APPENDIX 12: DR HOLT'S RESPONSE TO DRAFT INTERIM REPORT

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4 March 2004

Dr Helen Zorbas
Chair
NHMRC Review Committee on Microwave Cancer Therapy,
MDP100
GPO Box 9848,
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Via Fax: 02 6289 9197

Dear Dr Zorbas

Draft Interim Report entitled "Review of Use of Microwave Therapy for the Treatment of Patients with Cancer, March 2005" ("Draft Report").

Thank-you for providing Dr Holt with a copy of the Draft Report.

Dr Holt has instructed me to respond to you on his behalf to request that the following matters be expressly dealt with in the final Interim Report and that various matters in the Draft Report be clarified or modified, as relevant.

1 General Comments

Before dealing with the detail it is appropriate to set out some general but very fundamental issues that Dr Holt has with the Draft Report and the Review Committee's interpretation of its Terms of Reference.

1.1 UHF and UHF/Radiotherapy –Terms of Reference.

(a) Given the fact;

- public money is being used by the NHMRC to prepare the Report;

- the NHMRC is aware Dr Holt is in his eightieth year and is to retire from practice in June this year in circumstances where no successor proposes to provide the current UHF treatment or the UHF/Radiotherapy treatment formerly provided by Dr Holt; and

- Dr Holt advises he is currently being forced to treat patients less than optimally by not providing them with UHF/Radiotherapy (because of lack of access to radiation equipment);

it was our clear understanding (as recorded in the taped record of interview with Dr Holt), that the focus of the Review Committee would be a pragmatic, sensible one, namely an examination of the benefits of UHF/Radiation as well as UHF as a single modality.

This understanding derived from discussions at the January meeting (refer to the typed record of the final 14 minutes of the record of interview with Dr Holt appended as Annexure A) and the agreement on the part of the Review Committee to examine the files of 100 patients treated with UHF as well as 100 patients treated with UHF/Radiotherapy.

(b) At page 81 of the Draft Report it states the Review Committee proposes to review, "a consecutive series of patients who have been treated with the current-available treatment regime of microwave therapy and "glucose blocking agents".

No mention is made of the counter-balancing review of 100 patients treated with UHF and Radiotherapy.

An accurate record of what was agreed is set out in my email of 11 January (copy attached as Annexure B));

(c) It is extraordinary, having regard to the matters outlined in (a) and (b), that the Review Committee has focused exclusively on the validity of the UHF modality currently applied by Dr Holt, as compared to the superior dual modality promoted by Dr Holt.

(d) The NHMRC's Terms of Reference do not restrict the NHMRC from examining the benefits of UHF/Radiotherapy.

(e) If it had been apparent (prior to provision of the Draft Report) that the Review Committee considered it was limited to strictly interpreting the Terms of Reference to,

"the (UHF) technology as it is currently administered in Australia",

a protest would have been lodged with the Minister and the NHMRC early in the process (just as a protest was lodged in connection with the incorrect reference to the Tronado machine and to "microwave therapy" as compared to "UHF").

(f) Dr Holt has been and is keen to remain co-operative with the Review Committee. He is anxious to ensure that valuable, effective treatment options are revived/retained in Australia and made available for the benefit of cancer patients after his retirement.

(g) Dr Holt agrees that further research in connection with UHF/Radiation and UHF treatment is desirable. Dr Holt has practised by himself for the last 14 years, endeavouring to meet an ever increasing demand. He has not had the time available to prove-up the treatments to the extent he would have given a lesser workload.

However Dr Holt is in no doubt, given his experience of treating some 35,000 cancer patients in WA since 1961 (in excess of 5000 with the dual modality (1973 to 1991) and 1500 with glucose blocking agents and UHF only (since 1991) that this latter modality is of significant curative or therapeutic benefit (at least equal to that of conventional treatments and without the adverse side-effects) to a large cohort of cancer sufferers.

(h) Put simply it is a waste of time and public money for the Review Committee to confine its brief to UHF only and to construe its Terms of Reference narrowly. Given the small window of opportunity (to June 2005 when Dr Holt retires) and the considerable cost of conducting the review it is plain, old fashioned common sense to review the two treatment regimes simultaneously.

1.2 The Science of Dr Holt's UHF Treatment Regime

(a) Dr Holt considers the Draft Report is inaccurate and misleading in its description of the science and mathematics of the UHF treatment he currently provides.

(b) It appears this inaccuracy largely derives from;

- lack of adequate distinction in the Draft Report between UHF and microwave ("Microwave" is the generic descriptor for 300 MHz to 3,000 GHz radiofrequency "UHF" is the descriptor given to the lowest band (300 MHz to 3 GHz) within the broad microwave range. Dr Holt applies 433-434 MHz (self-evidently within the lower range of the lowest UHF sub-band)); and

- a resultant mis-understanding that Dr Holt's treatment involves hyperthermia.

(c) At pages 14 and 15 of the Draft Report a scientific view is proffered to the extent that radiation induced hyperthermia preferentially damages cancerous cell's DNA. The Draft Report then states,

> "non-ionising electromagnetic waves (ie microwave therapy) do have the potential to heat human issue".

In the last paragraph on page 14 the Draft Report provides,

> "The overwhelming majority of microwave therapy researchers believe that any therapeutic effect of microwave therapy is related to heating of the tumour cell, either directly or indirectly"

Dr Holt maintains that this has never been proven. Heating is not the basis for the therapeutic effect of Dr Holt's treatment.

Dr Holt's treatment of UHF (433-434 MHz) comprising 20 minutes exposure at 2,400 watts, results in a minor, insignificant increase in body temperature (0.4 – 0.6 Degrees C). Hyperthermia involves increasing the body temperature up to the limit of human endurance (41.8 degrees C).

Additionally and significantly Dr Holt's treatment does not work by reference to its effect on DNA.

Rather the application of 433-434 MHz UHF results in an increase in the cancer cell growth rate (by a factor of up to 10 times the normal growth rate). This is attributable to the fact that cancer cells conduct electricity, so absorb energy at a greater rate than

healthy cells, in turn growing faster. This accelerated growth rate is then destroyed by preventing the cancer cell using glucose from the blood as its energy source or by treating with X ray therapy after UHF.

The non-thermal application of 433/434 MHz radiosensitises cancer by any factor from 100 to 10,000 times. (Dr Holt advises the cell kill without the application UHF of say 150-160 rads may be 1,000 cells, 20 minutes after UHF this dose will kill 100,000 to 10,000,000 cancer cells. This effect will occur with a cancer temperature elevation less than 0.5 degrees C).

Despite the fact that Dr Holt's treatment does not rely on heating cancer tumours, numerous references appear in the Draft Report hypothesising that it is not possible to determine whether the lack of "convincing and consistent evidence" is due to ..."a failure in the practice of microwave therapy due to inability to adequately heat the tumour".

1.3 Conflicts and Due Process

I refer you to my email of 11 January 2005 in which I sought advice that Dr Van Hazel (the WA member of the Review Committee, an oncologist and the principal of a competitor business (Perth Oncology) to Dr Holt's practice) had assured the Review Committee that he did not have a conflict in this matter.

I have never had a response to this issue.

I note with some alarm that Dr Van Hazel is recorded as having resigned from the Review Committee in January 2005 (refer Annexure 3). Could you please explain the basis for Dr Van Hazel's resignation.

Additionally, and with a greater degree of alarm, I note from Appendix 5 that the list of organisations and individuals invited by letter to make submissions to the Review Committee included Dr Van Hazel (of Perth Oncology) and Michael Jefford.

Did Dr Van Hazel and Mr Jefford make submissions to the Review Committee?

If so please provide a copy of the submissions as soon as possible (obviously prior to the provision of the Interim Report to the Minister).

It is essential that we have the opportunity to assess the input and influence of Dr Van Hazel (and potentially other members of the Review Committee) in this process so far.

2 Specific Issues

2.1 Availability of Dual Modalities – UHF and Radiation

(a) On numerous occasions the Draft Report makes mention of the fact that Dr Holt does not administer UHF in conjunction with Radiotherapy (see paragraph 2 page 7; paragraph 3, page 11; paragraph 1 page12; paragraph 1, page 16; paragraph 2, page 27 etc).

(b) What the Draft Report does not record is the fact that this is not through choice.

The failure of the Review Committee to recognise this fact is disappointing. The Review Committee (Assoc. Professor John Boyages) specifically undertook to ensure that the Draft Report would "acknowledge" ... that Dr Holt's current treatment "is an alternative method which I am using because I have been excluded from conventional. Therefore in my opinion if you want to do any research, you should not do it on glucose blocking agents" (refer 3rd last page of transcript appended as Annexure A).

(c) Ideally Dr Holt would apply the dual modalities to optimise treatment results for cancer patients. However this is not possible as it is not within Dr Holt's financial means to acquire the equipment necessary for radiotherapy treatment. Dr Holt has sought to work in tandem with local Radiotherapists but the Radiotherapists he has approached have not been amenable to the idea. (The UHF and Radiotherapy treatment requires Radiotherapy immediately following UHF treatment, necessitating co-operation of local radiolotherapists). The method can only be practiced by having adjoining UHF and x-ray therapy treatment rooms.

(d) Dr Holt has advised the NHMRC on a number of occasions that it is his view that the optimal treatment regime is the dual modalities (refer the taped record of interview with Dr Holt). Consistent with this, in my email of 11 January 2005, I recorded the fact that Dr Holt agreed to the Review Committee examining 100 consecutive patient files for the 2000-2001 year Provided they also examined,

> "a consecutive series of 100 patients treated by Dr Holt at his former practice using the dual modalities of UHF and Radiation".

2.2 Bias

The Draft Report demonstrates an unfair bias against Dr Holt.

To illustrate this bias;

- As mentioned in 2.1, no mention is made of the fact that Dr Holt does not use UHF in conjunction with Radiotherapy because Radiotherapy is not available to him. An impression is created that Dr Holt does not provide Radiation by choice.

- The very first paragraph of Chapter 1 recants the negative findings of the 1974 NHMRC review of Tronado treatment, without qualification. The prior review is unrelated to this review, is irrelevant and reference to it is unwarranted and highly prejudicial.

- On several occasions in the Draft Report (see pages 9 and 18) a statement is made to the effect;

  " In particular it was hoped that submissions and personal testimonies would be received from patients, their carers and medical practitioners, and that these would provide additional clinical efficacy and safety data for consideration by the Review Committee".

  The Draft Report suggests that such submissions were not received or, to the extent they were received, they were not supportive of Dr Holt's treatment.

No direct comment is made in the Draft Report as to whether the overwhelming tenor of patient, carer and medical practitioner submissions was positive or negative. At page 78 an oblique statement is made to the effect,

"Whilst difficult to interpret in isolation, and subject to all the caveats outlined above, such information (ie information provided by patient submissions) may suggest a treatment effect that then warrants further investigation using research methodology where biases are eliminated".

- At the top of page 12, when describing the administration of glucose blocking agents (GBA's) the Draft Report states,

"NB. Doses are not titrated to body weight".

The alarmist note in the Draft Report should either be deleted or qualified by reference to the fact that the cyclosphosphamide component of the GBA is approximately $1/10^{th}$ of "safe" levels used in other conventional therapies. Dr Holt advises he uses 2.5-5 mg as this dosage avoids epilation (hair loss).

The other components of GBA are benign because they are all present in living human bodies. (Dr Holt advises that cyclophosphamide is the only cytotoxic compound which inhibits anaerobic glycolysis (the energy source of cancer (glucose burnt without oxygen) – Reference K Wight, D Burk, M Woods, L Lane. National Cancer Institute Bethesda, MA, USA. "Inhibitory action of cyclophosphamide in vitro and in vivo on tumour respiration and glycolysis." Proceedings of the American Association Cancer Research 1960 (3) p162 et seq).

- In chapter 3 under the heading "Regulatory and Reimbursement Status in Australia" two statements are made relevant to TGA and HIC issues that are prejudicial.

Firstly the proposition is advanced that microwave equipment used in a therapeutic context is regulated as a medical device by the TGA under various Commonwealth legislation. The Draft Report notes Dr Holt has not notified the TGA of his UHF equipment or of any medical trials involving the device. The suggestion is that Dr Holt is operating unlawfully. Given the very low radiofrequency applied by Dr Holt he was unaware the UHF machine that he designed and built had to be registered with the TGA. He will rectify this immediately. Hopefully by the time the Draft Report is finalised this matter will be resolved.
It should be noted and recorded that Dr Holt's UHF machine is checked annually for radiowave compliance.

It should also be noted that Dr Holt is not conducting clinical trials using the UHF machine.

Secondly a statement is made that "the microwave procedure itself is currently not listed on the Commonwealth of Australia Medicare Benefits Schedule (MBS) for public re-imbursement".

To be accurate and informative the Draft Report should state that of the cost ($6,550.00);

- $2,251.60 is rebatable (for initial and repeat consultations and for cytotoxic chemotherapy); and

- of the balance $4,298.40 up to 80% may be rebated under the new "safety net" arrangements.

The HIC is well aware of Dr Holt's treatment and has paid rebates for it for many years.

- In Part 1 of Chapter 4 under the heading "Mortality" a reference is made to 5 deaths, 3 involving patients of Dr Holt's who had been receiving UHF/Radiotherapy.

These deaths are not put in a fair context, either in the context of the total number of patients treated by Dr Holt (11,500 or more) or the context of deaths occasioned by conventional cancer therapies. It is noted at page 62 of the Draft Report that "Mortality associated with microwave therapy should be considered in the context of the disease prognosis and the mortality associated with other treatment options", however no information is provided to inform the conclusion that mortality from UHF is insignificant when compared to conventional cancer therapies.

- Additionally, under the heading "Safety Summary" (Part 1 of Chapter 4, page 74) broad statements are made that largely relate to the application of microwave intended to induce hyperthermia, as distinct from UHF. No distinction is drawn between treatments involving hyperthermia and those that don't. Additionally and most relevantly no mention is made in the Draft Report about the safety warnings and disclosures provided to patients of Dr Holt. At page 75 the Draft Report states,

  "Safety concerns are not insignificant and should be clearly articulated to patients".

  Appendix 8 to the Draft Report sets out a copy of the information provided by Dr Holt to patients but oddly no mention is made of this fact in the body of the Draft Report.

- At pages 9 and 18 the Draft Report states the Review Committee had hoped to receive submissions from Patients that they were informed the safety issue. It is noted that the NHMRC Invitation to Make Submissions (refer Appendix 4 of the Draft Report) did not mention or require comment or input on this issue. Patients were simply unaware that the Review Committee required input on this topic.

2.3.1 Accuracy Issues re Description of UHF Treatment

In several sections in the Draft Report it states that there is a waiting time of 30 minutes after the administration of the GBA's to the provision of UHF. This is not correct. The optimal timing is an interval of between 10 – 20 minutes or shorter, when possible.

2.3.2 Patent/Confidentiality Issues

Dr Holt has patented the GBA/UHF treatment in Australia, England, New Zealand and Europe.

I attach a Schedule of Patent particulars as Annexure C.

As you will appreciate it is not appropriate for the Report to recite the name and amount of the GBA ingredients.

Please delete this part of the Draft Report.

Additionally could you please advise the names of the principals of Health Technology Analysts Pty Ltd and the names of the key researchers who carried out the literature search.

As you will appreciate, given the history of Dr Holt's relationship with the "traditional" oncology sector in Australia it is important that Dr Holt is satisfied he is being reviewed impartially.

2.4 The Non-Referral/Non-Disclosure Issue

In 2.4 I refer obliquely to the unhappy relationship between Dr Holt and the oncology community.

I note the Draft Report records 77 of 293 submissions were assessed to be irrelevant on the basis they either requested information concerning Dr Holt's treatment or his contact details.

This speaks loudly of the tacit collusion within traditional medical ranks to keep Dr Holt's treatment and successes under wraps. It is unfortunate that the Australian community has to rely on a current affairs program aired on television to learn about the UHF therapy provided by Dr Holt.

This makes it all the more critical that the final Report and Report are accurate, fair and comprehensive, addressing UHF and UHF/Radiotherapy.

3 Executive Summary

To ensure procedural fairness to Dr Holt could you please provide him with a copy of the executive summary a reasonable time prior to provision of the final form Interim Report to the Minister.

I assume the Draft Report has been provided minus a draft executive summary in order to enable the Review Committee to factor in Dr Holt's comments on the balance of the Draft Report.

4 Dr Holt's Preparedness to Assist /Co-operate with Clinical Trials

As mentioned at the outset Dr Holt will retire from practice in June this year.

He has instructed me to advise the Review Committee that he is prepared to make his UHF machine available for use in clinical trials if that is a Report Recommendation.

Alternatively he is happy to assist in locating and procuring a state of the art UHF machine for use in such trials.

5 Concluding Comments

I trust the Draft Report is revised to take account of the various matters raised in this letter.

I am providing a copy of this letter under cover of a short enclosure letter to the Honourable Tony Abbott, Minister for Health and Ageing. The intention is not to embarrass the NHMRC or the Review Committee, rather to alert the Minister to the fundamental, threshold issues outlined in 1 above that require Ministerial guidance prior to finalisation of the Interim Report.

On behalf of Dr Holt, thank-you for the opportunity to make a submission on the Draft Report.

Yours faithfully

J Pickworth

cc The Honourable Tony Abbott
Minister for Health and Ageing

Phil Callan
A/g Director
Health Advisory Section
NHMRC

Annexure A

TRANSCRIPT FROM NHMRC MEETING 8 JANUARY 2005

JENNY PICKWORTH
Helen can I suggest, given that timing is tight and resources, presumably, are fairly limited, having listened to all of this, it seems to me is it worthwhile spending finite resources examining 100 cases or files of John's using his limited treatment as distinct from prioritising the examination of the 100 cases that are kept at his old practise? It seems to me – you know – that should be the priority. Looking at the, quite frankly the treatment that John recommends but isn't able because of his circumstances, to provide.

HELEN ZORBAS
That causes me a little bit of anxiety actually because we've got to – you know, 300 patients a year coming here receiving a treatment...

JENNY PICKWORTH
Yep. Yes.

HELEN ZORBAS
....that I think we also need to investigate.

JENNY PICKWORTH
Ok

HELEN ZORBAS
I think that is most important and I have no problem with investigating the preferred treatment as well....

JENNY PICKWORTH
Alright. Yes.

HELEN ZORBAS
But I think we have a case where a certain number of people are coming here on the premise of the effectiveness and safety of the treatment and we need to investigate that.

JENNY PICKWORTH
Although I suppose where I'm coming from is ...look, quite frankly John might have 6 months of working life left. So my concern is, you know, the future viability and so where do we direct and prioritise our resources and I must admit I think we are looking at somebody else – a new John Holt – picking this up and running with it. And that's why I'm talking about prioritising what John himself recommends as the optimal treatment as distinct from perhaps spending a lot of time examining whether, you know, we should be endorsing John continually??? limited??

HELEN ZORBAS
I think there is a couple of questions there. We have to look at the past. We're committed to doing that.

JENNY PICKWORTH
But radiotherapy has moved on a hell of a long way since then as well. So I don't know that you could necessarily transpose those results to today.

HELEN ZORBAS
Ok.

JENNY PICKWORTH
So I think we'd have to be very careful about the interpretation of the findings and today this is what we've got to look at.

ASSOC. PROF JOHN BOYAGES
But I guess, you know, as a concurrent process – I'm just clearing it up in my head – it does worry me - you know I guess all of you are worried about how many years have we got left, you know. We've got all these years of research, you know, we haven't got protocols documented well. We haven't – you know, can you have a writing process that says in the ideal world this is how I would do it? You know, if I was to set up a department, lets say where I work at the North West of Sydney, how would you do it. How would you set it up? How much space do you need and where – you know, where does the room have to be situated, next to a bunker, close to a bunker? It doesn't look that complicated, a bed bay and a room but you know, how would we create that? If we gave you a million bucks to create another one, how would you do it?

BILL MACHAM
I've done some work on that.

ASSOC. PROF JOHN BOYAGES
Have you?

BILL MACHAM
Yes. You'd have 6 or ---MEV & LINACS In the back room, in the bunker and 2 UHF therapy rooms or more down below, or next to it, adjacent...

ASSOC. PROF JOHN BOYAGES
Allocated. Yep.

BILL MACHAM
...and it's a very simple thing.

ASSOC. PROF JOHN BOYAGES
Where would you get the equipment from?

BILL MACHAM
I've already researched this. There is an Italian manufacturer and some in Germany. There is digital technology upon us now, the equipment we have at the moment is valve final amplifiers and there are digital ones around and you can do meticulous control of the output of your transmitter. You can phase it,

HELEN ZORBAS
But I'm looking at recent cases too, that's the reason.

DR MICHAEL HOLT
Yeah I know, but what – as I say my submission was to try and just catch your interest to such that someone can research it and say there's got to be an explanation for this and that's what I think we really have to do.

HELEN ZORBAS
So what your saying is not a patient trial?

DR MICHAEL HOLT
Well no, a patient trial – a prospective patient trial now...

HELEN ZORBAS
Yes

DR MICHAEL HOLT
...and if a report comes out that's looking at 100 consecutive patients and they all die, and everyone says well this is bloody useless then I think we've done my father a great dis-service and that's my worry. Because that's how committees work.

HELEN ZORBAS
But with due respect, how would you establish the case for conducting a trial otherwise.

DR MICHAEL HOLT
Well as I say, take a tumour like the pancreas – it's universally fatal.

ASSOC. PROF JOHN BOYAGES
But I guess what we're thinking is okay, lets say we've got 200 cases – what I'm hearing is it will be - particularly the radiotherapy group – there will be, you know, some good responses there and I'm getting the sense that you are getting phone calls of benefit. If we do 100 consecutive cases and there is no response, I don't think you – do you doubt that there will be – I mean your gut feeling is that there would be some responses in 100 cases where they had ...

DR MICHAEL HOLT
Well there should be sure, but as I say, the difficulty is – I mean if you looked at 100 sequential cases of say, an oncologist, you might end up with 100 dreadful results and if you put the same – it gets back to what Jenny was asking earlier about the parameters – if you compared say, this to chemotherapy treatment, if you had 100 sequential chemotherapy patients you'll have some that died of cardiac failure, you'll have some that died of respiratory fibrosis, you'll have some that died of renal failure, you'll have some that have nerve palsys, you'll have open wounds with fungal infections that may kill them and I worry, as I say, that we end up with a report that killed

us 30 years ago. And I remember those times as a second year medical student when the scales opened my eyes and I realised that doctors weren't a band of brothers pushing together against this disease. When your father is accused of witchcraft on the telephone when you're trying to have your evening meal its hard and if that happens again then it's a tragedy.

HELEN ZORBAS
I want to, sort of, re-iterate that we are trying to find the most objective way of going forward that will meet the criticism perhaps that may be levelled at us in our work and you in your work. I mean, we need to find a way that is going to be mutually agreeable and that is transparent. I think that's most important.

JENNY PICKWORTH
Look, from what I am hearing – detecting there, will be appropriate balance – put 100 cases with the dual modality, 100 with the single modality, you examine the 39 – I can't remember what sort of cancers they were ....

DR MICHAEL HOLT
Bladder.

JENNY PICKWORTH
...bladder and you know you have the benefit of the 15 testimonials of those, quite frankly, spectacular results. You are seeing a balance. What I'm also hearing is that in real terms, you won't have time to have analysed and collated and concluded the clinical prior to the submission of your report.

HELEN ZORBAS
No. No way.

JENNY PICKWORTH
So I see that as a positive in that it is a staggered approach and I think that is extremely good. It means it will be slow and thorough and considered and I think if John is confident that that is going to be the approach – very much one of balance and thorough consideration, we're not going to see.....

HELEN ZORBAS
We have nothing to gain by not taking that approach.

DR MICHAEL HOLT
Thank you.

JENNY PICKWORTH
John?

DR JOHN HOLT
Fine.

JENNY PICKWORTH
So on that basis then John I think, is agreeable to the 100 and you're provided with the balance of the 39...

ASSOC. PROF JOHN BOYAGES
Just with Michael's point about the random – consecutive patients. Are you able to extract from your records of 100 bladder cases for example? Is that possible?

DR JOHN HOLT
No...

NIKKI HILLMAN
I doubt we'd have that many.

DR JOHN HOLT
...no I haven't got that many.

ASSOC. PROF JOHN BOYAGES
Right. I presumed because a lot of our cases are now bigger than the threshold.

DR JOHN HOLT
When I was using x-ray therapy in the Institute of Radiotherapy we did an awful lot.

ASSOC. PROF JOHN BOYAGES
You couldn't find 30 bladders here and 30 bladders there? No.

NIKKI HILLMAN
Maybe.

Lots of talking amongst each other. Voices overlapping – indiscernible.

DR JOHN HOLT
As I said to ... this is an alternative method which I am using because I have been excluded from conventional. Therefore in my opinion if you want to do any research, you should not do it on glucose blocking agents.

ASSOC. PROF JOHN BOYAGES
We'll acknowledge that in our report.

JENNY PICKWORTH ?
But you still acknowledge that it's effective.

DR JOHN HOLT
Well its effective when nothing else can be done in some cases. It's not universally effective, don't get me wrong. But when you're using x-ray therapy with the sensitisation beforehand, it can kill 10,000 more cancer cells for the same dose of x-rays. You've got a tool which is world-beating.

JENNY PICKWORTH
Could I also ask the Committee that perhaps they might consider it appropriate to make a comment on the state of the patient on presentation to John. In other words, I think that that could be quite a distinctive marker between the state of patient on presentation to traditional oncologist/ radiotherapist and perhaps that might be something appropriate for comment. In other words, these people are coming here at last dire stage.

HELEN ZORBAS
That would be part of the ....

MALE
That's fair ... I think – I hope that will provide Michael with some reassurance as well that 100 patients that have no other treatment approaches left, even if 5 per cent of them had improvement in their quality of life for 2 months, that's still a significant benefit. You know, when there's no other treatment options. We're not looking for 100 cures.

JENNY PICKWORTH
Because I think that is a very significant aspect of John's practice.

ASSOC. PROF JOHN BOYAGES
Its end of the line stuff.

MALE
And that will clearly come through from the audit of 100 patients.

DR JOHN HOLT
Fair enough.

JENNY PICKWORTH
All right?

DR JOHN HOLT
Yep, sure.

JENNY PICKWORTH
I hope you're satisfied.

HELEN ZORBAS
We really again want to say thank you for the opportunity of coming personally to meet with you and your team and to view your premises and appreciate you for making that offer.

DR JOHN HOLT
Thank you all for coming. I appreciate it.

MALE
Thank you.

you can measure many, many, many parameters instantaneously and log it. And we were talking about this fluorescence and the collected power from a tumour. You can instantaneously log – as you sweep over the patient, you can measure their reflective power as you go down the body and this is one of the techniques we discussed earlier. By minimising that reflective power when targeting the tumour, you can measure your results quantitatively.

ASSOC. PROF JOHN BOYAGES
My trouble....

BILL MACHAM
And its cheap. The UHF part of it is cheap. The LINAC may be not but the UHF part of it is.

ASSOC. PROF JOHN BOYAGES
Relatively cheap? What do you mean by cheap?

BILL MACHAM
Because they are TV transmitters and because they are everywhere – cheap.

ASSOC. PROF JOHN BOYAGES
But what do you mean by cheap? Just something in the air, what are we talking about? $20,000? $50,000? $100,000?

BILL MACHAM
Oh no, keep going.

ASSOC. PROF JOHN BOYAGES
$500,000?

BILL MACHAM
Oh yeah, between half a mil and a mil.

ASSOC. PROF JOHN BOYAGES
That's cheap?!

BILL MACHAM
I mean, oh yeah, we've put it in a room and we've put it together and etc.

HELEN ZORBAS
Sorry we've got planes to catch so we only have to wind up. Is there anything else anyone wanted to say?

DR MICHAEL HOLT
I would just like to re-iterate looking at 100 patients here and 100 patients there – I know what the problem is and I know that as you say we've all got cases where there has been ... and all the rest of it. My worry is that if we're looking at the past cases, we are looking at the past, then we are not going to progress this forward and I think what...

ASSOC. PROF JOHN BOYAGES
Thank you.

JENNY PICKWORTH
Helen, just in conclusion. Just to confirm if you would provide John with copies of the selection criteria for the documentation search and it would be very helpful I think, in terms of John's capacity to assist the draft report if, when that list was available – and assuming it is available prior to your draft report, that could be provided to John.

HELEN ZORBAS
The list, sorry?!

JENNY PICKWORTH
There was going to be a.....

MALE
Search Strategy

JENNY PICKWORTH
....search strategy.

HELEN ZORBAS
Oh the search strategy is known now. We've got that.

ASSOC. PROF JOHN BOYAGES
You mean the list of references and that.

JENNY PICKWORTH
The list of references, when that is compiled and available, if John could have that as well. Because presumably that would be appended to the draft report and I am just trying to make a point that staggered presentation to John in digestible chunks makes it easier.

ASSOC. PROF JOHN BOYAGES
What you're saying is that if he can, you know, read that bit....

JENNY PICKWORTH
Yep.

ASSOC. PROF JOHN BOYAGES
...when he is on holidays or wherever.

HELEN ZORBAS
I just have to be careful that we've completed that bit.

JENNY PICKWORTH
Yes.

HELEN ZORBAS
I could only pass that on once the Committee was satisfied that..

JENNY PICKWORTH
Yes. Okay.

HELEN ZORBAS
Again, thank you.

JENNY PICKWORTH.
Okay thanks very much.

Annexure B

From: "Jenny" <bowman@bigpond.net.au>
Subject: **Fw: Dr John Holt**
Date: 4 March 2005 1:26:01 PM
[redacted]
Reply-To: "Jenny" <bowman@bigpond.net.au>

----- Original Message -----
From: Jenny
To: philip.callan.@nhmrc.gov.au
Sent: Tuesday, January 11, 2005 3:33 PM
Subject: Dr John Holt

Dear Dr Zorbas,
(c/- Mr P Callan),

The purpose of this email is to record what was agreed at Saturday's meeting:

1. Your committee will provide Dr Holt with a copy of the criteria for the literature review and (as soon as it is complete) a copy of the results of that review;
2. Your committee will provide Dr Holt with a copy of its draft report to the NHMRC in late February (and will provide it to him by email if he is overseas at the time)and give Dr Holt one week (minimum) to make comment on the draft;
3. Dr Holt will allow your committee to access the complete medical records for a consecutive series of 100 patients treated during 2001/2002 **Provided;**

- your commitee provides the resources to access and examine those records and undertakes to maintain the contents of the records confidentially and only to report in connection with those records on a patient de-identifiable basis;
- your committee simultaneously accesses and examines the complete medical records for;

  a consecutive series of 100 patients treated by Dr Holt at his former private practice using the dual modalities of UHF and Radiation ;
  Dr Holt's selection of his best clinical outcomes;and
  the 39 bladder cancer patients referred to by Dr Holt at Saturday's meeting.

As discussed it is important for Dr Holt to see that the Committee is taking a careful, balanced approach to the assessment of his clinical outcomes over time .
It is acknowledged that the Committee has agreed to look for and note any factors of significance to clinical outcomes (eg a trend of patient referrals as a last resort ; palliation effects of UHF treatment etc).

Dr Van Hazel's inclusion on the Committee remains of some concern. There is some reason to believe that Dr Van Hazel has criticised Dr Holt's treatments and sought to persuade patients against seeking treatment from Dr Holt. It would be appreciated if you could seek an assurance from Dr Van Hazel that he has not acted in this way
I have checked with Dr Holt's office staff and they advise their records indicate Dr Van Hazel has never referred a patient to Dr Holt. I accept this, of itself, does not necessarily indicate a bias against Dr Holt.

On a personal note, thank you for your graciousness and professionalism on Saturday.Given the 1975 NHMRC report on Tronado Dr Holt was (understandably) very wary of the current enquiry and your committee. I think he was very comforted on Saturday to see that he is dealing with with open, fair minded, fellow professionals.

Kind Regards,
Jenny Pickworth.

Annexure C

SCHEDULE

Patent Applications

APPLICATION NUMBER	DATE FILED	SUBJECT MATTER
GB 0326870.3	18 November 2003	Therapeutic methods and compositions for use therein
GB 0407993.5	7 April 2004	Therapeutic methods and compositions for use therein
GB 0418363.8	16 August 2004	Therapeutic methods and compositions for use therein
AU 2004231179	17 November 2004	Therapeutic methods and compositions for use therein
EP 04257119.0	17 November 2004	Therapeutic methods and compositions for use therein
NZ 536659	18 November 2004	Therapeutic methods and compositions for use therein

SIGNED as a Deed by the said John Alfred Gorton Holt: John Alf. Holt

In the pres[redacted]

Name:

Address:

SIGNED as a Deed by the said Mark Rowan Gorton Holt:

In the presence of:

Name:

Address: