerns about the risks to patients implicit in the 1966 trial, the Working Party's Report was extraordinary. It is appropriate to set out the Report in full.

**"Report of Committee of Inquiry into cases of Carcinoma in Situ:**

Introduction:

On the 20 June 1966, following a discussion by the Senior Medical Staff, the Hospital Medical Committee considered and agreed to proposals involving the supervision and management of certain patients showing positive smears of the cervix uteri.

The proposals were put forward by Professor Green and read as follows:

[Here the Committee sets out in full the 1966 Proposal]

"Professor Green also stated that 'If at any stage concern was felt for the safety of a patient, a cone biopsy would be performed.' In response to certain apparent misgivings voiced by some staff members a committee comprising the undersigned was appointed to consider whether the above policy has been adhered to.

"The concern expressed involved the citing of some 14 cases whose case notes have been referred to us (the Committee) and these we have studied in detail. An overall list of some 29 cases was originally presented to us. This included the 14 cases mentioned but investigation of the remaining 15 cases revealed that they did not apply to this inquiry.

"In the absence of our having been given specific terms of reference, we consider that our role has been to determine –

- a) Whether the agreed policy has been followed in each individual case.
- b) Whether invasive cancer was subsequently diagnosed.
- c) Comment on problems encountered in implementing the agreed policy.

"In summary, the results of our considerations of the cases in question analysed under these three headings is listed in Appendix 1.

**Comments:**

- 1) Of the 14 cases cited, one [Patient code 9G] was not assessed in detail because she came under supervision 5 years before the policy being considered was agreed to.
- 2) Of the 13 remaining cases who came under supervision after 1966, only 3 [Patient codes 6H, 7 J, 6Z] were under the age of 35 years at the time of presentation.
- 3) The Committee considers that in 12 of the 13 pertinent cases the agreed policy was followed.
- 4) In the 13 cited cases managed by the agreed conservative policy, invasive carcinoma was subsequently diagnosed.
- 5) Death resulting from the development of overt cancer occurred in one patient. The 12 other cases diagnosed as having invasive cancer in this series are at present alive and well with the exception of [Patient code 1F] who was killed in a motor accident 4 years after treatment.
- 6) Attention is drawn to the policy statement – 'If at any stage concern was felt for the safety of the patient a cone biopsy would be performed.' The Committee notes that this statement does not define whose concern is operative. It is not clear by statement or implication



whether such concern should be shared by the majority or be the prerogative of any individual member of the team involved in the management of the patient.

This deficiency in the policy agreement is seen by the committee as a potential (?realised) source of disquiet between staff members.

- 7) A second fundamental difficulty in the implementation of the policy concerns the action to be taken on a histopathology report stating 'carcinoma in situ with a query invasive lesion nearby'. The reluctance of a clinician to act on such a report in the absence of clinical or colposcopic evidence of invasive cancer has been associated with intervals of up to 3½ years before definitive treatment was instituted.

The Committee suggests that all cases within the last 10 years having such a histopathology report be assessed to determine in what proportion of cases the original suspicion was confirmed. Without such information action on future similar cases is likely to result in a) unnecessary cone biopsies OR b) unnecessary delays.

- 8) The Committee was concerned that in the case of [Patient Code 1F] delay may be said to have occurred as a result of inaccurate unconfirmed pathology reporting by a member of the junior medical staff.

- 9) It is not within the terms of reference of the committee to comment on the outcome of the clinical trial to which the agreed policy applies.

- 10) The Committee considers that it is regrettable that differences of professional opinion held by senior staff members have been allowed to result in conflicts which have had to come to arbitration.

It is the firm opinion of this committee that all staff members involved in the implementation of the policy concerned with the conservative management of carcinoma-in-situ of the cervix have acted with personal and professional integrity. It is further considered that the effective continuation of this trial depends upon:

- 1) The staff members concerned subjugating personality differences in the interests of scientific enquiry – and
- 2) The initial policy be clarified, in accordance with the following recommendations:
  - a) Define whose concern for the safety of the patient is to be acted upon.
  - b) Assess the numerical significance in this trial of histopathology reports stating '? invasive lesion nearby'.
  - c) Pathology reporting on cervical biopsy material must be made or confirmed by a senior histopathologist.
  - d) Restate the age limits of the patients for inclusion in the trial (committee members had differing interpretations of the present policy statement).

Signed: Alastair Macfarlane, R J Seddon, Bruce Faris. 18.9.75."

It is not possible to let this Report pass without making some comments on its content.

1. The Working Party largely developed its own terms of reference, yet in paragraph 9 of the Report it said:

"It is not within the terms of reference of the committee to comment on the outcome of the clinical trial to which the agreed policy applies."

It is astounding and of grave concern that the Committee, knowing of "certain apparent misgivings voiced by some staff members", chose to avoid the central issue: were patients at risk of developing invasive cancer, or having the diagnosis of invasive cancer delayed, as a result of the 1966 Proposal?

2. Of the cases actually reviewed in detail, the Report found:

"4) In the 13 cited cases managed by the agreed conservative policy, invasive carcinoma was subsequently diagnosed."

Yet the Working Party did not express any sense of alarm. It appears that as only one death had occurred from the development of overt cancer and the other 12 cases were still "alive and well, with the exception of [Patient code 1F] who was killed in a motor accident 4 years after treatment", there was no cause for concern.

3. Rather than investigating why Dr McLean chose to report 'carcinoma in situ with a ?invasive lesion nearby', the Working Party simply concluded that a histopathological report of that nature might result in the future in "a) unnecessary cone biopsies OR b) unnecessary delays".

Dr McLean told me that he had not been asked about this type of histopathological report at the time. If he had been, he could have explained his reason for reporting in that way.

In his evidence, he said:

*"I was aware that Green was excising only part of the lesion in selected cases of CIS and I thought it appropriate to give warning of the possibility of a more severe lesion. The obvious thing to do in my opinion was to do another biopsy if there was any doubt.*

*"Occult invasive carcinomas are not recognisable clinically. Why did a clinician with doubts about this form of diagnosis not discuss this question with me? No members of this Inquiry Committee 'The Working Party' discussed this matter with me."*

The Working Party did not understand that this type of report by Dr McLean was a warning to Dr Green of the danger of invasive cancer.

4. "It is further considered that the effect of continuation of this trial depends upon:
  - 1) The Staff members concerned subjugating personality differences in the interests of scientific inquiry...."

Against the background of debate on the 1966 trial and with the memoranda exchanged between Drs McIndoe, McLean and Green known to the Working Party, it was extremely naive to express the hope that senior staff members would work together better in the future.

5. Perhaps most important and disturbing of all, it does not appear that the Working Party critically assessed the potential risks to patients in the 1966 trial. It seems to me that those risks were considered secondary to scientific inquiry.

I have four principal concerns arising out of the Working Party's Report.

1. There was no explanation included about those 15 patients whose files were excluded from the Report.
2. There was no stated indication of concern when investigation of the remaining 14 disclosed that 13 had developed invasive cancer. No concern was expressed at the fact that one death had already occurred. Nor any concern for other patients who were being managed in the same way and who may have been at risk from invasive cancer.
3. Although the Working Party had been given a brief against which to consider the 1966 trial, it largely developed its own terms of reference. In adhering rigidly to its largely self-imposed terms of reference, it avoided the real reason for the requested

review. In view of the serious concerns raised by two of the Hospital's specialist staff, I would have expected the Working Party to review the 1966 trial and the Hospital Medical Committee to ensure that this was done. In fact, the Working Party did not even review all the patients' notes passed to it and certainly did not attempt anything more than a superficial evaluation of the trial.

4. The HMC and the Working Party should have been thinking of the patients' safety; instead they preferred to follow the time-honoured tradition of confusing etiquette with ethics in attempting to repair the relationships which had deteriorated in the Hospital as the result of the 1966 Proposal and its consequences for patients.

**Conclusions:** The instigation of the Working Party's review was the best opportunity the medical staff at National Women's Hospital had to confront the problems which surrounded the 1966 trial and exercise a genuine form of internal peer review. It is apparent that, right from the beginning, in their self-limiting terms of reference, they chose instead to avoid the real issue. If they had approached their task differently, or if Dr Kyle's recommendations had been acted upon, I do not believe this Inquiry would have been necessary.

### COLPOSCOPIC SERVICES

Long before the Working Party was established, Dr McIndoe appears to have taken another kind of action. In a letter of 25 June 1974 to the Medical Superintendent, Dr Green wrote:

"...I suggest that Dr McIndoe's position relative to D Team [Green's clinical team] and the Colposcopy Clinic needs to be clarified. He continues to appear on the roster for four D Team sessions weekly but has not attended any of these since September 1973. Although he appears on the official staff list only as a part-time visiting Obstetrician and Gynaecologist for Colposcopy he continues to solicit and receive reference patients directly without these going through the obstetrical and gynaecological staff members.

"I now have details of some ten cases which Dr McIndoe has handled in exactly the same manner that he apparently found so reprehensible in me and will let you and the staff have details of these cases whenever you like."

In retrospect, and knowing the events of the years between June 1966 and September 1973, I believe that Dr McIndoe had decided to avoid assisting Dr Green any further because he was concerned about the implications of the 1966 trial. This form of indirect protest is in keeping with the kind of person he was. I can only presume that he thought his non-appearance at clinic and the withdrawal of his services to Dr Green would lead other clinicians or the Hospital's administration to ask why he was not doing his job. It seems extraordinary that, as far as I can ascertain, no such investigation occurred with a subsequent review of Dr Green's management of patients.

In fact, the consequence of Dr McIndoe's non-appearance at D team sessions was beneficial to the patients. When he declined to assist Dr Green any further with colposcopic examinations, Dr Green reverted to performing cone biopsies in most new cases. This outcome may also have been another reason for Dr McIndoe's action.

### THE INTERNATIONAL DEBATE

As this Inquiry proceeded, it became apparent that what had begun as a small domestic dispute in a hospital in Auckland, had come to have ramifications in other parts of the world. Dr Green's work, particularly as recorded in his scientific papers, was well-known in the international community of gynaecologists. Many of these eminent gynaecologists were also aware of the world-wide debate surrounding Dr Green's work. All of them knew of his scientific papers and some had heard him speak.

Dr Jordan told me:

*"I have personally known of this work for many years. In fact, in 1971 Professor Green visited the Department in Birmingham in which I worked. The Head of that Department, Professor Hugh McLaren, was responsible for introducing cytology into the UK and was a vociferous supporter of cytology screening programmes from 1952.*

*"He had been involved with the treatment of patients found to have positive cytology from 1952 and was very distressed at the trial which was being conducted in New Zealand. He decided to hold a debate between himself and Professor Green. This took the form of an internal meeting within the Department, but present were those who were working in the fields of clinical gynaecology, cytology and pathology.*

*"It was as a result of helping Professor McLaren prepare his material and listening to Professor Green that I realised for the first time the true significance of the work which was being carried out in Auckland. Professor Green was adamant that what he was doing was an acceptable approach but was also aware that he was receiving worldwide criticism for his work.*

*"In fairness to him, he has always written about his work and nothing has been kept secret from other workers in the field."*

Professor Kolstad had the opportunity to comment during a visit to National Women's Hospital. He came to New Zealand in 1973 at the invitation of Dr McIndoe:

*"He [Dr McIndoe] was at that time extremely worried about the experiment Green had started in 1966. Time has shown beyond doubt that Dr McIndoe and Dr McLean were completely correct in their often spoken out concern. Dr Green has certainly proved that his fanatic belief that CIS is a harmless disease is a severe mistake."*

During that visit Professor Kolstad, together with Dr Green and Dr McIndoe, examined six patients with carcinoma in situ. Professor Kolstad advised them that they should excise the complete lesion. In his view the most effective method was conization. Professor Kolstad said:

*"Dr Green did not agree with me and he wanted only to follow the patients without any treatment. One special case had carcinoma in situ far down into the vagina and in this case I recommended treatment with vaginal radium irradiation. Also this case Dr Green would only observe."*

In fact, Professor Kolstad disagreed with the management of all six patients and recalled telling Dr Green that he was "experimenting with these patients, something like that. I cannot recall exactly the phrasing of it." When asked how strongly he put that criticism and how much he tried to persuade Dr Green, he said:

*"I think that I, at that time, was not aware of to what large extent he was doing this in the Hospital. So after I had explained my distress... that he didn't treat these patients that all had in situ, and perhaps especially the patient with in situ far down in the vagina, I didn't want to discuss it over and over again."*

Professor Kolstad now believes that Dr McIndoe invited him to Auckland "to try to tell Dr Green that he ought to stop this sort of study".

Professor Richart, Dr Jordan, Dr Pixley and Professor Kolstad each reviewed a small sample of files of women included in the 1966 trial while they were in New Zealand for this inquiry. Despite their familiarity with Dr Green's published papers on the trial and earlier discussions with him, I do not believe that any of them realised the seriousness of the problem until then. All of them displayed concern and even anguish at the consequences for the patients included in the 1966 trial.

Professor Kolstad, a man of robust views, described the treatment of one patient included in the trial as "another example of terrifying mismanagement of carcinoma in situ in a relatively young patient". His summary of the treatment for another patient who had also been part of the 1966 trial and who died in July 1976, illustrates the depth of feeling generated amongst these specialists. On admission in May 1966, a colposcopic examination

*"...showed a significant finding and a punch biopsy disclosed carcinoma in situ. A smear at that time showed cells suggestive of, but not conclusive for malignancy. She was followed with frequent colposcopic examinations and smears... This diagnosis was repeated up to 1973, when the smears showed cells strongly suggestive of malignancy."*

Eventually this patient was treated with radiotherapy after a diagnosis of a rare, clear cell carcinoma which is more malignant than squamous cell carcinoma. Professor Kolstad said:

*"Only two months after radiotherapy the patient started to complain about sciatic pain, indicating spread to the pelvic wall. This pain increased tremendously during the next month and she had to be admitted for pain relief."*

*"She died in July 1976. If you had treated patients with this special type of pain because of lymph node metastases of the pelvic wall, you will know that it is absolutely unbelievable how much they suffer. The handling of this patient must also be classed as severe mismanagement."*

Telling comment on Dr Green's hypothesis appeared in medical journals worldwide in the decade following approval of the 1966 Proposal. In 1970 'The Natural History of Cervical Carcinoma in Situ', a paper by Dr Green and JW Donovan, was published.<sup>1</sup> It was the subject of editorial comment in Obstetrical and Gynecological Survey.<sup>2</sup> The editor wrote:

*"I shall raise only one question and make one comment, for the issues were thoroughly discussed by Hugh Davis in his comment on a somewhat similar presentation by Ashley a couple of years ago...."*

*"Question: How certain are the authors that their patients are indeed free from invasive cancer? After conization, the presence of invasive cancer or indeed intraepithelial cancer is very difficult to ascertain by clinical methods. In some of the New Zealand women, who have had persistent biopsies of intraepithelial cancer, and one patient had three such biopsies over a period of 9 years, might not invasive cancer indeed be present if the entire cervix were available for study?"*

*"Comment: It is assumed in the discussions above and so stated in the complete article that the initial treatment has not altered the course of the disease. How often have you been impressed by the change in gross appearance of the cervix after having taken a simple punch biopsy? It seems to me that many times I have been amazed by the healing process initiated by simply taking a punch biopsy for many times after a period of five or six weeks the cervix appears entirely different than it did when the biopsy was taken. The authors report five patients who seemed to have had their entire intraepithelial lesion removed by biopsy. Other authors have reported the same thing. It has always seemed to me that the question is not whether the biopsy could have fortuitously removed the entire lesion but whether the biopsy initiated a reaction in the healing process which resulted in the rejection of tissue which after all is abnormal and presumably biologically handicapped. As can be seen, I have serious doubts that one can assume that the natural history of intraepithelial carcinoma of the cervix is not seriously altered by therapy, inadequate though it may be."*

This writer was raising a quite different objection to those already mentioned. He is suggesting that a study of the natural history of the disease may well be compromised once a biopsy for diagnosis has been performed.

Dr Green's hypothesis also received other kinds of editorial comment. Another paper written by Dr Green for publication in the 1970 edition of the Australian and New Zealand Journal of Obstetrics and Gynaecology was given an auxiliary heading, 'An Atypical Viewpoint'.

Professor Kolstad, in his evidence, referred to a textbook on gynaecological oncology published in 1972 from MD Andersen Hospital, Houston, where Boronow discussed current concepts of cervical intraepithelial neoplasia. Boronow stated that published data accumulated up until that time suggested that from 10 to 15 to 60 per cent or more cases would develop into invasive cancer. Boronow then said:

"Two relevant questions must be asked regarding such data:

- a) How long are the patients followed?
- b) How long was the diagnosis established?"

He went on to say:

"The controversial views of Green implies that few if any in situ cancers actually become invasive. His reports are provocative but are at present accepted by only a few authorities."

During his evidence Dr Green was at pains to explain that scientific knowledge cannot be advanced without debate and that on occasions he intended to be provocative in his papers. Dr Green's colleagues apparently realised that Dr Green held a minority view. In his evidence, Mr Faris said that in 1972 and 1973

*"We had the feeling that Professor Green might well have a minority view. He may still be right."*

While the comments made in textbooks and journals like these are directed more at the minority nature of Dr Green's views, nonetheless they were also expressions of concern about the validity of his trial. They ought to have been considered by him or by his colleagues when the Working Party was formed to review the 1966 trial.

## THE 1984 AND 1986 PAPERS

In 1974 Dr Green wrote up his trial for the last time in the paper, 'The Progression of Preinvasive Lesions of the Cervix to Invasion'<sup>3</sup> The summary to that paper states:

"In an effort to elucidate the problem of whether and how often the so-called precursors of cervical cancer do progress to invasion, some New Zealand data are presented. These consist of cervical cancer incidence and mortality figures for the Auckland Provincial area, 1946-1972, and for New Zealand, 1948-1970; these are contrasted with similar data from British Columbia.

"Allowing for the uncertainties inherent in the population approach to such problems, the data do not suggest that the removal of large numbers of in situ cancers from the population has favourably influenced incidence and mortality rates, and it is therefore concluded that the concept of progression of epithelial changes through a spectrum to invasion is doubtful. The results of management of a series of 750 cases of in situ cancer in which 10 or 1.3 per cent of the total cases apparently progressed to invasion, but of which 10 cases there were only two in which there was no clinical or histologic doubt about the progression, suggests that the proportion progressing to invasion must be small and is unlikely to influence favourably incidence and mortality rates.

"It is considered doubtful that present population or pathological data will ever solve the problem completely and some other approaches to its solution are briefly mentioned."

Until that time Dr Green had published readily on the data emerging from the trial. He was asked:

*"Dr Green, the 1974 paper you published didn't give the final outcome of your studies on CIS did it?"*

**Answer:** No.

**Question:** Can you tell me why you didn't publish the final outcome of your studies?

**Answer:** Yes, I can tell you that because I realised that it couldn't be carried on like that without a colposcopist and so I resorted to cone biopsies, early cone biopsy in almost every case that I had to deal with. And then I became aware after 1975, I was away in 1975 and 1976, that Dr McIndoe was going to write these up because he [was] always down in the Cancer Clinic getting records; and I knew from what Miss Owen had told me that he was writing them all up and so I imagined that he could do it very well.

**Question:** And you don't yourself have any unpublished figures or writings on the final outcome which are not before the Commission?

**Answer:** No, no.

So far as I am aware Dr Green did not take any steps himself to prevent Dr McIndoe and his co-authors reviewing and writing up the results of the 1966 trial and the patients he managed. Professor Bonham, however, was not prepared to tolerate a review by Dr McIndoe. On 16 November 1982 he wrote the following letter to the then Medical Superintendent of National Women's Hospital:

**"Follow-up of Carcinoma in Situ Cases.**

I have heard a rumour that Dr McIndoe and possibly another specialist, have been reviewing cases of carcinoma in situ that have been managed in the Hospital. I have no recollection of approval being given for a review of in situ cases belonging to other consultants and I wonder if they have been reviewing cases by courtesy of Miss Owen [a senior and respected consultation clinic clerk], without the approval of the clinicians concerned.

*"This may only be a rumour, but I think it may be worthwhile your having a look at it in the first instance because any publication emanating from this Hospital must be acceptable to the staff of the Hospital before it is submitted for publication, as I am sure you will agree."*

This letter shows only too clearly that after all the years spent trying to draw attention to the dangers inherent in the trial, Dr McIndoe was still experiencing real difficulties in getting anyone at the Hospital to listen to and consider his concerns. Professor Bonham said in his evidence that "it is normally an ethic of the profession if you are going to write up other people's cases to get their approval".

I agree that this usually is a matter of professional courtesy but I also believe that Dr McIndoe had gone beyond the point where such niceties matter. All his previous efforts had had no effect. I suspect that it was in desperation that he finally decided to write up the trial and its results for international publication.

When Professor Bonham's letter was put to the Dean of the School of Medicine, Professor Cole, he was obliged to disagree with the proposition that:

*"A publication emanating from this Hospital must be acceptable to the staff of the Hospital before it is submitted."*

He said:

*"It must stand the external appraisal and that it is clearly not nonsense or*

*seriously controversial, or damaging confidence, or in patients' names and things, but I don't believe that any scientist or any person in the area would condone a form of internal censorship.*

*"What often happens, I might say, is that a Head of Department sees as his responsibility to hone down and to smarten up if you like, and generally compress a paper that has been submitted and a good Head of Department, and I have watched them doing this, will work hard on a paper. His name may not be on it, but he sees it as his responsibility to get that paper into the best possible shape...to give assistance. Because it becomes in effect,...from his department or her department, it becomes part of the credibility of that department. But that is a little different from saying that it has to be approved and I don't believe that that would normally apply."*

Although Professor Bonham as Chairman of the Ethical Committee and Head of Department disapproved of the work undertaken by the authors, Dr Jones explained why he accepted Dr McIndoe's and Dr McLean's suggestion that he should assist them in writing the paper:

*"Quite simply, this material was in my view the most important modern evidence which substantiated the earlier view regarding the invasive potential of the precursor lesions (carcinoma in situ).*

*"There had already been a number of papers published on the subject from the National Women's Hospital, some indicating that carcinoma in situ of the cervix had a relatively unimportant invasive potential and others which doubted the value of mass cervical cytology screening.*

*"Taking these facts into account, I believe that it would have been morally wrong not to publish the material in a major international journal. Although the results presented in the 1984 Paper have come under microscopic examination during this Inquiry, they state nothing more than the views held by the rest of the gynaecologists in this country and overseas.*

*"I was also encouraged by the views expressed by Professor Mattingly, the editor of 'Obstetrics and Gynaecology'...."*

Dr Jones quoted from a letter addressed by Professor Mattingly to Dr McIndoe. An excerpt from the letter read:

*"I am sure you know how important this information is to the field of gynaecological oncology and how imperative it is to have this data published as a matter of scientific record. Without publication of your article, this experiment of nature will remain buried in the files of the National Women's Hospital.*

*"While I fully understand the medical politics involved in collecting the data, I cannot emphasise enough the importance that I and others place upon this singular study."*

The paper was ultimately published in the prestigious journal of the American College of Obstetricians and Gynecologists.<sup>4</sup> Its authors were William A McIndoe, MD, Malcolm R McLean, MD, Ronald W Jones, MD, and Peter R Mullins, MSc. The Abstract stated:

*"Nine hundred and forty eight patients with carcinoma in situ (CIS) of the cervix diagnosed histologically have been followed from 5 to 28 years. Among the 817 patients who have had normal cytology follow-up, 12 (1.5%) developed invasive carcinoma. A second group of 131 patients continued to produce abnormal cytology consistent with cervical neoplasia, and 29 (22%) of them, developed invasive carcinoma of the cervix or vaginal vault.*

*"Patients with continuing abnormal cytology after initial management of CIS*



of the cervix are 24.8 times more likely to develop invasive carcinoma than women who have normal follow-up cytology. Further, when compared with the population at large, the chances of patients with normal follow-up cytology developing invasive cervical or vaginal vault carcinoma increase 3.2-fold over women who have never had CIS of the cervix."

The paper concludes:

"The present study clearly demonstrates that CIS of the cervix had a significant invasive potential." (The full text of the paper is to be found in Appendix 7.)

The 1984 paper even today, represents one of the largest surveys of the invasive potential of CIS, both in terms of the numbers of patients involved and years of observation. By the time it was published three of the authors had already presented the material publicly at medical conferences in New Zealand, the United States, Australia and Japan, between 1976 and 1984.

Although the conclusions reached in the 1984 paper were widely disseminated, there was no noticeable reaction at National Women's Hospital from the HMC, the Ethical Committee or the Medical Superintendent. The Royal NZ College of Obstetricians and Gynaecologists took no steps to ensure that patients who had been included in the study were not at risk of developing invasive cancer.

Drs Jones and McLean published a further paper in the same journal in 1986. It was entitled 'Carcinoma in Situ of the Vulva: A Review of Thirty Treated and Five Untreated Cases'.<sup>5</sup> The Abstract said:

"36 patients with carcinoma in situ of the vulva have been followed from 2-23 years. Among 31 patients managed by surgical excision, there were 4 recurrences of vulvar carcinoma in situ and 1 patient developed a vulvar carcinoma 17 years later.

"4 middle-aged and elderly women managed only by biopsy all progressed to invasive vulva cancer in 2-8 years; 1 additional patient progressed to invasion after inadequate primary treatment. These last 5 cases all represented multi-focal lower genital tract neoplasia. Untreated vulvar carcinoma in situ, when seen as part of a multifocal lower genital tract neoplastic process, in middle and later life is likely to progress to invasion."

By the time this paper was published all five women whose disease had progressed to invasion had died. (A full copy of the paper is found in Appendix 8.)

### THE ARTICLE IN 'METRO' MAGAZINE

It was the publication of the 1984 paper in the journal of the American College of Obstetrics and Gynecology that prompted the article 'An "Unfortunate Experiment" at National Women's'. One of the co-authors had read the paper by McIndoe, McLean, Jones and Mullins. The writers' research and preparatory work involved letters to and interviews with a wide range of experts in the field of gynaecological malignancy, screening for cervical cancer and ethics of medical research, and teachers of obstetrics and gynaecology. The resulting article was published in the June 1987 issue of 'Metro', a monthly magazine published in Auckland and with a national circulation.

The authors, Sandra Coney and Phillida Bunkle, were parties to the current Inquiry. Sandra Coney gave evidence on their behalf and subsequently on behalf of Fertility Action, a women's health pressure group. She is an Auckland freelance journalist and a former editor of 'Broadsheet'. Phillida Bunkle is a Wellington academic. At that time she was senior lecturer in Women's Studies at Victoria University.

The significance of the magazine article was not lost on the Auckland Hospital Board. A memorandum from the Superintendent-in-Chief, Dr Leslie Honeyman, recommended that the Board pass a resolution requesting the Minister of Health to establish an Inquiry under Section 13(3) of the Hospitals Act 1957. Dr Honeyman summarised the issues of particular concern to the Board and divided them into two parts:

- “\* ethical issues concerned with informed consent to treatment, the conduct of clinical research and other matters.
- \* historical matters relating to a particular group of patients, from 1966 onwards.”

He recommended that “full investigation, both of the historical origins of these concerns and of present day practice and procedure is required, and...I do not think that it is desirable that this Board continue with its own investigation of the matter, but rather that an inquiry be made by outside independent person or persons”. Two days later, on 10 June 1987, this Committee of Inquiry was announced.

The magazine article had already become the subject of intense public comment. It was predictable, therefore, that it would be carefully scrutinised and much criticised by some of the witnesses who gave evidence before me. The most sustained criticism came from Dr Green. Professor Bonham was also worried about some of the statements made in the article.

### Was the magazine article accurate?

During the course of the hearing the original manuscript submitted to the magazine was produced and editorial changes made in the course of preparing the article for publication were explained. There were a number of errors in the article finally published in the magazine. Most were of minor import or caused by editorial changes. However, with the exception of matters to which I will refer specifically, the factual basis for the article and its emphasis have proved to be correct. It was an extensively researched and professionally written piece. It displayed an understanding of the condition of carcinoma in situ of the genital tract and invasive cancer that few lay people could hope to achieve.

#### 1. Significant editorial changes

The matter of accuracy was raised first by the authors themselves. In her evidence Sandra Coney drew attention to two editing changes which she considered substantially altered the meaning of sentences in the magazine article.

- (a) “Twelve of the total number of women had died from invasive cancer as had four, or 0.5%, of the group-one women, and eight, or 6% of the group-two women who had limited or no treatment.”

In the original manuscript the authors had written:

“Twelve of the total number of women died from invasive carcinoma. Four (0.5%) of the Group-one women, and eight (6%) of the Group-two women who had limited or no treatment. Thus the women in the limited treatment group were twelve times more likely to die as the fully treated group.”

I accept that the unedited material more accurately reflects the findings of the 1984 McIndoe paper. The edited version is not accurate.

- (b) In the original manuscript the authors wrote:  
“While in many countries it may not be necessary **to review the evidence**, says Skegg, in New Zealand it was....” (my emphasis)

The edited article stated:

“While in many countries **such a programme** might not be necessary, says Skegg, in New Zealand it was....”

Again, the change of words, in particular 'programme' instead of 'evidence', markedly alters the assertion made by the authors and, through them, Professor Skegg.

2. **"But there was no intention to cure them"**

There was one matter about which Dr Green was understandably extremely concerned. In the article it was said that:

"Some women with evidence of disease were to be left. They would be followed – that is, brought back for regular smears and possibly more biopsies – but there was no intention to cure them."

For any doctor to be told that he had no intention to cure a patient would strike at the foundation of his professional and personal values. In fact, I do not accept that Dr Green had no intention to **cure** his patients. During the course of the Inquiry there was no serious suggestion that he had anything other than a benevolent attitude towards his patients. In some areas, particularly the treatment of women with invasive cervical cancer, he was highly regarded.

There is, however, a difference between the overall intention to cure a patient and a decision not to treat a particular condition. It was, and I believe still is, Dr Green's view that CIS is essentially a benign condition. If a gynaecologist holds this view, then there is no purpose in treating the lesion. Indeed to do so might be to subject a woman to surgical procedures unnecessarily. By the time he was interviewed for the magazine article, Dr Green's view was that about 5 per cent of the lesions diagnosed as CIS might progress to invasion. It was clearly his thesis that it is preferable to achieve an early diagnosis of **invasive** cancer and treat that, than to attempt to screen the entire female population at risk for the sake of the 5 per cent who might proceed to invasion if they have a precancerous condition.

Although Dr Green was tireless in his efforts to diagnose and treat invasive cancer, he believed that CIS was likely to be a benign lesion in the great majority of cases. Therefore, he did not treat that lesion in some cases.

3. **"817 who had normal smears after treatment by 'conventional techniques'"**

In the paper published in 'Obstetrics and Gynecology' in 1984, there were 817 patients who came to be known as 'Group 1'. They fell into that group because after an initial diagnosis of CIS their follow-up cytology was normal. They were not necessarily offered 'conventional techniques' but their management had resulted in a return to negative smears.

4. **'Ruth'**

There was a description of the treatment of one patient known as 'Ruth' set out intermittently through the magazine article. Dr Green queried the emphasis placed on some of the notes in the hospital records, suggested that other doctors might on occasions have been responsible for particular consultations with 'Ruth', and questioned the histological and cytological reports set out in the notes. Nonetheless, a reading of her file proved that it was summarised accurately in the article.

This woman also gave evidence. Not only was she a classic case of a patient who had been brought back for smear tests and biopsies without definitive treatment for many years, but she also had been unaware that her condition was potentially dangerous.

Professor Bonham also raised a number of points to do with the magazine article. Some of his concerns coincided with those of Dr Green; some will be touched on at various stages in my report; and some are simply different arguments rather than errors of fact

or interpretation on the part of the authors of the article. I refer here to four of Professor Bonham's most significant concerns.

1. **"[Were] women told there were differences of opinion about the methods of treatment"**

The magazine article stated:

"In answer to a question about whether women were told there were differences of opinion about the methods of treatment, Green replied: 'I suppose not.' In answer to the same question, Professor Bonham said: 'I wouldn't know, you would have to ask each individual doctor who treated patients.'"

According to the evidence produced during the Inquiry both Professor Bonham and Dr Green are correctly quoted in the article. Few patients had heard the term 'carcinoma in situ' and few if any knew "they were getting anything other than standard management for their disease". I also hold the view, confirmed by Professor Bonham's statement, "In fact he [Dr Green] was chosen to be the clinician to teach students how to explain to patients with cancer, their condition and treatment", that Dr Green's explanation to patients with cancer was detailed; but to those with carcinoma in situ he did not give even a basic explanation.

I heard no evidence to suggest that Professor Bonham did not explain the nature of and treatment for carcinoma in situ to his patients.

2. **"There was no hospital plan to seek the agreement of the women to their unorthodox treatment"**

I have concluded that some women were offered unorthodox treatment and some no treatment at all. National Women's Hospital has always sought the written consent of patients about to undergo operations. However, I have no evidence which persuades me that the Hospital ensured the group of patients being monitored with positive smears were told their management was unorthodox or based on minority views.

3. **"Professor Bonham had ultimate responsibility"**

In an interview before the magazine article was published, Professor Bonham was asked: *"...in terms of the structure of the Hospital...who is ultimately responsible [for Professor Green's study]?"*

He answered:

*"It would fall between both the academic side – that's Consultant Professor Green, and the Medical Superintendent and the Hospital Medical Committee...."*

Professor Bonham could not be said to have conceded that he had **ultimate** responsibility for the 1966 trial. I accept that responsibility for research involving patients is shared as he said between the academic and clinical branches of the University and the Hospital. However, he did concede while being cross-examined on the study involving vaginal swabbing of neonatal (newborn) babies that overall responsibility for research lay with the head of the academic unit, although he emphasised that in practical terms he might not always know that a trial was still under way.

#### 4. Confusion between colposcopy and colposcopic biopsy

In his evidence in chief Professor Bonham said:

*"...the authors confuse the difference between colposcopy and colposcopic biopsy. Colposcopy itself is not treatment. Colposcopic biopsies can be treatment, in that they can remove part or all of the lesion."*

The magazine article had said:

*"Where others define colposcopy as a diagnostic tool, Bonham refers to its use as 'treatment'. Of course, if colposcopy is 'treatment', then it is not possible to claim that no patient went 'untreated', for all had colposcopic examination."*

In fact the authors had highlighted Professor Bonham's own confusion or loose use of terminology. When he was interviewed for the article this exchange took place:

**Question:** *Though they had problems with cytology, but still no more was done.*

**Professor Bonham:** *They had repeated biopsies and they were treated by colposcopy.*

**Question:** *But that's more diagnosis.*

**Professor Bonham:** *Not really because once you find that they are getting to a stage of something that is bad, you take it out.*

**Question:** *But if you were following them just with more diagnosis that isn't treatment is it?*

**Professor Bonham:** *It can be. It depends how much lesion they have got.*

**Question:** *But if you know there's more?*

**Professor Bonham:** *If you know that the...*

**Question:** *It's not treatment is it?*

**Professor Bonham:** *...Yes, but you are still watching with a 'scope. Yes I take your point and I think at that time, between 1965 and 1975, that was fairly acceptable in terms of what was appropriate knowledge at the time....*

**Question:** *Are you saying that you were just following people with cytology, you are not actively treating, but you are following them up to make your diagnosis and then if something nasty happens, you get rid of it? You were leaving them until the prognosis is actually much worse.*

**Professor Bonham:** *It is very difficult here. That's a theoretical argument and I think that's right. On the other hand, how much do you take away, because the patients that went wrong, a third of them got ultimately carcinoma of the vagina. Would you recommend taking everybody's vagina and uterus at the beginning of the study?*

**Question:** *But don't you actually treat somebody with a significant lesion?*

**Professor Bonham:** *Yes, that is what we do now.*

**Question:** *But that's not what was going on then. So that the point of saying, how much would you carve away, means that you would excise surely, until you had negative cytology.*

**Professor Bonham:** *Yes, I think that's fair.*

**Question:** *But this includes, it involves treatment until you produce negative cytology.*

**Professor Bonham:** *It wasn't a very large group that were watched.*

I do not think the mistake was the authors'. The confusion arises out of the convoluted answers to their questions.

**Conclusions:** Apart from the matters I have touched on in the preceding pages and which could not seriously be described as careless or deliberate errors in the context of a subject that is vast and complex, I have not been able to uphold the assertion in the introduction to Dr Green's evidence that:

*"By far the greatest source of errors is the Metro article which played such a significant role in the formation of this Commission of Inquiry. Innumerable mistakes are contained in that story; in fact, over 40 pages of Dr Green's evidence is devoted to dealing with the errors contained in that publication."*

## THE MEDICAL PROFESSION'S RESPONSE FROM 1966 TO 1986

Dr McIndoe and his co-authors and the authors of the 'Metro' article shared a similar experience: the reaction to their articles. They met with a wall of resistance, particularly from members of the academic unit at National Women's Hospital. All the writers used extraordinary determination to find the truth. A great deal of energy has been put into trying to control the damage arising from the 1966 Proposal. I would have expected that effort also to have been directed towards a formal review of the Proposal, and in particular, some of the issues raised by the 1984 and 1986 papers. Yet none of these issues or earlier concerns were addressed.

Dr McIndoe's written and oral concerns were not taken seriously until 1973 when, with Dr McLean, he was encouraged by Dr Warren the Medical Superintendent to record in detail the progress of the 1966 trial to date.

Although in 1975 the Working Party reported to the Hospital Medical Committee, no action was taken to consider what risk there might be to patients included in the 1966 trial. The HMC, which was responsible for the clinical organisation of the Hospital to ensure that the professional and scientific work was properly carried out, did not insist on any such review.

The risks to patients had been reduced to some extent by a move away from under-treatment or no treatment of certain patients to an increased number of cone biopsies when Dr McIndoe stopped assisting Dr Green with colposcopic services. After the Working Party Report in October 1975, the HMC decided to review procedures for the management of CIS.

It was almost three years later, in July 1978, that those management guidelines were agreed upon. It must be stressed, however, that on no occasion was the 1966 trial evaluated for its consequences to the patients or stopped. There was one group of 30 patients in particular, referred to in McIndoe's 1984 paper, who were among patients excluded from that survey. In discussing the reasons why the authors said:

*"Thirty patients with continuing abnormal cytology after the diagnosis of CIS, but in whom a final histologic diagnosis had not been made (at review dated June 1983), have also been excluded from this study. The authors assume these women have continuing CIS but, without a further biopsy, this cannot be confirmed."*

During the Inquiry Dr Jones said that Dr McIndoe had discussed the paper with the then Superintendent of National Women's Hospital and drew his attention to these 30 patients with continuing disease who were at risk of developing invasive cancer. He suggested that an attempt be made to locate and treat them. But they were not specifically reviewed. There was no intervention, beyond their usual examination, after publication of the 1984 or 1986 papers, to ensure those patients were not at risk of developing invasive cancer.

On the thirtieth day of the public hearings, during cross-examination, Professor Bonham was asked if any attempt had been made to review those 30 patients since the 1984 paper was drawn to his attention. He said:

*"The responsibility I think for this falls with the people who have taken up this responsibility. That is to say, they have written about them. I have already explained I think to you, that these cases will have been seen as they are continuing."*

**Question:** *So you think there will have been a review carried out in the normal course of Hospital practice?*

**Professor Bonham:** *Unless these patients have disappeared, moved to another country or city, or have failed to come, some have perhaps moved to private care and so on, they will have been reviewed. The numbers are significant and handleable and I will anticipate that they have been reviewed.*

*Up until quite recently Dr Green was not playing any clinical part in the Hospital, but he was looking after the review. He was sitting going through the notes of these patients to make sure they were attending and being seen and until he stopped this, which was quite recently really, since I think the Inquiry started, those would have been reviewed as part of the overall review scheme.*

**Question:** *I just wondered if you could tell me whether there had been a special attempt to review those particular 30 and to offer them any further treatment if necessary?*

**Professor Bonham:** *No. But I am only anticipating that they will have been seen by the system.*

In this exchange it appears to me that Professor Bonham considered that the responsibility for reviewing those 30 patients fell to Dr McIndoe, Dr McLean, Mr Jones and Mr Mullins, and that neither the Ethical Committee nor the HMC nor any of the senior clinicians at the Hospital had any part to play. The end result, of course, is that there was no special review of those patients within the Hospital.

Dr Graeme Duncan, the President of the Royal NZ College of Obstetricians and Gynaecologists, was asked whether the Royal College at any stage from the 1960s onwards received any expressions of concern about Dr Green's management of patients. The 30 patients were not specifically referred to, but again the result was the same. The Royal NZ College did not receive any expressions of concern nor did it take any actions to ensure that the 30 patients were reviewed following publication of the 1984 paper.

Dr Duncan made the point that from the 1960s the process of peer review was in operation at National Women's Hospital, "senior staff of the Royal College were... active members of the specialist staff at NWH" and so, if they had wished to raise the matter with the College, then "they would have done so". He made an interesting comment:

*"We must remember that the traditional freedom of professional action can quickly become a veil of secrecy surrounding management..."*

Mr Faris was asked:

*"Have you had any indication within the medical profession or with National Women's Hospital itself of any think tank or internal medical inquiry being set up into the findings of that paper [the 1984 paper]?"*

Mr Faris felt he could not speak for the Hospital because he had not been an active member of staff since that time. He did say that he was quite certain that D-team (Dr Green's clinical unit) and the colposcopists had analysed the paper in some detail.

Professor David Cole, Dean of the University of Auckland School of Medicine, who had not read the 1984 paper was asked whether, in his capacity as a high-ranking member

of the Auckland medical profession, he had noticed any indication at all of an inquiry by the profession into the matters raised in the 1984 paper. He replied:

*"No."*

**Question:** *Not between publication of that paper and the setting up of this public inquiry?*

**Dean Cole:** *I don't believe so.*

When Dr Gabrielle Collison, Medical Superintendent of National Women's Hospital, gave evidence, she told me that she had become aware of the 1984 paper around mid-1985 and thought it might have been Dr McLean who brought it to her attention. Dr Collison had said in response to an earlier question that she had discussed current treatment with Drs Jones and McLean, but not the article specifically. She was also asked whether either of those doctors, or any other doctor at the Hospital, had suggested that there ought to be further investigation or discussion of the information contained in the 1984 paper. Dr Collison replied that no one had.

On day 50 of the Inquiry hearings, the Medical Superintendent-in-Chief of the Auckland Hospital Board, Dr Leslie Honeyman, was asked a similar question. He recalled that he had read an Abstract of the article prior to its publication, but when asked if it had rung any alarm bells, he said:

*"No, not at all."*

He was also asked:

*"Are you aware of any indication that the medical profession itself may have set up an inquiry into the matters that this Commission has been asked to inquire into?"*

Dr Honeyman said that there had been no such call from the profession at large, or from a group within the profession, nor from National Women's Hospital itself. Twenty years of oral and written expressions of concern by Dr McIndoe, supported for much of the time by Dr McLean and latterly also by Dr Jones, failed to persuade any part of the medical profession to review the implications of the 1966 trial for the patients.

## CONCLUSIONS

I reserve particular disquiet not only for the fate of the 30 patients mentioned in the McIndoe et al paper, to whom there was a special duty owed, but also for the future of peer review within the medical profession, if it cannot confront issues squarely and resolve them after such sustained, detailed and well documented statements of concern about the treatment of a group of patients and the minority view advocated by one clinician. The Hospital Medical Committee and Ethical Committee had a duty to ensure that the 1966 trial was terminated, at the very latest when the 1984 paper was published. There had been many earlier opportunities for either of the Committees to take this step.

During the course of this Inquiry the legal profession's involvement has been criticised, as has their questioning of the actions of the medical profession with regard to the 1966 trial and its consequences. The publication of the 1984 and 1986 papers represented the medical profession's last opportunity to exercise its own assessment. It failed to do so.

At the time when Dr Green retired, the Medical Research Council was under the impression that his work had been taken over by Dr Murray Jamieson. In the magazine article Dr McIndoe was quoted as saying that he believed the trial "never came to an end" and that Dr Green "carried on with varied managements to the end of his days [at the Hospital]". In my opinion Dr Green confirmed this when he said in evidence:

*"[In the article] the question of whether or not a programme of conservative treatment was ever stopped was raised. Until my retirement in January 1982, I continued to manage patients of mine on the same conservative basis approved by the Hospital Medical Committee.*



## CERVICAL CANCER REPORT

*"It is fair to say, however, that my attitude, and the practice adopted by others at National Women's Hospital, changed a little from 1965 to 1977 in that by 1977, virtually no patient would have been initially treated by punch biopsy alone."*

Professor Bonham said that:

*"The programme itself was not stopped. It was modified to increase the role of cone biopsies in management and to allow an increase in participation by other specialists."*

In July 1978, guidelines for the future "definitive diagnosis of preclinical cervical cancer" had been adopted by the HMC. However, I still have no evidence before me that the 1966 trial has been formally terminated.

1. Journal of Obstetrics and Gynaecology of the British Commonwealth. 1970.
2. Obstetrical and Gynecological Survey 1970 : 876
3. NZ Medical Journal 1974, 80; 279-287.
4. 'Obstetrics and Gynecology' 64, No.4, October 1984.
5. Obstet.Gynecol.68 : 499, 1986.