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INDEPENDENT COMMISSION AGAINST CORRUPTION

THE HONOURABLE DAVID IPP AO QC

PUBLIC HEARING

OPERATION CHARITY

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TRANSCRIPT OF PROCEEDINGS

AT SYDNEY

ON FRIDAY 25 MARCH 2011

AT 11.05AM

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MR ALEXIS: Commissioner, as I indicated yesterday afternoon that's all of the questions that I wish to ask Ms Lazarus. I understand Ms Furness wishes to ask some questions and as indicated Ms Soars wishes to ask questions.

THE COMMISSIONER: Yes. Ms Lazarus, could you return to the witness box.

10 <SANDRA SYNTHIA LAZARUS, on former oath [11.06am]

THE COMMISSIONER: Yes, Ms Soars.

MS SOARS: Commissioner, could I just indicate that I have just informed my learned friend that we require Mr Radulovic I think his name is.

THE COMMISSIONER: You require?

20 MS SOARS: We request his presence for cross-examination - - -

THE COMMISSIONER: Mr who?

MS SOARS: It's the statement that we were given yesterday evening when I reserved my position on as to whether we'd need him to ask questions.

THE COMMISSIONER: And why do you need, what is there that's controversial about his statement?

30 MS SOARS: Well, Ms McGilligan gave evidence that she took Ms Lazarus to the security office in November 2007 and a security pass was issued. Ms Madunic gave evidence that she conceded that it's possible that that could've occurred notwithstanding that other documentation which she completed in April had not been completed. I wish to ask him some questions about whether it's possible that that date of 5 August, 2008 is an updated date to reflect different information being put into the system such as to reflect that Ms Lazarus is now recorded as a doctor for some reason in

40 THE COMMISSIONER: There is a difficulty that we intend to finish today
and there are two more witnesses to be called.

MS SOAPS: Yes, Commissioner, the statement of

THE COMMISSIONER: I don't know whether he's available. Is he available today?

MR ALEXIS: Commissioner, can I just indicate that I was told this at a minute past 11.00 when I walked into the hearing room. Can I just say, Commissioner, that the tender of Mr Radulovic's statement arose following Ms Lazarus' denial of the date of issue of the ID security pass which the screen print from the computer information confirms in Exhibit 127. A short background, of course, is that when Jessica Lazarus was cross-examined on the same document she accepted without question that it reflected the date of issue of her pass which was 14 July, 2008. So in response to the apparent denial of this and having tendered Exhibit 127 I

10 then tendered Mr Radulovic's statement Exhibit 133. Now, the statement is dated 11 February, 2011 it's obviously been in our possession since then but until the matter was put in issue it wasn't material for me to tender the statement. It was provided to my learned friend after we concluded yesterday with an invitation to let me know whether or not Mr Radulovic was required for cross-examination and we're told at 1 minutes past 11.00. Now, the short answer to your question, Commissioner, as to his availability I'm unable to say, we're making inquiries but - - -

THE COMMISSIONER: All right. Well, make an inquiry but what is the
20 explanation, Ms Soars, for waiting so long before - - -

MS SOARS: Commissioner, I think I told Ms Furness at quarter to 11.00, that's not much earlier, and I can't get access to Mr Alexis after I arrive because the door is locked. I could've, Ms Daly has said to me I could've rang - - -

THE COMMISSIONER: What about last night?

MS SOARS: I didn't get instructions last night, I'm sorry. Ms Lazarus
30 lives in, - - -

THE COMMISSIONER: I have no idea what - - -

MS SOARS: - - - in Penrith - - -

THE COMMISSIONER: What has instructions got to do with this? This is a legal decision, it's got nothing to do with her, it's your decision.

MS SOARS: Commissioner, I made that in conjunction with my client this
40 morning in conference - - -

THE COMMISSIONER: She can't decide who has to be called, you decide.

MS SOARS: I did decide after having a conference with my client this morning.

THE COMMISSIONER: What's she got to do with it, you heard the evidence.

MS SOARS: Commissioner,

THE COMMISSIONER: You're in the best possible position, you could've at least, anyway.

10 MS SOARS: Commissioner, I can only say that I, in my submission it's unfair. The statement having been dated 11 February - - -

THE COMMISSIONER: Well, you've heard, I don't want to hear it. I mean - - -

MR ALEXIS: Commissioner - - -

THE COMMISSIONER: - - - you heard the explanation for that.

MR ALEXIS: Commissioner, we - - -

20 MS SOARS: It's no explanation, Commissioner. In my submission - - -

THE COMMISSIONER: But the matter was an issue.

MS SOARS: - - - it is as to why the question wasn't asked earlier. My good client has been in the witness box many times.

30 THE COMMISSIONER: The matter was not an issue. You could have, there are many ways in which you could have informed the Commission earlier last night or early this morning and, and I mean, the excuse that you had to actually get instructions I find odd, on a matter that is purely a legal, a matter of forensic issue. It doesn't involve her in any cost. It doesn't involve her in any aspect of the matter that concerns, that could prejudice anything she has said. It's a pure forensic decision.

MR ALEXIS: Commissioner, could I - - -

40 MS SOARS: Commissioner, if I could just address that. In my submission I needed to get instructions from my client as to whether she had any explanation as to why the dates were so and what questions - - -

THE COMMISSIONER: Well she was asked that in the witness box.

MS SOARS: - - - and what questions could be put to Mr Radulovic. And I got those instructions this morning, Commissioner.

THE COMMISSIONER: Yes.

MS FURNESS: Commissioner, I anticipate having instructions direct from Mr Radulovic and in the very few minutes available, those instructing me have ascertained he'll be available at 2.00pm this afternoon.

THE COMMISSIONER: Yes. But I won't be. I won't be available until 2.15 and I have to stop at 12.45 and we've got two witnesses to call.

MS FURNESS: It's a matter entirely for you, Commissioner.

- 10 THE COMMISSIONER: But I am grateful to you for finding that out. Thank you.

MR ALEXIS: Could I just, and this may, and the answer to this question may help. Could I ask my learned friend to identify to what issue this witness is required for cross-examination. Exhibit 133 contains the evidence of this witness, who I should say is the Acting Manager of Security Services for the Northern Hospital Network Randwick Campus. And he attaches what's described as a screen dump from the security computer system which is the document that became Exhibit 127. And
20 based on that document in paragraph 16, he says Ms Lazarus was issued with a photo identification card from the Campus Security Service on 5 August, 2008. He then goes on to talk about when it was revoked. Now in paragraph 18 of that statement he says Ms Lazarus was listed as a doctor within the Royal Hospital for Women, but was given access to all clinical areas. Now when one looks at the computer screen dump attached to the statement, there doesn't appear, unless I've missed something, to be any express reference to the description doctor. It may be that what's said in paragraph 18 of the statement is based on something that isn't reproduced as an attachment to the statement. Although I've just had attention drawn to a
30 reference that might support what's said in the statement, but if that's the issue to which there is concern, then I won't paragraph 18 of the statement, because - - -

THE COMMISSIONER: Paragraph 18?

MR ALEXIS: Yes. It's the paragraph that refers to Ms Lazarus being listed as a doctor.

- 40 THE COMMISSIONER: Yes, but it also refers to her being given access to include all clinical areas.

MR ALEXIS: I'm sorry, what I meant was I won't read the reference to being listed as a doctor.

THE COMMISSIONER: Yes.

MR ALEXIS: Because it's really not germane to what the purport of this evidence is. The purport of the evidence is to identify as a matter of record

as distinct from a matter of recollection, which is what was, which was what
Ms McGilligan's evidence was based on and Ms Madunic's evidence was
based on. But as a matter of record we have the date. Now is it to be
suggested that the computer screen dump is wrong? Is it to be suggested
that in some way there's been some error made as to this document actually
relating to the security records of the hospital? Now if that proposition is
put, it should be understood as, we should understand that now. And if
that's seriously an issue then we'll make arrangements for this witness to be
available. But if the concern is really about the description of document in
10 paragraph 18 - - -

THE COMMISSIONER: I understand.

MR ALEXIS: - - - then I will not read that sentence and (not transcribable)

THE COMMISSIONER: Well, Ms Soars, what paragraphs of Mr
Radulovic's statement are challenged?

MS SOARS: I didn't hear the last, challenged. I wish to ask him some
20 general - - -

THE COMMISSIONER: No, what paragraphs - - -

MS SOARS: 16.

THE COMMISSIONER: - - - are challenged? Now, what part of paragraph
16 is challenged?

MS SOARS: The date.

30 THE COMMISSIONER: Is it denied that she was issued a photo
identification - - -

MS SOARS: Yes.

THE COMMISSIONER: - - - card on 5 August - - -

MS SOARS: Yes.

40 THE COMMISSIONER: - - - 2008?

MS SOARS: Yes. On my instructions it was issued in November 2007.

THE COMMISSIONER: Mmm, she said that.

MS SOARS: I understand, Commissioner, but I haven't had an opportunity
to put to Mr Radulovic the, what Ms Madunic and Ms McGilligan say - - -

THE COMMISSIONER: All right. I know you haven't.

MS SOARS: - - - and ask for an explanation as to whether - - -

THE COMMISSIONER: Ms Soars, I just want to get on with this.

MS SOARS: Thank you, Commissioner.

10 THE COMMISSIONER: I understand that. Just tell me what other paragraphs there are. What other issues there are? That's 16 you challenge, yes, what else?

MS SOARS: I wish to ask him some questions about 18.

THE COMMISSIONER: What do you challenge in 18?

MS SOARS: I wish to question whether she might have initially been listed as a student and then her status changed following - - -

20 THE COMMISSIONER: Are you challenging that she was listed as a doctor?

MS SOARS: I'm trying to understand the basis for that, it's not clear from his affidavit or the attachment.

THE COMMISSIONER: The documents here are littered with statements emanating, could only emanate from your client to the effect that she called herself a doctor so what's the point of this?

30 MS SOARS: Commissioner, well, Commissioner, this, the date is a serious matter and - - -

THE COMMISSIONER: Please don't repeat yourself. I just want to know what the other allegations are that you challenge?

MS SOARS: Well, well, I want to understand how, how it is that it was listed as doctor and - - -

THE COMMISSIONER: How it is that - - -

40 MS SOARS: Well, how - - -

THE COMMISSIONER: All right. Anything else?

MS SOARS: No, those are the two matters.

THE COMMISSIONER: Those are the two matters. Well, you know, Mr Alexis, do you want, what do you intend to do?

MR ALEXIS: Well, my learned friend says that the date on the record in is in issue following her client's denial and if she wants to cross-examine on the document in relation to that issue well, you know, she ought to be given that opportunity subject of course to the ability to get him here and we'll do our best to get him here this afternoon.

THE COMMISSIONER: Yes. Now, Ms Furness, you wish to - - -

MS FURNESS: I could, I can have him here at 2 o'clock. Is that what is
10 desired? 2.15.

THE COMMISSIONER: Have him here at 2 o'clock. Did you hear, I'm sorry, I spoke softly?

MS FURNESS: I did hear that, thank you, Commissioner.

MR ALEXIS: Thank you.

MS FURNESS: Commissioner, do you propose to - - -

20 THE COMMISSIONER: Yes, you are still under your oath, Ms Lazarus, and the section 38 order continues to apply to you?---Yes.

MS FURNESS: Thank you, Commissioner.

Ms Lazarus, in 2008 and 2009 you described your occupation as medical researcher, is that right?---Yes.

30 And at that time your qualifications were a Bachelor of Medical Science from the University of Western Sydney?---That's correct.

Did you hold any other formal qualifications?---Yes, a Masters in Computer Science.

And did you attain that?---I can't recall the exact date. I think it was 2002.

Thank you. Now, in 2008 and 2009 your evidence is that you carried out various clinical trials and pilot studies using the Medex device. Is that right?---Yes, that's correct.

40 Did you carry out any trials or pilot studies using any other device during that time?---In 2008 and 2009?

2008 and 2009?---No.

Now you had training in the use of the Medex device, did you not?---Yes, that's correct.

And you understood that its use could be considered in the area of a screening tool for various different types of cancer at different sites in the body. Is that right?---That's what it was outlined by Medex Australia.

And you understood that as a screening tool it, its use was in determining whether or not a patient may have indications of the presence of cancer that could require further investigation?---My understanding was based on documentation provided by Medex Australia.

- 10 And your understanding was to the effect I've just asked you?---Roughly but based on - - -

THE COMMISSIONER: Roughly, what does roughly mean?---That means based on reading journal articles that Medex Australia provided, hadn't conducted any trial myself.

MS FURNESS: You also understood, did you not, that to determine as a matter of diagnosis whether a patient had cancer at any site in the body a biopsy was necessary?---Sorry?

- 20 You understood that to determine whether there was presence of cancer in any site in a patient's body a biopsy was necessary?---Not for - - -

You knew that the Medex device was a screening tool but to properly diagnose the presence of cancer a biopsy was needed?---That's not correct.

In relation to cervical cancer you understood that a biopsy was necessary to diagnose cancer?---That's not correct. There are other screening methods.

- 30 Well, you understand there's a difference between a screening method and a diagnosis method don't you, Ms Lazarus?---Roughly, yes.

THE COMMISSIONER: Roughly? That is a word that you keep using. What do you mean by it?---Well, there are other factors that need to be looked at.

- 40 Well, I just would like you to be more accurate in your replies because the word roughly just introduces an element of vagueness that seems to be characteristic of the way in which you give your evidence?---Well, for example, I - - -

It's just an admonition to you?---Well, - - -

Just ask the question.

MS FURNESS: Thank you. Now, in order to apply the Medex device to a patient one needs to place electrodes on various parts of the body?---No.

Electrodes on the hands and feet?---No, that's incorrect.

Do you need to place electrodes on any other part of the body other than hands and feet?---That's correct. No electrodes are placed.

What do you place on the hands and feet?---It's a small device, it's a handheld and it doesn't include any electrodes.

10 Now, the purpose of doing that is to determine the possibility of the presence of cancer in the body, is that right?---Along with other disorders.

Well, let's just confine ourselves to cancer for the point of my questions today, Ms Lazarus. Do you understand that??---Yes. Can you please repeat that question again?

Well, you've answered the question, Ms Lazarus?---No, I haven't, I don't think so.

20 Yes, you did. You said cancers as well as other disorders?---Yes. But as outlined in journal articles presented by Medex Australia.

But you understand that the Medex device is not a device which can diagnose the presence of cancer, one needs to perform a biopsy in order to do that, that's right?---That would not be correct. My understanding wouldn't go as far as that, sorry.

Is that because your qualifications don't permit you to know the manner by which cancer can be diagnosed?---That would be, that's why the clinicians and supervisors are there.

30

So, in fact, you don't know one way or the other how one determines whether or not as a matter of diagnosis that cancer is present in a body? ---Sorry, you're going to have to elaborate on that question.

So you don't know one way or another whether or not cancer is determined in a body by way of biopsy only?---Again your question's very vague, I'm sorry, it's not very particular, it needs, I can't - - -

40 THE COMMISSIONER: Your question is absolutely clear?---No, it's not. Again, I will have to give a rough estimate unless you want an explanation. I do apologise.

MR FURNESS: I'm not asking for an estimate of anything, Ms Lazarus, I'm asking for your understanding?---My understanding will again have to be divided up. I cannot give you a yes or no answer that you're looking for, I do apologise.

There's no need to apologise to me, Ms Lazarus?---Yes.

Do you understand or did you understand in 2008 and 2009 that the Medex device may have been capable of screening a patient for the presence of cancer?---May have, yes.

And did you understand in 2008 and 2009 in order to diagnose the presence of cancer one needed to take further steps?---Further steps, yes, further conventional testing.

- 10 In fact the screening test, that is, the Medex device is not a diagnostic tool is it?---That's correct. For the reason why it had to be - - -

THE COMMISSIONER: The answer is yes.

MS FURNESS: Now, did you understand from your discussions with Professor Hacker that he was interested in the device to test on precancerous patients?---What I understood was that the Medex device was to be used on patients with - - -

- 20 THE COMMISSIONER: That's not the question. The question concerns your knowledge of Professor Hacker's understanding?---I can't answer for Professor Hacker, sorry.

MS FURNESS: I'm not asking you to answer for Professor Hacker, Ms Lazarus. I'm asking you of your understanding from your discussions with Professor Hacker that his interest in the Medex device was in relation to screening pre-cancerous patients?---Patients with abnormal pap smears, yes.

And patients with abnormal pap smears - - -?---Yes.

- 30 - - - may or may not have fallen in the category of pre-cancerous patients. That's right?---I'm sorry I wouldn't be able to answer that question.

Your qualifications don't permit you to understand whether or not they were pre-cancerous. Is that right?---I'm not sure what you mean by qualification. Are you saying that I can't read a pathology report or I can't make an assessment from a report? I'm sorry - - -

- 40 THE COMMISSIONER: The question is crystal clear. Your qualifications do not give you the understanding to answer Ms Furness' question. Is that your answer?---No, that would be incorrect.

Then your qualifications do permit you to answer the question do they? ---No, I've lost the question, sorry.

MS SOARS: Could it be repeated, Commissioner.

THE COMMISSIONER: Yes, Ms Furness.

MS FURNESS: Is it the case, Ms Lazarus, that your qualifications do not permit you to understand whether or not a patient presenting with an abnormal pap smear may or may not have a pre-cancerous condition?
---Reports would need to be checked.

THE COMMISSIONER: No, that's not the, that's not an answer to the question?---Sorry, I don't understand - - -

- 10 The question is whether you have an understanding or not?---Whether I understand if a patient looking at a pap report whether the patient has cancer or not? Is that what you're saying? I'm sorry - - -

MS FURNESS: I'll ask you again, Ms Lazarus?---If you're going to repeat the same question I'm not going to understand it. Sorry, like I said, can you please elaborate on that question.

No, I'm not going to elaborate, I'm going to ask you a question and I'm going to ask you to listen carefully to it and attend to the answer?---I am.

- 20 Do you understand that?---I do, thank you.

Is it the case that your qualifications don't allow you to understand whether a woman presenting with an abnormal pap smear has or has not a pre-cancerous condition?---It would to some degree.

What would to some degree? You qualifications?---That's correct.

- 30 And what is the degree that your qualifications would permit you to answer that question?---I believe it would be clearly outlined in the pap report. It would be just a simple reading that pap report. In terms of degree, I don't, like I said, that's what I don't understand your question. Are you talking about reading a report or, I'm sorry, it's just - - -

Now as part of your use of the Medex device - - -?---Yes.

- - - you understood that the task was for there to be a comparison between the results obtained by using the Medex device on the one hand. That's right?---So comparing the results obtained from the Medex device, yes.

- 40 Yes. With the results obtained on biopsy?---That's incorrect.

So you were comparing the Medex device - - -?---Yes.

- - - and the test results that were derived from it - - -?---Yes.

- - - with a diagnosis that had been obtained elsewhere in relation to the same patient?---What do you mean elsewhere?

Well either by biopsy or some other means?---Well other conventional testing methods.

Well when you say conventional, are you suggesting that the Medex device is unconventional?---It's in testing stage. That's why the clinical trials have been run.

- 10 So when you're talking about conventional devices, are you talking about conventional screening devices?---That are available in the public at the moment.

And one conventional screening device is the use of a pap smear?---That's correct.

Another is a mammogram for breast cancer?---That's correct.

And another might be a blood sample for prostate cancer?---That's correct.

- 20 And are they what you refer to as conventional screening devices?---That's correct. Yes.

Now in terms of a diagnostic test, the diagnostic test in relation to cervical cancer is a biopsy. That's right?---It depends on what stage, it's not always a biopsy.

Well a biopsy is a determinant method of diagnosing cervical cancer isn't it?---It is, yes.

- 30 Now when you are using or were using in 2008 - - -?---Ah hmm.
- - - and 2009 on your evidence - - -?---Yes.

- - - the Medex device - - -?---Ah hmm.

- - - the purpose was to compare the results from using the Medex device - - -?---Yes.

- 40 - - - with the known diagnosis of the patient?---With the known, yes, and that did not go up to a biopsy or any, it had to be just one of the three or one of the four conventional methods, depending on what type of patient it is and whether it's a pilot study or if it's a known positive that we're looking at. But - - -

You're comparing the Medex test against a diagnosis that had been obtained in relation to that same patient?---Yes, either any of the conventional testing methods, depending on the patient.

Now, in order to understand whether or not the Medex test was an effective test - - -?---Yes.

- - - you needed to test it against patients who both had a diagnosis of cancer and those who didn't have a diagnosis of cancer. Is that right?---Do you mean in terms of conventional or the Medex?

Well, I'm comparing Medex - - -?---Yes.

10 - - - to a, let's use cervical cancer for an example, to a woman who has a diagnosis of cervical cancer - - -?---Yes.

- - - and also comparing Medex to a woman who has a diagnosis that there is no cervical cancer present?---O.K. Ah hmm.

So that's the purpose of the test, isn't it?---Yes, that's correct.

And the tests that are interpreted are done so using terms like sensitivity and specificity?---Yes, that's correct.

20 And sensitivity refers to the number of false positives, doesn't it?---Yes, that's correct.

And a false positive is whether the Medex test indicates there may be the presence of cancer - - -?---Yes.

- - - but the diagnosis is that there is no cancer?---That's correct.

And that's a false positive?---That's correct.

30 And specificity is measuring false negatives?---That's correct.

And that's where the Medex device tells you that there is likely to be no cancer but the diagnosis is that cancer is present?---That's correct.

Now you need to have both in order to determine the effectiveness of the Medex device, don't you?---That's correct.

40 Because there's no point just looking at false positives, you need to also understand false negatives?---That's correct.

And how that relates to the test is that high sensitivity means a low number of false positives?---Ah hmm.

And high specificity means a low number of false negatives?---Yes.

That's as you understand it?---Can I have a piece of paper?

No?---Well, sorry, I'm mapping it out as fast as I can in my head, it doesn't, like I said, I have problems with numbers and words.

THE COMMISSIONER: It's got nothing to do with numbers?---Well, I can't imagine it.

MS SOARS: Well, perhaps the question (not transcribable) a double question.

10 THE COMMISSIONER: What was a double question?

MS SOARS: It was high sensitivity means something and - - -

THE COMMISSIONER: She's already answered this question.

MS SOARS: I don't think she did answer the question.

MS FURNESS: She did, she answered both questions. She agreed with both propositions and then asked for a piece of paper.

20

MS SOARS: Can I just ask the witness if - - -

THE COMMISSIONER: She did do that.

MS SOARS: Could I ask there's anything else she wishes to say in answer to those questions?

THE COMMISSIONER: You can do that when it comes to you to ask questions.

30

MS SOARS: Thank you, Commissioner. It would be helpful if you - - -? ---Well, my answer's just based on what Ms Furness said and (not transcribable)

THE COMMISSIONER: No one asked you to comment?---That's fine.

MS FURNESS: Now, Ms - - -

MS SOARS: Excuse me, Commissioner, in, I object - - -

40

THE COMMISSIONER: Are you interrupting again?

MS SOARS: No, I'm making - - -

THE COMMISSIONER: Now, I have limited today - - -

MS SOARS: Yes, Commissioner.

THE COMMISSIONER: - - - and I expect cooperation from counsel.

MS SOARS: I am endeavouring to do that, Commissioner, but I - - -

THE COMMISSIONER: I don't notice it very strongly.

MS SOARS: My submission is that Ms Lazarus should be allowed to answer the questions completely.

10 THE COMMISSIONER: She did answer them completely and then she said, having answered them completely she asked for a piece of paper.

MS SOARS: As, as the Commission pleases.

THE COMMISSIONER: Well, do you challenge that?

MS SOARS: I think, my submission is that she was asking for the piece of paper because she wanted to use that paper and then elaborate on her answer.

20 THE COMMISSIONER: The answer was either yes or not.

MS SOARS: The answer was put to her as yes or no but witnesses are entitled to give a full answer if it's qualified - - -

THE COMMISSIONER: For that question there is no mystery about this, these are the meanings of words that are, words that are used in the work that she alleges that she does constantly so she can, if the word, the meaning put to her is right she can say yes, if she thinks it's wrong she can say no.

30 She said yes.

MS SOARS: Commissioner, I'll deal with it - - -

THE COMMISSIONER: So what, what does she want a piece of paper for then?

MS SOARS: I haven't been able to ask her, Commissioner, and I perhaps should leave it for reply unless you would like me to ask her now?

40 THE COMMISSIONER: Certainly not. You will be given full opportunity in reply to clarify anything that you think should be clarified - - -

MS SOARS: Thank you.

THE COMMISSIONER: - - - and that's the time to do it.

MS SOARS: Thank you, Commissioner.

THE COMMISSIONER: Yes.

MS FURNESS: Thank you, Commissioner.

Ms Lazarus, when reporting on the Medex test results - -?---Yes.

- - - there is also a concept known as negative and positive predicted values, isn't there?---That's correct.

- 10 And in order to understand the negative and positive predicted values one needs to have an understanding of the prevalence of the disease, whatever it may be, in the community. Is that right?---No, that's incorrect.

Do you know that to be incorrect or do you not know one way or another? ---I'm not sure. The calculations I've used are based on diagnosing, sorry, calculating the specificity and the sensitivity for any device that's been tested and compared to conventional testing and the biostatistician that I did go to is a biostatistician that's based in the University of Sydney, her name is Professor Jenny Peat and based on her work and her book, that's how it was calculated as illustrated in the letters or the reports, sorry.

- 20 So is it the case that you looked to Professor Peat to determine what the negative and positive predicted values are?---Yes, in terms of the calculation.

THE COMMISSIONER: When you say you looked to her do you mean you read her book or did you speak to her personally?---No, no, I have several meetings with her.

- 30 MS FURNESS: Professor Peat was involved with you, in determining some test results, that's right?---In calculations from a biostatistician point of view.

And those calculations included the negative and positive predicted values? ---I cannot remember, they would have, I would touched base on them based on the information provided by a biostatistician.

- So is it the case that you left the statistics to Professor Peat?---What do you mean left it?

40 You left her to determine what the statistical analysis that was necessary to be performed was performed, you left that to her?---Why would I leave that to, sorry, I don't understand, what do you mean?

What role did Professor Peat play in determining the test results?---I was unclear as to how, I had an idea but I was a little unclear in terms of how to accurately calculate, Professor Peat is available for students, that's her role, a student, many students go to her when they need to calculate the test

results for various experiments not just for comparing tools or, there are others as well. For that reason through the university she's available. I contacted her, her name's there for people who can get help from her and things like that. I contacted her, made an appointment, she explained and gave me photocopy material of how - - -

Did she perform any calculations for you?---Yes, she showed me several calculations, of how I can calculate, how - - -

- 10 But she didn't actually calculate the results of any of the tests that you say you carried out?---The calculations were then emailed to her and there is email evidence of that, just to make sure that the calculation I was following was correct, just to verify from her I was, like I said, unclear. She is someone that's an expert in the area and hence there's email correspondence showing that.

Did she talk to you about the need for having a confidence value in determining statistics?---I cannot remember, sorry.

- 20 You can't remember one way or the other?---A what value?

A confidence value, is that something that you're familiar with?---I am not familiar with that, sorry.

Now it's the case, isn't it, Ms Lazarus, that if there were ten women who had a positive diagnosis and it was unknown to the tester if you tossed a coin the chances are that you would get half of them right?---I'm sorry, that's coin tossing, I, are you talking about probability?

- 30 About chance, yes?---Sorry, I can't answer that question, it's not on, this is not based on probability.

No, no, no, my question is about whether if you had ten women who were positively diagnosed with cervical cancer and if you tossed a coin to determine which of them had it and which of them didn't, probability or chance tells you that you'd get about half right, doesn't it?---That's the probability for anything, how many times, sorry, that's just a very weird question, sorry, I don't understand that question in terms of that. If I toss a coin - - -

- 40 THE COMMISSIONER: You understand the question very well, just give the answer?---Well, if I tossed a coin I'm going to get heads or tails, it will be 50/50 wouldn't it?

That's what, that's what Ms Furness is putting to you?---Oh, O.K. Oh, O.K. That's a coin toss. If I had a dice it'll be six out of one, sorry.

MS FURNESS: So did you understand from your discussions with Professor Peat that given the presence of chance that you would need to have a sensitivity and specificity percentage of more than 90 per cent to be confident that your test showed anything of value?---No, that's incorrect.

She didn't tell you that?---No, she wouldn't tell me that.

Did anyone else - - -

- 10 THE COMMISSIONER: Did (not transcribable) tell you that?---No, we were working out numbers, why would she - - -

Did she tell you that or did she not tell you that?---She didn't tell me that. Not that I can remember.

Well, that's the answer?---The only thing that we worked on was the calculations and simply how to calculate and there were times where we just used random numbers.

- 20 Well you answered that.

MS FURNESS: Did anyone else tell you that in order to show that the Medex device could add value there needed to be results of close to 100 per cent if not 100 per cent?---I'm sorry, I haven't worked in experiments like that. I don't - - -

- That wasn't the question. Ms Lazarus, please listen to the question. Did anyone else other then Professor Peat tell you that for the Medex device to have any value you needed to attain results of 100 per cent?---I don't recall anyone telling me that.

30 Can the witness be shown the, the proposed tender bundle that was produced by her the other day?

THE COMMISSIONER: Exhibit 1?

MS FURNESS: No. Her tender bundle.

- 40 MS SOARS: Just, could you mark it as an MFI at the moment, Commissioner?

THE COMMISSIONER: Yes. Ms Lazarus' tender bundle will be marked MFI1, I think, 2.

#MFI 2 - EVIDENTIAL BUNDLE PRODUCED BY SANDRA LAZARUS

MS FURNESS: Now Ms Lazarus, can you turn to the third tab?---Yes.

Now do you see the first document behind that tab is an email from Professor Ross Smith to yourself, beginning Hi Sandra?---Yes, that's correct.

And that's dated 23 September, 2008?---Yes, that's correct.

- 10 Now I think you were asked some questions about this email yesterday. That's right?---Oh, yes.

And you recall receiving this email?---Oh, yes.

Now do you see that Professor Smith is responding to your request to review an article you had prepared?---Oh, yes.

That's right?---Yes, that's correct.

- 20 And that was the breast journal article wasn't it?---That's correct.

And that concerned the use of the Medex device on women with breast cancer or might be suspected of having breast cancer?---That's correct.

Now if we look at the - - -

THE COMMISSIONER: I'm sorry, Ms Furness, I have, I haven't been able to find this email. Did you say it's behind tab 2?

- 30 MS FURNESS: It's the first document behind tab 3, Commissioner.

THE COMMISSIONER: Oh, I see.

MS FURNESS: I think - - -

THE COMMISSIONER: Yes, sorry.

MS FURNESS: It has page 6 on the bottom.

- 40 THE COMMISSIONER: My error. Yes.

MS FURNESS: Now do you see that Professor Smith - - -?---Yes.

- - - is saying to you in the second sentence and I quote, "I think you have to indicate that this test is not valuable as a screening test because the sensitivity was 60 per cent and the screening test needs to be 100 per cent, particularly if it so different to the usual screening method." Do you see that?---Yes, I do.

Now did you when you read that take that to mean that if your results were less than 100 per cent then the test was not valuable?---What do you mean the test is not valuable?

Well precisely that, the test was not valuable?---Well the test will still be very valuable to me from a research point of view. But if you mean the test is not valuable from Medex point of view then that's something Medex will have to, you'll have to ask Medex.

10

Did you take that sentence to mean that results of less than 100 per cent meant that the clinical trial or pilot study revealed that the test was not effective in - - -

THE COMMISSIONER: The Medex test.

MS FURNESS: - - - the Medex test in, as a screening tool?---For which disorder?

20

For any cancer in any site of the body?---I'm sorry, I'm not at a position to make that assessment. For that assessment to be made there'll probably thousands and thousands and thousands of patients that need to be screened and compared. From a researchers point of view about 80, actually more than 80, 95 per cent of researchers lead to figures that are not what everyone's looking for. Like for example, you're looking for a cure for a disorder, you're not going to find the same (not transcribable)

30

THE COMMISSIONER: But Professor Smith tells you that a screening test needs to be 100 per cent and explains why. He says in the email the risk of missing a cancer is too terrible?---That's correct.

So therefore if you have a test which shows a sensitivity of 60 per cent - - -?---Yes.

- - - for the Medex test the lab test shows that the Medex tool should not be used?---Yes, that's fine.

40

MS FURNESS: Well it also tells you, indeed Professor Smith tells you that in his opinion you have to indicate in any paper that the test is not valuable if the results are less 100 per cent. Isn't that right?---Yes, that's correct. Yes.

Did you after receiving Professor Smith's email redraft your breast cancer paper to take into account his opinion?---I would have because it would have gone back to him and when it was submitted he would have received a copy electronically through the journal it was submitted to.

Now you say you would have, Ms Lazarus, do you have a recollection of having done so?---Yes, I would have.

THE COMMISSIONER: No, no, but have you got a recollection that you did it?---Yes, I would have.

No, no, you keep saying I would have?---Yes, that, the steps would have been taken to do that for me to submit that.

- 10 Do you have a recollection of actually taking the steps?---I, I cannot recall, sorry.

MS FURNESS: In the bundle in front of you - - -?---Yes.

- - - did you include the final version of the breast cancer article, that is the version that was submitted?---Submitted to?

A journal?---A journal, I think so, yes. There is two copies.

- 20 And that final version reflects the changes that you made having read and taken into account an applied Professor Smith's opinion?---Like I said I would have but I cannot recall. If there was an error he would have pointed it out again.

Can you - - -

THE COMMISSIONER: Are you transferring responsibility on to Professor Smith again?---No, I'm not.

- 30 Everyone else is to blame expect you?---I don't think I was blaming anyone and I haven't blamed anyone.

MS FURNESS: Ms Lazarus, can you tell the Commission the page at which that final version might be found?---I'm sorry, I cannot, unless I go through the whole article and would you permit me to do so?

Perhaps I might ask for the luncheon adjournment so that Ms Lazarus, through her counsel - - -

- 40 THE COMMISSIONER: Yes, I did indicate that, well I've made arrangements so we will go on to at least 1.00 and we will start at 2.00.

MS FURNESS: Thank you, Commissioner.

MR ALEXIS: I understand it's page 18. That might be of help (not transcribable)

MS FURNESS: Ms Lazarus, can you turn to page 18?---Yes.

Now from page 17 it appears that the document that begins on page 18 was forwarded to the Pleiksna's. That's right?---Yes. Correct.

And is it the case that that was the final version of the article?---No, that's not correct.

Do you see at the top of page 18 it says submitted to the New England Journal of Medicine?---Yes, that's correct.

- 10 Does that assist you to understand whether or not it's the final version?
---No, because there was an error in my title and that needed to be corrected.
And that was done so.

What you meant you're not an MD?---That's correct.

And you're not a PhD?---Yes, that's correct.

- 20 THE COMMISSIONER: And, but the, the letter to the Messrs Pleiskna, the email - - -?---Ah hmm.

- - - says the following attachment is the breast cancer article and the submission to the journal?---That's correct. That's a draft submission.

So you're telling him, it doesn't say draft. You're sending it to him on the basis that this is what you submitted to the journals?---Yes, and the journal only takes it as a draft until it's (not transcribable).

- 30 But this is the document you sent to the journals?---That's correct. On the first occasion.

MS FURNESS: In fact, Ms Lazarus, I think it's been marked as Exhibit 51, the final version, which has you as a PhD rather than an MD and a PhD?
---I'm not sure if that's the final version.

THE COMMISSIONER: Why would you take out the MD and not the PhD if it wasn't the final version?---Like I said I cannot recall if there's another one after that, because I just don't have it in front of me.

- 40 You mean first took out the MD and left the PhD and then you thought better of it and you took the PhD out?---No. I'm just saying if there were any changes that needed to be made in the text of terms of professors or supervising (not transcribable) - - -

No, I'm asking you about the PhD and the MD?---I cannot recall.

Because there is a change from the MD, PhD to only PhD?---That's correct.

Is that the only change you ever made?---Like I said, I cannot recall. If the text needed - - -

So it's possible that you left the PhD in deliberately?---No, I'm talking about the text of the article.

Well I'm talking about the MD and PhD?---No, I would have removed it.

10 So why didn't you remove it when you removed the MD?---I just, like I said in my evidence I would have thought I would have completed it by then.

Why did you, when you removed the MD because you realised that that was wrong why did you not at the same time remove the PhD?---It was an error made by me.

What kind of an error is it where you realise that you're not an MD and take it out and right next door to it are the letters PhD and you know you're not a PhD but you leave that in?---Like I gave evidence before by the time I thought this would be published and again, I had full blessing to do so - - -

20 No, no, I'm asking, you had full blessing. You're saying you're putting the responsibility on someone else are you?---In terms of instructions given to me, it's not terms of responsibility, I could've removed it and I didn't.

So you're saying Professor Smith told you to leave in PhD thereby authorising you to make a false representation, that's what you're saying? ---It was never taken out.

That's what you're saying?---That's exactly what I'm saying.

30 So you deliberately left in the PhD knowing it was false because Professor Smith told you to do so?---He didn't tell me to leave it in, like he didn't tell me to write it in but there were no changes, he did, at no point did he point it out to remove it. He queried about it and that's when it was pointed out - - -

He queried about it?---Yes, that's correct.

40 He queried about what?---About the error that I made with the MD and PhD. He said, You must remove the, I said, I do apologise, and I removed that and the article was resubmitted.

He said you must remove what?---MD.

Not PhD?---No.

MS FURNESS: Might the witness be shown Exhibit 41? 51, sorry. Now, Ms Lazarus, you were shown that exhibit yesterday by counsel assisting? ---Yes.

Remember that?---Yes.

And you were asked whether that was the article which was ultimately submitted for publication. Do you recall that question?---Yes.

And your answer was, "That's correct. This is the article."?---Yes. But again in terms of details I had to read through the whole article to be certain.

- 10 THE COMMISSIONER: You have already given an answer under oath. Are you trying to blur that answer now?---No one's trying to blur that answer. The question is, this article is a copy, it's not a submitted copy.

You answered yes yesterday, are you now withdrawing that answer yes?---It may as well, it could have been, I'm not saying either way yes or no.

- 20 You said yes, why did you say yes yesterday then?---Yes and no answers which I'm elaborating on. Like I said this is a copy, it might be the exact copy, it could be a small change in there but I cannot be certain unless I read through the whole article and then compare to what I've actually submitted.

MS FURNESS: So is it the case, Ms Lazarus, that you wish to revisit the evidence you gave yesterday in relation to whether or not this is the article which was submitted?---I do not wish to revisit that evidence. Like I said if you would like to go through line by line and if there is a variation or if there was an update or an alteration that required there could've been an alteration in that. On face value yes, it is the exact article on face value looking at it but without reading it I cannot be 100 per cent.

- 30 You were 100 per cent yesterday?---No, I wasn't 100 per cent yesterday, I simply answered the question on the face value of the article without given the opportunity to read through it.

THE COMMISSIONER: It's your article, you produced it?---In 2009. I don't understand that everyone would remember every word they've written in 2009, people forget what they sign apparently.

- 40 MS FURNESS: Can the witness be shown Exhibit 1. Can the Exhibit 51 remain but can the MFI 2 be returned. Ms Lazarus, would you turn to page 288 of Exhibit 1.

THE COMMISSIONER: I beg your pardon?

MS FURNESS: 288, Commissioner.

THE WITNESS: Yes.

MS FURNESS: Now, 288 is a letter with Dr Kenneth Vaux's name on page 2, is that right?---Yes, that's correct.

And you've given evidence that you prepared this letter?---Yes.

And did you prepare this letter from information available to you from the tests that you say you have carried out?---In terms of numbers, yes, that's correct.

10 I'm sorry, I didn't hear that?---In terms of the numbers there, yes.

When you're talking about the numbers are you referring to the second page and the table that appears on that page and the numbers that are referred to there under?---Yes, that's correct.

The remainder of the letter was obtained from a source other than your tests that you say you carried out?---What do you mean?

20 Well, I asked you whether the source of this letter was your knowledge based on the tests you'd carried out and you said yes in relation to the numbers?---That's correct.

There is text as well as numbers in this letter?---All numbers related came from experiments.

And the text?---And the text, what do you mean, based on - - -

What's your source of information for the text in this letter?---What I drafted or - - -

30 Yes?---Just previous articles. I don't understand.

So you're general knowledge?---What do you mean? How did I come about writing that paragraph?

What was your source of information for the text in this letter?---My head.

Your head, is that your answer?---What do you mean? Sorry, I don't understand. Where did I draft that paragraph from?

40 No, not where you drafted it from, where the information that is contained - - ?---Can you be a little bit more - - -

Ms Lazarus, if you'd wait till I've finished the question I'd appreciate it?
---Sorry.

Where did the information that is contained in the text of this letter come from?---In terms of numbers?

No, in terms of the text?---In terms of the writing?

Yes?---The writing came from my understanding and small alterations made by Kenneth Vaux, Vauxan, Vaux.

Now, if you can turn to the first sentence of that letter?---Yes.

10 You refer to the Medex test as a bioelectrical impedance analysis method, do you see that?---Yes.

To accurately diagnosis symptomatic prostate cancer patients?---That's correct.

Now, it wasn't a diagnostic test was it, it was a screening test?---Either way I think you can put that.

20 You understand there to be a difference between a diagnostic test and a screening test, Ms Lazarus?---I think Kenneth Vauxan would've been in a better position to work that out.

No, I'm asking you, Ms Lazarus?---Like I said, like you pointed out I don't have the qualification to determine that.

So you don't know one way or another whether the Medex test is a screening test or a diagnostic test?---It's used to screen in terms of diagnostics. Do you mean make a final decision? I don't understand, sorry, you'll have to elaborate.

30 THE COMMISSIONER: I'm sure you know exactly what diagnostic test is?---Like you said I'm not in a position to answer that.

Why not?---Like it's mentioned I'm not qualified to, the person who received this, in this case, being Kenneth Vaux he would've been in a better position to have highlighted that error.

MS FURNESS: You accept it's an error then to call it a diagnosis, is that right?---Diagnosis?

40 Well, you said to accurately diagnose a symptomatic prostate cancer patient. Do you accept that's an error?---(NO AUDIBLE REPLY)

Is that right, Ms Lazarus?---I'm still reading that sentence, sorry. Because what you're suggesting is a little bit vague to me. I'll have to read the sentence.

Well, Ms Lazarus, you just said that it was up to Dr Vaux to correct an error in relation to diagnosis?---That's correct.

So is it the case that you believe the use of the word diagnosis in relation to the Medex test was an error?---Like I said I cannot say either way. Like it's mentioned it's a screening tool, it's used to diagnose as a secondary screening tool.

You really don't understand the difference between a screening tool and diagnostic tool do you, Ms Lazarus?---What do you mean?

- 10 Do you understand the difference between a screening tool and a diagnostic tool?---Did you want - - -

THE COMMISSIONER: Do you understand the difference or don't you? ---Again, vaguely, yes, I would have some understanding but not at the same level as Kenneth Vauxan.

MS FURNESS: So in the event that a qualified registered medical practitioner - - -?---Yes.

- 20 - - - with a specialty in oncology and in surgery was of the view that the Medex test was a screening device and not a diagnostic tool, I take it you would defer to their opinion. Is that right?---Why would I defer?

Because you don't know, you don't have the qualifications to express an opinion, do you?---Like I said, that's why every piece of paper went back to them to make sure that errors were pointed out and there would change accordingly. If that's left in then there's something he didn't pick up.

- 30 So you don't know one - - -?---You see it as an error, like you said, I'm not in a position to make an assessment.

Now, if you read that first sentence it's the case, isn't it, that there is an error in relation to the use of the word diagnosis rather than diagnose. Is that right? Do you accept that?

THE COMMISSIONER: It's just a matter of English?---Yes.

MS FURNESS: You accept that's an error?---It's a matter of English.

- 40 But you accept that's an error?---If, if, like I said, my grammar's not that correct, I'm dyslexic.

THE COMMISSIONER: Do you accept that it's an error?---If I made that error, it's an error.

And do you accept that it's an error?---It could, I can't say either way, sorry.

What do you mean? You mean you're not able to say whether the phrase "to accurate diagnosis prostate cancer patients" is an error or not?---Yes, that's an error.

Your English is so poor that you can't actually - - -?---No, no, no, it's an error, yes, I see what you mean. Sorry about that, I do apologise.

MS FURNESS: Now, with the second sentence you refer to prostate cancer patients who were pre-diagnosed, do you see that?---Yes.

- 10 Now, what do you understand to be the meaning of pre-diagnosed?---My understanding from there they were patients who were, who already had abnormal PSAs and were diagnosed accordingly.

Well, an abnormal PSA isn't a diagnosis is it?---It is a diagnosis.

You think it's a diagnosis?---That's what my understanding is.

- 20 And that understanding is based on what people have told you, is it?
---That's correct.

It's not based on your own learning or qualifications, is it?---No, that's why I relied on the supervisors, yes.

Now, the 200 patients that you refer to, whose patients were they?---The urology department at Royal North Shore.

- 30 Were they the patients of one doctor or more than one doctor?---They would have been from that clinic, they would have been underneath the supervision of Kenneth Vaux, Vaux, yeah.

Well, I'm asking you who were the doctors (not transcribable)?---There would be a number of them I suppose, yes.

Can you the Commissioner who they were?---Dr Rice, Rice, Reece.

THE COMMISSIONER: Mr Vaux, V-A-U-X, is that the one you're talking about?---Vaux, yes and Dr Rice, Reece.

- 40 Dr Rice?---Rice or Reece, I can't, again the pronunciation - - -

MS FURNESS: How do you spell it?---I wouldn't know, sorry. It's Rice or - - -

Does it start with an R or a W?---R.

Who else?---There is another medical visiting officer, I can't, cannot recall his name, sorry, and I've met on several occasions.

So that's three doctors?---That's correct.

Including Dr Vaux, is that right, Vaux?---Dr Vaux's patients are at Mona Vale.

I beg your pardon?---Dr, patient - - -

10 THE COMMISSIONER: Dr Vaux's patients are at Mona Vale?---They are, as well.

MS FURNESS: And that's included in these 200 patients?---No, I never went to Mona Vale. I have already given evidence - - -

Well, then, I'm asking you who were the doctors who had those 200 patients? You've said Dr Reece or Rice. Who else?---The visiting medical officer.

Whose name you can't recall?---I cannot recall.

20 That's two?---Yes, and there's another third one whose name I cannot recall, sorry.

So Dr Vaux was not the doctor treating any of those 200 patients?---I wouldn't be able to clearly tell you that. I believe he would be because once it does go to a certain level of diagnosis to my understanding they do become Dr Vaux's patients.

30 THE COMMISSIONER: Why didn't you mention him when you were asked the question first?---I did answer the question.

You didn't mention Mr Vaux when you were asked the doctors, you said, you mentioned three other doctors, two who you couldn't remember, one was Dr, Dr Reece or Rice, you didn't mention Dr Vaux?---You never asked to elaborate on that, you just said where, who sat in that clinic. Sorry, that's why I'm telling you, I need to be, the question needs to be divided. There is no yes, no answer and when you ask for a yes, no answer it looks like the question hasn't been answered.

40 Yes, Ms Furness.

MS FURNESS: Now, who was the physician who examined those patients for eligibility?---What do you mean?

Well, who was the physician who examined those patients to determine their eligibility to be screened?---Sorry, can you be a little bit more specific in terms of the question you're asking?

Who was the physician that screened those 200 patients to determine their eligibility for the screening by the Medex test?---Who was the physician that diagnosed that they had - - -

No?---- abnormal PSA, is that what you're saying?

No, that's not what I'm asking. I'm asking you precisely what I said. Can you answer that question?---No, I cannot answer that question. I don't understand at what stage you mean, there are several stages - - -

10

THE COMMISSIONER: Can you just find out whether she accepts that there has to be a physician who screens.

MS FURNESS: I'm coming there, Commissioner?---Sorry, I didn't mean - - -

THE COMMISSIONER: Well, I should think that has to be put first.

MS FURNESS: Do you have Exhibit 1 in front of you?---Yes, I do.

20

Can I ask you to turn to page 151?---151.

Now, that's the beginning of the ethics application?---That's correct.

And that was an application that you prepared?---Yes, that's correct.

And ultimately didn't submit?---Yes, that's correct. I was waiting for feedback from some of them still.

30

I'm sorry, waiting for?---I was still waiting for feedback from some of the professors listed.

But this was the protocol that's set out in here that you proposed to follow in the work at North Shore Hospital?---Draft.

Yes, but in terms of the draft that was what you proposed to follow?---Just in terms of draft.

40

Just turn over to page 153, do you see about the middle of the page there's "Title and Summary of Project", do you see that?---(NO AUDIBLE REPLY)

It's a bit hard to read, it's been shaded?---Oh, yes, yes, yes.

And then underneath that the formal title of the proposal?---Yes.

And then secondly the description of the project in plain language?---(NO AUDIBLE REPLY)

Do you see that?---Yes.

And then in that second box the last paragraph is study structure?---Yes, that's correct.

And it says that the chief investigator will recruit patients into the study, a physician will evaluate the participant for eligibility, do you see that?---Yes, that's correct.

10

So who was the physician who evaluated the participants, that is your 200 patients for eligibility?---That would be based on the report.

No, no, no, not based on. Who was the physician who evaluated each of those 200 people for eligibility?---Kenneth Vaux, he would have looked at all the 200 patient graphs that were being developed by Medex. I don't still understand your question.

20

Notwithstanding that Dr Vaux's patients weren't included in that 200, is that right?---He would have looked at the graphs for Medex.

THE COMMISSIONER: That's before you did the tests?---What do you mean?

This is an evaluation, evaluate the participant for eligibility means eligibility for testing?---Oh, for the Medex test?

Yes?---Thank you. I didn't understand that, sorry.

30

MS FURNESS: Well, read it, Ms Lazarus, read - - -?---Yes.

Who was the physician who evaluated the participant for eligibility? That's what it says, who was it?---That, that was based on the PSA report, that was there in the patient file. Hence the urology clinic that's there, 80 per cent of the patients are there with abnormal PSAs, but that's what it's based on.

Ms Lazarus - - -?---Yes.

The 200 patients you refer to in this letter - - -?---Yes, yes, that's correct.

40

- - - who was the physician who evaluated each of those people for eligibility into the student?---The physicians that were sitting there. They would have, it was their patients, it was their reports. It would clearly outline if they have a abnormal PSA or not. Based on that those patients were recruited.

How did they communicate to you, that is the physicians communicate to you, that they had positively evaluated a person for eligibility?---It would be

outlined in the patient file and the report that they have a patient has abnormal PSA.

So you needed to have access to the patient file before you screened any patient to know what they had been positively evaluated for eligibility, is that right?---That's not correct.

- Well, if the message was communicated to you via the patient file, that has to follow doesn't it?---That's what the report would be but like I said, the 10 patients that are there, 80 % of the patients are there with abnormal PSA's that's what the neurology clinic is there for.

So is it - - -?---It's a matter of if you walk in the clinic out of – eight out of ten patients there will have abnormal PSA, it's matter of just walking up to them with a consent form which I had been instructed to do so and ask them, "Are you here, do you have abnormal PSA?", based on that I would take the patient in. In terms of what the physician did or I'm sorry, I just don't understand what, what you're saying in terms of that.

- 20 So - - -?---And that's the exact protocol that was followed in recruiting patients for cervical cancer, breast cancer and prostate cancer.

So is it the case Ms Lazarus, that in fact you didn't have a physician evaluate each of those participants for eligibility?---No, that's correct.

That's correct.---No physician pointed out that patient's available, that patient, there was no need for them to do that.

- 30 Because you assumed by their presence in the waiting room that they had a certain condition which meant that they were eligible.---And based on a report, a pathology report.

So it's the case that the study you say you did of the 200 patients was not carried out consistently with the study structure as set out in your draft application.---That would be incorrect in terms of physician, there would be a physician evaluating the final. In terms of pointing out that's patient available that – no physician is going to do that doesn't matter what trial it is, they're just not available to do that and it's left up to the researcher.

- 40 Ms Lazarus, you indicated yesterday that it was, in your experience, common practice for trials or pilot studies to be conducted before or without ethics approval.---That's correct.

If indeed that was common practice, why did you go to the trouble of preparing an application?---You still need final approval, you need to put in an ethics application for final approval. My, my understanding comes from I believe there's a protocol that's, that's just become available and was ceased from my possession when the search warrant was executed. That

outlines in Gil Burton's handwriting in terms of the number of patients he wants for the pilot study which clearly indicates I had written in the protocol there were 50, he's crossed that out and written 20 patients for a preliminary study and underneath that he's written ethics and he's put a question mark on it, saying that there's no need, well given indication in conversation he told me, there was no need, his handwriting would indicate that also - - -

You actually didn't lodge this application did you?---This application was (not transcribable)

10

But there was no question of obtaining final approval was there?---What do you mean there was no question?

Well, you couldn't get final approval if you hadn't even lodged the application could you?---Like I said, I was still waiting for their feedback.

THE COMMISSIONER: And Ms Lazarus, something I want to clarify. You keep saying that you had documents which the Commission ceased which don't exist anymore apparently which (not transcribable)- - ?---I know it's there, it's coming up as an exhibit.

20

Well, I just want to know, are you saying that you had documents which the Commission ceased which have disappeared?---Oh, no, no, no, no, it's there, it's going to be presented, it's there's a- - -

Are you saying that the Commission has done away with any evidence?---No, I'm not saying that, no, the documents that are - - -

30

I must have misunderstood you.---No, the document I'm referring to, it's there, there's a photocopy provided to me.

I'm not just talking about this document I'm talking about generally.---No, I never made that suggestion.

I see.

MS FURNESS: Now, Ms Lazarus, can I ask you - - ?---I haven't finished answering the last question.

40

Well, it wasn't a responsive answer, Ms Lazarus.---I think it was.

In the event that Counsel wishes you to provide further material by way of answers to questions I'm she'll ask them to you. Can you attend to page 228 please.---288. Yes.

Now, do you see the sentence beginning, "for the purpose", in that first paragraph on page 1, it's about half way down.---Yes.

Now, are you right Ms Lazarus?---Yes, sorry.

I'll read that sentence.---Yes, thank you.

For the purpose to this report the results of the biopsy results are outlined with biopsy as the standard. Do you see that?---Yes, that's correct.

I think there's a couple of errors in that sentence isn't there?---Yes.

- 10 Firstly, the word shouldn't be to it should be for.---That's correct.

And there shouldn't be results appearing twice.---Yes.

And they are mistakes you made.---Yes, that's correct.

And your reference the biopsy as the standard is, I take it, that you were comparing the results obtained by use of the Medex device with the diagnosis that was obtained as a result of the biopsy.---That's correct.

- 20 Now in the next sentence you refer to a, by a statistical method used to calculate sensitivity and specificity with the PSA and biopsy as the medical standards.---Yes, that's correct.

Now in fact, you just mean the biopsy as the standard, don't you?---Yes, that's correct, yes.

PSA - - -?---There will be patients who would have had abnormal PSA's and then gone on for a biopsy.

- 30 But in fact, you only looked at those patients that had a biopsy, you didn't, you didn't ultimately gather results from those with just the abnormal PSA did you?---No, that would be incorrect. Would you like (not transcribable)

If you turn over the page Ms Lazarus, you will see that the test results you record there relate to 48 patients.---That's correct.

And those, those were 48 patients who would have had a biopsy.---That's correct.

- 40 You didn't in fact, in your results on page 2 refer to those who had had abnormal PSA without a biopsy.---No, that's correct.

So therefore coming back to page 1 on the end of that first paragraph - - -?
---Yes.

- - -you shouldn't have the reference to PSA and, should you?---Yes there would be um, I think the sentence just needs to be structured a little bit better but PSA will be always mentioned. PSA is always carried out first.

No patient will go to a biopsy straightaway, that's just not, that's just not proper.

What you're seeking to convey in this last sentence Ms Lazarus is that you looked at a particular biostatistical method - - -?---Yes.

- - -to calculate sensitivity and specificity with the PSA and biopsy as the medical standards. That's what you're saying isn't it?---That's correct, that's correct.

10

Now firstly that's inconsistent with the previous sentence which refers to the biopsy as the standard isn't it?---Um, no, as a standard for the calculation but like I said, the result from the PSA would be positive for them to even go through, to the stage of a biopsy.

Now in the last paragraph on that page that first sentence, and I'll read it, "true positive predictive values and the true negative predictive values calculations."---Yes.

20 That doesn't make sense does it Ms Lazarus?---It would.

Well, it doesn't does it?---Well, I think it does.

Well there's no verb in it is there?---I'm sorry, are you picking on my grammar? I don't understand.

No, I'm picking on whether or not this sentence makes sense. Are you saying it makes sense?---To me it does.

30 THE COMMISSIONER: What does it mean?

THE WITNESS: But that just would be my poor grammar.

MS FURNESS: What does it mean?

THE COMMISSIONER: What does it mean?---A patient with a true patient and a patient with a true negative value.

Does what?---That conflicts with the value that's there.

40

MS FURNESS: Well, it doesn't say that does it?---Well, it does to me, that's my understanding hence that sentence is structured that way.

True positive predictive values and the true negative predictive values calculations.---That's correct. Perhaps there should be a colon there may be, it's got a full stop there. It makes perfect sense to me, hence it's there.

Perhaps you could explain it again then if it makes such perfect sense to you so that the rest of us can understand.---You would like an explanation now?

No, no, no, I'd like you to explain what that sentence means?---Well, to me it means there's, the value of a true positive that's given and a true negative that's given will be calculated using the method below which is for a true positive it will be $a's$ over $ab+$, sorry, $a + b$. For a true negative it would be -- sorry for a negative it would be d over $c + d$ and for, sorry for the true negative it would be that and for the sensitivity specificity I would calculate using similar methods, that's what it makes to me.

10 THE COMMISSIONER: So if you'd insert the word "follows" after the word "calculations" in the first sentence that would give the sense of what you're saying?---That's right. I put a colon or something.

No, it needs the word "follow"?---Okay.

Is that right?---Yes.

20 MS FURNESS: Now, turning over to page 2, Ms Lazarus, and the table that appears at the top of that page?---Yes.

Now, do I understand that the word "biopsy" as it appears in the top right-hand section of the table should properly be in the bottom section of that table?---Did you want to put it at the bottom, I've put it on the top.

30 Well, aren't you seeking to convey by that table that there are in fact 48 patients who had a biopsy, is that right?---That's correct. But that's just a matter of where you would like to place it. As you can see in the draft breast cancer one I've actually placed the screening methods in exactly the same place where I've done that. That's on page 13 of this Exhibit 51.

Do you accept that - - -?---I've done the same (not transcribable).

Do you accept that the table would make more sense if the word "biopsy" was placed where I suggested?---From your point of view, not from my point of view. Like I said I've done that indicating - - -

40 THE COMMISSIONER: Well, what does the biopsy show? You've got biopsy there in the top left-hand side, what is it intended to indicate?---That that's the test, that that's the test that's been (not transcribable).

But what is the test?---That biopsy test, that's the calculation for the biopsy. It will perhaps make a little bit more sense if you go to page 13.

MS FURNESS: Just stay with page 289. If the word "biopsy" was to the left of the word "total" it would tell you that they, the total of patients who had a biopsy were 48, 20 were positive, 28 were negative, is that right?

---Perhaps to you but not to me. It could clear that too but it makes perfect sense either way to me.

And the way we read this table is that the Medex test revealed that there were 15 patients who were screened positive, is that right?---With the Medex test, yes.

And those 15 were diagnosed on biopsy as having cervical cancer, sorry, prostate cancer, is that right?---That's correct, yes.

- 10 And that - - -?---The biopsy was positive. I can't say, like the biopsy was positive. Can't make that diagnosis.

Well, do you know what it's positive for?---For prostate.

And then do we read that two patients were screened positive with the Medex test and those two patients were diagnosed negatively with the biopsy?---That's correct.

- 20 And that's how we get to 17?---That's correct.

And then underneath that that five patients were screened negatively on the Medex test but those five received a positive biopsy, that's right?---Yes.

And 26 patients were screened as negative on the Medex test and they were also diagnosed as negative on biopsy?---That's correct.

So that if you look at the calculations underneath that box you're determining sensitivity and specificity aren't you?---That's correct, yes.

- 30 And do you see with sensitivity you've got 15 oblique, 15 plus 3, do you see that?---Yes.

That's a mistake isn't it?---That's an error that I've made, I should say 2.

It should say 5 shouldn't it?---5, it should say 5.

So it should say 15 over 15 plus 5?---That's correct.

- 40 Now, I take it you prepared this letter on or shortly before June 2009?
---That's correct.

By which stage you had well and truly received Professor Smith's email telling you that the screening test needed to be 100 per cent?---In terms of the email, yes. But he's referring to - - -

Sorry?---He's referring it to the article that I've sent through, yes, he's replying to that.

Did you take that into account when you were drafting this letter?---No, I didn't, no. There would be no need for me to.

Well, wouldn't it be consistent with Professor Smith's email to say in the letter that the sensitivity of 75 per cent was in fact was indicative that the test wasn't valuable as a screening test because it was less than 100?

---That's correct, wouldn't be valuable based on his email.

- 10 And similarly with the specificity of 93 per cent?---That's correct based on his email.

You didn't add that in this letter?---Why would I add that in that letter?

Well, it would more accurately reflect the view of the value of the results you'd obtained wouldn't it?---What do you mean? Should I have added Ross Smith's comment in this letter?

- 20 No, I'm not suggesting you should've added Ross Smith's comment. I'm suggesting to you that you should have reflected in that last paragraph the view that the value of the screening test on the basis of these results indicated that it was not valuable because it was less than 100?---Well, a view has already been given that further testing needs to be done, that's why I saw no need, if there is a final decision that needs to be made it was up to Kenneth Vaux to make that decision and hence I've put in there which he replied, which he agreed with and made no changes that a larger subject pool needs to be assessed.

- 30 But in fact you drafted this and you were the one who received the email from Professor Smith, isn't that right?---I did draft it and this was sent on to Kenneth Vaux via email, email which I have produced following by a conversation with him and then another email followed to his secretary which again have been produced outlining that it needs to be printed and presented to him before I see him.

- 40 Can I suggest to you, Ms Lazarus, that Dr Vaux would not have signed this letter given the number of errors which we have dealt with in it. What do you say to that?---That would be incorrect because he has signed it and he had a look at the email which he has already, I believe, said that he has received that email which I'm not clear again, evidence that needs to be presented. He has signed it, he, when it was presented to him again when he was in person, like I said he'd made minor changes again and that is his signature. Like I said it's a very attractive signature, it's his signature including the errors on there.

THE COMMISSIONER: Do you say signed it in front of you?---He signed it in front of me in the, in the cafeteria at Royal North Shore Public. And you have the original of that. There's two originals actually.

Yet again?---Yes, one was sent off to Medex and the one that was seized by the ICAC from my, that was in my possession.

Why was it in your possession by the way?---That was a report I was keeping with me as a reference. So the original is available for any analysis.

MS FURNESS: Ms Lazarus, can you turn to page 277 in that bundle?---270

10

Seven?---Yes.

You have 277?---Yes. I've got a hundred and seventy, I do apologise. Yes.

Now, that's a letter you prepared?---Again, that's a letter I prepared, yes.

And you prepared it based on your general knowledge of conducting research trials as well as your knowledge of the particular trials that you say you refer to in this letter?---That's correct. My general knowledge, that's correct.

20

Now, who was the research team that you refer to in the second paragraph? ---That would include any physician and myself and even the receptionist or whoever's involved, that would be the research team.

Do you tell the Commission who is the research team that you refer to in this letter in relation to what you say is an in-house preliminary research trial?---Well, in terms of this one it will just be Gilbert Burton, Gil Burton and myself.

30

Now, you say in this letter that you used the device on ten patients, is that right?---That's correct.

Whose patients were they?---Gil Burton's. I've already given evidence to that effect.

And you refer to ten positively diagnosed patients?---That's correct.

And they were patients who'd been diagnosed after a biopsy. That's right?

40

---Um, I cannot recall, but they were positively diagnosed patients. It's not compared to um, a particular method of diagnosis in the- - -

Now, you didn't compare the Medex test results to ten women who had been diagnosed as not having the cancer, did you?---No, that's correct.

So in fact what you derived was a specificity amount but not, I withdraw that. You devised a sensitivity but not a specificity. That's right?---Um, that would be correct, yes.

And in fact it's nonsense, isn't it, Ms Lazarus, to purport to do a research trial- - -?---Ah hmm.

- - -where you only look at positively diagnosed without looking at patients who have had a negative diagnosis?---Well, you'll have to ask my superior that, um, in this case it's Gil Burton um, as to why he suggested I only look at positively diagnosed patients. Like I said, it is a instruction that he's outlined in handwriting on a back of a protocol where he's actually made
10 changes.

But isn't it the case, Ms Lazarus, that you understood from the work that you had done that in order for there to be a trial that had any value at all, there needed to be both specificity and sensitivity determined?---Like I said, I'm not qualified and any understanding that I have is overridden by my superior and basically follow their instruction, in this case, handwritten instructions.

So you agreed with me earlier that you needed both sensitivity and
20 specificity?---To my understanding, yes.

But in this case you knew that this trial was useless because it was only sensitivity but you continued nevertheless because Dr Burton told you to?
---That's correct.

Is that your evidence?---That's, like I said um, what my superiors tell me overrides what my understanding is.

30 THE COMMISSIONER: I just want to understand. Do you say that he told you orally or are you just simply relying on what you say are handwritten instructions?---No, he told me orally and handwritten instructions, when you do the full flow map, what I need to do, the number of patients, there's extensive details in that protocol which he's done, handwritten, and while going through the structure of the trial with me, orally as well.

MS FURNESS: Now, Ms Lazarus- - -?---Yes.

- - -you've calculated the sensitivity for the ten positively diagnosed patients as 80 per cent. Do you see that?---Yes.
40

Now, again based on the advice that you had from Professor Smith, that indicated that the test wasn't valuable as a screening test, didn't it?
---Like I said um, I've read um, Ross Smith's email and um, based, when I wrote these letters I had not kept that in mind.

Oh, you didn't have that in mind. So you accept, do you- - -?---There was no point.

- - -that in fact to say that the results show that there was enough merit for the Medex test when the sensitivity for only positively diagnosed people was 80 per cent just made a nonsense of this letter, didn't it?---Um, no, because um, it would go forward again to a larger trial, a larger pool patient to actually make some sense of it. Like you've pointed out on many, several occasions, looking at positive patients, and to my understanding as well, only positive patients, would not make sense, but I'm only following the instructions of a superior.

- 10 THE COMMISSIONER: But why do you say that the results show that there is enough merit for the Medex test when it's, you only get a figure of 80 per cent, even for sensitivity?---Um, this is not for a full trial, this is just a pilot trial to show that, this is what I've been told, again this is from my understanding- - -

- So you're putting, you're putting this on somebody else again?---No, no, no. I've been told and what I, my understanding is, I did say what my understanding is um, that the pilot trial is just, again it's written in handwriting as well, just to see if, and people have given evidence about it
20 as well, a pilot trial is to see if there is enough merit for example for it to actually go to a larger pool.

- But why, why was there enough merit? That's what I'm trying to understand. Why was there enough merit for it to go to a larger pool when it only gives rise to an 80 per cent sensitivity?---Um, that would be because eight out of ten patients were positively diagnosed by conventional method and were positively diagnosed with the Medex. Two patients were positively diagnosed with the conventional method and were a false negative um, for example.

- 30 I understand that that's what happened?---Yes.

But that shows that it had no value?---Um, eight out of ten, they're considered it would have a value, hence the letter was prepared and discussed in several meetings.

According to Professor Smith it would have no value, and you knew that? ---Um, well, like I said, everything- - -

- 40 You got the email, didn't you?---Like I said, anything that I, my understanding is gets overridden by a superior.

So it's somebody else. You're transferring responsibility again? ---I'm not transferring. If you, that's what you like to say, that's, but I have to follow what my superior tells me and that's what I've done in every occasion.

MS FURNESS: Now, in the second-last paragraph- - -?---Yes.

- - -you say that, "We recommend"- - ?---Ah hmm.

Do you see that?---Yes.

"That the larger trial"- - ?---Yes.

"Includes symptomatic and asymptomatic patients?"---That's correct.

- 10 Now, if they were symptomatic patients, that would mean that they were well past the pre-cancerous stage, wouldn't it?---Ah, yes, that's correct.

And in fact if they were well past the pre-cancerous stage, there's no point in screening them with the Medex device, is there?---Um, that again would just be based on my understanding, you will have to go to a specialist to actually get a proper answer for that.

- 20 So you don't know one way or the other whether saying symptomatic makes sense or not?---It would to me, and I would only give you my understanding at that point. Um, like I said, it would be incorrect or correct, it would just be my understanding.

Now, further on in that sentence you say, "As well as patients with known and know diagnosis." Do you see that?---I'm sorry, can you slow down a little bit? Sorry.

Still in the same sentence?---Yes.

- 30 Second line of that sentence. "As well as patients with unknown and know, K-N-O-W, diagnosis?"---Yes.

Do you see that?---Yes.

Now, I take it that that's an error, the K-N-O-W, and it should be known? ---Yes.

- 40 Now, I suggest, Ms Lazarus, that to include in a trial patients with an unknown diagnosis is pointless?---Um, to my understanding and what I've, in terms of not laying blame on anyone, but what my understanding is um, and what I had been given and what evidence has been given by the person who signed this letter, Gil Burton, that a pool of unknown patient is quite valuable as a control. This is my understanding. And again, evidence has been given by that, that that would be- - -

Well, a control group is not unknown. A control group can be people who you know have a diagnosis one way or another?---Well, like I said, it's just my understanding um- - -

THE COMMISSIONER: That you got from Dr Burton?---No, no. No laying blame on anyone. That's my understanding in terms of - -

Where did you get it from?---From conducting experiments and for other experience unrelated to this.

MS FURNESS: But if you don't know the diagnosis how can you compare the results of the Medex test?---Wouldn't it be after you'd, it would be like a blind study? Wouldn't that be a blind study?

10

Well, a blind study refers to you carrying out the study without knowing the results of the biopsy at the time you carry out the study. That's what you understand a blind study?---That's correct.

This is not suggesting a blind study, is it?---I think it is suggesting it's a blind study but it's just worded incorrectly. Like you said, it should say known instead of know.

20

Well, can I suggest to you, Ms Lazarus, that Dr Burton would certainly not have signed this letter in this form containing as it does, nonsense?---Ah, that's not correct. Ah, he did sign it containing all the nonsense that it does. There are again two copies of it and the original that's in your possession. Again he was given a blank um, sorry, a, a, a copy without the letterhead which was printed from his office to make the relevant changes. He did make some changes. A copy was printed on his letterhead provided by his receptionist. Um, two copies, one was sent off to um, not sent off, was presented at the um, the, the meeting that they had with, that Gil Burton had with Pleiksna and one copy that I had and it's the original copy that's in the possession of the ICAC.

30

Can I ask you to turn to page 96 of Exhibit 1?---Yes. I'm sorry, if it's not, can I have that break if it's not a crucial point?

I'll only be another few minutes.---It's quite- - -

Well, in your- - -?---I know, but I need a break. If it's not a crucial point I would like to have a break.

THE COMMISSIONER: It is a crucial?

40

MS FURNESS: It's not.

THE COMMISSIONER: I thought you said it was a crucial point.

MS FURNESS: No, certainly not crucial, but I only need a few more minutes, that's all.

THE COMMISSIONER: Well, we just need a few more minutes with you. Can't you, if you want to adjourn now you can adjourn now, but we'll only need a few more minutes with you?---Well, can I get that far, I just need to walk and perhaps come back.

We'll adjourn for five minutes?---Thank you.

SHORT ADJOURNMENT

[12.40pm]

10

THE COMMISSIONER: Yes.

MS FURNESS: Thank you, Commissioner. Ms Lazarus, would you turn to page, page 96 of Exhibit 1 in front of you?---Yes.

96?---Yes.

Now that headed agreement For Clinical Trials?---Yes, that's correct.

20

Can I ask you to turn to page 99 of that bundle?---Yes.

Which is the last page of that document?---Yes.

Do you see that?---Ah hmm.

Now I want to put to you Ms Lazarus, that Professor Hacker did not sign that document?---That would be incorrect.

30

And indeed you caused his signature or a signature similar to his to be put on this document?---That's incorrect.

Now yesterday when you were giving evidence, Ms Lazarus, you were asked questions about the entry that you made into the clinical trials registry. Do you remember that?---Correct, yes, vaguely, yes.

And if you need to have regard to it, the registry documents appear at page and following of that bundle.

40

THE COMMISSIONER: Of which bundle?

MS FURNESS: Of Exhibit 1?---Yes.

Now you were asked questions in particular about the entry you made on page 7 in relation to ethics approval?---Yes, that's correct.

And the answer you gave that you did that either under instructions from Professor Hacker or with the full knowledge of Professor Hacker. Do you remember giving that evidence?---Yes, that's correct.

Now when you gave evidence on the first day of this inquiry, on 14 February - - -?---Ah hmm.

- 10 You were asked questions about the trials registry document and in particular your entry in relation to the Ethics Committee. How do you recall giving that evidence?---No, no I don't recall, sorry.

All right?---When was that?

It was on the first day of the hearing on 14 February?---Okay. Ah hmm.

Perhaps if page 24 of the transcript can be brought up. From about line 20. Now do you have that on the screen in front of you, Ms Lazarus?---Line 20, yes.

- 20 Line 20. You were asked a question in relation to the entry I've just taken you to on page 7 and the question is in relation to the study receiving approval from at least one Ethics Committee. Have you got that?---Yes, that's correct.

And you accept that you had responded to the question in the affirmative? ---Yes.

- 30 And were then asked a question as to whether the Commission should understand that that answer was based on the experience at Strathfield and not the result of anything that Professor Hacker told you about this particular proposed study. Do you see that question?---(NO AUDIBLE REPLY)

And then you answered no, that's correct. It's, here it says any one committee in regards to the clinical study and there was approval, full complete approval from the Concord Ethics Committee for the Medex research trial?---Yes.

So based on that I've said yes. Do you see that?---Yes, that's correct.

- 40 Now it's the case isn't that when you made the entry of yes on the trials registry document you did so because of your knowledge of approval from the Concord Ethics Committee and not because of anything Professor Hacker said to you?---That's not correct. He has seen that website and the conversation was through with him, it was in support, what I'm saying I'm not saying that's incorrect, that is correct, because with ethics application the Concord approval was also attached. Based on those two things it was yes.

THE COMMISSIONER: Sorry, I don't understand that, based on what two things?---Based on the, my answer there and in conversation with Neville Hacker that was ticked as yes, ethics approval.

What conversation with Professor Hacker?---In regards to the clinical registry trial and (not transcribable) application.

That you could do it without, without - - -?---That is correct.

10

But that doesn't mean that you've got it?---That's correct.

Why does a conversation with Professor Hacker mean that you've got ethics approval?---In terms of what I need to do with the registry, 'cause once he had a look he said, oh, yes, you can mark yes because it is the same device, Concord's already approved it, they've always said that. And I'm not laying blame - - -

20

Well I'm just simply asking you whether you are saying that Professor Hacker gave you ethics approval?---No, no, no. That's not what the question is. That's, that's not what Ms Furness - - -

Well you said based on two things, one was the Concord and one was what Professor Hacker told you?---Yes.

So I was, that's what I was trying to understand what you meant by what Professor Hacker told you?---In terms of what I should indicate on the website.

30

Yes?---Yes. Not as ethics approval was given by him.

MS FURNESS: So it's the case isn't it Ms Lazarus that on 14 February when asked the question about why you answered yes - - -?---That's correct.

- - - to has the study received approval, your answer was based on approval from the Concord Ethics Committee?---In terms of documentation, yes.

40

And you didn't on 14 February say that it was based on either instructions from or with the full knowledge of Professor Hacker did you?---That's correct, I didn't say that.

And when you were asked yesterday about that same entry you didn't say did you, oh well it was because it had full complete approval from the Concord Ethics Committee?---That's correct. In answering that question, it should be properly answered by putting the two together.

THE COMMISSIONER: So your answer on, on page - - -

MS FURNESS: 24.

THE COMMISSIONER: - - - 24 is wrong?---Is incomplete.

No, it's wrong?---It's not wrong.

- But it says you said the question was, should the Commission understand that your answer to the question about ethical approval was based on the experience that you've told us about Strathfield and not the result of
10 anything that Professor Hacker told you about this particular proposed study and you say that's correct.

And then you go on to say expressly - - -?---No, I say, no that's correct.

Yes. But you explain what that means, you say there full complete approval from Concord Ethics Committee for the Medex research trial so based on, on that I've said yes?---That's correct. And - - -

- It is not based on what Professor Hacker said but based on full complete
20 approval from Concord Ethics Committee for Medex, for the Medex research trial?---That's correct in terms of documentation. But that - - -

Well you don't say in terms of documentation there at all?---Well, like I said, it's incomplete. It needs to be completed. And there is documentation to prove that.

MS FURNESS: So it's also the case that your evidence yesterday was false too wasn't it?---It's not false. It would be incomplete.

- 30 You didn't in fact receive any instructions from Professor Hacker to insert the word yes on that trial registry did you?---That's not correct. I wouldn't have changed it otherwise.

And you didn't do it with his full knowledge did you?---That's very incorrect as well. I, like I said in my evidence, for me to write down his name on the website, I would have to have his approval.

Nothing further. Thank you, Commissioner.

- 40 THE COMMISSIONER: Yes. Ms Soars.

MR ALEXIS: Commissioner, before Ms Soars starts, I need to draw attention to something that occurred yesterday afternoon that I need to have corrected.

THE COMMISSIONER: Yes.

MR ALEXIS: And it's been brought to my attention during Ms Furness' cross examination and it's appropriate that I raise it at the earliest opportunity. Yesterday, the last topic in fact led to the tender of Exhibit 132, which was a bundle of non-order vouchers apparently signed by Doctor Pavlakis. And I put to Ms Lazarus at transcript 1,540 line 5 and following a series of propositions that were founded on a basis which I now understand not to be available. The proposition was that vouchers had been prepared without any invoices and had not been submitted for payment. What's been
10 brought to my attention is that those vouchers with invoices were submitted for payment to the Royal North Shore Hospital but they were not paid and that's why those vouchers together with those invoices are not reproduced in Exhibit 1 and my error was, and I have to accept that I've made an error, that my error was when I came across those vouchers from the material seized in execution of the search warrant and when I compare them against the content of Exhibit 1, the conclusion I drew was the one that was put to the witness yesterday. I need to withdraw the suggestion, I need to do so with an apology to Ms Lazarus for making that error and in the circumstances the appropriate course in my submission is for me to
20 withdraw submission, withdraw the tender of Exhibit 132 and can I indicate to my learned friend, Ms Soars, that no submission will be made by me on the basis of answers commencing at 1540 of the transcript from line 5.

THE COMMISSIONER: Yes. Exhibit 132 will be withdrawn.

#EXHIBIT 132 - WITHDRAWN

30 THE COMMISSIONER: Yes, Ms Soars.

MS SOARS: Thank you, Commissioner. Commissioner, could I call for the original of the ethics application and supporting documents that we've asked for previously and I understand is available. Royal Hospital for Women. Commissioner, I wish to show this to the witness and then tender it if it's convenient.

THE COMMISSIONER: Yes.

40 MS SOARS: If it could be shown to the witness. Could I, could I approach
- - -

THE COMMISSIONER: Yes.

MS SOARS: - - - because there's some additional documents.

Ms Lazarus, I'm showing you a document that has been produced relating to ethics committee documentation for Royal Hospital for Women. The first

letter is a letter of 25 June, 2008 to Professor Hacker in relation to an ethics application. There is then a copy of a letter of 10 April, 2008 which accompanied the application for ethics approval that was sent and then there is the body of a document and I'd like you to have a look at it and if you could confirm to me that that's the documents following comprise the documents that form part of the ethics application that you submitted in respect of Royal Hospital for Women under cover of the letter of 10 April, 2008. Could you confirm that for me after looking at those documents.

10 Could I just inquire, are you likely to require some time to do that because perhaps we could do it over the luncheon adjournment and then I could tender it after lunch, Commissioner, and I can proceed with something else.

THE COMMISSIONER: Yes, very well.

MS SOARS: Are you likely to require some time, Ms Lazarus?---Yes.

Is it - - -

20 THE COMMISSIONER: I'm not sure if I'm prepared to release that into Ms Lazarus' possession alone.

MS SOARS: No, I will keep it in my possession, if I could, in the conference room outside and confer with Ms Lazarus about it.

THE COMMISSIONER: Very well.

MS SOARS: Thank you, Commissioner.

30 Ms Lazarus, do you recall on Wednesday, 23 March, 2011 you were asked some questions about a trip to Pakistan in 2008 that you made?---Yes.

THE COMMISSIONER: Can we just get the details of that trip to shorten the time?

MS SOARS: Yes, Commissioner.

THE COMMISSIONER: If you want to tell us what the dates are you might as well just tell us that and that'll be regarded as evidence if the Commission accepts that so we don't have to waste time on that.

40

MS SOARS: I apologise, Commissioner, I don't quite understand, I'm - - -

THE COMMISSIONER: Just tell us the dates.

MS SOARS: Oh, O.K. Thank you, Commissioner. I seek, I seek to tender the pages from Ms Lazarus' passport - - -

THE COMMISSIONER: Yes.

MS SOARS: - - - and they show, Commissioner, that, an excerpt - - -

THE COMMISSIONER: The Commission, just give me the dates.

MS SOARS: Yes.

THE COMMISSIONER: Give me the dates.

- 10 MS SOARS: They do not show any entry and exits into and out of Australia because - - -

THE COMMISSIONER: The Commission has made its own investigations - - -

MS SOARS: As the court pleases, as the Commission pleases.

THE COMMISSIONER: - - - and has, and that's, that's why no questions were asked about this.

- 20 MS SOARS: As - - -

THE COMMISSIONER: So there's no, it is not sought to draw any inference against Ms Lazarus in connection with any trip to Pakistan so that really is the end of it then as far as you're concerned.

MS SOARS: Thank you, Commissioner. If I could just ask one question about the, the document.

- 30 THE COMMISSIONER: Yes. Well, look, the Commission has found that Ms Lazarus left Australia on 29 June, 2008 and returned on 8 July, 2008 and on that questions that - - -

MS SOARS: I see, Commissioner, if that is, if that is accepted then I don't, I don't propose to tender the document. I wasn't aware that those inquiries had been made, I apologise, Commissioner.

THE COMMISSIONER: Well, that's why no questions were asked.

- 40 MS SOARS: There were certain questions asked but - - -

THE COMMISSIONER: Once that was discovered no further questions were asked.

MS SOARS: Thank you, Commissioner.

THE COMMISSIONER: Overnight investigations will be made.

MS SOARS: Thank you, Commissioner. Ms Lazarus, could you inform the Commission of what training you say you undertook in relation to the Medex test device and when?--In 2007.

And what training was that?--There was training with Johel Neiron to start with over at least two weeks, not complete days. Then there was an official training, the date I cannot remember but it was 2007 where Itzhak Reitzfeld was present to give the training as he was the specialist in Medex.

- 10 And did you carry out the training with Dr Reitzfeld with anyone else, were there other participants?--At the - - -

Training session?--Training session. Yes, there were about three other clinicians, doctors from various institutions. There were two nurses or three, I cannot remember, there were nurses there. There was another doctor that was present, I think he was a Medex doctor, I can't remember, and with Jessica Lazarus.

THE COMMISSIONER: Ms Soars, how long will you be?

- 20 MS SOARS: Somewhere between an hour and an hour and a half or two hours, I can't precisely tell, it depends how long to extract information.

THE COMMISSIONER: We'll never finish.

MS SOARS: Well, it may be that I can keep to an hour, Commissioner, I'll try to only deal with the important matters.

THE COMMISSIONER: All right. We'll adjourn until quarter to 2.00.

30

LUNCHEON ADJOURNMENT

[1.03pm]