COMMONWEALTH OF AUSTRALIA

Official Committee Hansard

SENATE

COMMUNITY AFFAIRS LEGISLATION COMMITTEE

ESTIMATES

(Budget Estimates)

TUESDAY, 3 JUNE 2003

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SENATE

COMMUNITY AFFAIRS LEGISLATION COMMITTEE

Tuesday, 3 June 2003

Members: Senator Knowles *(Chair)*, Senator Allison *(Deputy Chair)*, Senators Barnett, Denman, Hutchins and Tchen

Senators in attendance: Senators Allison, Mark Bishop, Carr, Jacinta Collins, Denman, Chris Evans, Ferguson, Forshaw, Greig, Harradine, Heffernan, Humphries, Knowles, Lees, McLucas, Moore, Nettle, Tierney and Webber

Committee met at 9.03 a.m.

HEALTH AND AGEING PORTFOLIO

Consideration resumed from 2 June 2003.

In Attendance

Senator Patterson, Minister for Health and Ageing

Whole of Portfolio
Executive
Ms Jane Halton, Secretary
Mr Philip Davies, Deputy Secretary
Ms Mary Murnane, Deputy Secretary
Professor John Mathews, Deputy Chief Medical Officer
Business Group
Mr Alan Law, Chief Operating Officer
Mr Stephen Sheehan, Chief Financial Officer
Ms Wynne Hannon, Head Legal Services
Portfolio Strategies Division
Mr David Webster, First Assistant Secretary
Ms Karen Bentley, Assistant Secretary, Budget Branch
Mr Nhan Vo-Van, Assistant Secretary, Parliamentary and Portfolio Agencies Branch
Ms Shirley Browne, Director, Parliamentary and Corporate Sector Support Section
Ms Carolyn Smith, Acting Assistant Secretary, Aust-US Free Trade Agreement Health Liaison

Audit and Fraud Control
Mr Stephen Dellar, Assistant Secretary, Audit and Fraud Control
Information and Communications Division
Dr Rob Wooding, Chief Information Officer

Ms Gail Finlay, Assistant Secretary, Communication Branch
Ms Laurie Van Veen, Director, Social Marketing Unit, Communications Branch
Ms Virginia Dove, Director, Public Affairs Unit, Communication Branch

Outcome 1—Population Health and Safety

Population Health Division

Mr Ross O'Donoughue, First Assistant Secretary
Mr Greg Sam, Assistant Secretary, Communicable Disease and Health Protection Branch
Ms Sarah Major, Acting Assistant Secretary, Food and Environmental Health Branch
Ms Jenny Hefford, Assistant Secretary, Drug Strategy and Health Promotion Branch
Mr Brendan Gibson, Assistant Secretary, Strategic Planning Branch
Therapeutic Goods Administration
Mr Terry Slater, National Manager
Dr Leonie Hunt, Acting Principal Medical Adviser
Dr Neil Mitchell, Acting Director, Drug Safety and Evaluation Branch
Dr Brian Priestly, Director, TGA Laboratories
Mr Pio Cesarin, Director, Non-Prescription Medicines Branch
Ms Rita Maclachlan, Director, Conformity Assessment Branch
Ms Ngaire Bryan, Acting Director, Trans Tasman and Business Management Group
Ms Catherine Patterson, Director, Trans Tasman Group
Dr Fiona Cumming, Director, Office of Complementary Medicines
Dr Margaret Hartley, Director, Office of Chemical Safety; Director, National Industrial Chemicals Notification Assessment Scheme
Dr Sue Meek, Gene Technology Regulator
Ms Elizabeth Flynn, Assistant Secretary, Policy and Compliance Branch, Office of the Gene Technology Regulator
Mr Jonathan Benyei, Assistant Secretary, Evaluation Branch, Office of the Gene Technology Regulator
Ms Robyn Foster, Assistant Secretary, Trans Tasman and Business Management Group
Dr Larry Kelly, Departmental Officer, Therapeutic Goods Administration Laboratories
Mr Tony Gould, Good Manufacturing Practice Auditor, Office of Devices Blood and Tissues
Mr Noel Fraser, Good Manufacturing Practice Auditor, Office of Devices Blood and Tissues

Dr David Briggs, Departmental Officer, Non Prescription Medicines Branch
Dr Albert Farrugia, Manager, Blood and Tissues Unit, Office of Devices Blood and Tissues
Mr Stephen Howells, Section Head, Surveillance Section, Trans Tasman and Business Management Group

Portfolio Strategies Division

See Whole of Portfolio

Primary Care Division

Mr Andrew Stuart, First Assistant Secretary
Ms Rosemary Huxtable, Assistant Secretary, Policy and Evaluation Branch
Mr Rob Pegram, Principal Medical Advisor
Ms Leonie Smith, Assistant Secretary, General Practice Access Branch
Ms Sandra King, Acting Assistant Secretary, Primary Care Quality and Prevention Branch
Ms Cath Halbert, Assistant Secretary, Red Tape Taskforce

Australian Radiation Protection and Nuclear Safety Agency

Dr John Loy, Chief Executive Officer

Food Standards Australia New Zealand

Mr Graham Peachey, Chief Executive Officer
Dr Marion Healy, Chief Scientist
Ms Claire Pontin, General Manager, Strategy and Operations
Mr Gerg Roche, General Manager, Food Safety, Legal and Evaluation
Mr Peter Liehne, General Manager, Standards
Mr Kent Brown, Program Manager—Corporate
Ms Geraldine Lynch, Program Manager—Finance
Dr Chris Branson, Program Manager, Product Standards
Ms Sue Campion, Program Manager, Nutrition and Labelling

Outcome 2—Access to Medicare

Medical and Pharmaceutical Services Division
Dr David Barton, Medical Officer, Diagnostics and Technology Branch
Ms Pauline Clynes, Director, Pharmaceutical Benefits Branch
Dr Jane Cook, Medical Officer, Medicare Benefits Branch
Ms Joan Corbett, Assistant Secretary, Pharmaceutical Benefits Branch
Ms Jan Feneley, Assistant Secretary, Office of Hearing Services Branch
Dr Ruth Lopert, Director, Pharmaceutical Benefits Branch, Executive Section
Mr Ian McRae, Assistant Secretary, Medicare Benefits Branch
Mr Andrew Mitchell, Director, Pharmaceutical Benefits Branch, Pharmaceutical Evaluation Section
Mr Raino Perring, Acting Assistant Secretary, Medicare Benefits Branch

Dr John Primrose, Medical Officer, Pharmaceutical Access and Quality Branch
Mr Allan Rennie, Assistant Secretary, Pharmaceutical Access and Quality Branch
Mr Chris Sheedy, Assistant Secretary, Diagnostics and Technology Branch
Dr Bernie Towler, Director, Diagnostics and Technology Branch, Executive Section

Acute Care Division

Dr Louise Morauta, First Assistant Secretary
Mr Charles Maskell-Knight, Principal Advisor
Mr Richard Eccles, Assistant Secretary, Australian Health Care Agreements Taskforce
Mr Peter De Graaff, Assistant Secretary, Blood and Organ Donation Taskforce
Mrs Christianna Cobbold, Assistant Secretary, Blood Products Unit
Mr Alan Keith, Assistant Secretary, Hospitals Branch

Primary Care Division

See Outcome 1

Information and Communications Division

See Whole of Portfolio

Health Insurance Commission

Mr James Kelaher, Acting Managing Director
Mr Geoff Leeper, Deputy Managing Director
Ms Ellen Dunne, Acting National Manager Operations
Mr David Hancock, Manager, Pharmaceutical Benefits Scheme Branch, Program Management Division
Mr John Trabinger, Manager, Medicare Branch, Program Management Division
Mr Lou Andreatta, Manager, Medicare Reform Taskforce, Program Management Division
Dr Janet Mould, General Manager, Program Review Division
Ms Donna Daniell, Pharmaceutical Advisor, Pharmaceutical Benefits Scheme Initiatives Group, Program Review Division
Dr Brian Richards, Chief Information Officer
Ms Sharon Rose, Manager, Privacy Branch

Outcome 3—Enhanced Quality of Life for Older Australians

Ageing and Aged Care Division

Mr Nick Mersiades, First Assistant Secretary
Ms Jane Bailey, Assistant Secretary, Quality Outcomes Branch
Mr Warwick Bruen, Assistant Secretary, Community Care Branch
Ms Virginia Hart, Assistant Secretary, Policy and Evaluation Branch
Ms Lesley Podesta, Assistant Secretary, Residential Program Management Branch

Mr Mark Thomann, Assistant Secretary, Office for an Ageing Australia
Dr David Cullen, Executive Director, Aged Care Price Review Taskforce

Aged Care Standards and Accreditation Agency

Mr Mark Brandon, Chief Executive Officer
Ms Kristina Vesk, General Manager, Corporate Affairs

Outcome 4—Quality Health Care

Primary Care Division

See Outcome 1

Acute Care Division

See Outcome 2

Medical and Pharmaceutical Services Division

See Outcome 2

Health Services Improvement Division

Mr Bob Wells, First Assistant Secretary, Health Services Improvement Division
Dr Vin McLoughlin, Assistant Secretary, Health Priorities Branch
Mr Dermot Casey, Assistant Secretary, Mental Health and Suicide Prevention Branch
Mr Brett Lennon, Assistant Secretary, Workforce and Quality Branch
Ms Phillipa Lowrey, Director, Rural Health and Palliative Care Branch
Ms Jan Bennett, Assistant Secretary, Rural Health and Palliative Care Branch

CRS Australia

Dr David Graham, General Manager

Outcome 5—Rural Health Care

Health Services Improvement Division
See Outcome 4

Outcome 6—Hearing Services

Medical and Pharmaceutical Services Division
See Outcome 2

Health Insurance Commission

See Outcome 2

Outcome 7—Aboriginal and Torres Strait Islander Health

Office of Aboriginal and Torres Strait Island Health
Ms Helen Evans, First Assistant Secretary
Dr Patricia Fagan, Medical Adviser
Ms Mary McDonald, Assistant Secretary, Program Planning and Development Branch
Ms Yael Cass, Assistant Secretary, Workforce, Information and Policy Branch
Ms Helen McFarlane, Acting Assistant Secretary, Health and Community Strategies

Outcome 8—Choice through Private Health Insurance
Acute Care Division
See Outcome 2
Medibank Private
Mr George Savvides, Managing Director
Private Health Insurance Administration Council
Ms Gayle Ginnane, Chief Executive Officer
Private Health Insurance Ombudsman
Mr John Powlay, Private Health Insurance Ombudsman
Outcome 9—Health Investment
Health Services Improvement Division
See Outcome 4
Information and Communication Division
See Whole of Portfolio
Office of the National Health and Medical Research Council
Professor Alan Pettigrew, Chief Executive Officer
Dr Clive Morris, Executive Director, Council of Australian Governments Implementation Taskforce
Ms Cathy Clutton, Executive Director, Centre for Health Advice, Policy and Ethics
Ms Suzanne Northcott, Executive Director, Centre for Research Management
Mr Tony Krizan, Acting Assistant Secretary, Centre for Corporate Operations

CHAIR—I declare open this public hearing of the Senate Community Affairs Legislation Committee considering the budget estimates. The committee will now continue examination of the health and ageing portfolio. I welcome back the Minister, Senator Patterson, and officers of the Department of Health and Ageing. The committee has completed outcomes 2, 6 and 7, and we will now commence with ARPANSA in outcome 1, Population health and safety, followed by the TGA and then other questions relating to outcome 1. Outcomes 5, 8, 9, 3 and 4 will follow, as well as any questions on corporate matters which are spread across all outcomes.

[9.04 a.m.]

Australian Radiation Protection and Nuclear Safety Agency

CHAIR—I now welcome Dr Loy, and I call for questions on ARPANSA.

Senator CARR—I want to ask you some questions that go to the construction of the replacement reactor at Lucas Heights. Can you provide the committee with a timetable of events relating to the failure of design work on the reactor pool tanks at Lucas Heights?

Dr Loy—I assume, Senator Carr, you are referring to the matters that were raised in an article in the *St George and Sutherland Shire Leader* last week?

Senator CARR—There are two matters, in fact. There is the ongoing problem with the cooling tank. The matter raised last week was that the pipes did not seem be in alignment.

Then there are the problems with the additional licensing requirements that I understand you imposed last year. So there are two discrete incidents. I am asking you to go through the time line on the events relating to the design work and the matters raised last year, which I understand led you to requiring, on perhaps five occasions, additional licensing requirements in terms of the wells on those pipes. Do you want to start with that?

Dr Loy—Unfortunately, this cannot be quite a short answer, but I will run through things as I understand them. First, to put it in context, after issuing the construction licence for the reactor in April 2002, one of the conditions of licence was that, for items important for safety, ANSTO needed to come and get the approval of the CEO to construct those items and needed to demonstrate that the detailed design of the item was consistent with their application, the application being the basis for my licensing decision. So it was not a one-off licensing decision for a whole range of matters. They have had to come to ARPANSA to seek approval for the construction of individual structures and components. Among these, of course, was the reactor pool tank, which is the stainless steel tank which holds the cooling water and is embedded in the reactor concrete block. I gave approval for the construction of that reactor pool tank and some other associated structures in July 2002. At that time, I did impose an additional licence condition that required that the piping and the butt wells on that tank be subjected to 100 cent radiographic or ultrasonic testing. That was done because ANSTO and INVAP were taking the view that a lesser degree of testing of those wells was consistent with their application. After examination, I took the view that 100 cent was consistent with the standards required and I imposed that by way of licence condition. Subsequent to that particular component, there have been other components, including piping in the primary coolant system, where we have imposed similar licence conditions for basically the same reason.

Coming back to the reactor pool tank, in and of itself it is quite a simple structure. It is simply a large tank, but it does contain a very significant number of penetrations for various pipe work to go in and out of the reactor. On the bottom of the tank there were some quite large penetrations concerned with the heavy water system. In my approval of July to construct the tank, I said, 'You can construct the tank but not those penetrations. I need to look at the design of the heavy water system before I approve those penetrations.' Subsequently, we learnt that the bottom of the tank had been constructed with the penetrations, inconsistent with my licence decision. That is a matter that I have examined and made certain decisions on, which I am reporting to the parliament under section 61 of the act. Basically, I found that there was a breach of the licence condition. In the event, we have taken the view that it did not raise a matter of safety because, in the end, we were accepting that the penetrations were appropriate. However, it was of concern that they had gone ahead, but that was a decision that had been taken by the designer to proceed that way. As I said, we have made some findings which we will be reporting to the parliament very shortly.

The next matter related to the reactor pool tank is that ARPANSA were notified on 9 May of what is called in the quality system a non-conformance. What appeared to have taken place was a mistake in interpretation of drawings by the subcontractor manufacturing the tank. If you are constructing a tank, you have a flat piece of steel which you roll into a tank. The drawings of the holes in that flat piece of steel have to have a projection—like a map of the

world, if you like. It seems, I understand, that the Australian contractor misinterpreted the projection used by the Argentinean designers and so put 22 holes in the wrong place. This obviously meant that the reactor tank is not licensed. It is inconsistent with the approval of the licence conditions.

After discussions between my technical people and ANSTO's, I have written to the Executive Director of ANSTO providing some regulatory direction, basically saying that the repairs should not further proceed until I am satisfied on the basis of information provided by ANSTO that the repaired tank would conform with the terms of my original approval—that the repaired tank would be in every way as safe and effective at its role as the originally approved tank. Obviously I need information from materials and welding experts et cetera who will examine the repair strategy that they may have in mind and bring forward some views about that before I make a decision as to whether the repaired tank would be consistent with my original approval.

In addition, the fact that a mistake was made raises a question of whether other mistakes of a similar kind have been made. So I need some reporting on that. Similarly, the system itself that allowed for the mistake to be made needs further examination, and I will be reviewing that. So the time scale for that notification was that ARPANSA were notified on 9 May, and I wrote to the executive director on 23 May.

Senator FORSHAW—Do you have your own experts that you commission to check, in this case, the welding and other technical matters to do with the construction? When you are satisfying yourself, who do you rely on to tell you?

Dr Loy—Where we feel we do not have sufficient expertise in-house, we certainly commission other expertise to assist us in examining either a specific issue of the kind I have just described or the workings of any particular system, structure or component. For example, the construction of the main reactor block itself involves quite sophisticated—if that is the right word—high density concrete. While we have good civil engineers or mechanical engineers, our expertise in the ins and outs of concrete needed some assistance. We commissioned experts to assist us in the evaluation of the concrete proposals for the reactor block. Similarly, in this case we will ensure that we get some external experts looking at whatever proposals ANSTO might put forward for the repair of the tank.

Senator CARR—There were five separate incidents last year revolving around the issue of welding certification. Did you undertake an investigation of those incidents?

Dr Loy—I would not describe them as incidents. ANSTO put forward a proposal to construct pipe work and, as part of that, described the proportion of the welding that would be directly inspected. We took the view that, for these particular kinds of welds, the proportion should be 100 per cent rather than the proportion that they proposed.

Senator CARR—I appreciate that; I understood what you were saying before. My question was: did you undertake any investigation into those particular matters, however you describe them—the dispute that arose and required you to institute additional licensing requirements? That was quite a serious move, I would have thought.

Dr Loy—The issue turned around judgments about the standards to be applied to the primary coolant system. The view from ANSTO and INVAP was that a lower standard was

acceptable, given the overall design of the reactor and the very low probability of a loss of coolant accident having an impact on the core. ARPANSA had what I acknowledge to be a more conservative position, saying that, while we accepted that the design of the reactor had particularly taken into account loss of coolant, we did not want that system challenged and that 100 per cent inspection was an appropriate piece of conservative design for what we were constructing. It was not a matter of investigating; it was a matter of examining the judgments made on the proposals put forward and comparing them with what we regarded as the proper principles for construction.

Senator CARR—Did you find that any of the welds were faulty?

Dr Loy—The actual inspection of the welds is done by the constructors. Our overall process is that, for the matter to proceed, ANSTO have to demonstrate that the equipment has been subject to 100 per cent inspection and any flaws have been dealt with—they have to demonstrate it to us. In addition, to ensure compliance we use the inspection powers under the ARPANS Act and have our officers visit places and so on.

Senator CARR—I am confident that you are doing your job diligently. My question, though, went to the issue of whether or not any faulty welds were found.

Dr Loy—I do not know whether at any stage of the process there were faulty welds. There probably were, and I could get you an answer on notice to that. The answer, ultimately, is that there will not be in the final product.

Senator CARR—And that is your job: to make sure that the final project has met all the licensing requirements. My issue though goes to the question as to whether or not the safety standards throughout the construction period have been maintained. It would appear, given that you have had to impose additional licensing requirements, that at least at some point last year you felt that they were not being maintained.

Dr Loy—I think you are putting it more starkly than I would. There were some differing judgments between ANSTO, the designer and ARPANSA as to the standards that should be applied to this pipe work in particular.

Senator CARR—Were there breaches of the terms of the licence to construct at any point last year?

Dr Loy—I have mentioned the case of the lower penetrations, the penetrations in the bottom plate of the tank. They were constructed. At the time, the licence did not permit that.

Senator CARR—Okay, so there is that incident. In regard to the welding on the pipes, were there any breaches of licensing arrangements at any point last year?

Dr Loy—I have not found any licence condition breaches in that regard. I should remind you, of course, that I am required to report to the parliament on any licence condition breaches.

Senator CARR—Yes, and you have not reported any.

Dr Loy—Apart from the one that I have just referred to.

Senator CARR—Have you undertaken any investigations as to whether or not the licence conditions were complied with last year?

Dr Loy—We continue to monitor compliance with the licence conditions.

Senator CARR—Yes, so did you undertake an investigation last year?

Dr Loy—We continue to monitor and we undertake, if you like, investigations and inspections all the time.

Senator CARR—I am led to believe that, firstly, there was an investigation into a number of faulty welds and that, secondly, there were internal inquiries within your organisation as to whether there were breaches of a licence to construct. Can you confirm that?

Dr Loy—All I can think you are referring to is that there was some misinterpretation of our licence conditions which referred to a particular type of weld being required to be 100 per cent inspected. Some views said that that was every single weld in the entire component, and that was not the case. So there was some misunderstanding and misinterpretation, but no breach of the licence conditions.

Senator CARR—So there was no report prepared?

Dr Loy—That is correct.

Senator CARR—In regard to the second incident—that is, the penetration issue—what action was taken by ANSTO in response to your findings?

Dr Loy—Are you referring to the most recent one?

Senator CARR—As I understand it, we are talking about three separate sets of events. There is the question of the welds last year and your decision to have additional licensing requirements. Did you, during 2002, demand higher standards from ANSTO and INVAP in four critical pipe work areas in July, September and twice in November?

Dr Loy—I certainly imposed additional licence conditions referring to welding in the primary coolant system in July, September and November; that is correct.

Senator CARR—Was it twice in November?

Dr Loy—Yes, it was twice in November.

Senator CARR—Were there further upgrades and inspections on the types of piping used in the cooling and purification systems also in November? Was that the fifth matter?

Dr Loy—I can give you the additional licence conditions that I imposed.

Senator CARR—I would appreciate it if you could table that; that would be helpful. However I am asking a direct question here: was there an additional incident in November last year that went to the issue of upgrading of inspections and the type of piping used in the cooling and purification systems?

Dr Loy—This may be what you are referring to, but it took place over some months last year. There was a discussion—a debate, if you like—over the use of seamless piping within the primary cooling system and the reactor and service pool cooling system versus piping with longitudinal wells. Certainly we were taking a view, which was debated, that where possible seamless piping should be used, to the extent that it was readily able to be obtained. At the end of that discussion we imposed a licensing condition in November related to a

number of systems to ensure that seamless piping is used within those systems where the nominal diameter is not greater than 200 millimetres.

Senator CARR—You are quoted as saying that there is certainly an ongoing issue on the channel of communications between ARPANSA, ANSTO and INVAP, John Holland, Evans Deakin Industries—INVAP's Australian construction partner and their subcontractors—and back again. That is from an article by Mr John Mulclair in the local paper. Mike, what is the name of the local paper?

Dr Loy—The *St George and Sutherland Shire Leader*.

Senator CARR—Yes.

Senator FORSHAW—Published Tuesdays and Thursdays.

Senator CARR—Did you say that, Dr Loy? Is that an accurate quote of your view?

Dr Loy—Probably, yes. I have no reason to doubt it.

Senator CARR—What action has been taken in regard to resolving this ongoing issue regarding the channel of communication?

Dr Loy—It was certainly a matter we raised in the context of the fact that the penetrations in the bottom of the tank had been proceeded with, albeit that the licence conditions—

Senator CARR—This is in an article that appeared much earlier than that, though. This is an article that appeared prior to the second incident occurring in regard to the penetrations.

Dr Loy—There are two matters concerning penetrations. One is in the bottom of the tank, where there were penetrations for the heavy water system. That was a matter where we had not settled in our minds—in ARPANSA's mind—that they were the appropriate size and shape and in the right place. So we said, 'Go ahead, construct the tank but not those penetrations at this point.' INVAP late last year directed that those penetrations be cut, even though our licence condition prevented it. Ultimately, that had no safety implication, because we were, in the event, happy with the penetrations. But that was the case that was raised in the article you have just quoted. That led to, obviously, a significant investigation as to how that happened.

As I said, I am reporting that in detail to the parliament. I expect that the report will be tabled this week. But basically, I did find a breach of licence condition as a result of that, and one of the root causes of it is this chain of communication of our licence conditions from ARPANSA to ANSTO to INVAP to John Holland to the people on the floor. Certainly we required that INVAP's procedures be amended to make sure that ARPANSA's directions are explicitly included in all of that written chain of command so that finally there is no likelihood that the person on the shop floor will not have the direction that is ARPANSA's licence condition. That flowed from that investigation, and subsequently we have received revised procedures from INVAP which ensure that.

Senator CARR—It just seems to me to be a comedy of errors. We have incident after incident now involving these sorts of mistakes, given that with the latest incident there appears, according to the press reports, to have been a three-month delay between the point at

which the faulty welds were actually discovered in the pipe work and ARPANSA being informed of the problems. Would you concur with that?

Dr Loy—My understanding is that the delay was actually between the mistake being made and presumably discovered on the shop floor at the subcontractor and ANSTO being notified. My understanding is that ANSTO was not notified until 9 May that this error had occurred, even though it appears that it occurred some time in February. ANSTO subsequently immediately notified ARPANSA. Having said that, that is a matter of concern. At the very least, in my view, the matter should have been brought immediately to ANSTO's attention and then it would have come to our attention, I believe. So that is a matter that requires further investigation, and I have taken that up in my letter to the executive director.

Senator CARR—So, essentially, you are relying on other people telling you what is going on?

Dr Loy—No, not entirely. Obviously it is important that other people tell us what is going on, and that really flows from the licence conditions. Basically the licence conditions and my approvals for construction under those licence conditions mean that what is approved to be constructed is precisely as has been defined. If something else is constructed, that lies outside the licence conditions and obviously I need to know about that.

In terms of our own intelligence gathering, we certainly have used the inspection powers of the ARPANS Act and we have one officer who spends virtually all his time doing that, whether that be at ANSTO itself, JHEDI or the manufacturers' places. Part of the licence conditions we can impose also covers witness or hold points—that is, you can go so far in this construction and then we, ARPANSA, have to have a look at it or we have to witness the construction of the particular item or you can go so far and we will review and give you permission to proceed further. So there are quite a number of mechanisms that we use to make sure that we do know what is going on. It is a complex beast. I am not surprised that errors are being made. In some ways, I think it is better that we are finding out about problems, even though that has its public relations issues—and, to date, I believe we are dealing with them.

Senator CARR—Public relations issues is putting things somewhat mildly, isn't it? This is a highly controversial project, with $500 million worth of capital being invested in it. Sooner or later you are going to have to make a decision as to whether or not they are granted a licence to turn this thing on. There has been this litany of issues now emerging with regard to various aspects of the construction process. It is a bit more serious than just a bit of a public relations problem, isn't it?

Dr Loy—No, I was not putting it in that perspective. I was saying that of course it is a serious and important matter, but it is very complex and therefore you would expect problems to arise. The question is whether I can feel confident that we are across problems when they arise and making sure that they are properly dealt with. There will be problems—there will be more. I feel relatively confident that we have a system that ensures these things will come to light and be dealt with.

Senator CARR—Do you anticipate areas where there will be problems?

Dr Loy—So far we have given approval for construction of some 55 major components, and there are many more still to come. So there is plenty of room for issues to arise in the construction of many of those things. At the moment, we are dealing with some of the basic structures. A little bit down the track there will be the complexities of instrumentation and control and there will be issues connected with the fuel, the fuel type and the core. So there are plenty of complex systems still to be addressed and, as I said, I would expect issues to arise in many of those, just from a priori experience. But I believe the fact that we fully examine each of the major systems before they are approved for construction, together with the licence conditions we impose and our inspection abilities, means that we are able to assure ourselves that we find any problems and deal with them.

Senator CARR—In a statement last Friday, an ARPANSA public affairs officer said:

> ... ANSTO must demonstrate that a thorough examination has been undertaken of the quality assurance process applied by the tank manufacturer ... to show that appropriate steps have been taken to assure that there will be no repeat occurrences.

Do you really think that is enough?

Dr Loy—We are looking specifically at the manufacture of these metal, stainless steel, parts. It is clear that one in one sense very simple but obviously fundamental mistake was made. And it could be as simple as that: someone made a simple but important mistake. It has obviously been discovered, and it may be able to be dealt with by repair. That may be the end of the story, or there may be issues in the overall quality system that do need to be changed and restructured to ensure that it does not happen again. That is the examination that has to go on.

Senator CARR—There are pretty substantive differences between those two options—either a simple mistake or a fundamental flaw in a quality assurance regime. How long will it take you to establish which one it is?

Dr Loy—I do not know.

Senator CARR—How long have you got? When will this project be concluded?

Dr Loy—The point is that, until I am satisfied about these matters, the repair of the reactor pool will not be able to proceed.

Senator CARR—Are you now saying that you are prepared to actually stop the construction?

Dr Loy—I am saying that the reactor pool has to meet our requirements.

Senator CARR—What is happening on the site at the moment with regard to the construction? Have you stopped the construction?

Dr Loy—The pool itself is of course not on the site at the moment; it is in the subcontractors premises being constructed. What will happen from here is that there will be some discussion between our experts—and we will bring in some external experts, including some members of the Nuclear Safety Committee—and they will look at the repair proposals, ANSTO will put forward its argument and my experts will make a recommendation to me as to whether a repair tank would meet the requirements. At the same time, I would expect to

receive information about the other matters that go to quality assurance. Then I would make a decision as to whether construction can proceed.

Senator CARR—What is likely to be the delay as a result of these matters?

Dr Loy—I do not know.

Senator CARR—Do you expect there will be a delay?

Dr Loy—It is not in my hands. It is in ANSTO's hands.

Senator CARR—Do you anticipate there will be a delay?

Dr Loy—I really do not know. Obviously, it is a complex project and parts of it are coming from all sorts of different directions. Whether the reactor pool tank is now on the critical path or whether something else is, I really do not know. In a sense, I do not care.

Senator CARR—That is fair enough. It is not your job; it is ANSTO's job to get that sorted out. Your job is to make sure that the thing is safe and that you have met the licensing requirements to the letter. Is that how you see it?

Dr Loy—Yes.

Senator CARR—It is just that on previous occasions ANSTO has said to us that there are no problems in the quality control chain and the management of the project. That is clearly not the case, is it?

Dr Loy—There were matters raised by the licence breach that I found, and we required further changes to be made. Whether you call that the quality system or something else is probably a matter of taste, but certainly it needed some attention. These matters that subsequently have arisen certainly need examination. Whether at the end of the day it means that the quality system is at fault or, as I said, it was simply a simple mistake, we will see.

Senator CARR—That is right. You cannot predetermine the outcome there, but clearly it is a matter of concern. Given your statement to the local newspaper, which I referred to earlier in these proceedings, is it still the case that there are ongoing issues in the channel of communication between ARPANSA, ANSTO, INVAP and John Holland's?

Dr Loy—No. We have received revised procedures from INVAP, and I believe that they address those issues and ensure that the specific communication of ARPANSA's requirements will move down that chain of command without a problem.

Senator CARR—Are the events that occurred on 9 May covered by the revised procedure?

Dr Loy—No. I think it is a different issue, but let us see when we look at it in more detail. It does appear that it was a misinterpretation of a drawing rather than lack of communication of a licence requirement.

Senator CARR—Putting 22 holes in the wrong place is a bit more than just a misinterpretation, isn't it?

Dr Loy—No, it is not—or it may not be. It may be as simple as INVAP having projected from the first angle and the engineering firm having interpreted that being from the other side.

Senator CARR—You do not think that is a substantial communication problem?

Dr Loy—It could be a simple mistake—that in Argentina you do it this way and in Australia you do it that way.

Senator CARR—That is what I am saying. You do not think that is a substantial communication problem?

Dr Loy—That is obviously very important, yes. We certainly need to make sure that that mistake has not been evident anywhere else, but a priori you would not expect it to be.

Senator CARR—Given that on 23 May you made a direction that no repairs be made unless you are satisfied, do think you need to make those sorts of directions without there being a serious communication problem?

Dr Loy—I think that I need to be very clear about what I want to have happen.

Senator CARR—Absolutely; that is my point. So you think that the way to fix the communication problem is to issue stiffer directions?

Dr Loy—Yes. It is certainly a part of it, but I think the experience of humanity tells you that sometimes simple mistakes that nobody thought of can be made. The question is: are you going to pick them up and deal with them?

Senator FORSHAW—Does INVAP have people on the site and, in the case of where the pool tank is being constructed, on that particular site?

Dr Loy—INVAP certainly have offices and personnel in Australia. How they dispose of them, I do not really know; but I am sure that they would visit the manufacturer from time to time.

Senator FORSHAW—If this had come about because of some misinterpretation or misunderstanding between the contractor and INVAP, how could that have occurred if the people who had been responsible for the design are present in the same way as an architect might be on a building? I appreciate that you can say that mistakes happen on building sites too, but the pool tank is a pretty critical part of this project. You don't know, do you?

Dr Loy—I honestly cannot comment. That will obviously be part of what is reported to me as part of that further investigation.

Senator CARR—But there are these particular cases of the subcontractor discovering a problem in February but not telling ANSTO until May basically, and then you not being able to act until later on that month. There is a substantial gap in the whole process. Do you think more work needs to be done on the communications issue?

Dr Loy—That gap is a concern, yes.

Senator CARR—That is why I come back to this point. Clearly you do not believe it to be satisfactory—is that a fair description of your view?

Dr Loy—The gap is a concern. I would have regarded a satisfactory process as being much faster reporting.

Senator CARR—Yes. How can you assure this committee that this event will not occur again—that it will not be three months between the discovery of a significant fault and action being taken?

Dr Loy—All I can say is that I have asked for the issue to be examined and for that to be put to me so that I can be satisfied that it will not happen again.

Senator CARR—When will that review be concluded?

Dr Loy—That is in the hands of ANSTO and the other parties.

Senator CARR—And the subcontractors.

Dr Loy—Yes.

Senator CARR—One presumes it is a matter we will have to return to at the next estimates, so you will be able to tell us then.

Dr Loy—And I will obviously report on it in reports to the parliament.

Senator CARR—Yes, I appreciate that. Can you confirm that previously you have indicated that the satisfactory resolution of the issue of a comprehensive waste strategy will be a prerequisite for any licence to operate the new reactor?

Dr Loy—I think you are putting words into my mouth a little bit.

Senator CARR—This is your chance to tell me what your view is.

Dr Loy—I need to take care. The issue principally arises in the context of a strategy for dealing with spent fuel from the reactor. If you like, I will come back to low-level waste after that, but I have said that by the time of the issuing of an operating licence I believe I would need to be satisfied that there were steps being taken that would satisfy me that there will be a store for the spent fuel waste product when it returns from conditioning overseas from the replacement reactor. So it is not that a store will actually be in existence but that there will be sufficient steps taken to satisfy me that one will be in place.

Senator CARR—Does that include that you have to be confident that it will actually be built as distinct from an announcement that the government intends to build one?

Dr Loy—I guess I need to qualify all of this by saying that I make my decision on the operating licence based upon the act, what is put to me by ANSTO and what comes forward in public submissions. I make that decision at the time. If you like, I am giving an opinion as to how I would be thinking about that issue of disposal of spent fuel and I have put it in terms such that I would need to be satisfied that a store will exist.

Senator CARR—So you mean physically exist and not virtually exist?

Dr Loy—Yes. I am not sure there is any other form of existence.

Senator CARR—Yes, but in this government! So you are looking for a serious proposition that the store will be up and running?

Dr Loy—Yes.

Senator CARR—Can I ask you then whether you have been consulted about the siting of a mid-level radioactive waste store?

Dr Loy—You are referring to a store that would be intermediate level, including the spent fuel?

Senator CARR—Yes.

Dr Loy—There is an ARPANSA officer on the National Store Consultative Committee, which is a group of experts that advises the Department of Education, Science and Training about issues related to the store. One of my officers is a member of that committee, so in that sense we are being consulted through that mechanism.

Senator CARR—When do you expect that matter to be finalised—an actual short-list of sites, for instance?

Dr Loy—It is not in my hands.

Senator CARR—You have not been advised?

Dr Loy—Only that I understand that the committee has certainly advised the department on criteria. I believe the department has then contracted with organisations to, if you like, examine the Australian continent against those criteria. Where it is up to now, I am not aware.

Senator CARR—You are aware, surely, that the announcement of the short-list of sites is now 12 months behind schedule?

Dr Loy—I was not aware of a schedule, but I believe it is taking longer than originally anticipated.

Senator CARR—What impact do you think the delay will have on your deliberations?

Dr Loy—Not necessarily any at this point, but I would certainly be looking for more progress.

Senator CARR—What time lines are you working on in having to make a decision on the granting of a licence to actually operate the reactor?

Dr Loy—Again, that is not my hands. That will ultimately be in ANSTO's hands as to whether, when they come, they have sufficient information to present to seek a licence to operate. There will be a process. At the moment, the licence to construct goes up to the point where you would load nuclear fuel, so they would be seeking a licence that, in the first instance, gave them the ability to load nuclear fuel and commission the reactor. That, in turn, might take quite a period of time while the commissioning tests were undertaken.

Senator CARR—But that does not necessarily give the go-ahead to operate?

Dr Loy—No.

Senator CARR—It is just a licence to test?

Dr Loy—That is correct. You would expect some kind of stepwise process of commissioning, and the results of the commissioning tests would then inform whether you could go to an operating licence and what conditions would be upon that operating licence if it were granted. ANSTO has talked about 2005 for the operation of the reactor, but whether that comes to pass or not I do not know.

Senator CARR—How long would it take, do you think, to run an inquiry into the granting of a licence to actually operate?

Dr Loy—As I have said, it will be something of a stepwise process. I have not really turned my mind to exactly how that would be managed. It will obviously be a significant

inquiry and it would involve the seeking and consideration of public submissions. I really cannot be any more precise than that.

Senator CARR—In light of the fiasco that has arisen around the siting of the low-level repository, how much opportunity do you think there will be for genuine public comment?

Dr Loy—In what regard?

Senator CARR—On the intermediate-level dump.

Dr Loy—I guess you are asking the wrong person. My role in relation to both of those installations is the licensing in terms of radiation protection and nuclear safety. The issue of the siting and what consultation goes into the siting is for the Department of Education, Science and Training.

Senator CARR—Fair enough. Were you consulted about the various sites named in the EIS for the low-level waste dump?

Dr Loy—Again, officers of ARPANSA took part in the equivalent of the consultative committee. There was again an expert committee that gave advice on the siting criteria for the repository. ARPANSA provided comments to DEST on their draft EIS and provided advice and some checking of calculations to Environment Australia when they sought some assurance.

Senator CARR—Did you have any reservations about the 42a site?

Dr Loy—You will have to remind me which one that is.

Senator CARR—That was the one near the rocket range. The Department of Defence seemed to have a view about it. Did you have a view as well? In terms of safety, it is not a good idea to put a waste dump next to a rocket range.

Dr Loy—I think you can separate the issues into the likelihood of a rocket striking the repository and the radiological consequences of that. There was a lot of debate about the likelihood calculations, but we had a view that the radiological consequences would not be particularly severe in any case. Having said that, it is a judgment as to whether it is desirable for that to be tested, if you like. While we did not have a particularly strong radiological concern, we certainly understood the reasons why that might be—

Senator CARR—Did you express those?

Dr Loy—We confined ourselves very strictly to doing the figures and presenting—

Senator CARR—The mathematics.

Dr Loy—Yes.

Senator CARR—The probability of a rocket landing in the middle of a waste dump.

Dr Loy—That, but also the consequences of that in terms of radiological exposure of people.

Senator CARR—On the question of exposure, I turn to the Maralinga report. Is it correct that ARPANSA approved the health physics procedures of the Maralinga rehabilitation project?

Dr Loy—Yes. We did not provide the health physics services, but we agreed to them and oversaw them.

Senator CARR—You did agree to them?

Dr Loy—Yes.

Senator CARR—Attachment 5.5 suggests that you reviewed these procedures but that they were actually technically approved by the department. Is that right?

Dr Loy—I think you need to go back to when this was happening. ARPANSA did not exist; instead, there was the Australian Radiation Laboratory, which had the relevant expertise but did not have a regulatory role. When you ask whether it approved them, technically it said, 'These health physics procedures are okay,' but that was not a formal regulatory approval, because that power did not exist.

Senator CARR—So you think it is basically a semantic point as to who actually approved them; it is just the way the report is written up?

Dr Loy—Yes. I think, at the end of the day, in a formal sense it had to be DEST, because they were the Commonwealth authority. There was no formal Commonwealth regulatory authority but DEST, who took advice from the expertise in ARL.

Senator CARR—What role did ARPANSA play in approving the ISV technology as part of that process?

Dr Loy—It was a health physics role. The decision to undertake ISV was recommended by the original technical assessment group that brought forward options for the Maralinga clean-up and subsequently overseen by MARTAC, the Maralinga Rehabilitation Technical Advisory Committee.

Senator CARR—Did the requirements for ISV change after the contractor changed—that is, the transfer of responsibilities from Geoscience through to you?

Dr Loy—Through to me?

Senator CARR—Was there not a change in the contractor from Geoscience through to the responsibilities being transferred to ARPANSA?

Dr Loy—We have never had direct responsibility for carrying out anything. The change that you are referring to, I presume, is the change in the organisational structure of the project that is set out at figures 2.1 and 2.2 of the MARTAC report. That did not change then ARL's role.

Senator ALLISON—Is it not the case that ARPANSA had no part at all in the approval process after 1998?

Dr Loy—The approval of what, Senator?

Senator ALLISON—The approval of health physics procedures. Is that not what we are talking about?

Dr Loy—My understanding is that we remained the technical adviser on health physics procedures throughout the entire project.

Senator ALLISON—That is not the report says. It says that the regulator formally approved all health physics procedures and had the opportunity to review all radiological work permits and methods of work statements that subsequently followed.

Dr Loy—I do not understand. My understanding is that there was no change in ARL's role in the project until ARPANSA was formed early in 1999 and ARL became a part of ARPANSA and therefore our role became a formal regulatory one. In the MARTAC report they have taken the view that the best way to describe the process is to call ARL the regulator throughout, even though in a formal sense it did not have any regulatory power.

Senator ALLISON—Let us ask about whether ARPANSA could have been the approving authority when they effectively had no interest in the cost. Is not part of this process of formal approval also related to the cost of the project, ticking it off as it were?

Dr Loy—As a regulator, everyone tries to behave sensibly but cost effectiveness is what you are on about and what you are aiming for is the safety of the project. Our roles were about approving the health physics—that is, the safety of the people employed on the project on the one hand, and assessing whether the clean-up had met the objectives set for it on the other. That particularly applied to the clean-up of the material on the surface. Once we had a formal regulatory role as ARPANSA the whole project came under our regulatory purview, but it remains the operational role of the Department of Education, Science and Training—DPIE as it then was.

Senator ALLISON—So DPIE in fact was the approving authority even though you have a role in the health physics procedures.

Dr Loy—But DPIE would have certainly said, 'Yes, we will seek to deal with it, pits by ISV or not.' That was its ultimate say. It was in charge of the project in that sense and the decision maker.

Senator ALLISON—Why doesn't the MARTAC report reflect that?

Dr Loy—I think it does.

Senator ALLISON—Can you point to where it does?

Dr Loy—In the pictures on figures 2.1 and 2.2, the organisational structure, and the text that supports all of that.

Senator ALLISON—Where is the text that supports that?

Dr Loy—Chapter 2 deals with organisation and management. I think that entire chapter sets it out in some agonising detail.

Senator ALLISON—Page 63 says:

The Regulator formally approved all health physics procedures and had the opportunity to review all 'radiological work permits' and 'method of work statements' that subsequently followed.

Page 314 says:

A listing of health physics procedures, all of which were approved by the Regulator is presented in Attachment 5.3.

Dr Loy—Health physics procedures were examined by ARL, subsequently ARPANSA. ARL's role was to act as if it were the formal regulator, so it agreed the health physics procedures, but the formality of it was that it did not have the legal power to impose them. That is the difference between pre-ARPANSA and post-ARPANSA. The role in and of itself did not change in relation to health physics, which is simply about protecting the workers undertaking the various jobs from exposure to radiation.

Senator ALLISON—Can you explain why the department's health physics management document was not attached to the MARTAC report?

Dr Loy—No.

Senator ALLISON—Do you think it ought to have been?

Dr Loy—I do not know. It is not on the CD even?

Senator ALLISON—Is that a question of me?

Dr Loy—Yes, it is. I am sorry. I honestly do not know.

Senator ALLISON—It is not. I have not put the CD into my computer. I might do that later and see if it is on there.

Dr Loy—I do not know. I have no reason to believe it could not be made available if it were of interest.

Senator ALLISON—Perhaps you could take that on notice and provide a copy.

Dr Loy—Certainly.

Senator ALLISON—As you would be aware, this report has been heavily criticised. I wonder if it is possible to start working through some of that. Pages 94 and 95 show a project activity summary that lists work that is done with start and finish dates. Table 2.4 shows a heading 'Pit exhumation and restoration', but it does not say which pits it refers to. It shows exhumation of debris pits at Taranaki taking place in the period 27 July to 20 September 1997, but in fact, as I understand it, no pits were exhumed at Taranaki until the ISV project was cancelled in 1999. Can you explain why the report would indicate that?

Dr Loy—I think it may be the term 'debris pits' that lies behind it. There was a collection of pits that were of no particular radiological significance. It may be that that is being referred to in that table.

Senator ALLISON—Perhaps you can take that on notice to clarify that. The table shows pit exhumation of the TMs site in the period 21 to 23 October, but in fact it is understood that the exhumation of those pits took much longer than three days. For instance, pit 2U was the first remediation work at the TMs site, and that took nine days—page 294 confirms that. There was a delay of two days during exhumation of pit 22, an area of some consistency in terms of the reporting.

Dr Loy—I think I need to say that the operator of this project was what is now the Department of Education, Science and Training—

Senator ALLISON—So I should ask them?

Dr Loy—and they ultimately take responsibility for what is reported in this report—albeit that the report comes from MARTAC—and of course for the operation of the project itself. I am able to help you as much as I can based on my knowledge of it, but—

Senator ALLISON—I will take that up with the department. An area that you were responsible for under ARL was the area within which contaminated soil was to be removed for burial, and I understand that technicians from ARL delineated the boundaries. Page 189 describes how ARL set the boundaries. It says:

The final soil removal boundary was set at least 30 m outside the last detected visible fragment or particle exceeding MARTAC criteria.

But isn't it the case that there were fragments beyond that boundary? Why is it that that did not appear in the report?

Dr Loy—I believe that the report we have made about our assessment of the final clean-up is accurate and does deal with those issues.

Senator ALLISON—Let us take the area which I understand to be about four metres outside the boundary. This area was contaminated with lead bricks between the Taranaki north-east and north plumes.

Dr Loy—And you are saying that contamination remains?

Senator ALLISON—When the health physicist went to remove this material, the lead bricks, after soil removal was complete they apparently had to dig down some 600 millimetres to retrieve it. So there is, firstly, the question of it being there and, secondly, that it was covered up by contaminated soil at some stage.

Dr Loy—What date are you referring to?

Senator ALLISON—I do not have a date for that.

Dr Loy—I will take that on notice.

Senator ALLISON—Thank you. On page 205 the report says that after soil removal was complete additional scanning was carried out. It says:

... scanning was carried out to a substantial distance beyond the outermost particle or fragment located.

Could you clarify what 'substantial distance' means and why it was not more precise?

Dr Loy—I will do that on notice also. It is probably covered in the detailed appendix of our assessment.

Senator ALLISON—Would you agree that ARPANSA certified that the burial trenches were constructed consistent with the national code of practice for near-surface disposal of radioactive waste? I think that was part of the minister's speech on 25 March.

Dr Loy—It referred to the criteria for the materials that could be disposed of by near-surface disposal according to the near-surface disposal code, yes.

Senator ALLISON—How is it that you are able to do that given that no-one from ARPANSA or ARL was actually involved in any way in the positioning, design, excavation, filling or the covering of the trenches? How could such a claim be made?

Dr Loy—We are very knowledgeable about the way in which the trenches were designed, constructed and filled. In terms of the inventory—

Senator ALLISON—How can you be knowledgeable without being involved?

Dr Loy—In order to provide a view that what was being done was consistent with good practice, we needed to obtain that information.

Senator ALLISON—And how did you do that?

Dr Loy—Through MARTAC and through the department directly. Certainly our officers were very much on the site on many occasions and so were familiar with what was going on. I do not have any feelings of doubt or any difficulty about that.

Senator CARR—Let me put it another way, Dr Loy. Are you familiar with the remarks of the American geochemist Dale Timmons in regard to this particular project?

Dr Loy—No, I am not.

Senator CARR—Well I will ask you to take this on notice. Could you examine the remarks made by Mr Timmons, in particular his remarks that MARTAC had no understanding of how the ISV process worked. Given the government's attempts to discredit Mr Timmons—which it has since retracted—I am wondering if you could advise the committee if the lack of expertise on the part of MARTAC actually concern ARPANSA?

Dr Loy—I am happy to answer that question now. I believe MARTAC did a most thorough examination of ISV, which is described at great length in the report, and there have been responses by Geosafe. So the issue is certainly explored in what one could almost say is mind numbing detail in the MARTAC report, and I think it stands on its own. Of course there was great controversy about the decision not to proceed with ISV, and that is not unexpected. But, at the end of the day, one of the ISV activities exploded. It could have caused serious injury. It could have caused death.

Certainly, from the point of view of ARPANSA—by then a regulator—we would have been very wary, without full knowledge of the root cause of that explosion, of agreeing that the process could continue. There were other criticisms made of the ISV process and they are explored in detail, as I said, in the MARTAC report, but for us the issue was the fact that there had been a serious accident and we had no confidence that the cause of that accident had been sufficiently identified and dealt with in such a way that you could say it would not occur again.

Senator CARR— I will ask you another question with regard to that particular matter. I would ask you to also take this question on notice, because these are quite serious issues. This committee was advised—I presume that Senator Allison has received similar correspondence—by people who were quite intimately involved with the project and had occupied very senior positions within the project in a technical sense, of the following:

This section of the report—

the section that deals with the ISV—

shows how requirements changed, especially after the transition from ARL to ARPANSA It also makes spurious claims about the requirement to melt steel amongst the debris; melting to the bottom of

individual pits; and the presence of debris and plutonium under the ISV blocks. Reference to other documents that are not appended show that MARTAC's claims are ill-founded. In at least one instance, MARTAC relates comments made by ARPANSA, but leaves out a vital sentence which denies the point they are attempting to make.

Could you have a look at the comments you made to see whether or not they have been edited in the report? As I said, I expect you will take that on notice and establish whether or not it is the case that in that section ARPANSA's comments have been edited.

Dr Loy—I will happily do that but I would reiterate that, while there were debates about the melting of steel or the non-melting of steel, or what was enclosed within the individual melts and so on and so forth—and they are important issues—the main thing, ultimately, in our minds was the fact that one of the melts exploded. In addition to those debates about the effectiveness of the process overall, the cause of the explosion had not been determined, and therefore we could not say it would not happen again. But I will certainly respond to your question on notice.

Senator CARR—Thank you very much. Alan Parkinson has apparently contacted you on a number of occasions concerning the issue of the safety checks after the clean-up—the measuring of the safety of the site and the presence of radioactive elements. Is it the case that you have failed to respond to Mr Parkinson on that matter?

Senator CARR—On two occasions Mr Geoff Williams of ARPANSA has had this matter raised with him, particularly with regard to the question of the dust after the soil removal. Is it the case that there has been no response to Mr Parkinson from ARPANSA about that particular issue?

Dr Loy—As I said, I am not aware of it. Certainly if there had been some correspondence it should have been responded to; it would be wrong if there has not been a response.

Senator CARR—I will have a number of other questions to put on notice on that matter. I have to go to another committee so I will leave you in Senator Allison's capable hands.

Senator ALLISON—Would you comment on the soil removal. On page 193 there is a brief description of how soil was removed by scrapers, with the assistance of a bulldozer and then a road sweeper to brush and vacuum away the soil. It does not mention that final bits of contaminated soil were removed, as I understand it, by a man with pick and a vacuum hose. That is apparently clearly shown on the video related to the soil removal. Why was that not included in this report?

Dr Loy—I do not think that is my responsibility, with respect. I think that is an issue you should take up with DEST.

Senator ALLISON—Okay, I will do that. Can you confirm whether it was originally the recommendation of ARPANSA that the debris should be encased in concrete?

Dr Loy—No.

Senator ALLISON—It was never a recommendation of ARPANSA that this be the case?

Dr Loy—I am not aware of that. Which debris are you referring to? The debris in the pits?

Senator ALLISON—The debris that was originally planned for ISV but then was located in the trenches and covered.

Dr Loy—No. The sequence of discussions, as I recall them, were that, obviously, the decision to proceed with ISV had been part of the option put by the TAG in the first instance and it was then recommended by MARTAC and taken up by Primary Industries and Energy, and that proceeded. There was discussion about how to deal with particularly the outer pits, which were much less well defined. The next proposal was a kind of hybrid option of constructing a pit and moving the debris from these less well-defined pits into that and using the ISV process in a much more controlled environment, and that was being discussed. Then the explosion took place and there was some view that perhaps the hybrid option would be the way to go but, ultimately, the decision was taken that it would be appropriate to excavate the remaining pits and put them in a trench and cover them with clean fill.

Senator ALLISON—I do understand the history but my question to you was—

Dr Loy—I do not think we have ever had a view that they needed to be encased or enclosed in concrete; the burial in the trench with the clean fill was sufficient.

Senator ALLISON—Going back to the health physics review team, as I understand it one of the members of that team was from ARPANSA. Is that right?

Dr Loy—The health physics review team?

Senator ALLISON—Yes.

Dr Loy—I am not sure of that. The health physics team on site was provided by CH2M Hill, I believe—I think that was the firm. Our role was to review health physics procedures as well as to provide the service for whole body monitoring both on site and at ARPANSA.

Senator ALLISON—After January 1998 who are you saying actually approved the procedures, taking into account the cost?

Dr Loy—The whole project was run by the department. Any ultimate responsibility for doing one thing or another lay with the department. As I said, they refer to the 'regulator' prior to 1999, but that was an informal role then, a technical advisory role. It was acting as if it were a regulator, but it was not a regulator. Ultimately the responsibility lay with DEST and its predecessors.

Senator ALLISON—If I put it to you that that department had no suitably qualified staff to do this—and this is a question I put to the department as well—what is your view about that?

Dr Loy—The department operated the project through a project manager and the contracting of expertise of all kinds.

Senator ALLISON—So you would reject that criticism?

Dr Loy—I would say that the department operated the project through a project management structure rather than having its substantial internal expertise.

Senator ALLISON—Does that mean that GHD would have effectively been the approving body for the procedures?

Dr Loy—They were the project manager.

Senator ALLISON—I know that.

Dr Loy—You would expect the health physics procedures to have a tick from ARL and on that basis be approved by the operating organisation, which is ultimately the department. Whether the procedure said that that could be signed off by GHD I am not sure, but ultimately the responsibility was the department's. I would have expected that all health physics procedures would have received—and I am sure they did—clearance, approval, agreement, whatever the right word is, from ARL as 'regulator'.

Senator ALLISON—Page 63 of the report says that the regulator formally approved all health physics procedures and had the opportunity to review all radiological work permits and methods of work statements that subsequently followed. What do you say to the suggestion that confusing health physics procedures and work procedures is inappropriate?

Dr Loy—I think that is wrong. Health physics is about work procedures. It is about saying whether you can go in an area or not. It is about saying: 'If you go in this area, you need to wear this protective clothing. If you do that, you need to do this.' Health physics ultimately is about work procedures. It is about how to do certain work so as not to receive significant doses of radiation.

Senator ALLISON—What do you say to the criticism that radiological work permits followed from health physics procedures but the methods of work statements did not and that the latter were part of the engineering design process?

Dr Loy—I think it has to be both, in one sense. You have to have work procedures that say, 'This is the work that you have to do.' That obviously flows from the project itself, but work procedures also take into account how the work is to be done because of the health physics requirements.

Senator ALLISON—Page 185 says that workers were required to sign the job safety analysis form. Do you know anything about that process?

Dr Loy—No, I do not.

Senator ALLISON—Perhaps you can take that on notice. It suggested that the job safety analyses were internal Thiess documents and part of an engineering design process, not part of a health physics regime, and that radiation workers were required to sign the radiological work permit after receiving suitable training. Can you explain why it was necessary, even though members of MARTAC considered that the ISV process was superior to any other option, for the report to go to such great lengths to discredit that process. I do not need the history of it; I know what happened. Is it not the case that this process has subsequently been used in the US I think on six occasions, in which it has used ISV for similar storage of contaminated waste? Why was it necessary, as I said, to diminish that as a process so significantly?

Dr Loy—I would not necessarily accept that characterisation, but certainly it was a major issue that MARTAC considered in terms of the effectiveness of the ISV process as applied in the Maralinga context. I think that also needs to be borne in mind: it was in a particular context with a particular set of issues and difficulties. That does not say necessarily anything

about the process applied in a different context but, in one sense, putting all of that aside, as far as ARPANSA are concerned, the big issue was the explosion. That was the showstopper as far as we were concerned. The other issues were important technically but did not play a really major role as far as our assessments were concerned.

Senator ALLISON—We all know the arguments about that. But why does their report not deal with the question of the sorting of debris, which might have identified an object that would cause an explosion?

Dr Loy—I am sorry; I did not hear the latter part of your question.

Senator ALLISON—Why does the report not include a discussion about what has been since a very contentious question about the sorting of the material to be included in the ISV pit? There are arguments that there was an explosion not because of the ISV process being inappropriate but because material was in there that should not have been there that ought to have been sorted. Why was this not canvassed?

Dr Loy—One of the great advantages of the ISV process was that you did not have to sort the pits; you did not have to go to the radiological exposure of workers to get material out and sort it. The value of the process was that it would confine all the material, no matter what it was, in a safe fashion. I think that was the particular attraction of it. If you needed to sort the material, you have already undertaken a hazardous activity, and a simpler disposal method might well have been more appropriate.

Senator ALLISON—Can you point to the document that indicates what you have just suggested.

Dr Loy—I think it is in the TAG assessment. That is why they brought forward the ISV as a proposal and thought that it had strong merits, because it meant that you could address the issue of the pits in a much simpler ultimate fashion without causing exposure to people who sort through them. In my view, it has never been clearly identified why the pit exploded in a manner that would satisfy me, for example, that it would not happen again. It may well have been something external.

Senator ALLISON—If we take, for example, an unexploded ordnance or a gas bottle—a number of ideas have been canvassed as to what might have caused the explosion—

Dr Loy—Indeed, a number ideas were canvassed, but the problem is that a number of ideas were canvassed and none of them was able to be demonstrated as being the root cause.

Senator ALLISON—But you are saying that, no matter what was in there—anything could have been in there—it should not have exploded.

Dr Loy—That was the attraction of the ISV process: you could address the pits without them being sorted.

Senator ALLISON—If there were an unexploded device or a gas bottle, you would expect that in the ISV process that should not have exploded?

Dr Loy—No-one had any reason to believe that there were such things in the pits. If TAG had thought that that was a significant problem, maybe they would not have recommended ISV—I do not know. Nonetheless, given people's understanding of what was in the pits, TAG

recommended ISV, or put it strongly as one of the options, for the reason that it avoided sorting—that was one of the reasons—and gave you a good product that dealt with everything in the pit. I think to go down the track of then sorting everything would take away many of the advantages of the ISV process. It may have been something of that kind that caused the explosion, but it was not able to be demonstrated.

CHAIR—Senator Allison, we asked TGA to be back at 10 o'clock and we are running very seriously over time for the rest of the portfolio. Have you any idea how much longer you will be going?

Senator ALLISON—I have got a little bit more to do.

CHAIR—How much is a little bit more?

Senator ALLISON—Maybe to 11.

CHAIR—That puts us an hour behind.

Senator ALLISON—Nobody asked me how long I would need.

CHAIR—Our times were set last night.

Senator ALLISON—As I said, no-one asked me.

CHAIR—You were here last night.

Senator FORSHAW—I do not want to dispute this, but my recollection is that we thought we would be an hour. I have to concede that we—being the opposition—have gone beyond that. I also have some questions for Dr Loy, but they will not take any longer than 10 or 15 minutes.

CHAIR—That means quarter past 11.

Senator FORSHAW—It could do, yes.

CHAIR—All right, go on.

Senator Patterson—I would ask that we try and speed up because it does mean that some portfolios get squashed at the end and they do not get proper scrutiny.

Senator FORSHAW—We will ensure that does not happen, Minister.

Senator ALLISON—I have a question about the decision to drench the blocks that were to be broken open. Why were those blocks not allowed to just cool naturally?

Dr Loy—I think that is a question you should direct to DEST.

Senator ALLISON—There are probably quite a lot of questions here that can be directed to DEST. I might actually stop at this point and let Senator Forshaw ask his questions.

CHAIR—That was a very quick half an hour, Senator Allison. You go to the top of the class.

Senator ALLISON—It just means that quite a lot of questions will be on notice rather than asked directly.

Senator FORSHAW—I have a couple of issues, Dr Loy. The budget papers for ANSTO show that there will be an expenditure of about $18 million over four years on increased

security at the Lucas Heights site. Does ARPANSA have any role in the assessment or development of those new security arrangements?

Dr Loy—Yes, insofar as part of our overall licensing requirements is that ANSTO have a security plan—whether it be for the HIFAR reactor, fuel operations or whatever—for the site overall. We would expect that security plan to be developed in conjunction with the security agencies of the government. In addition, the Australian Safeguards and Non-Proliferation Office have their own role in relation to the protection and physical security of nuclear material under safeguards. So they also have a role. While we have our formal licensing requirements for security plans, we probably let the major running be taken by ASNO and the security agencies, but we keep an overall eye on it.

Senator FORSHAW—I understand that there is an analysis or report prepared by ARPANSA called the radiation consequences analysis, a report on the impacts and extent of radiation exposure from the new reactor. Has that report been compiled?

Dr Loy—Yes.

Senator FORSHAW—Am I correct in understanding that you have refused to release that publicly?

Dr Loy—I have decided that it should not be a public document, that is correct.

Senator FORSHAW—Could you tell me why you think it should not be made public?

Dr Loy—At one end, you can characterise a report like that as a description of how to go about the sabotage of an installation and a suggestion on how to produce maximum consequences. We endeavour to deal with that as best we can by generalising the language and not being too descriptive. We did that for a number of drafts, but I took the decision at the end of the day in the current security environment it was not appropriate to release it publicly. I have undertaken to fully brief New South Wales authorities on that analysis and its implications for emergency arrangements and I have written to the head of the New South Wales cabinet office to arrange such a briefing.

Senator FORSHAW—Does the analysis include—and I appreciate, given you have said that you do not intend to release it, that you may feel some difficulty in answering these questions—an estimation of the impact and extent of radiation exposure in the Sydney area or the surrounding area of the Sutherland shire which could result from an incident, sabotage or accident? If so, why would you not at least release those findings, given that this is the subject of ongoing debate and claims about the impact?

Dr Loy—The difficulty is positing what you are looking at and what actually takes place. In the case of an accident, we understand the nature of the new reactor, the nature of the old one and the sorts of accidents that could take place. Therefore we understand what could happen to the core of the reactor and what, in an extreme case, might be released. When you are looking at a sabotage event, you really have no firm basis on which to do that. You can think of the vulnerabilities of the reactor and you can think of how they are protected by the physical security systems, but what do you posit as being the sensible maximum credible event? If you go to the extreme of assuming everything away—nothing works and the whole

inventory is released and you get an absolute extreme case—the value of advising the public of that seems to me to be pretty limited.

Senator FORSHAW—Why? That is a judgment you have made.

Dr Loy—Because it is not something that is sensibly founded. It is just throwing your hands up and saying, 'We don't actually have any basis for determining what is sensible here. So we have just thrown everything at you.' As I said in my decision stating that the reactor could go ahead, we certainly looked at what might be the consequences of crashing an aircraft into the facility and assuming that it got through all the shielding and exposed the core and assuming the containment was open, there would be a buoyancy because of the fire and the radiation distribution would go higher into the atmosphere than in an accident and that you might expect some radioactive contamination at a distance further from the reactor than in the case of an accident. On the other hand, it also would have spread more so that the impact on individuals would not be such as to cause you to say that the reactor should not be constructed. To go beyond that seems to me to be not particularly worth while and also has security implications.

Senator FORSHAW—But did your analysis not do just that? You told me a moment ago that your analysis looked at the maximum possible—

Ms Halton—It did not look at the maximum credible accident; it looked at a maximum event, if you will, together with a substantial fire. As I said, I do not think that has a value in public discussion. I think it is sensible for us to talk to the emergency authorities about that so that that possibility can be appropriately incorporated into their plans. I think it means an extension of planning, rather than any fundamental change. My view is that, in the present security environment, releasing that information would not be of assistance to the public.

Senator FORSHAW—What do you mean when you say that the reason you would not release it is the current security environment? I understand what you are saying. If there are scenarios within the analysis which, if people got hold of them, could provide information about how to commit an act of sabotage, that is understood; but, beyond that, what is the feature of the current security environment that would suggest you would not release it now.

Dr Loy—I guess that essentially was what I was meaning by saying that, in the environment in which people are focusing on various installations that one imagines in some scenario could be attacked, releasing information about them is simply not helpful. In 20 years time, we might be in an environment in which no-one even conceives of that happening.

Senator FORSHAW—It is a bit hard these days to rule out possibilities, given the current security environment around the world. If anything, September 11 taught us that even the most wildly imaginative incident could take place.

Dr Loy—That is right, and of course it is incumbent upon me, as a safety regulator, to think about that and to think about the implications of it. I have done that, and it is also necessary and appropriate that the people involved in emergency planning do some thinking about it. They have done that also; but, as I said, I have offered to have a full briefing of the emergency agencies in New South Wales. There have been some discussions with them already.

Senator FORSHAW—Dr Loy, you would be aware that there is an ongoing debate or differences of opinion about the impact upon Sydney of a serious major accident or serious incident at Lucas Heights. Some people say that it would have only a small impact in a very narrow radius. Others argue that it could mean 80 or 100 kilometres or more of serious radiation exposure across Sydney. Given that those arguments are out there in the public arena all the time, if your analysis, for instance, said that even in a worst case scenario the dangers to the people of Sydney are very minimal, wouldn't you release that? Wouldn't you tell people that? If you do not tell them that, doesn't that then lead people to think, 'Hang on a minute, ARPANSA has done this serious study and then won't tell us what their findings are'?

Dr Loy—I take the point you are making.

Senator FORSHAW—It is not just me making it; other people are making this point—that is why I am asking.

Dr Loy—It comes down to a matter of judgment and taking account of security considerations. Certainly, I can say that the notion of serious consequences out to 50 kilometres or 50 miles—whatever the number is—is not there; otherwise, I would not have licensed the construction of the reactor. As I said, the difference in these scenarios really is because of the buoyancy induced by a fire: you can get impacts at different places to where you would get them from an accident, and that requires some adjustment or thinking through of how to respond if such an incident occurred in an emergency. Certainly you are dealing with consequences, but I would not characterise them as severe radiation consequences other than on the site itself; otherwise, I would not have proceeded to licence its construction.

Senator FORSHAW—There is just one other issue, Dr Loy. There was a report again in the *St George and Sutherland Shire Leader* newspaper on 13 May regarding three workers at the Lucas Heights facility being 'contaminated'—that is the word used—with radioactive noble gases. ANSTO disputes that. What can you tell me about this incident, Dr Loy? When were you first advised and what are your findings?

Dr Loy—We have notified ANSTO that we are undertaking a formal inspection of that facility in the near future. Inspection is the term used under our act, but it is like an audit—we will be looking at it in detail. In particular, recently there have been some changes to the ventilation facilities in building 54, and obviously we will want to satisfy ourselves that that incident was not related to the implementation of that new ventilation—it would obviously have important implications if it were. That is a matter that we will be looking at in particular in this inspection. I am not sure whether that will take place this week or next week, but it will be soon.

Senator FORSHAW—Why the delay? I understand that incident took place on 8 May. When I say that I am relying on the report in the *St George and Sutherland Shire Leader* newspaper of 13 May, which said it had occurred on the previous Thursday, which was 8 May. Why is it taking until next week for ARPANSA to undertake an investigation?

Dr Loy—I do not think the incident in and of itself is a particularly major issue. Certainly, we take the view that it is something that we should know about, but in and of itself it is not a major problem. But our particular concern is to be satisfied that there is not an ongoing problem because of the ventilation system.

Senator FORSHAW—We asked you earlier—although in answering the earlier questions you did not go to this—when was ARPANSA informed of this incident? Do you recall? And how were you informed?

Dr Loy—I am not sure that we were formally informed of it. I would have to check our records.

Senator FORSHAW—I have an article from the *St George and Sutherland Shire Leader* written by John Mulcair. You know who John Mulcair is, don't you?

Dr Loy—I have had a conversation with him from time to time.

Senator FORSHAW—You know that he used to work for ANSTO and is now a journalist with the newspaper?

Dr Loy—Indeed, and he appears to have some good sources.

Senator FORSHAW—I am sure that he would have. The article says:

> ANSTO would not say when the contamination took place.

The article then quotes a spokesperson who says:

> These are internal issues, not a path we want to go down in the public arena.

The article then goes on to note that the *St George and Sutherland Shire Leader* was tipped off, presumably by a source within ANSTO, about this incident. So the incident gets into the newspaper with the headline 'Radioactive gases contaminate workers', yet it is not communicated to ARPANSA. Does that concern you?

Dr Loy—As I said, I think the incident, just looked at in and of itself as if it were a microcosm, may well not be reportable. I think we would take the view however that, particularly given the potential for it to be linked to the implementation of the recently installed ventilation system, it is something that we should have known about. So certainly part of our inspection will address that issue.

Senator FORSHAW—Let me just quote the article further. It says:

> The nuclear regulator, the Australian Radiation Protection and Nuclear Safety Agency, began inquiries after an anonymous tip off.

Can you confirm that?

Dr Loy—I suspect that one of our people was on the site and had a conversation with someone they knew. Subsequently, the regulatory branch would have made some phone calls. As I said, I would have preferred that we had been formally notified of the event, particularly because of the potential for it to be related to the ventilation system.

Senator FORSHAW—The incident happened on Thursday, 8 May and it was reported in the newspaper the following Tuesday, which was their next publication date, as I am sure you are aware. Would it not be good practice for ANSTO to advise ARPANSA of all incidents that occur where there is some suspected radiation exposure, even if only to not have to be continually responding to my questions about these situations?

Dr Loy—In one sense, people working at ANSTO get exposure all the time.

Senator FORSHAW—Yes, but you know what I am talking about.

Dr Loy—Abnormal occurrences happen quite often, as they do in any process. At some level, we need to be notified and we have attempted to define that. We think we should have been notified in this instance, so we will examine why we were not and why ANSTO thinks it should not have. I think we will make some changes to bring that about.

Senator FORSHAW—Do you follow up on what actually happened to the individuals? It says in the article:

> One man is believed to have breathed in the gases and the clothing of all three was contaminated.

If that is correct, it would suggest that the protective clothing and breathing apparatus did not work satisfactorily. Maybe it was not being worn; I do not know.

Dr Loy—I do not think they would have been wearing any substantial protective garments.

Senator FORSHAW—This is why I am asking questions.

Dr Loy—With noble gases, if they breathed them in, they would have breathed them out again. So I do not think the important issue was the dose received by the workers, because it will have been trivial. But the fact that there was some exposure of noble gases in that area and that is not what the area is designed for leads you to question the ventilation issues.

Senator FORSHAW—That the noble gases got in there when they should not have been there?

Dr Loy—Yes.

Senator ALLISON—In relation to contaminated soil, the MARTAC report talks about the need to suppress the dust on the site. It says:

> This requirement to suppress dust was mainly for operator perception and for visibility and plant movement safety reasons.

Do you agree with that?

Dr Loy—Yes. In terms of the operation on the site, given that the workers who were working in the cabins of the machinery were very well protected, the fact that they were raising dust outside in and of itself was not a radiological issue for them. Obviously they did not want to bump into each other due to the fact that they could not see, so that was important. That, in my view, would be the main reason you would look for dust suppression due to such an operation.

Senator ALLISON—Isn't there another issue about the enormous quantities of soil that were removed through dust blowing onto other areas?

Dr Loy—My view is that that is not a major issue. Perhaps we could answer that in more detail. Simply the fact that you can still detect and measure defined plumes over the 40 years since the minor trials leads you to believe that the distribution through dust raising is not a significant issue, otherwise the plumes would have been smeared out. I would be happy to expand on that answer, if that would be helpful.

Senator ALLISON—Yes, thank you. Could you also check the lots which had been checked by ARL and given clearance certificates which subsequently had contaminated soil blown onto them at quite some depths.

Dr Loy—Perhaps we could put those issues together in a response on notice.

Senator ALLISON—By way of a general comment about those couple of pages on dust suppression, there is a lot about the considerable effort and the difficulties, but the report does not in fact say how, at the end of the day, it was achieved. As a general criticism of the report, there are a lot of attempts at trying various methods of suppression, but we are not left with any great sense of knowledge about how it was done in the end or whether it was done.

Dr Loy—As I said, in terms of the radiological issues, the primary protection was the measures taken on the ventilation of the cabs of the equipment. We would not have seen it as a major issue from that point of view. But obviously, directly from the operational point of view, it is important. I have no real, intimate knowledge of what was achieved at the end of the day.

Senator ALLISON—My understanding is that it was not successful until quite late in the project when Taranaki and the TMs site were dealt with and that it was only then that the project managed finally to deal with the dust suppression. The question is why doesn't the report indicate that? I will leave that with you.

Dr Loy—I point you to DEST on that one in particular.

Senator ALLISON—Yes. I will do that. Regarding the use of depleted uranium in Iraq, was your department consulted at all by the Department of Defence on the question of American weapons, including DU?

Dr Loy—No, not in relation to hostilities in Iraq as far as I am aware.

Senator ALLISON—Has ARPANSA considered this question?

Dr Loy—We have certainly considered the questions of DU and its health impacts in war areas, as a kind of general issue. We assisted and participated in the preparation of the WHO work on DU, and one of my officers also took part in a mission to Kuwait to assess the impact of DU munitions in that country as a result of the first Gulf War. So we have a fair degree of knowledge about it and have applied that knowledge specifically in the Kuwait situation.

Senator ALLISON—How was it applied?

Dr Loy—First of all, it was a mission to assess the degree of contamination by DU in various areas and to prepare a program for measurement of the contamination at different areas so that a more complete and formal assessment could be made. That program of measurement has been completed. I think it has finalised its report and it is within the IAEA and will be released shortly.

Senator ALLISON—Might that method of measuring be adopted in Iraq?

Dr Loy—I think it is reasonably standard form but it certainly gives an approach to making the measurements you need to make for an assessment of a particular area's contamination by DU. There would be no reason why it could not be used in some other circumstances.

Senator ALLISON—How does this compare with the work that the US administration has done? I am trying to see where, with Kuwait, this fits in with the bigger picture.

Dr Loy—Our involvement has been through the International Atomic Energy Agency, which put together a team of experts from different countries, and that included one of our

officers. As I said, we also worked with WHO on their report which was, if you like, a kind of background assessment of DU without referring to specific sites.

Senator ALLISON—Is that material publicly available?

Dr Loy—The WHO report certainly is.

Senator ALLISON—And Australia's contribution to it? Is there a document?

Dr Loy—We worked as part of the group that put together that report. The Kuwait report will be released by the IAEA soon.

Senator ALLISON—Was advice ever sought from ARPANSA by the Department of Defence about the Australian use of weapons including DU? We do not use them, and even the ones we purchased from the US were not DU? Is that because of a concern about radiation exposure?

Dr Loy—My understanding is that Defence made that decision some years ago. I am not sure whether they consulted us but I can certainly check and let you know.

Senator ALLISON—Would it be your view that it is inappropriate for Australia to use such weapons?

Dr Loy—I do not necessarily see it as my role to enter into that debate. The overall assessment of DU contamination—thinking, if you like, of the post-battlefield situation—is that in general it is not a high radiological problem. You can imagine scenarios in which children could ingest substantial amounts, but probably the chemical toxicity issue would be more damaging if there were ingestion of significant quantities of depleted uranium.

Senator ALLISON—They do have dust storms in Iraq, don't they?

Dr Loy—Having said that in that context, whether that means Australia or any other country should or should not use those weapons is not something I want to essay an opinion on.

Senator ALLISON—But, talking about dust suppression, they do have lots of dust storms in places like Iraq, do they not?

Dr Loy—I imagine so. Whether that resuspends the heavy particles, I am not sure. Basically uranium, especially depleted uranium, is not particularly radioactive, and you have to ingest a lot to get a really significant dose. If you did that, the chemical toxicity of the material would be more concerning to your health in the immediate future. That is the assessment in post-battlefield circumstances and, as I said, the consequences of that in policy terms will obviously be played out in other forums.

Senator ALLISON—Indeed. Thanks.

CHAIR—Any further questions for Dr Loy? Thank you, Dr Loy. We will now go back to the TGA.

[11.14 a.m.]

Therapeutic Goods Administration

Senator FORSHAW—When we finished last night, I had asked whether the committee could be supplied with a copy of what is known as the Corcoran review, the review of TGA

audit and licensing of good manufacturing practice. I think you took that on notice. Can you tell me what the position is on that?

Mr Slater—I did indeed take that on notice. Having consulted with the parliamentary secretary, I am very happy to table the report for the committee. We did bring along 12 copies, but unfortunately we failed the photocopying test and we have only got three good ones. But we will have nine others for you shortly. I think it would be a good thing if we also table, for the committee's edification, a progress report on the implementation of those recommendations. We have 12 copies of that for you.

Senator FORSHAW—Thank you for that. Can you tell me why there was a change of heart by the parliamentary secretary in agreeing to provide this today?

Mr Slater—It was not a change of heart by the parliamentary secretary. I should emphasise that. It was the department thinking about whether we should just table these sorts of internal working documents which guide our concentration on constant improvement and management improvement documents when they relate to internally driven reviews rather than externally driven ones.

Senator FORSHAW—Mr Slater, a request was made for a copy of the report of the Corcoran review through the Parliamentary Library earlier this month, I believe, and we were advised that the library was going to get a copy from the TGA. But then something happened and we were then advised that, unfortunately, it would not be provided. Are you aware of any requests coming through to the TGA from the library?

Mr Slater—I was not personally. But I was advised that we did get a request for that. The answer as to why we did not respond positively to that request is, as I said, this is an internal working document. It is one that was driven by the TGA's wish to review its own processes and procedures. This was not driven by an external review, and we needed to think carefully as an organisation about which documents which guide our thinking we would make public.

Senator FORSHAW—Was it made available to any groups or companies at all?

Mr Slater—The report was made available in consultation with our industry associations.

Senator FORSHAW—Made available to who?

Mr Slater—To the peak industry bodies, so that we were able to effectively consult with them about the implementation of those recommendations.

Senator FORSHAW—So they were actually provided with the report?

Mr Slater—Yes.

Senator FORSHAW—The review, of course, did involve consultations with industry about the issues and the processes involved, did it not?

Mr Slater—That was fundamental to the effective outcomes of the review.

Senator FORSHAW—That is right. It would have been very useful to have had the review when the request was first made through the library so we could pursue questions at estimates today. We are still going to try and do that. Thank you for providing it this morning. You put a fair amount of detail on the web site about this review, did you not?

Mr Slater—In respect of the fact that the review was being conducted and that we would have consultations with industry associations around it.

Senator FORSHAW—Are you saying that that is all you put on the web site—that you were conducting the review?

Mr Slater—The report itself was not on the web site.

Senator FORSHAW—I know the report was not on the web site, otherwise I would not have asked you for it. But can you tell me what was on the web site in regard to the Corcoran review?

Mr Slater—It was the sort of information where we said, 'We are doing this study and we will be consulting with stakeholders in developing the findings, and consulting with them about the conclusions and the recommendations that arise from the study.'

Senator FORSHAW—I have had a look at the web site and I can find four pages of dot points—admittedly large print, but three to four pages—including the fact that the review was being undertaken and that it was the most detailed review, along with the terms of reference, a summary of the findings, some of the key recommendations and some proposals in regard to the implementation of the recommendations. You put a lot of headings and comments about this review on your web site, but then you do not make it available.

Mr Slater—This is the TGA being open and transparent about its processes.

Senator FORSHAW—It has the window half open. Why did you put those points on the web site? What was the purpose of doing that if you had provided the report to the industry associations?

Mr Slater—We provided those points on the web site so that we were indicating that we were conducting this review and that we would be doing it with external stakeholders so that we could ensure that the findings, conclusions and recommendations that were developed from the review were relevant, that they had appropriate input and they were practicable for implementation.

Senator FORSHAW—Don't you think it is natural that, if somebody goes to your web site and sees a reference to the review—and there are fairly detailed references to the review, from the fact that it is being held and the terms of reference through to what the findings and recommendations are—it will lead them to say, 'Can we get a copy of the review?' It becomes a bit more than an internal review if it is put on the web site, doesn't it? Hopefully you believe that a lot of people are looking at your web site.

Mr Slater—What I mean by internal review is that this review was initiated by the TGA. It was not an external review where the TGA was directed to undertake a review or where the terms of reference were set externally. We have a lot of international regulators who are great readers of the TGA web site, particularly in this region, where we are the first-line regulator. We are considered to be one of the world's three leading regulators and we have a lot of international regulatory agencies trawl our web site for the latest information.

Senator Patterson—Senator Forshaw, I do not know from your questioning whether you think it would have been better to not put it on their web site so that nobody knew what the TGA was doing at all, or to put it on the web site and say: 'This is the summary—this is what

we were going to do, this is what happened and this is the summary of the recommendations.' I do not understand. The concern I have is that—

Senator FORSHAW—Have you had a look at the web site?

Senator Patterson—No, I have not looked at the web site.

Senator FORSHAW—Have a look at the web site and then you might understand the questions.

Senator Patterson—The thing is that this sort of questioning would make some agencies think, 'Why would I bother doing a review?'

Senator FORSHAW—Can I just continue my questions? Just let me get on with the questions. You can express your views—

Senator Patterson—I can express my views. I have every right to say what I think in this committee hearing.

Senator FORSHAW—Of course you do, but you are just taking up time and you have been complaining about wasting time.

Senator Patterson—Don't you tell me about wasting time. I am saying that there is an accusatory tone in what you are saying about the TGA, who have actually initiated a review rather than going on—as they had been—to get an outside review. They have been transparent in putting it on the web site. I will have a look at the web site. I try and look at lots of the departmental web sites, but I do not get to see them all all the time.

Senator FORSHAW—Mr Slater, let me take you to the summary of findings that you have put on the web site. It is pleased to say, obviously, that the GMP audit was highly valued by industry. That was one of the findings in the report. It also said that audit staff were highly competent, individual audits were done well and there was a sound risk management framework. You put these positive findings of this review on the web site, but then you do not want to make the review—the detail of what is actually in the review—available publicly.

Mr Slater—It was a question really of precedent here. This was an internally focused review. When you asked me the question last night I was not expecting it, and I believe that it was appropriate for me to consult with the departmental secretary and the parliamentary secretary about it. It was the sort of internal review that we would think carefully about; I would define it as internal working documents which are not for publication. It was certainly not intended to make this report available other than to a select group of stakeholders.

Senator FORSHAW—The web site also states that—and I assume this was a finding of the review—there was significant scope for improvement, and it identifies a number of areas.

Mr Slater—I thought you would be pleased that we were open and transparent.

Senator FORSHAW—I am pleased that you put these on, and that is what led me to then think that it would be useful to get a copy of this whole review and to actually read the document that led to these findings instead of just being told what the findings were by the TGA.

Mr Slater—As we made available this morning—

Senator FORSHAW—I have got it now.

Mr Slater—we have also given you an up-to-the-minute implementation progress report, which shows you how far we have got in implementing the review in a very short period of time.

Senator FORSHAW—Can I just identify some of the areas where, it was found, there was significant scope for improvement. They were management information systems, managing risks and work performance, and increasing sponsor responsibility. They were key findings. Do you acknowledge that?

Mr Slater—Yes.

Senator FORSHAW—It then apparently made some key recommendations, one of which states here on the web site 'improved consistency in GMP auditing'. Because I have not had an opportunity to read the entire report you have just provided, could you tell us what that involved?

Mr Slater—I will make some introductory remarks about it, and then I will ask Ms Maclachlan, who is the head of the area, and also our chief general GMP auditor to join me. One of the thoughts of the consultant here was that the TGA should have, as part of its audit process, an opportunity to pass on to companies the benefits of its knowledge rather than merely just focusing on compliance and fault finding. Hence, the consultant's thinking has gone to the fact that he believes that all audits should be scheduled, for the very reason that appropriate people can be there, that planning can be carried out in advance and that people can be there at the close-out to ensure that the TGA passes on information.

A second key feature of his thinking was that we should introduce a peer review process so that auditors could ensure there was a consistency in approach. Certainly, one of the concerns industry had was that some auditors were a bit hard. They thought that maybe in a peer review process a shared audit approach might well ensure that there was a more consistent view from auditors.

Senator FORSHAW—Were you going to add some comments, Ms Maclachlan?

Ms Maclachlan—You will see from the document that we are also tabling which relates to the implementation of the recommendations from the Corcoran review that we have undertaken extensive consultation with the regulators of the TGA as well as with industry in implementing these recommendations. In relation to audit consistency, we now have a program in place whereby the chief GMP auditor or the acting chief GMP auditor—and I have Mr Tony Gould here beside me who is actually in that particular role—will undertake a peer review of the auditors on a regular basis. This will involve shadow audits and other forms of reviews, including looking at their audit reports, how they actually conduct the audits and how they interact with the industry. So that particular recommendation about audit consistency has been put into place with our auditing team.

Senator FORSHAW—I would like the opportunity to have a quick read of the review, so we will come back to it a bit later. But I have a few other questions. You mentioned yesterday, Mr Slater, and I think again this morning, that this was a consultancy. Who undertook the consultancy?

Mr Slater—The consultant was Mr Brian Corcoran.

Senator FORSHAW—Yes. The review was provided in March last year, 2002.

Mr Slater—Yes, 2002.

Senator FORSHAW—Can you tell me where in the annual report it identifies that this consultancy was occurring?

Mr Slater—Yes, I can. It is in last year's annual report.

Ms Halton—It is in the list of consultancies.

Senator FORSHAW—Can you take me to it in the annual report?

Mr Slater—We will point that out.

Ms Halton—It is on page 442.

Mr Slater—It is under the heading 'Diagnosis Pty Ltd'.

Senator FORSHAW—I had looked at the list of consultants on that page and I came to the conclusion that that was probably the one that we were talking about, but it does not say 'Mr Corcoran'; it says 'Diagnosis Pty Ltd'. They are one and the same?

Mr Slater—That is right.

Senator FORSHAW—So is Diagnosis Pty Ltd Mr Corcoran's own consultancy company or does he work for this company? What is his relationship with Diagnosis Pty Ltd?

Mr Slater—I would need to take that on notice. I am not sure of that.

Senator FORSHAW—Thank you. Can you tell me what the total cost was? It says here that the contract price was $20,000 including GST. What was the cost of the consultancy?

Mr Slater—The total cost of the consultancy was $29,700. The annual report says $20,000 because that was what had been paid to 30 June 2002. A further $9,700 was paid on completion of the report.

Senator FORSHAW—But the annual report says that the contract price was $20,000.

Mr Slater—Yes.

Senator FORSHAW—Can you clarify that?

Mr Slater—That was the contract price we had agreed with Mr Corcoran. At the end of the consultancy the work that he had done, with additional things that had arisen during the course of the consultancy, led to a total cost of $29,700.

Senator FORSHAW—Was the potential for additional payments over and above the contracted price provided for in the original contract?

Mr Slater—For the amount of work that was required as we went through the consultancy process, it was agreed between the consultant and the TGA that this additional work should be covered.

Senator FORSHAW—That is not quite what I asked. Was that provision in the original contract?

Mr Slater—The original contract price was $20,000.

Senator FORSHAW—Yes, I know. I am asking whether that contract for $20,000 included a provision whereby Mr Corcoran or this company could obtain a greater amount by agreement? Can you take that on notice?

Mr Slater—Yes. I have not got the contract document with me.

Senator FORSHAW—I will ask you—and I am sure you will take this on notice—whether you could provide us with a copy of the contract.

Mr Slater—Certainly.

Senator FORSHAW—Thank you. Was this contract published on the web site in accordance with the Senate order regarding publication of contracts?

Mr Slater—The contract details, yes. The contract documents would not be published on the web site.

Senator FORSHAW—No. The order requires that details be published, I think it is generally through the web site—not full details or a copy of the contract but an identification that a contract has been entered into.

Ms Halton—We are just checking the details. My understanding is that it is amounts above this amount that have to go on the web site. I have just asked someone to give us some advice and we will come back to you.

Senator FORSHAW—How was the consultant selected?

Mr Slater—It was through a tender process.

Senator FORSHAW—When was the tender called?

Mr Slater—It was certainly towards the end of 2001. I can get you the exact date for that.

Senator FORSHAW—As I said, I want to come back to this review later in this section. I would like to turn to TG audits and testing processes. How often do you conduct on-site audits or on-site visits?

Mr Slater—The process for determining our scheduling of audits is based on risk profile and those risk profiles are drawn up around previous audit history. They are based on intelligence tip-offs that we might have, they are based on safety issues that may have arisen with the products, such as any recalls that might have occurred, and they are based on other factors that we might build into the profiling which determine the frequency. The average is around two-yearly, but for high-performing companies where there is a very good history that might be three to four years. It is not uncommon in a number of overseas countries to be longer than that. For what we might call more risky or where there is a requirement for more frequent auditing, we do that.

Senator FORSHAW—How much warning do you give to a manufacturer before an audit is conducted?

Mr Slater—For what we call routine audits it is generally up to a month. If we do an unscheduled audit, there is no notice.

Senator FORSHAW—How many unscheduled audits have you undertaken in the last 12 months?

Mr Slater—We have done 12 in the last 12 months.

Senator FORSHAW—Is that of 12 different manufacturers?

Mr Slater—No, there are some multiples.

Senator FORSHAW—Are you able to provide us with a list of those manufacturers that have been audited through unscheduled visits?

Mr Slater—Yes, we can.

Senator FORSHAW—When you are talking about 12 months, are you talking about financial years?

Mr Slater—When you said 12 months, we have taken 2002 and 2003 to date.

Senator FORSHAW—I assumed you would have. We are nearly at the end of this financial year. So there were 12 visits in 2002-03. How many in the previous year?

Mr Slater—Six.

Senator FORSHAW—Can you provide us with that list too?

Mr Slater—Yes.

Senator FORSHAW—Thank you. Did the unscheduled visits involve an audit? Can you explain what a visit would include which did not include an audit? What would happen?

Mr Slater—We would have to look at them on a case by case basis. Take the Pan unscheduled audit in January, for example. That was specifically to go in and have a look at the issues around travacalm and their uniformity of content issues. When we went to do that unscheduled audit, we did not intend that it would be a factory-wide review.

Senator FORSHAW—When was that?

Mr Slater—That was in January 2003.

Senator FORSHAW—That followed the information coming to light about travacalm?

Mr Slater—That is right.

Senator FORSHAW—I am sure we will get onto Pan eventually, but you have raised it at this point. How did that unscheduled visit take place? What did you do, just rock up one morning, knock on the door and say, 'We're here'?

Mr Slater—Within four working days we had detected five adverse reactions to travacalm. We had those reviewed by our relevant expert committee and called for the data from the sponsor, Key Pharmaceuticals, who was using Pan as a manufacturer. We asked for the data of uniformity of content and their laboratory results. They had information from Pan that said the data was in conformance. We did our own laboratory testing and were in a position to determine that there was up to seven times the allowable active ingredient in some tablets down to zero in others. On 21 January, four days after we got the fifth and final adverse reaction, we recalled the product. On that basis we determined, given the disparity between the company's laboratory analysis and ours, that we needed to go in and do an unscheduled audit. We conducted that audit on 30 and 31 January and, yes, we attended the company's site without notice.

Senator FORSHAW—You said that you tested travacalm prior to the visit. How did you obtain the travacalm? Did somebody purchase it from a shop?

Mr Slater—We just purchased it from the shelves.

Senator FORSHAW—Is that a regular practice or was that on this occasion?

Mr Slater—It is what we do for some of our targeted and random surveillance of products in the marketplace. In this case we went and grabbed those products from the shelves of supermarkets.

Senator FORSHAW—Do you do that on a regular basis? In this case it came about as a result of some people getting rather seriously ill and that being brought to your attention. Had you ever tested travacalm before by somebody purchasing it off the shelf and then testing it through the TGA resources?

Mr Slater—I cannot answer the question for the history of travacalm, but Pan only commenced manufacturing travacalm in June 2002, so we certainly had not tested the Pan manufacturing of travacalm.

Senator FORSHAW—Is it a practice that you would randomly purchase products and test them, even if something had not been drawn to your attention about a particular concern with a product?

Mr Slater—Yes, it is a feature of our post-market monitoring program where we have a random and particularly targeted testing of products that are in the marketplace.

Senator FORSHAW—How often does that happen?

Mr Slater—It is on a regular basis.

Senator FORSHAW—How regular?

Mr Slater—I would have to ask Dr Larry Kelly to come and give some information on that.

Ms Halton—While he is doing that, can I just go back to your question about whether this contract was published on the departmental web site. You can correct our understanding if it is not right, but the Senate standing orders require contracts of over $100,000 to be published on the departmental web site and we operate in accordance with that standing order.

Senator FORSHAW—I am aware that that is the requirement of the order. We like to encourage openness, but that is another committee on another occasion. Dr Kelly, I think you are going to supplement what Mr Slater has said about randomly purchasing products and testing them.

Dr Kelly—Yes. You were asking about the nature of the testing program and how we decide on what samples to test. We have a mix of arrangements whereby we have samples that we test against the targeted program and samples about which we have no choice, provided to us by way of a complaint; or, in the case of travacalm, as a result of adverse reactions. In some cases we choose samples from retail outlets; in other cases we seek samples from sponsors.

Senator FORSHAW—Can I come back to the visit which turned into an audit of Pan. Mr Slater, following the travacalm issue coming into notice, can you tell us just exactly what happened when you visited the factory? What did the TGA do?

Mr Slater—We did not visit; we undertook an audit.

Senator FORSHAW—It was an unscheduled visit that turned into an audit. Isn't that what you said?

Mr Slater—No, it was an unscheduled audit.

Senator FORSHAW—Take me through the process of this unscheduled audit.

Ms Maclachlan—Indeed, as Mr Slater said, this was an audit. The company were not aware that the TGA were going to arrive on the morning of 30 January, but from our point of view the audit was planned. We went with a team of auditors—two quality systems auditors from our Manufacturing Assessment Section and a chemistry specialist from the TGA Laboratories. Their specific task was to look to see whether there were any manufacturing deficiencies in the processes that Pan employed to give rise to the very serious uniformity of content variations that we had seen with travacalm upon TGA laboratory testing.

CHAIR—Senator Humphries also has a question on travacalm.

Senator HUMPHRIES—I want to ask whether the problems extended beyond travacalm. I have heard it suggested that only travacalm was a problem. Can you outline the problems you found at Pan during the audit process other than with travacalm and the risks to consumers if these products had not been recalled?

Mr Slater—Ultimately, the TGA found nine critical breaches of the code of good manufacturing practice by the company. Firstly, the company breached a standard condition applicable to all licences to manufacture therapeutic goods in that the company did not have in place quality control measures that maintained adequate controls. Secondly, the company had manufactured at least one product which required a uniformity of content test contrary to the conditions of its manufacturing licence. That relates to the fact that we conditioned the licence on 5 February for them not to manufacture microdose products and they continued to manufacture microdose products after we had conditioned that licence.

Thirdly, the audit found there was data manipulation of raw data relating to the testing of finished products so as to misrepresent out of specification results, so that they complied with specifications. Fourthly, there was results fabrication—the fabrication of finished product testing results obtained from a third party laboratory so as to misrepresent products as complying with specifications. Fifthly, there was substitution of bovine chondroitin sulphate with shark chondroitin sulphate and vice versa. Sixthly, there were deficient raw material and finished product controls.

Seventh, there were breaches of marketing authorisations, including noncompliance with conditions of registration or listing of products included in the Australian Register of Therapeutic Goods. Eighth, there were unsatisfactory process controls, including unsatisfactory process capabilities, inadequate control over manufacturing documentation, insufficiently detailed manufacturing requirements and/or inadequate record keeping. There were no finished product assays. There was noncompliance with documented procedures.

There were inadequate computer controls. There was an incomplete process validation. There were unsatisfactory change control processes and there were inadequate investigations and remedial action following the process and testing of problems and failures. Lastly, there was inadequate assurance regarding cross-contamination where equipment was shared—in other words, there was inadequate and unvalidated cleaning of equipment, which would lead to batches of new product going through being potentially contaminated with material from previous batches.

Senator HUMPHRIES—It does not sound as though that was accidental or due to inadvertence. I take it that much of that must have been as a result of deliberate decisions made by Pan.

Mr Slater—The TGA's view is that this is evidence of a culture of concealment within the company and deliberate manipulation of data to produce products that were claimed to be within specification and had certain ingredients in them which they did not contain.

Senator HUMPHRIES—In relation to travacalm, how long to did it take for the TGA to take action in response to reports of adverse events?

Mr Slater—The TGA received its first adverse reaction report on 10 January. Within four working days it had received reports of five adverse reactions, and it acted immediately on the fourth day.

Senator FORSHAW—Since that unscheduled audit took place, how many another unscheduled audits have occurred with respect to Pan?

Mr Slater—Overall, there were three unscheduled audits since January 2003.

Senator FORSHAW—When were they?

Mr Slater—On 30 and 31 January, on 24 and 25 February and on 7 to 14 April.

Senator FORSHAW—So there were three in total, including the one as a result of travacalm?

Mr Slater—Yes.

Senator FORSHAW—When you make a decision to undertake an audit, particularly if it is an unscheduled audit, do you do any risk profiling of the company? How do you determine who you are going to audit in that respect?

Mr Slater—As I outlined earlier, we have a profile that we draw up which identifies how frequently companies should be audited. That risk profile is drawn around previous audit history. It is based on an adverse reports data. As Dr Kelly outlined to you, we have ongoing monitoring, both targeted and random, of the marketplace. We have intelligence reports. We have surveillance activities that we undertake. We also might have information from tip-offs from previous employees et cetera and from competitor complaints. Competitor complaints is a significant source of information in a competitive market.

Senator FORSHAW—Is it correct that travacalm was withdrawn on 20 January?

Mr Slater—Travacalm was originally recalled on 21 January.

Senator FORSHAW—You have listed in answer to a question from Senator Humphries a long list of faults and concerns.

Mr Slater—I must make the point that they related to the total process, not to the first audit.

Senator FORSHAW—I was going to go to that. Clearly, one would have assumed that those sorts of problems would have run right across the manufacturing process of potentially all of their products, and not just this particular one. Do you agree?

Mr Slater—Yes.

Senator FORSHAW—I am going to come to Pan in a bit more detail later. So the recall of travacalm occurred on 21 January. How did you then inform Key Pharmaceuticals of the recall?

Mr Slater—Immediately we had our laboratory results to hand, which was on 17 to 18 January, we took up with Key Pharmaceuticals the concerns we had and asked them to initiate a recall. As the sponsor, they have the responsibility for organising the recall, undertaking the advertising and ensuring that the recall is conducted in accordance with the agreed Commonwealth-state uniform recall processes.

Senator FORSHAW—Is that what is called a voluntary recall—that is, where you ask the company to undertake it?

Mr Slater—It is, because we have not mandated it. As the law stood at the time, for us to mandate the recall we would have had to cancel the product.

Senator FORSHAW—Yes, I just wanted to clarify that. If a company did not comply with the request for a voluntary recall then you could move to the next step?

Mr Slater—Yes.

Senator FORSHAW—Do you follow through on ensuring that the companies—for example, in this case, Key Pharmaceuticals—actually carry out the recall and advise the shops and do all the other things that you would expect them to do? How do you monitor that?

Ms Maclachlan—Under the agreed procedure that we have for recalls of therapeutic goods, if it is a voluntary recall and if it is at consumer level, as travacalm was, the sponsor of the product is required to place advertisements in the print media in all states and territories, and they are required to notify the wholesalers and the retailers to whom they have supplied those products. They are to arrange appropriate recovery and destruction of the goods. They are required to report to the TGA on a two-weekly basis and then there is a final report six weeks on from the recall.

Senator FORSHAW—Do you, say, check their web site?

Ms Maclachlan—We may check their web site.

Senator FORSHAW—You see, my understanding is that after the date of the recall—21 January—travacalm continued to appear on Key Pharmaceuticals' web site as a product. Are you aware of that?

Ms Maclachlan—I would like to talk about the process of a recall. In this particular case we had discussions with Key Pharmaceuticals and they agreed that the product had to be recalled. They provided to us the recall announcement, which we have to approve, and we then issued that notice to states and territories on 21 January. My understanding is that the actual advertisements in the print media for travacalm's original recall occurred on 23 January. That is because the company actually has to book ahead and get space in the newspapers. They are also required to put these advertisements fairly close to the front of the newspapers so that consumers see them. There is no point in having a consumer level recall with a consumer level advertisement on page 17, for example.

Mr Slater—To answer your question about the web site—

Senator FORSHAW—That is what my question was about.

Mr Slater—The product is still legally able to be supplied by Key Pharmaceuticals. When the TGA issued the recall it was the affected batches that were being recalled. At that point, Key Pharmaceuticals, who were using Pan as a manufacturer, were still legally able to advertise that product. It is still on the market. There may not have been any product on the shelves—

Ms Maclachlan—All affected batches that failed to meet the uniformity of content requirement were recalled.

Mr Slater—To take that a step further, if they had had Pan as one of several manufacturers, which would have been quite legal, they could well have had products in the marketplace from other manufacturers. They have a legal entitlement to have that product on their web site.

Senator FORSHAW—So are you saying that there could be a product of the same name—travacalm—manufactured by a company other than Pan? Do you know that to be the case?

Mr Slater—It was not the case in this circumstance, but what I am trying to get across to you is that the product as a legal entity still had not been cancelled. What had happened, as for Arnott's biscuits or whatever, was that the product—in this case, the travacalm—had been recalled but the company was still able to legally supply it in future when batches complied with the TGA's requirements.

Ms Maclachlan—If I could just give you some more information relating to travacalm, that first recall was the travacalm original. Other travacalm products were being manufactured. One was travacalm natural and the other was travacalm HO. Travacalm HO was subsequently recalled. It was a product manufactured by Pan. Key Pharmaceuticals, however, also used another manufacturer to manufacture their travacalm products. That product was tested by the TGA and passed the uniformity-of-content test.

Senator FORSHAW—What did Key Pharmaceuticals put on its web site, if anything, with respect to the recall? Given what you have just said, there might be a bit of confusion out there amongst people who logged onto their web site, whether they had seen the ads in the paper or not.

Mr Slater—The legal requirement for Key Pharmaceuticals was to advertise a recall in the metropolitan dailies and to undertake the recall to consumer level. There is no legal requirement for them to put a notice on their web site.

Senator FORSHAW—There is no legal requirement, but have you sought to ask them to do that, given that web sites, as we know—and the TGA itself uses a web site frequently—are an instant and effective means of communicating? I say the word 'effective' with a qualification, I suppose.

Mr Slater—As I said, we do not have the legal power to require it. Frankly I do not have the information with me to say whether we ever contacted them about the web site. Certainly we had nothing more than, if you like, moral suasion available to us to target the web site.

Senator FORSHAW—You have just acknowledged that there was at least a delay. I understand there can be a delay of a couple of days in getting an advertisement into a newspaper. You are saying that the legal requirement is to just advertise in the newspapers and therefore, if they do that, you have not asked them to also put on their web site—in the same way as they are going to advertise it in a newspaper—the fact that the product is going to be recalled.

Mr Slater—One of the reviews that we are undertaking—and again it is internally driven—with the Commonwealth and state agencies involved is a review of the uniform procedures for recall. The suggestion you have made is a good one and we will take it to that review.

Senator FORSHAW—It came about because we noticed that it was still listed on their web site. Just to go back to visits: what is the purpose behind a scheduled or an unscheduled visit if it is not an audit?

Ms Maclachlan—If I could clarify, we do not visit per se—we audit.

Senator FORSHAW—All visits are audits—is that what the position is?

Ms Maclachlan—What I am saying is: it is not appropriate to use the word 'visit' here in that context. Under the act, we are required to ensure that the manufacturers meet the appropriate manufacturing principles, and we actually go in and audit them. We audit their quality systems, we look at their quality control procedures, we may look at the testing that is undertaken, we look at their documentation and how the product is released for supply. Our audits cover looking at their documentation as well as looking at the processes on the factory floor. We refer to it as an audit rather than a visit.

Senator FORSHAW—In addition to notifying the manufacturer regarding a recall, do you also advise any other agencies?

Ms Maclachlan—Yes. In relation to recalls, first of all we contact all state and territory health departments to tell them that a recall is being undertaken. They have certain obligations under the uniform recall procedure for therapeutic goods. We advise any other agencies within Australia, for example, that may have products manufactured—maybe it is a veterinary product or a food, for example—by the manufacturer we have audited. Then we also advise overseas regulators that the recall has been undertaken. We are required to do that through

arrangements—mutual recognition agreements—that we have and also by being a member of the Pharmaceutical Inspection Cooperation Scheme.

Senator FORSHAW—Just out of curiosity, do you advise, say, the Australian Stock Exchange?

Ms Maclachlan—No, that is not something we do.

Senator FORSHAW—Are there differences in the regime of monitoring, in terms of frequency or degree of scrutiny, between prescription medicines and other products?

Ms Maclachlan—I will start off answering that and perhaps Mr Gould may then like to give a bit more detail. We certainly undertake a risk profile of the products that are being manufactured and of our knowledge of the level of compliance of the manufacturer to the manufacturing principles at the previous audit. As Mr Slater has said, we may have other intelligence that comes to us through adverse reactions, recalls and medicines problem reports that add to a risk profile of the manufacturer. That, essentially, is what determines the frequency with which we will undertake an audit, and if it would be a scheduled one or a non-scheduled one as far as the company understands it.

Mr Gould—I can add some more detail, if it would help. What we do is classify manufacturers based on the type of product they manufacture. A sterile product would be a high-risk product. An over-the-counter cough and cold medicine, for example, might be medium risk. Something like medical gases or aromatherapy oils would be low risk. So it would depend on that. During an audit we assess the level of compliance as being just over the line, average compliance or highly compliant. Based on that matrix, the reaudit frequency for a high-risk manufacturer would be 12 to 24 months, I believe. The reaudit frequency for a low-risk manufacturer would be 12 to 36 months.

Senator FORSHAW—So high would be 12 to 24 months and low would be 12 to 36 months?

Mr Gould—Yes—

Senator FORSHAW—What is medium risk?

Mr Gould—And that is for compliant manufacturers. If a manufacturer is found to be unacceptable—below the line—it then goes to an internal review panel. That panel looks at the circumstances, the nature of the issues and decides where to take it next.

Senator FORSHAW—I think you said you classify the manufacturers in those categories. Do they have one category for all of their products or do you differentiate depending upon—

Mr Gould—It would be based on the highest risk product that they manufacture.

Senator FORSHAW—So, if they had a high-risk product, they would be deemed high risk even if they only had one product and all the others were deemed low risk?

Mr Gould—Yes.

Senator FORSHAW—That is in respect of the nature of the product, but of course the processes, such as those you uncovered with respect to Pan and the travacalm situation, could turn a low-risk product into a very high-risk product, if things were happening that should not

be happening, such as ingredients or impurities getting into the product that should not be there.

Mr Gould—During an audit, a report is prepared and any deficiencies are classified as critical, major or other. It does not matter what type of manufacturer it is: if they have a critical deficiency, it means that there is a significant risk to public health and safety, and immediate action ought to be taken. That addresses that issue. It does not matter what the profile of the product is: if there is a critical deficiency, which is interpreted according to the type of product that is involved, they would immediately be critical, and that means that there is a risk to public health and safety, and immediate action would be taken.

Senator FORSHAW—Yes. But I am seeking information, in relation to a new respondent against these categories, about the degree, if you like, of scrutiny that might be involved in an audit. What is the position? Say you are a manufacturer in the high-risk category, and you are conducting an audit, is that going to be more intensive than one that is a low-risk category?

Mr Gould—All audits attempt to be thorough. The difference would be the nature of the team that undertakes the audit. Many high-risk products would have different technologies involved, for example, in the use of sterilisation, so we might take an expert in sterilisation as part of the team.

Senator FORSHAW—In the case of travacalm, what sort of profile did Pan have?

Mr Gould—Pan were medium risk, based on their mixture of herbal, vitamin and over-the-counter type preparations.

Senator FORSHAW—Have they always been in that category?

Mr Gould—Since we have had the system of classifying like that. We have only had this system in place for the last three or four years.

Senator FORSHAW—That system, to go back to an earlier answer, would have taken into account previous history as well?

Mr Gould—That is the internal process; that is the standard frequency, if you like. It is designed to give an overall reaudit frequency across all manufacturers of two years, which is regarded as international best practice. There is always room for an auditor at the end of any audit to take any issues to a review panel, and that frequency can be overridden on a case-by-case basis if necessary. Those times are not necessarily absolutely rigid.

Senator FORSHAW—I am not sure if you clarified what I was asking earlier: are there differences in the regime of monitoring and auditing between prescription and non-prescription products in terms of things such as frequency of audits and the degree of scrutiny?

Mr Gould—Because prescription medicine would be a high-risk product and over-the-counter would be a medium-risk product, there is immediately a different frequency.

Senator FORSHAW—Do prescription medicines generally all fall into the high-risk category?

Mr Gould—Yes.

Senator FORSHAW—Do any of the over-the-counter or what is referred to as complementary health products et cetera fall into the high-risk category?

Mr Gould—Based on our system, if something is an over-the-counter or a herbal type medicine they would fall into the medium category.

Senator FORSHAW—Would that be notwithstanding the history of the company? If they had an audit history which suggested that there was a need for greater scrutiny, greater auditing and so on, would that mean that they could be classified as high risk?

Mr Gould—Irrespective of the classification of the company as far as product risk is concerned, there is also included in the matrix the level of compliance. So a company that we had concerns about would be on the lower end of the level of compliance and would therefore be subject to more frequent audits.

Senator FORSHAW—On the TGA's web site there is a statement which says:

TGAL has 125 staff consisting of scientists, engineers, technicians and support staff. Approximately one-half of the staff are graduates in science, with over one-third of these holding doctorates.

I am happy if you want to take this on notice, but can you give us a breakdown of the 125 staff—for instance, how many are involved in actual testing?

Mr Slater—That figure relates to one branch, or one office, of the TGA. I understand that that data you are referring to is from the Therapeutic Goods Administration Laboratories.

Senator FORSHAW—Yes, it is. I am interested in the break-up of that.

Ms Halton—Just in that part of the TGA?

Senator FORSHAW—Yes, just those 125.

Dr Priestly—I am not sure which particular document you are referring to, but it could well be the TGAL business plan. Is that correct?

Senator FORSHAW—I got this off the web site. I can give you the web site address, but it is quite long.

Dr Priestly—It is just that the number you quoted is larger than the current number of staff that we have in the laboratories. In terms of the distribution, I have not got precise figures that I can give you at this stage—I can take that on notice—but quite a substantial proportion of those staff are in fact involved in the testing program.

Senator FORSHAW—I would appreciate your giving us some more detail about the numbers. As I said, you can take that on notice. I would like a break-up of the functions of the staff in terms of numbers out of that 125. The web site goes on to say:

Samples for the testing program are obtained from manufacturers, wholesalers, chemists, hospitals or retail outlets. There are about 16,000 medicines and approximately 25,000 medical devices on the market in Australia. TGAL tests, on average, more than 1000 samples of products annually and problems with quality are noted.

What is the budget for product testing? Could you give me a break-up of the budget?

Dr Priestly—I believe I will have to take that on notice too.

Senator FORSHAW—I would like a break-up that shows such things as employee wages costs and equipment depreciation, if possible.

CHAIR—Senator Forshaw, would you mind if Senator Harradine asked a couple of quick questions.

Senator FORSHAW—Sure.

Senator HARRADINE—I refer to the decision on 15 May by the minister to refer the matter of consumer information about drugs manufactured or tested using human embryos to the TGA for examination as to feasibility and options for the best way of achieving a consumer's right to know. Could you please let us know how it has gone thus far?

Mr Slater—Certainly. We have engaged two consultants. We could not go through a tender process on this occasion because of the fact that we are required to have a report tabled in the Senate within one calendar month from 15 May.

Senator HARRADINE—Who are they?

Mr Slater—They are Oceania Health Consulting, of which the principal is Mr Brian Wall, and Matthews Pegg Consulting. The lead consultant there is Andrea Matthews, who is familiar with the work that was done on the regulatory system for the NHMRC.

Senator HARRADINE—So who have they consulted to date?

Mr Slater—At the moment, as you could expect given the tight time frame, they are working as quickly as practicable to consult a wide range of stakeholders. I know for a fact that they have consulted all of the various therapeutic goods industry associations. They have had some consultations with various companies who are in the biotech industry. They are consulting the NHMRC. They are also getting views from state and territory governments. While I cannot be exhaustive in the list of whom they have consulted, they are going through a process of trying to get together the information that the minister promised, which was to provide information on the practicality and feasibility of your proposed amendment and also the regulatory options.

Senator FORSHAW—The figures I read out earlier were that there are 16,000 medicines and 25,000 medical devices, which is 41,000 if you add the two together for the purposes of this question. You are conducting 1,000 samples annually, which is around 2.4 per cent. Has that been a constant percentage of products in terms of testing for the TGA?

Mr Slater—I have some figures of the types of products surveyed over the last three years. That is fairly consistent. In 1999-2000 there were 1,658. In 2001 there were 1,297. In 2002 there were 1,525.

Senator FORSHAW—What has been the growth in the number of products—medicines and other devices et cetera—on the market?

Mr Slater—It is not linear, because these are commercial decisions. The TGA does not initiate applications. Companies come forward as they see market opportunity in new products. For example, in the area of prescription medicines, along with the rest of the world we are seeing some fall-off in large new chemical entity applications. Applications are one side of the equation. The other side is what products come off the market when they are

considered by companies to have reached the end of their useful marketing life. For example, in 2000 there were 32,595 medicines on the market and in 2001 there were 33,406 medicines on the market. You can see that that is less than 1,000—one in 30-odd—which is about three per cent. In 2002 that figure has fallen to 33,351, which reflects what I was saying about the equation. At 30 May this year there are 31,359, which is another fall.

Senator FORSHAW—What do those figures of approximately 32,000 and 31,000 refer to? The web site that I just quoted from talked about 16,000 medicines and 25,000 medical devices.

Mr Slater—They are registrations, and there are multiple products sometimes with an individual registration. So the figure I gave you about products is a more meaningful figure for the data you are talking about in terms of the sample rates.

Senator FORSHAW—But I am only quoting the laboratory's web site, which says:

There are about 16,000 medicines and approximately 25,000 medical devices on the market in Australia. TGAL tests, on average, more than 1,000 samples of products annually ...

Why do you put 41,000 on the web site? I know you like to promote the work you are doing, but it is a bit of an overstatement, isn't it?

Ms Maclachlan—Mr Slater was talking about actual entries of products onto the Australian Register of Therapeutic Goods. The figures that you have relate to registrations or listings that may contain multiple products.

Senator FORSHAW—They are your figures, not mine. On the basis that I have quoted, but even allowing for your figures, it is somewhere between two and three per cent. Given that it is a very small percentage that you are testing, how often would a product be tested on average? Do you retest products over a cycle of so many years? Can you expand a bit on the testing that is done? Each year, is it a new product, as it were?

Dr Priestly—Each year the laboratories work with all regulators in the TGA for prescription medicines, for over-the-counter medicines, for complementary medicines and for devices and develop a testing program that is risk based. It does not specifically have a program of retesting samples every certain number of years. Each year we develop a program that takes into consideration new products coming onto the market and products that exist on the market and, as I say, they develop a risk based program for doing that. This generally means that of the number of products that are tested in any one year—and in fact the numbers are generally closer to between 1,300 and 1,500 products—a fairly high percentage are in the prescription medicines area. Some of those include new products coming onto the market and some of them include biological substances such as vaccines, where we have a batch-testing release program. So these are the sorts of determinations of what actually goes into the testing program in each year. That is the routine testing. As part of that program we also develop contingency type testing where, if there are complaints issues that are brought as a result of surveillance, these are given a high priority in the testing and they will form part of the overall testing program in the year.

Senator FORSHAW—To go back to those staff numbers, you are going to get me some specific detail, but did you say, Dr Priestly, you would give me a percentage of the number involved in laboratory testing?

Dr Priestly—I said that I would take that on notice, but a reasonably high proportion of the staff are involved in testing. We cover a broad range of scientific expertise in the laboratories branch. For example, we cover areas of chemistry, biochemistry and protein chemistry, microbiology, immunobiology and, in the devices area, some people with expertise in material science and so on.

Senator FORSHAW—On average how many products would an individual member of the staff test in a year?

Dr Priestly—I do not know that I could give you that figure because it would depend a lot on the type of products we were testing. Some of them come through in batches and we may test quite a number together. Others may require a lot more developmental work and would require a longer time to do the testing. So it is very difficult to give you an overall figure.

Senator FORSHAW—Could you try?

Dr Priestly—Not off the top of my head. I could try to give you that sort of information after I have had a chance to look through and give you a more considered opinion.

Mr Slater—If I could add an anecdotal aspect to this: often in the area of herbals, for example, no fingerprinting has been undertaken in the world. I know for a fact that the TGA in the area of skullcap preparations, for example, did all the scientific work around the fingerprinting to determine the different types of skullcap that were available so that when it was able to do the testing of skullcap products on the market it was able to identify whether the correct variety of skullcap was in the product. In this particular area, they can have quite different reactions, ranging from tranquillity effects on the one hand to dealing with inflammation on the other hand. That preparatory research aspect is fundamental to opening up new avenues of being able to correctly identify for consumers what is in the products and whether those products are safe for the purpose.

Senator FORSHAW—I do have a few other technical questions in this area regarding instruments and testing procedures that I will put on notice rather than confuse me and anyone else at the moment. I want to turn to the issue of isoflavones. There was a lot of media coverage regarding the product produced by Pan called Natural Nutrition Menopause. I understand the TGA undertook some testing and found major discrepancies in the product. Can you tell us what happened in regard to this issue, Mr Slater?

Mr Slater—Is this the report which is in the *Medical Journal of Australia 2002*?

Senator FORSHAW—You are probably looking at the medical journal; I am looking particularly at a newspaper article that was in the *Sydney Morning Herald* on 3 May. The article says:

A leading supplier of herbal products stopped selling a remedy used to reduce the symptoms of menopause after an independent test found some brands had less than 1 per cent of the active ingredient.

Senator Patterson—Senator Forshaw, I can hardly hear you.

Senator FORSHAW—Sorry, I have a cold.

Senator Patterson—You might need a complementary medicine for that cold.

Senator FORSHAW—Yes, I had better read the papers to find out what is left that is safe for me to take!

Ms Halton—We could give advice on that.

Senator FORSHAW—After today, it is getting fewer and fewer. This article did follow a report in the *Medical Journal of Australia*; so we are talking about the same thing.

Mr Slater—The report that was published in the *Medical Journal of Australia* in February 2002 was from a group of University of New South Wales scientists who had analysed several herbal products purchased from Sydney pharmacies in 1999. I should emphasise that these are not microdose products. There were some Pan products amongst those tested. The herbal products had claims that they might relieve menopausal symptoms in women. The article alleged that the levels of isoflavones, which are used as a marker for the herbal ingredients that might be effective in reducing menopause, were below the content stated in six of the nine products tested. I should point out to the committee that isoflavones are also found in foods, particularly soy based foods, and the amounts in the herbal medicines were all within safe levels of intake. In other words, we are talking about a group of very low-risk products here, and certainly there were no safety concerns that occurred as a result of the article in the *MJA*. The TGA was aware that Bullivants, the sponsor of the product which had the lowest level of reported isoflavones, had already conducted its own independent analyses and had voluntarily ceased supply of the product from this source in February 2002. The TGA was also aware that Bullivants had 11 manufacturers nominated as the possible supplier of the isoflavone in question. So there was no reason at that time to connect that particular incident with Pan. In fact, among the better performing group of products in the test there were also products for which Pan was listed as a possible manufacturer.

Senator FORSHAW—The article says that the product was 'later returned to retail shelves with a new formulation' and then it was made the subject of an official recall.

Mr Slater—There were 11 manufacturers who could have produced that particular product. The TGA had no safety issues. It took up with the sponsor the fact that there was an underreporting and the sponsor ceased the supply of that particular product.

Senator FORSHAW—The sponsor was Mayne; is that right?

Mr Slater—No, it was Bullivants, which is a subsidiary of Mayne.

Senator FORSHAW—Was there an official recall?

Mr Slater—No, there was no safety related issue here.

Senator FORSHAW—So that report is not correct. I appreciate that you do not have the benefit of having this newspaper article in front of you, but that is what it says.

Mr Slater—What they might be confusing there is the fact that appropriate regulatory action was taken to cease production of that particular product.

Senator Patterson—The papers normally get it wrong.

Senator FORSHAW—That is true, but the bit they did get right, Minister, was that the study had been carried out by—

Senator Patterson—That was not very hard.

Senator FORSHAW—people from the University of New South Wales department of clinical pharmacology. Did the TGA ever contact the researchers?

Mr Slater—The articles that appear in the *Medical Journal of Australia* are refereed.

Senator FORSHAW—They are what? I am sorry, I did not catch that.

Mr Slater—They are refereed before they are published.

Senator FORSHAW—Yes, but did you contact the researchers? Because Mayne apparently disputed the test results and conducted some of their own.

Mr Slater—I repeat: these articles that appear in the *Medical Journal of Australia* are refereed.

Senator Patterson—With scientific journals, when a group of people submit an article, it goes before an editorial board that may call on experts outside—and you might be a member of an editorial board because you have a specific interest in X, Y or Z—and that is what they refer to as 'refereed'. It is nothing to do with a football match.

Senator FORSHAW—That is irrelevant to my question.

Ms Halton—It is relevant, Senator, because we knew about this article before it was published.

Senator FORSHAW—Yes, but Mayne disputed the test results, and you are dealing with Mayne. You are dealing with the manufacturer or the sponsor. A report is published in a medical journal by—

Mr Slater—I thought you asked whether we had contacted the authors.

Senator FORSHAW—Yes, I did—the researchers. That is what I asked you.

Ms Halton—The author or the manufacturer, Senator?

Senator FORSHAW—You did not say no. You just said, 'The article is refereed.' You are telling me something that I do not really need to know for the question I am asking. I do actually understand how scientific journals work, or at least how articles are published, but here we have the company disputing the results. You are then dealing with a situation where the company—

Mr Slater—I think I need to make it clear—and we normally would not reveal this—that the TGA was the referee for this article before it was published. I might ask Dr Cumming to talk you through some of the science around this and why we did not need to contact the authors.

Senator FORSHAW—You have answered my question. The answer is then yes, isn't it?

Mr Slater—We normally would not reveal that.

Senator FORSHAW—You could have said to me that there were reasons why you could not answer that question. I was not trying to trap you; I was just going on the report in the paper that followed up the report in the *Medical Journal*. Given that the company disputed the test results and went away and apparently did their own, and given that the researchers then, according to this article, did not accept the views of the company, all I was seeking to ascertain was whether or not you had approached the company. But you have answered the

question. The answer is that you did not contact the researchers again after the article was published.

Mr Slater—The TGA is made up of academics, and we have a lot of expertise in this area. We were the referees for the journal, so it would have been inappropriate for us to contact the authors.

Senator FORSHAW—Presumably, from that I take it their report was deemed to be credible?

Mr Slater—I think we need to be careful here. Rather than talk about that, we might ask Dr Cumming, who is an expert in this area, to make some comments about what we consider to be some of the concerns in putting too much emphasis on the issue of isoflavones in this particular article.

Dr Cumming—I will go into a little bit of chemistry about isoflavones. It is necessary so that you understand Mr Slater's explanation. The first issue is that there is no standard definition internationally for isoflavones. There are a number of different chemicals which are called isoflavones in the broad category of isoflavones. Further, some of those might be glycosylated—have a sugar attached—which makes them bigger molecules and some of them are not glycosylated, which makes them smaller molecules. An important feature here is that that affects their molecular weight but not necessarily efficacy. The *MJA* article did not explain which chemicals it measured to come up with a total measure of isoflavones. In Australia, the regulatory system requires that, if you are going to mention isoflavones on the label, you measure seven different chemicals and we have no idea whether the article did that or not. Secondly, there was at the time no standard method for testing isoflavones, so there are a whole lot of different ways you could test which potentially could give different results. That, indeed, could be enough to potentially explain some of the differences between the published *MJA* results and the sponsors' results.

If we then come to the practical significance of all of this, first of all, isoflavones are not listable ingredients in medicines. The medicines may contain herbs that contain isoflavones such as red clover or soy, but it cannot list a medicine purely as an isoflavone. If a sponsor chooses to mention isoflavones on the label, they are doing it as a marketing tool, not as a regulatory requirement.

All of these products were indicated in one way or another as helping to relieve menopausal symptoms. Isoflavones may or may not be a marker of efficacy for helping to relieve menopausal symptoms. They are certainly a measure of how much of a herbal substance may be in the product, but it is the total package of the product that actually delivers the efficacy in relieving menopausal symptoms. Most of these were multiherb products where they had a number of different herbs that were interacting to deliver their effect. So, essentially, we had no safety issue. The isoflavones were not purely a marker of efficacy and, because there is no accepted definition for isoflavones and no standard way of measuring them, ultimately the results were not terribly meaningful.

Senator FORSHAW—Are you saying this article claims certain test results that clearly show or claim to show that the level that is advertised is not in fact present? So what we have here is people being told on labelling or through marketing that a product contains certain

ingredients or certain levels of ingredients which it does not, the TGA in one form or another referees the article, allows it presumably to go ahead without criticism—

Dr Cumming—Would you like me to comment—

Senator FORSHAW—and now you tell me that it does not really mean much anyway.

Dr Cumming—When the TGA refereed that article, they raised those concerns that I have just mentioned to you—point 1. Point 2: we were not the ones who allowed it to go ahead. It is always ultimately the editor's choice.

Senator Patterson—You would not know if there were other referees.

Dr Cumming—No. It would be normal to have more than one referee. Thirdly, as I was saying, while there may be a truth in labelling issue, as you just said, in terms of advertising, there was no safety, quality or efficacy issue of significance.

Senator FORSHAW—Of significance?

Dr Cumming—There was no safety issue.

Senator FORSHAW—But we are not talking necessarily about safety here, are we? We are talking about quality and efficacy.

Dr Cumming—The efficacy of the products was not dependent on the isoflavone content; it was dependent on the total package of the ingredients in the product. The isoflavone was purely a marker of how much of the total herbal material may or may not be in the product.

Senator FORSHAW—Were you were able to check the results yourself? Were you able to do your own analysis? Can I just go back to the *Sydney Morning Herald* article. Mr Tassie from Mayne, as quoted here in the paper, repeats what you have said. The article says:

> Mr Tassie said Mayne stood by its testing procedures despite the embarrassing revelation.
>
> "Isoflavones are extraordinarily difficult to test for. You need multi-million-dollar equipment, which is the sort of thing only universities would have. Probably no companies in Australia test for that.
>
> "The broader context is that in testing herbal products there is not one compound [to search for]. Not even the TGA [Therapeutic Goods Administration] in its audits can test the full range of compounds."

Then it goes on to say:

> The husband-and-wife research team said this was absurd.

Can you respond to those observations.

Dr Cumming—In responding, I will go back to something that Dr Priestley and Dr Kelly said earlier, and that is that in our testing program we apply a risk based approach to deciding what we test. As I said, we did not have quality, safety or efficacy concerns and so, while we do have the matter of menopausal products on our testing program, it is not high on our risk profile.

Mr Slater—The other thing is that, on the revelation of this information, the manufacturers ceased production.

Senator FORSHAW—Yes, I know. It becomes serious, one assumes, if the manufacturer ceases production. It is a bit hard to then sort of—

Mr Slater—But, from the regulator's point of view, that is a satisfactory conclusion to the issue.

Senator FORSHAW—They got there in the end, but I am trying to understand what role, if any—and it does not appear to be much other than acting as a referee—the TGA play. If you go back to your corporate plan, Senator Tambling, as he then was, when he was the parliamentary secretary, said, 'The Australian public expects medicine and medical devices to be safe, to be of a continuing high standard and to deliver the benefits they claim.' And, 'The key objective of the TGA is the regulation of therapeutic products in Australia to ensure they meet high standards of safety, quality and efficacy.' This issue goes to quality and efficacy, doesn't it? That is one of your clear objectives.

Mr Slater—For low-risk medicines and low-risk devices, as they were under the old system, the TGA does not check efficacy unless there is a claim made about the performance of the product which takes it out of the low-risk category and out of the low-level claims category. We check listed medicines for quality and safety, not for efficacy.

Senator FORSHAW—Wasn't this the same sort of problem with travacalm?

Mr Slater—No.

Senator FORSHAW—But in terms of what was actually claimed to be in the product—

Mr Slater—No. That is quality and safety.

Senator FORSHAW—I know that in respect of travacalm safety was obviously the critical issue—people started getting very sick. But it goes back to the level of the ingredients that was in the product. That is what I mean by the same type of issue, if you like. What was said to be supposedly in there was not in there.

Ms Halton—We should let Dr Cumming make a scientific point about this.

Dr Cumming—The issue with these products is, first of all, they were not on the market for their isoflavone contents per se; they were on the market for their herbal material that would deliver the menopausal relief effect. Isoflavones may have been mentioned incidentally on the label—and I am not sure it was on the labels of them all—so that is a truth in labelling issue. The quality, safety and efficacy of the products was delivered through the total herbal package of ingredients.

Senator FORSHAW—Some of these products were manufactured by Pan, weren't they?

Mr Slater—Potentially. Pan was one of 11 manufacturers of nominated Bullivants products and also one of the nominated manufacturers for several other, better-performing products that were in that list.

Senator FORSHAW—So we get back to Pan. I think that is probably a good time to adjourn for lunch.

Proceedings suspended from 1.01 p.m. to 2.02 p.m.

Senator FORSHAW—Regarding the paper we were discussing, why were the TGA prevented from pursuing issues with either the persons who wrote it or indeed with the companies that were affected by it in terms of making contact directly with them? I am talking about the TGA as distinct from those academics personally.

Mr Slater—There is no problem with that. I think you would acknowledge that, having got the journal article in advance and having provided detailed comment on it, we were aware of the findings. So having a fully informed situation, we pursued it with the authors through refereeing the journal article back to the MJA. One makes the assumption the MJA would have passed on our comments to the authors. We have concluded the need to pursue it any further. In fact, probably to have pursued it further would have been grandstanding.

Senator FORSHAW—Why would it be grandstanding if the issue that was involved was one that went to the quality and to the discovery that what was being claimed to be in a product was not in a product? That is an important issue for the TGA, isn't it? As a general rule, I know you have safety issues to address, but this is not an unimportant aspect of the role of the regulator.

Dr Cumming—The TGA's primary responsibility lies with safety—ensuring the safety of the community. This was not a safety, quality or efficacy issue; this was a truth-in-labelling issue.

Senator FORSHAW—It is not a quality issue?

Dr Cumming—It was a truth-in-labelling issue. The products were not listed on the TGA's register for their isoflavone content; they were there for their herbal content. If I use the analogy of a banana, for example, it is as if they listed a banana but happened to mention that the banana contained some potassium. The potassium is not listed on the register; the banana is. And it is the banana that delivers the benefit.

Senator FORSHAW—Yes, but you do not put the potassium into the banana.

Dr Cumming—You do not put the isoflavones in the herbs; they are there naturally.

Senator FORSHAW—But the manufacturer reports upon the—

Dr Cumming—There is no requirement for the manufacturer—

Senator FORSHAW—But they do.

Dr Cumming—It is as if the banana seller reported the potassium. In this instance the sponsors chose to mention the isoflavones.

Senator FORSHAW—Senator McLucas, do you want to follow up on isoflavones before we move on?

Senator McLUCAS—There is just one question that came to my mind with the point that you were making, Dr Cumming, about it not being a safety issue because the level of isoflavone was not the significant part of the compound. That is probably not the right scientific language, but I think you know what I mean. Surely, though, this is an issue of the consumer having a right to expect that the product that they are going to put in their mouth is what it says it is on the label.

Dr Cumming—What these products would have said they were on the label is a mixture of herbs, and they were those mixtures of herbs.

Senator McLUCAS—I have not seen the label but I understand isoflavones appeared in lights and you made the point yourself that it was potentially a marketing tool. If it is a marketing tool and a consumer is expecting to be getting isoflavones—efficacious or not, and

I do not want to go into that argument—then surely they should expect that the regulator could make sure that if they are expecting that percentage of isoflavones they should in fact get it.

Dr Cumming—Not all of them had the isoflavones mentioned on the label.

Senator McLUCAS—But some of them did.

Dr Cumming—Some of them, yes. As I said, it is a truth-in-labelling issue but it is not a safety, quality or efficacy issue.

Senator McLUCAS—I want to pursue the issue of whether or not it is a quality issue, because if people are expecting to get that product they may believe that the isoflavone is the active ingredient for them.

Dr Cumming—That would be a belief rather than the science.

Senator McLUCAS—And another group would believe that the St John's wort, for example, was the important element for them. So we have these groups of people—

Dr Cumming—The active ingredients for these products were the herbs and, in some cases, they had some calcium added as well. Those were the active ingredients.

Senator McLUCAS—Earlier you used the words 'it was a total package'.

Dr Cumming—Yes, there is a total package.

Senator McLUCAS—Does the total package include the isoflavones?

Dr Cumming—The total package—those are my simple words—includes the active ingredients that were included in those products. So the total package was the number of herbs in each product and also the calcium, where it was added.

Senator McLUCAS—But for some—I think you have made the point—isoflavones were advertised as being part of that total package.

Dr Cumming—Incidentally some of those total packages would contain isoflavones, and some of those sponsors chose to mention isoflavones, but the active ingredients were the herbs and the calcium.

Senator McLUCAS—Some people may think that the isoflavones are an important part of that package of herbs and calcium. Is that not reasonable?

Dr Cumming—People are free to believe what they like, but that is not what the products were regulated for. The products were regulated for their active ingredients, which are what deliver the effect.

Senator McLUCAS—Do you have any power over, or do you discuss with the producers of these drugs, what goes on the list of active ingredients?

Dr Cumming—There are strict criteria, strict requirements, as to how your active ingredients are listed.

Senator McLUCAS—Can they put things on that list of active ingredients that you do not require them to?

Dr Cumming—No, but they can, on their label, make mention of other things that are true about their product.

Senator McLUCAS—If it says on the label in a big star 'fantastic isoflavones', can you tell them that that is possibly misleading to the consumer?

Dr Cumming—That is a truth-in-labelling issue.

Senator McLUCAS—Do you have any discussion with the manufacturer about that?

Dr Cumming—Indeed. We discuss with manufacturers when there are truth-in-labelling issues, but our primary role is safety, quality and efficacy. As I have said, for these products, there was not a safety, quality or efficacy concern.

Senator McLUCAS—That is even though the isoflavone level that was expected to be in the product was in fact not there?

Dr Cumming—We cannot say that. If we come back to the testing and the chemistry, as I mentioned previously, there are many, many chemicals that make up the family of isoflavones. We have no idea what was actually tested for by these university researchers—how many chemicals they tested to say, 'This is what we define as isoflavones.' There is no standard definition. They could have chosen to measure nine or three, and they have not defined it. It is not fair to say that these products did not contain isoflavones, because their manufacturers could have used a different testing method and tested a different range of chemicals.

Senator McLUCAS—But they are using the presence of isoflavones as a marketing or therapeutic tool. We do not want to debate whether or not—

Dr Cumming—It would not be true to be doing it as a therapeutic tool—maybe a marketing tool.

Senator FORSHAW—But they are also saying that they contained a much greater quantity than was found to be—

Dr Cumming—As I said, it depends on how you test and what range of chemicals you test for what results you get.

Senator McLUCAS—So you test for a set of chemicals that are listed in the active ingredients of any product and then the company can say, 'And it also has this other product in it,' and you do not test for that because it does not have a safety impact.

Dr Cumming—In testing those medicines, we would have tested for the herbs and the calcium that were the active ingredients.

Senator McLUCAS—Even if the company then markets the product saying that something else is good for you, you do not test that?

Dr Cumming—Not primarily.

Senator McLUCAS—So you could be a company and you could market this tablet that has these active ingredients, but then basically sell it as having something else that you really have no control over.

Dr Cumming—There are various kinds of controls that can be exerted. As I said, it is back to a truth-in-labelling issue. The Therapeutic Goods Administration is primarily responsible for safety, quality and efficacy. The ACCC, for example, have a role in truth in labelling also. It is something that we can choose to test for but, as I also said earlier, we do risk based testing and, where we do not have a quality, safety or efficacy concern, it is difficult to divert a testing program away from the potentially real risks to something that is not a safety, quality or efficacy issue.

Senator McLUCAS—Do you refer those types of products to the ACCC?

Dr Cumming—We have dialogue between the two of us, certainly.

Senator McLUCAS—But do you refer potential failure in labelling to—

Dr Cumming—We have over the years, yes.

Senator McLUCAS—On this particular issue to do with these products, have you referred anything to do with isoflavones to the ACCC?

Dr Cumming—No, because there is no evidence that these product are not true to their labelling claims.

Senator McLUCAS—I understand that. It is the way they are marketed that I think is the point.

Dr Cumming—If they are mentioning isoflavones on their label and they are measuring them according to the way they are meant to in Australia if they are going to mention them, that is fine. But we have no idea how these researchers measured them, and the testing was done in America, so there is no way of saying that the two sets of data match or do not match.

Senator McLUCAS—I understand that. Thank you.

Senator FORSHAW—According to a newspaper article, Dr Jan Howse, who was one of the authors of the report, says that it is about quality control. Let me read her statement. She said:

Any company which is claiming to have that in the product should have quality-control procedures and, as it is the major ingredient, they should be testing it. They have to do the analysis.

Dr Cumming—The issue is that they were not—

Senator FORSHAW—Do you disagree with Dr Howse?

Dr Cumming—I think there may be a fundamental misunderstanding of how the products are regulated there. Those products were on the market because of their herbal content, and there is no reason to think that their herbal content was not as it said it was.

Senator FORSHAW—So your position is that it is not about quality. I have to say that I fail to see how you can just say it is truth in labelling. The quality issues could not relate, clearly, to truth in labelling. There is a failure of the quality—

Dr Cumming—The quality relates to the active ingredients in the product. Therefore, there were no concerns about quality, safety or efficacy.

Senator FORSHAW—Are you saying that an issue of major discrepancies between what is claimed to be in a product and what actually is in a product is not an issue of quality?

Dr Cumming—The regulations do not require any amount of isoflavone in those ingredients. The active ingredients are the herbs. They are not required to contain isoflavone. Therefore, the quality relates to the active ingredients, which are the herbs.

Senator FORSHAW—That suggests, Dr Cumming, that issues that go to what the manufacturers claim about their products, even if that is not true, are not really all that important to the TGA if it is not something that has a consequence in terms of actual safety. Is that the position?

Mr Slater—What Dr Cumming has said, if I can just distil it into lay language, is that the measure of isoflavones is in dispute because the testing methods that were used by the authors through a university in the US are not known. There are many chemicals that make up isoflavones. We do not know what chemicals they tested for. The isoflavone content is drawn from the herbs. What is required in a product is not isoflavones but herbs. The herbs were there. There is a dispute about whether the authors got it right and reported it correctly, because we do not know the extent of the tests that were done. Dr Cumming is giving you a scientific view about the fact that there may well not be an issue at all here, even in truth in labelling.

Senator FORSHAW—What was the role, then, of the TGA staff members acting as referees? What did they actually do?

Mr Slater—They gave a scientific academic view in refereeing for the journal, as any academic referee would.

Senator FORSHAW—Did they give it a tick or did they raise—

Mr Slater—They raised the very concerns I am talking about. That was done in writing, of course, as you would with a refereed article.

Senator NETTLE—I have just got a few questions to do with the Pan recall. They follow some questions you may have seen that the member for Calare asked in the House of Representatives and which I understand the minister may be in the process of responding to. Has the TGA conducted any tests on the products manufactured by Pan that it recalled? What tests, if any, have been conducted on the recalled products?

Mr Slater—There have been none, because—as I pointed out in answer to Senator Humphries' question earlier—there were such widespread endemic bad practices by the company, particularly in the lack of cleaning of equipment between batches. They might have had a batch of veterinary products, for example, going through before a batch of products that might have been used specifically for infants. As a result, the range of possible contaminants was so vast that it is not possible to test for the safety of individual products. The TGA took the findings of this audit report to an expert committee. The expert committee determined that there was a risk of death, serious illness or serious injury and that that risk was here now, increasing over time, and could be realised at any time. It was on that basis that the TGA made the decision that it had to move immediately to recall these products.

Senator NETTLE—I have couple of questions arising out of that one. Is the expert committee you are talking about any relation to the expert committee that is doing the review

at the moment? Was it a different expert committee, prior to the establishment of the current one?

Mr Slater—This was an expert committee that the TGA drew together from its two expert evaluation committees in the area of over-the-counter medicines and complementary medicines. It constituted an expert group which gave the TGA advice specifically about the public health and safety issues arising from the audit. If the TGA had not had advice from the committee that there was an immediate risk of death, serious illness or serious injury then it would have been required to give notice to Pan and every other sponsor involved, which would have enabled us to do a very easy and orderly recall. But because we had advice that there was an imminent risk of death, serious illness or serious injury we had to move immediately, which meant we then had the difficulty of organising a recall without notice.

Senator NETTLE—I understand. I am not asking questions around the decision to make the recall but, subsequent to the recall being in place, has there been any procedure in place for there to be subsequent testing of those recalled products?

Mr Slater—Had that been appropriate, that could have been done but, as I explained, the range of potential contaminants was so vast that that was not possible. For example, while the company did not manufacture a range of prescription medicines for the Australian market, it manufactured a range of prescription medicines for export. They had very active ingredients in them. There was a range of potential contaminants, including metal contamination that was identified in the audit. Every product that Pan manufactured was a possible contaminant for any other product—any ingredient. So what would you test for?

Senator NETTLE—The reasons for asking the question are to try to understand at what point there is a capacity for the TGA to say to consumers that these products are no longer under investigation. Is there any capacity or are we saying everything that has been recalled to date and that is it for those products? For the purpose of consumers knowing, is there any point at which you go back and say, 'These are now found to be safe' or is that not a part of the procedure?

Mr Slater—The expert committee's words on this were, 'The expert group lacks confidence in the quality of any products manufactured by the company.' The group advised that poor quality products have an increased risk of failure in both safety and efficacy.

Senator NETTLE—I will leave that there. I have two other questions. On page 60 of the portfolio budget statement there is a list of areas on which the TGA will be focusing. One of those is—and I am wondering what it means—'completion of the Australian Guidelines for the Regulation of Complementary Medicines, following extensive stakeholder consultation'. Can someone explain what are the guidelines, what are they about and what is this component of that list?

Dr Cumming—Yes. Much of the Australian Guidelines for the Regulation of Complementary Medicines are in a late stage of draft. Let me take you a step back. For the other medicine sectors—the prescription medicine sector and the over-the-counter medicine sector, which have very long histories of being regulated—there are quite thorough guidelines for sponsors as to how to lodge an application for approval of a new medicine or a new ingredient. In the complementary area we do not have such comprehensive guidelines because

the Office of Complementary Medicines is reasonably new and we have been working with the complementary medicines industry to help them understand the standards that they need to meet and the most appropriate way to meet those standards. Those guidelines are about writing down for sponsors the exact details they need to have in applications and how they might be able to get that data, rather than just saying, 'You need this, this and this. Give us your application.' It is attempting to be very helpful in showing them how to put together an application that will stand up to regulatory scrutiny.

Senator NETTLE—So the guidelines are being developed by the Office of Complementary Medicines?

Dr Cumming—Yes.

Senator NETTLE—Will you explain for the committee the process of stakeholder consultation that is taking place in the development of the guidelines?

Dr Cumming—They are being developed by a broad group with eight members drawn from various sectors of the complementary medicine industry and the regulator, which is the first form of the consultation. Then as each section is being developed, it is put out for more broad consultation with the industry and other stakeholders more widely.

Senator NETTLE—Is it possible to get a list of the eight people who are involved in this first stage of the process?

Dr Cumming—Yes, I can take that on notice; I cannot do it immediately.

Senator NETTLE—I understand that. Then as you explained, that is the preliminary stage and there will be further consultation within the specific sections of the industry that relate to the guidelines.

Dr Cumming—As each section is finished, it will be circulated to the industry and other stakeholders more broadly. It will be put on the web site, as we usually do. We will call for comments and then finalise section by section.

Senator NETTLE—In terms of getting an understanding of where the process came from, is the development of guidelines an initiative of your office within the TGA or is it something that has been raised by various members of the complementary medicines industry?

Dr Cumming—It is twofold. As I said, the other sectors, the prescription medicines sector and the over-the-counter sector, have long had guidelines produced by the regulator. The office has recognised the desirability of developing guidelines for our sector, and the industry have said that they would very much like them too. We have been working with them to develop appropriate guidelines.

Senator NETTLE—I will leave my questioning on that there. I just have one more set of questions which relates to the expert committee doing the review process. When did the government decide to establish the expert committee?

Mr Slater—The expert committee met on 23 April 2003.

Senator NETTLE—I am asking about the expert community doing the complementary health care review.

Mr Slater—The government announced that on Monday, 12 May 2003.

Senator NETTLE—Can you outline the basis on which that decision was made?

Mr Slater—Yes. As a result of the Pan recall there was a lot of debate in the community, a lot of consumer concern and a lot of concern about the outcomes for consumers' reliance on complementary medicines. There were issues around practitioners, there were issues around quality and there were issues around efficacy. Hence the regulatory framework that we have is one aspect that certainly came in for a round of discussion publicly.

The government determined in the context of those community concerns, those issues which came from professionals and those issues which came from researchers that, in the context of the national medicines policy framework—which looks at, on the one hand, regulation of products and, on the other hand, the subsidy around medicines that are on the market, practitioners and a viable industry—it would have a look with an expert group to see if there were recommendations that should come forth to government for its consideration.

Senator NETTLE—So was the establishment of the committee the initiative of the TGA, the initiative of the minister or the initiative of the parliamentary secretary?

Mr Slater—It was an initiative of the government.

Senator NETTLE—Presumably under the auspices of the parliamentary secretary.

Mr Slater—Government being the executive arm of government.

Senator NETTLE—So the announcement was made by the parliamentary secretary?

Mr Slater—Yes, the announcement was made by the parliamentary secretary.

Senator NETTLE—Do we have an idea of how much the review is expected to cost? I am happy to put that on notice.

Mr Slater—We will have to take it on notice.

Senator NETTLE—Could you outline the process by which the review will be conducted?

Mr Slater—The review is under the chair of Dr Michael Boland. It will have several meetings. I guess the committee itself will determine how it goes about its work. It has terms of reference which are on the public record, and I am sure you would have a copy of those. It is required to report by August 15.

Senator NETTLE—In terms of the planned process for the committee, is there any proposal for any public consultation? How far down the track are we in determining what the process is for that review?

Mr Slater—I will ask the head of the secretariat to the expert committee to comment on that. Again I have to say to you that the committee itself will determine how it goes about its work. They have had one meeting already, which was held last week, which I am sure outlined the framework for how they might move ahead. I will ask Dr David Briggs to outline that for you.

Dr Briggs—I am responsible for the secretariat for the expert committee. As the national manager has indicated, the expert committee has quite wide-ranging expertise. There are 18 members on this committee. It is a rather large expert committee. Given the time lines, the

committee decided that they would rely to an extent on their own expertise and would consult with appropriate people as the experts thought fit. Because of the rather short time line—the report has to be to the parliamentary secretary by 15 August—there is very little time to go out with wide consultation. So the individual experts on that committee have agreed that they will consult with appropriate people as they think necessary to provide the expert input into the decision making process.

Senator NETTLE—The reason I was asking what mechanisms for consultation existed in the committee is that, when I look at the terms of reference, they are quite extensive and, obviously, given the short time frame, there are increasing pressures on the committee. In putting those two things together, I was thinking perhaps one of the ways to enable the committee to meet those broad terms of reference would be a public consultation process.

Dr Briggs—I can understand the preference for that but, given the time lines, we are relying on the experts to provide their expertise and consult as they think appropriate to provide input into that committee. We are doing that largely because of the need to be able to get the report completed on time. To go out for wide consultation would not allow us to meet those time lines.

Senator NETTLE—Subsequent to the report being completed in August, is the intention for that report to go through a further process of public consultation?

Dr Briggs—That is not the intention at this stage. As we go through the particular terms of reference, it may be necessary to revise our approach to the report. The report itself may even have recommendations for consultation, but this is for the expert committee to decide.

Senator NETTLE—Perhaps you could explain for me what level of consultation there was, or if consultation existed, with the industry before the establishment of the committee.

Dr Briggs—I am afraid I have not been privy to those discussions. It was a government decision to establish the expert committee.

Senator NETTLE—So the TGA was not involved in any consultation with the industry prior to the establishment of the expert committee by the parliamentary secretary?

Mr Slater—The expert committee membership was determined by the government.

Senator NETTLE—I have further questions in relation to membership, but at the moment I am just looking at the establishment of the committee and whether the TGA had any role—it seems perhaps not—in terms of consultation prior to the establishment of the committee.

Mr Slater—It was a decision taken by the government.

Senator NETTLE—Just going back to the comments that Dr Briggs was making about the reporting date, can you explain for me why we have such a close reporting date for this? The terms of reference seem very comprehensive, as you have outlined.

Mr Slater—The date of 15 August was around three months from the date that it was set up, so it was asked to report within three months. I would expect that some of the subject matter that the expert committee has to deal with is very wide ranging. For example, looking at the regulation of practitioners in Australia is something that an expert group might spend a great deal of time on, and the implementation of it involves state and territory governments—

that is why there is a state and territory government chief health officer on the expert committee. I would expect that on subjects like that they will come forward with recommendations about how to take these issues forward. I imagine that within the three months, in a number of areas, they will be pointing the directions and making recommendations to government about how to take issues forward—first identifying the issues, then indicating how to take them forward and, in some cases, being able to make very firm recommendations about what should be done as a matter of immediacy if there is an issue around safety, quality or efficacy, for example in the area of therapeutic goods.

Senator NETTLE—Did the TGA play any role in advising or making recommendations as to the membership of the expert committee?

Mr Slater—The TGA would have been subject to discussion with the minister, as they would over many issues, but at the end of the day the minister—in this case the parliamentary secretary—may have consulted a wide range of groups to form a view and to make a decision on it.

Senator NETTLE—Including the TGA?

Mr Slater—Yes, certainly including the TGA.

Senator NETTLE—So there were not specific recommendations from the TGA put to the minister in this regard?

Mr Slater—Sorry, I missed that question.

Senator NETTLE—Were there specific recommendations put to the minister in relation to the membership, or are we talking about a less formal consultation?

Mr Slater—We certainly had an input and were consulted around the terms of reference and the timing and conduct of the review as, I imagine, were a number of other parties that would have had input to the parliamentary secretary making a decision about whether to have a review, what the terms of reference of that review might be, the timing of it and who might be on it.

Senator NETTLE—The question comes from concerns that have been raised about the membership of the committee: in particular, their representation from the Complementary Healthcare Council and the complementary health care industry generally, in terms of determinations having been made as to which peak bodies should represent the industry on the membership. That is where the question has come from. Is there any understanding on the part of the TGA as to why a particular industry group—ASMI—is represented on the committee by an executive director, whereas the Complementary Healthcare Council is not represented on the committee?

Mr Slater—I beg to differ with you, Senator. There is a member of the Complementary Healthcare Council, Philip Daffy, who worked with Blackmores. There is also the chief executive officer of Blackmores on the expert committee. There are a number of other experts in complementary medicine that are on that committee.

Senator NETTLE—I think—as you have rightly pointed out—that Daffy, who formerly worked with Blackmores, is an ex-member but now operating as a consultant to the board of the Complementary Healthcare Council. I know you also commented on the CEO of

Blackmores. We both know that Blackmores is a member of the Complementary Healthcare Council as well as being a member of ASMI. But unlike with ASMI, where the executive director is represented on the committee, in the instance of the Complementary Healthcare Council there is no chief director, no executive, no president of the Complementary Healthcare Council represented on that committee.

Mr Slater—My understanding is that Mr Philip Daffy is a CHC representative.

Senator NETTLE—That is certainly not my understanding. Philip Daffy provides a role as a consultant to CHC.

Mr Slater—To my understanding, he is certainly one of the nominees that were put forward by the CHC for representation on the committee.

Senator NETTLE—So, as you understand it, that is a position that Philip Daffy holds. It is a CHC position on that committee, and he happens to hold that.

Mr Slater—My understanding is that he has been added to the committee as a CHC nominee.

Senator NETTLE—Was the Complementary Healthcare Council offered a position on that committee and they then made the determination that Philip Daffy would be the representative of the Complementary Healthcare Council on that expert committee?

Mr Slater—My understanding is that Philip Daffy was one of the names that the CHC put forward as somebody they would like to see on the committee.

Senator NETTLE—One of the names, there having been other names also put forward?

Mr Slater—Yes.

Senator NETTLE—Is it your understanding that the CHC made a decision as to who should represent them on that committee or do you understand that that decision may have been made by somebody else?

Mr Slater—Let me make it clear that the government decided who was going to be on that committee. The committee is an expert committee. It is not there to represent groups. Hence, in that process, the CHC nominated Phil Daffy as their person who had expertise in complementary medicines.

Senator NETTLE—Just so I have got it clear, and then we can move on, your understanding is that the CHC put forward a number of names and the government made a determination as to who would fulfil that role as a representative of the CHC.

Mr Slater—No, I did not say that. I said it is an expert committee that does not represent any groups.

Senator Patterson—Not every committee that we have is a representative committee, Senator Nettle. This is one that's not. It one of the advantages of being in government. We are in a party that has enough numbers to govern to make decisions like that.

Senator NETTLE—Perhaps the minister could explain the basis on which the decision was made that this committee would not be a representative committee of the complementary

health care industry, given that the review, as we have outlined and talked about already, is to be a comprehensive and broad-ranging review of the complementary health care industry.

Senator Patterson—There are a lot of committees we have to review various aspects of the portfolio. They are not always committees for which we call for representative membership. We choose people on the basis of their skills in a particular area because they have an expertise in the area in which the review is on. It is not always the case that we call for representatives.

Senator NETTLE—Perhaps I could read for the minister a comment made by one of the members of the expert committee, Professor Alistair McLennan. He commented:

> We shouldn't support the complementary medicine (industry) or subsidise it. It's a bit like subsidising the tobacco industry or the gambling industry.

Perhaps the minister could explain why in a review of the operations of the complementary health care industry the minister thought it was appropriate that this gentleman—and his views as articulated in that statement—should be an expert to provide advice on the whole framework of regulation for this industry.

Mr Slater—Professor McLennan is an expert in epidemiology of complementary medicines.

Senator NETTLE—That being the case, does it surprise you at all to have a comment such as the one I have just read out attributed to Professor McLennan?

Mr Slater—I am unable to comment on that. I do not know whether he was accurately reported. You would have to take that up with him.

Senator NETTLE—So, in your view, Professor McLennan is an appropriate representative to be on an expert committee looking at the regulations of complementary medicines.

Mr Slater—As I said to you earlier, this is the expert committee membership. Its terms of reference and reporting time were determined by the government, not by the TGA.

Senator NETTLE—But you said Professor McLennan was an expert in epidemiology—

Mr Slater—In epidemiology of complementary medicines.

Senator NETTLE—All right. I will leave those questions there.

Senator FORSHAW—You have raised the expert committee. We have some questions on that that we will follow through with.

Senator Patterson—I think it is an appropriate point to say that, during the debate on the therapeutic goods administration legislation on the last day of the Senate, I turned and asked for advice from one of the people in the advisers box about whether complementary medicines had issued a press release and I was advised that they had. That was not the case. I think they had seen a draft. But I will make a full statement to the whole Senate about that, because it was thought that a press release had gone out.

Senator NETTLE—If you are going to make a statement to the Senate, I will leave it at that.

Senator FORSHAW—Senator Nettle asked questions regarding the time frame, and I agree it seems rather short given the extensive nature of the terms of reference. Who drafted the terms of reference?

Mr Slater—I indicated in answer to Senator Nettle that the terms of reference were decisions of the government.

Senator FORSHAW—Did you have input into it?

Mr Slater—Yes, I indicated the TGA was consulted, but I cannot answer who else might have been consulted or who the minister or the parliamentary secretary may well have sought input from.

Senator FORSHAW—In her media release of 15 May, the parliamentary secretary referred to the Pan Pharmaceuticals recall. I appreciate it is not necessarily a question for you, Mr Slater, but it may be for the minister. The terms of reference do not actually mention Pan Pharmaceuticals at all. They do not mention TGA audit processes. Can we be assured that these things will be looked at? The terms of reference do not actually refer to the Pan Pharmaceuticals recall, even though the parliamentary secretary made a particular point about that in her media release when it was announced. It also does not mention audit processes as being something that would be looked at within the terms of reference. Why are they not specifically being addressed?

Senator Patterson—Ms Worth has the responsibility for this area but, as I always say as the health minister, I am ultimately responsible for it. But in the guidelines—I think you have a copy of them—it says:

The committee will examine and provide advice on the national system of regulatory controls which require that complementary medicines meet appropriate standards of quality, safety and efficacy.

I presume that they will look at various examples of where that has not occurred as a guide to how it could be changed, if that is necessary.

Senator FORSHAW—It is one thing to presume it, Minister. I can read the terms of reference and endeavour to interpret them, as has already been raised. Those terms of reference are very broad and quite extensive for a 10-week inquiry following on from the biggest single recall in the history of the world, as I understand it. How can we be assured that the Pan Pharmaceuticals saga will be examined in the course of this review—or won't it be?

Senator Patterson—The terms of reference are very clear, and that is the role that the expert committee has been given. As I said, they will no doubt consider examples of where there may be a possibility of changing the regulatory controls to reduce the likelihood of something like Pan Pharmaceuticals occurring again. But we must take into account that we already have some changes in the Senate as a result of the Pan Pharmaceutical issue, and I appreciate the Senate's cooperation in that.

Senator FORSHAW—Do you have any comment to make, Mr Slater?

Mr Slater—No.

Senator NETTLE—Minister, following on from your comment, do you feel that the concerns the government has over the Pan Pharmaceuticals recall in particular have been addressed by those amendments that you just spoke of? Do you see the review as providing a

more comprehensive or ongoing review but not necessarily related to the Pan Pharmaceuticals recall? Would that be correct, based on the comments you have just made?

Senator Patterson—Short of you putting words my mouth—which is most probably unhygienic—

Senator FORSHAW—It might be safer than some of the things that are out on the shelves!

Senator Patterson—I suggest that you look at the terms of reference. We have immediately put in place some changes to the legislation which we thought were warranted and needed to be addressed very quickly. I am sure, given the extent of the Pan Pharmaceuticals recall, that it would be unusual if the expert committee did not take into account the issues surrounding that in examining the regulatory controls that already exist, the new legislation and anything else that might need to be done to reduce the likelihood of it happening again. It is a bit like terrorism: you cannot actually ensure that it will never happen again. What you can do is put as many measures in place as you can without strangling the industry to reduce the likelihood of it occurring again. I would be surprised if the review did not take into account what occurred, since one of its terms of reference is to examine and provide advice on:

The national system of regulatory controls required to ensure that complementary medicines meet appropriate standards of quality, safety and efficacy;

Senator NETTLE—In relation to the question that Senator Forshaw was asking about there not being a specific term of reference that relates to any audit or recall procedures, I may imagine that there may be lessons to learn out of the Pan recall as to how such a process may proceed in the future. Is that something that is considered to be part of the terms of reference? Reading through the terms of reference, I cannot necessarily see—

Senator Patterson—The last one says:

The regulatory and industry activities necessary to promote an innovative, responsible and viable complementary medicines industry in Australia.

I presume that it would not be viable if you had similar things occurring again, and if you look overall at the terms of reference we are clutching at straws to say that the expert committee would not take into account the recent events involving Pan Pharmaceuticals.

Senator NETTLE—I have one more question in relation to the terms of reference. I understand that at the time of the introduction of the GST there were negotiations about whether GST needed to be charged on complementary health care practitioners. I understand that there was an agreement reached between the Democrats and the government at the time which related to there being, three years subsequent to the introduction of a GST, a review to ensure that practitioners within the complementary health care industry would be registered at that point—that the GST would not be charged for practitioners at the time but that in three years there would be a review with the intention that those practitioners would be registered. My question relates to the term of reference we have spoken about already which opens up the opportunity to look at regulation for complementary health care practitioners. Are we looking at this being the review to determine whether health care practitioners will be

registered or is this setting up a framework within which we will subsequently do a more comprehensive review of the registration of health care practitioners?

Mr Slater—The expert committee is looking at issues around the regulation of practitioners. Those practitioners could be mainstream medicine practitioners; they could be alternative medicine practitioners. The regulation of practitioners rests with the states. So the expert committee's recommendations in this area would need to be taken forward through state governments.

Senator NETTLE—How does this particular review looking at the regulations of the health care practitioners fit with what I understand to have been an agreement on the introduction of the GST to carrying out in three years time a review with the intention of ensuring that health care practitioners were regulated? Are we talking about two separate reviews or is this the review?

Mr Slater—There are two separate reviews. I cannot comment on the progress of the one that was announced with the GST. That is, I think, with another area of the department. This issue is to look at complementary health care in the health care system as it is impacted by the regulation of practitioners.

Senator NETTLE—That has made it clear that there are two reviews. Ms Halton, could you explain what part of the department of health is doing the review that was announced with the introduction of the GST?

Ms Halton—We will get you some advice on that. We just have to work out exactly which program it sits under.

Senator NETTLE—Given that the TGA is involved in a review of registered practitioners, it would be nice to be able to find where the two interact—or perhaps they do not. So I am happy to wait.

Ms Halton—Essentially, this is not the responsibility of the TGA; it is the responsibility of a different part of the department. That part of the department is not here, because they are not required under this program.

Senator NETTLE—I do not have questions to ask of them; I am just asking which part of the department they are.

Ms Halton—We can probably tell you the officer, but I will have to inquire as to which part of his body sits under which program for this activity, if you see what I am saying. A number of our officers are responsible for a number of the different programs; so, even though we can probably identify the person, I cannot tell you instantly which program this is under. But I will get you that advice shortly.

Senator NETTLE—Thanks.

Senator FORSHAW—How is the expert committee being funded?

Mr Slater—The expert committee is being funded by the TGA.

Senator FORSHAW—What is the estimated cost?

Mr Slater—Senator Nettle asked that—

Senator FORSHAW—I am sorry; I have been having some trouble with my computer, as you have probably noticed.

Mr Slater—and we have promised to take that on notice.

Senator FORSHAW—Can I now go back to go to the Complementary Healthcare Consultative Forum. This was established back in June 1999 by Senator Tambling, as he then was, when he was the parliamentary secretary. Can you confirm for me that the committee met five times between when it was established in June-July 1999 and June 2001?

Mr Slater—That is correct.

Senator FORSHAW—Has it met since then?

Mr Slater—No.

Senator FORSHAW—Why not?

Mr Slater—At the close of the last meeting, which was just prior to the election, Senator Tambling encouraged the forum members to take up issues separately with the various political parties as considered necessary. He indicated that there would not be another meeting of the forum before the election. He did leave open the possibility of future meetings.

Senator FORSHAW—There was a response to a request from the Library— as I am sure you are aware, Dr Cumming, because you sent in the response—which stated what Mr Slater has just said. So are you saying that there is no more work for the forum to do?

Mr Slater—No, I am not saying that. I am saying that there has not been a need for it to meet. To my knowledge, there has been no request from the industry, any practitioner group or members for a meeting to be held, nor have any issues been put forward for discussion. The only contact we have had was from a consumer member of the forum from the Northern Territory who asked whether she could have any potential meeting dates for her diary.

Senator FORSHAW—Would you say that the reasons for the forum's establishment, as stated by Senator Tambling, were all fulfilled?

Mr Slater—It was part of the reform agenda for regulation of complementary medicines, providing a forum for industry, practitioners, consumers and other interested representatives to bring issues to the table. It met, as you said, five times over two years. The agenda of issues that it covered in that time was not vast—they went over similar ground, which is not unexpected in a forum. It was not a decision-making body and it certainly was not an expert committee. Whether it ever meets again depends on whether issues suited to being taken forward by such a forum arise.

Senator FORSHAW—For instance, what about the issues that arose leading to the eventual Pan Pharmaceuticals recall and demise? Would the issues that arose in the lead-up to that have been appropriate for the agenda of the forum?

Mr Slater—It is a consultative forum, so I would have thought that the answer to that was no.

Senator FORSHAW—I am getting a lot of consultations from companies and people in the industry now as a result of what has happened, so obviously it is an issue that they are very concerned about.

Mr Slater—You said 'in the lead-up', and I certainly do not think that in the lead-up it would have been appropriate. But I am happy to take that thought forward to the parliamentary secretary—whether the forum might be a vehicle for discussing some of these issues.

Senator FORSHAW—I am asking you whether you, the TGA, think it is the sort of issue that might be put on that forum's agenda to discuss. When I said 'in the lead-up', I meant that a number of things that we know happened were brought to the attention of the TGA, one way or another. Eventually you had the recall—in May—and we know what has happened with Pan. That is what I was talking about. So no meetings of this body have been held since June 2001, and no steps have been taken to bring the forum together to discuss some pretty critical issues facing the industry at least all of this year?

Mr Slater—It is a consultative forum. It is open for any one of the constituents of the forum to make a case for a forum meeting to discuss issues that fit within the terms of reference. The generator of those issues and of the need for a forum meeting could well be government, could well be industry or could well be consumers. So it is left open at this point.

Senator FORSHAW—It appears that the TGA did not think that it would be useful or important to bring the forum together to discuss these issues.

Mr Slater—Do you mean before?

Senator FORSHAW—At any time.

Mr Slater—Certainly we did not feel there was a need to discuss the issues during the midst of our investigations at Pan, if that is what you are suggesting.

Senator FORSHAW—When Senator Tambling announced the formation of the Complementary Consultative Healthcare Forum in his press release of 17 June 1999 he said that it was established:

> ... to facilitate consultation between government and the complementary healthcare sector to enable the exchange of information on broad policy, regulatory performance and other related issues ...

This was to include:

> ... healthcare research needs, regulation and education as well as industry, consumer and practitioner issues ...

They sound to me like the sorts of issues that arise out of what has gone on over the last six months or more and yet the forum has not met. You have to ask: why not?

Mr Slater—It has been four weeks since Pan—

Senator FORSHAW—The issues have been there since at least late last year or early this year.

Mr Slater—But, as I said to you, I do not think the events that unfolded at the beginning of January were ones that we would have taken in the course of our investigations to the Complementary Consultative Healthcare Forum.

Senator FORSHAW—So travacalm gets recalled and—

Mr Slater—Travacalm was not a complementary medicine.

Senator FORSHAW—The TGA would have the ability to call this forum together. You have seen no reason at all to bring this forum together since June 2001 and certainly since the election. I note also that presumably the parliamentary secretary or the minister could have asked for a meeting to be held as well.

Mr Slater—I acknowledge that there may be some very good discussion to be had post Pan. I say to you again that since Senator Tambling held the last meeting in June 2001 there has been not been, in any way, a request from members from any of the groups to have a meeting of the forum. I think you will agree with me that it would have been unwise for the TGA to take the Pan issue to the forum during its investigations. The TGA's action unfolded on 28 April. It has been, I can tell you, 4½ short weeks since then and the complementary healthcare forum's discussion of the Pan events has not exactly been the top of the list, as you could well expect.

Senator FORSHAW—What I am interested in particularly is what was happening prior to the events of 4½ weeks ago, and indeed prior to January this year when the unscheduled audit was undertaken. I am interested to know what was happening in respect of the sorts of issues that we now know are major areas of failure over the course of the last couple of years. You have a consultative forum established by the parliamentary secretary that is going to particularly bring government and the sector together to look at regulatory performance and so on. At the five meetings that were held, what sorts of issues did they discuss?

Mr Slater—The major issues were research in complementary medicines and international trends in regulating complementary medicines. There were discussions around practitioner regulation and the GST issue, which Senator Nettle referred to. There was complementary medicines and national medicines policy. There were issues on the implementation of the new advertising arrangements, including the revisions to the TGA advertising code. There was considerable discussion around the Internet and its advertising issues. There was discussion on the food-medicines interface and there was briefing on the emerging trans-Tasman issues.

Senator FORSHAW—Were issues such as the auditing processes on the agenda or discussed at these meetings?

Mr Slater—No.

Senator FORSHAW—Not once?

Mr Slater—Not once.

Senator FORSHAW—What about product safety?

Mr Slater—Product safety—that is certainly a very wide brief that you have given me there.

Senator FORSHAW—It is your core business, according to Dr Cumming—so you tell me.

Mr Slater—Certainly 'international trends in regulating complementary medicines' would have had a focus on safety; and research would have had a focus on issues around practitioner regulation which also would have had as an objective the safety aspects of it. I am advised that the review of GMP that was the basis of the Corcoran review was also a briefing item at the forum.

Senator FORSHAW—So the issues that were in the Corcoran review were on the agenda?

Mr Slater—I am sorry, I am misleading you. Somebody has picked up another committee where we briefed the industry around the Corcoran review. I apologise for that.

Senator FORSHAW—The Corcoran review went to the very issues that we are focusing on.

Mr Slater—Yes, I am sorry. I have a piece of paper here which has picked the wrong committee.

Senator FORSHAW—In one way or another, audit processes would have been within the scope of this forum. If the Corcoran review was raised—

Mr Slater—The Corcoran review, as you know, came after the last meeting of the forum. The Corcoran review was completed in March 2002 and the last meeting of the forum was on 29 June 2001.

Senator FORSHAW—But you just said it was raised at meetings.

Mr Slater—No, I apologise. I had a piece of paper put in front of me which talked about another consultative forum, not this one. I have made that clear. I have read you out the list of the major issues that were considered at the forum.

Senator FORSHAW—Can you—and you can take this on notice—provide us with copies of the minutes of those five meetings?

Mr Slater—Certainly. They are on the web site.

Senator FORSHAW—The full copies of the minutes are all on the web site?

Mr Slater—Yes. I am advised that that is the case.

Senator FORSHAW—The forum is still mentioned on the web site, isn't it?

Mr Slater—Yes.

Senator FORSHAW—It was also referred to in the 2001-02 annual report as an ongoing committee. Is that correct?

Mr Slater—That is correct.

Senator FORSHAW—The annual report says:

The TGA has numerous forums available for consulting with industry and consumers, including the TGA-Industry Consultative Committee, the Complementary Healthcare Consultative Forum ...

Does it still exist or doesn't it?

Mr Slater—As I have said, no-one has said that—

Senator FORSHAW—The TGA has not called for a meeting either.

Mr Slater—the forum will not meet again. It is an available tool that was introduced as part of the reforms to the regulation of complementary medicines. The last meeting was in June 2001. It may well be, as you have conjectured, that there is scope for it to meet in the future.

Senator McLUCAS—Who instigated the convening of the five meetings that were held?

Senator FORSHAW—Good question.

Senator McLUCAS—You made the point earlier that it is up to any of the members to instigate a meeting.

Mr Slater—Yes. It was agreed at the end of each meeting when the next meeting would be.

Senator McLUCAS—I have got an agenda from one of the meetings. It does not actually have an item that says 'next meeting', but was that the normal course of events?

Mr Slater—Yes.

Senator McLUCAS—So at the end of every meeting they would say when the next meeting would be?

Mr Slater—There was a discussion about if and when the next meeting would take place. At the last meeting, and I think this is the point that Senator Forshaw went to, Senator Tambling encouraged members to take issues of concern separately to the various political parties as considered necessary. He indicated that it was unlikely there would be a further meeting of the forum before the election and left open the possibility of a further meeting.

Senator McLUCAS—Do the members of the consultative committee know that it is within their gift to ask for a meeting to be convened?

Dr Cumming—It was actually on each agenda, except the first agenda. The next meeting is an item on each of the other agendas.

Senator McLUCAS—I have only got the first one. Thank you. Do the members know that it is within their gift to call a meeting?

Mr Slater—That is the nature of a forum.

Senator McLUCAS—But do they know?

Mr Slater—If there were a need, you would get agitation for it.

Senator McLUCAS—Who pays for the attendance at the meetings?

Mr Slater—The TGA.

Senator McLUCAS—Is there a meeting fee?

Mr Slater—A meeting fee to attend?

Senator McLUCAS—For the forum members?

Mr Slater—No, there are no sitting fees, except that the TGA would pay for consumer representation. Their costs are per diem for the consumers to attend, which is normal practice.

Senator McLUCAS—I understand.

Senator FORSHAW—This forum was established by Senator Tambling. Is it the case that the government called the first meeting?

Mr Slater—It arose out of the deliberations of the government industry committee that was set up to look at the regulation of complementary medicines. One of its recommendations

to government was to establish a forum, and so it was accepted by government to establish the forum.

Senator FORSHAW—But the question was: did the government convene the first meeting?

Mr Slater—Yes.

Senator FORSHAW—Have members of the committee been given any advice as to its future?

Mr Slater—Senator Tambling's advice was very clear.

Senator FORSHAW—That was before the election.

Mr Slater—Senator Tambling left open the possibility of future meetings. As I said, nobody has come forward asking for a further meeting. The only contact we had was from the consumer representative in the Northern Territory wanting to make certain that her diary was clear in the event that a meeting was scheduled.

Senator FORSHAW—I would have thought that, at least for the good reason of having everything nice and orderly, if a forum that is established by the government in such a formal way as this was is not going to meet, or is not likely to meet, or if the government or the TGA is not interested in having it continue to meet, it would do something about that: either it would say that its work has ceased or people would be advised formally that it exists but is in abeyance, which I would have thought was a bit unusual anyway. Don't you think that could be a neat and tidy way of doing this? What is the point of having it and advertising in your annual report that you have got this consultative forum with the industry if it has not met for the last two years or so?

Mr Slater—I understand your point, Senator.

Senator FORSHAW—I understand it too, but what are you going to do about it?

Mr Slater—Certainly, I will be very conscious of your thinking on it. I will have a discussion with the parliamentary secretary—

Senator FORSHAW—You do not know what my thinking on it is. I could come to the conclusion that it might not have been a bad idea for it to meet, but I am not a member of it. I am just wondering why you have this forum that was announced with such fanfare by the government, established as an industry-government consultative body, and it has not met for close to two years. It is just sitting there, in suspension.

Mr Slater—In summary, it met five times. It felt it had dealt with the agenda of the day and Senator Tambling said there would not be a further meeting before the election and left open the possibility of meeting after the election.

Senator FORSHAW—That was sensible in the circumstances.

Mr Slater—I again say to you that it is open to have further meetings. Your thoughts about whether it would be timely to have one now is something I will relate to the parliamentary secretary.

Senator FORSHAW—If I were a representative on the forum, I would probably like to know what its future is, given that it had not met for two years. You would start to ask yourself the question a lot earlier than two years whether it had any future.

Mr Slater—As I said, nobody has questioned whether the forum was going to meet again. If I were to surmise from that, what I said—that it had dealt largely with its agenda as it was at the time and felt comfortable that it had taken those issues as far as the forum wanted to take them and left open the possibility of future meetings—would be as far as I could go.

Senator FORSHAW—Thank you.

Senator McLUCAS—The web site says that the committee meets twice a year.

Mr Slater—When it was initially instigated, that was the thought—that it would meet a couple of times a year.

Senator McLUCAS—I will just check; I am on the web site.

Senator FORSHAW—That is wrong, is it not?

Mr Slater—That is not true, Senator. It met five times over a two-year period and, as I said in summary, because nobody has expressed the desire for a further meeting, the agenda of the day had been exhausted.

Senator FORSHAW—They have absolutely nothing to discuss. The TGA have nothing at all to discuss.

Mr Slater—Nobody had raised, among any of the parties, the need for a further meeting of the forum—neither industry nor the practitioner or consumer groups, nor the TGA.

Senator FORSHAW—Will you correct your web site?

Mr Slater—As I said, it is open that the forum could meet again.

CHAIR—Can I ask senators how much longer you consider we will be discussing the TGA?

Senator FORSHAW—We want to get on to Pan Pharmaceuticals, which will probably be the last major issue we will be covering. Pan could take some time. We have had a look at our brief and we are prepared to put some remaining matters on notice in the interests of moving things along.

CHAIR—We will proceed with Pan.

Senator FORSHAW—It is hard to know where to start with this one. You said earlier, Mr Slater, that there have been 12 unscheduled audits in the last year, 2002-03—I think that was the answer you gave me this morning—and there have been three with respect to Pan.

Mr Slater—No, I do not think we gave any figures on Pan.

Senator FORSHAW—You did.

Mr Slater—Did we? Sorry—yes, three unscheduled audits in the last two years of Pan.

Senator FORSHAW—There have been 12 in total in the last year.

Mr Slater—That is correct.

Senator FORSHAW—Were any of the other nine audits of Pan earlier than this calendar year?

Mr Slater—No. There were three out of the 12 unscheduled audits. Were there any other audits of Pan in that time? Yes.

Senator FORSHAW—You said earlier there had been an unscheduled audit in January, didn't you, following the travacalm situation and then there were two more? I was just wanting to check whether there had been any other unscheduled audits earlier than those three going back to the beginning of this financial year.

Mr Slater—Yes. The April audit in 2002 was a scheduled audit.

Senator FORSHAW—If we look at 2002, there was one scheduled audit of Pan in April.

Mr Slater—That is correct.

Senator FORSHAW—Can we have a copy of that audit?

Mr Slater—Audit reports are clearly marked 'commercial-in-confidence'.

Senator FORSHAW—Are you able to tell us anything about what was in that report?

Mr Slater—Yes, we are happy to talk you through what the deficiencies were in the audit.

Senator FORSHAW—Please do. You can also tell us what methodology was used in undertaking that audit.

Ms Maclachlan—I will start off, and then for detailed questioning I will defer to Mr Gould. Indeed, the TGA undertook an audit of Pan Pharmaceuticals Ltd on 30 April and 1 May 2002. In that audit we looked at the documentation of the company, its record, its standard operating procedures, its quality control testing, the training that it had in place for its employees and its environmental monitoring.

Senator FORSHAW—Thank you. Now are you going to tell us what the findings were? I think Mr Slater's word was 'deficiencies'?

Mr Gould—There were 12 deficiencies. I do not have the information about where they actually fell, except that they were not critical deficiencies at that time.

Ms Maclachlan—Then the company was required to provide us with its corrective action report following our providing the company with our formal report, and that report was signed off.

Mr Gould—It was a normal full audit by an auditor and a specialist in laboratories, and it was observed by Health Canada. It was closed up and dealt with in the normal fashion.

Senator FORSHAW—So it was a normal audit. Was that 12 monthly, two yearly—what frequency was this normal audit?

Ms Maclachlan—In this particular case, I think it was a 12-monthly audit, if we looked at the previous audit record.

Mr Slater—If I have a look at the total audits of Pan since the TGA was established to audit them in 1992, I see there were 14 audits over that period of time. That is 14 audits in 11 years, which gives some indication, if we go back to the discussion we had this morning,

about risk profiling. It would be normal that in that time, over that 11 or 12 years, there would be five or six audits, and this company we audited 14 times in that period.

Senator FORSHAW—When you said it was a normal audit, what do you mean? Was the nature of the audit normal?

Mr Slater—It was not an unscheduled one.

Ms Maclachlan—It was not an unscheduled audit. The purpose of the audit was to look at the level of compliance of the manufacturer with the code of good manufacturing practice for medicines—essentially what we refer to as a quality systems audit.

Mr Gould—A 'routine audit' would be a better way of putting it.

Senator FORSHAW—That is the nature of the audit. But you are saying, aren't you, Mr Slater, that you audited Pan more times than would otherwise have been normal in that period since 1992?

Mr Slater—The point I was making is that, if you go back to the discussion we had this morning about risk profiling, for a company that has medium-risk profiling, which is what you would normally equate for Pan, as Mr Gould said, then you would have expected an audit once every two years on average. So I am going to averages there, and I said that over the period of time we were doing it twice as frequently, or more, on average.

Ms Maclachlan—Can I also comment on the risk profiling of Pan Pharmaceuticals. The company actually over a number of years moved sites, so every time that it moved site it required an audit. It also added to its licence, for example, liquids; so that would have also required an audit to be undertaken.

Senator FORSHAW—How many times did that occur?

Ms Maclachlan—In recent times it moved to the Moorebank site, where it consolidated its activities.

Senator FORSHAW—You said there were 14 audits since 1992. Do they include the three this year?

Mr Slater—Yes.

Senator FORSHAW—So prior to this calendar year—

Mr Slater—It is still one per year.

Senator FORSHAW—It is 11, yes, that is right. Were they all scheduled audits or were any of them unscheduled?

Mr Slater—There were some that were unscheduled.

Senator FORSHAW—How many?

Mr Slater—There were two other unscheduled audits conducted prior to that period.

Senator FORSHAW—Could you provide us with a table of when the audits occurred and whether they were scheduled or unscheduled? I am sure you have something like that.

Mr Slater—Yes, we will be pleased to.

Senator FORSHAW—When were those two unscheduled audits?

Mr Slater—There was one in September 1992 and another in February 1994. I might relate for the edification of the Senate that it was in that period that the TGA took enforcement action and court action against Pan for illegal activities. The company went into liquidation in 1997 or 1998, or thereabouts, and came back with a new facility in November 1998 at Moorebank. That was a new first-class facility which they had built from the ground up.

Senator FORSHAW—You were saying, Mr Slater, taking account of the risk profile and what we discussed this morning, that the suggestion was clearly coming through that Pan Pharmaceuticals were being subjected to more than would otherwise be the usual auditing frequency. Is that the case? It is now being said that, if you do not count the three this year and there were some audits because of relocation—

Mr Slater—No, I am still saying that the risk profile here—it might be worth my while, since the new factory came into being, to talk about how the risk profile may work here. We audited in November 1998 and we conducted a further audit in January 2001, which is just around the two-year mark. Of course, we set our risk profile subject to what we found. We then did an audit a little over a year later at the end of April 2002. Then we were back to do the three audits that you are aware of in January, February and April this year.

Senator FORSHAW—You indicated earlier, Mr Gould, that there were 12 deficiencies which you identified. Can you provide the details of those to us.

Mr Gould—I said that I do not have those details here.

Senator FORSHAW—You could take it on notice and get them for us.

Mr Gould—They would be in the inspection report.

Mr Slater—I am comfortable to release the deficiencies. The document is commercial-in-confidence, but I think it is appropriate, seeing that I have discussed the other audit deficiencies earlier today.

Senator FORSHAW—What we have is a fairly intensive history of audits and obviously some ongoing concerns within the TGA about this company, concerns which are part of the TGA developing its risk profile. The question we then come to is: what, if any, indications were known to the TGA about the problems that subsequently arose this year? Were any of those things picked up in those audits?

Mr Slater—The key issues of concern, the critical deficiencies that I talked about in answer to Senator Humphries' question earlier this morning, related to data manipulation, falsification of data, substitution of ingredients and what I would call inadequate process controls—where, for travacalm, the company mixed and used a dry granulation method when the sponsor required a wet granulation method for mix and, to get the uniformity of content, put it into a plastic bag and shook it. Those issues certainly did not surface at the April audit in 2002, otherwise we would not be here discussing this particular issue now.

Senator FORSHAW—That was a scheduled audit, so they were given notice that you were coming. Is that the case?

Mr Slater—I do not think the manipulation of data are issues.

Senator FORSHAW—Just answer the question. They knew you were coming to audit them.

Mr Slater—Certainly, yes, they knew we were coming.

Senator FORSHAW—And just about all the other occasions they knew you were coming too. That is correct, isn't it?

Mr Slater—Except where we did unscheduled audits.

Senator FORSHAW—Yes, I think you said there were two of those. Were those audits similar in nature each time and did they cover the whole of the factory?

Mr Gould—In December 2002 it was a special audit to extend their licence to include liquid and semi-solid products or creams and ointments. The other audits were routine full audits.

Senator FORSHAW—Was there any reason why you did not do any unscheduled audits, given what you know? You obviously had concerns about this company—it had some form, including some earlier legal issues.

Mr Slater—Unscheduled audits is one tool that is at our disposal. The committee has a copy of the Corcoran report. As you go through it you will notice Corcoran's view of the audit process—and I quote:

> However, even the best of GMP audits do not guarantee identification and subsequent rectification of all non-compliances of the GMP code, and certainly do not guarantee continued full compliance for the full one to three year period between audits.

Corcoran goes on to put great weight on the fact that audit processes should be scheduled to allow for effective two-way dialogue at exit on the audit findings and on associated risk ratings. Unscheduled audits, as I mentioned this morning, are only one aspect of how we go about having information about whether there is a need for regulatory examination of a manufacturer. The TGA has its targeted sampling of products. TGA has a world leading system of adverse drug reporting. Acknowledged worldwide as one of the best two—if not the best—in the world, it has intelligence that it gathers from complaints and from competitors. It has consumer concerns that might be raised and it has its surveillance activities as well. Besides auditing, it has the ability to get information which gives it the basis for taking regulatory action. In this case, as I said in answer to Senator Humphries' question, the TGA acted on five adverse reactions it got within a period of four working days and that was the basis for going in and doing an unscheduled audit at Pan. I think that that was a very quick response to a developing situation.

Senator FORSHAW—It has been stated by former employees of Pan, including on the *Sunday* program, that the sorts of practices that have recently been exposed had been going on for quite some time and indeed had been communicated to the TGA.

Mr Slater—Maybe I should go to the *Sunday* program.

Senator FORSHAW—Should you?

Mr Slater—The *Sunday* program alleged that in June 1992 an employee contacted the TGA. That is wrong. The employee in fact wrote to the New South Wales health department

in June 1992. Nine months later the New South Wales health department sent the complaint to the TGA without having taken any action on it. That letter was received by the TGA on 24 March 1993. The TGA had completed a full GMP audit of Pan one month previously, on 9 and 10 February. It found poor hygiene and sanitation, equipment that was not correctly calibrated, equipment design faults giving concern about cross-contamination between different products, documentation that was deficient, and the company's internal inspection program was not effective—which accords very much with what was claimed by the employee. The TGA had already taken those issues up with the company—before the employee's letter arrived at the TGA—and had in place corrective action to remedy the problems. On 18 March the TGA also had in place the first of its investigations under warrant of the Pan facility.

Senator FORSHAW—If you had carried out unscheduled audits during this period, would you have picked up the practices that you have now picked up as a result of the ones that occurred this year?

Mr Slater—That is a very complex question because it goes to how do you determine—

Senator FORSHAW—Well, you picked them up this year.

Mr Slater—How do you determine or how do you uncover—that is a better expression—deliberate concealment and falsification and a culture to mislead and deceive?

Senator FORSHAW—You uncovered it this year, right?

Mr Slater—Yes.

Senator FORSHAW—The question arises of why—knowing what you knew about Pan Pharmaceuticals, knowing the concerns you had over a long period of time—that sort of unscheduled audit that occurred this year did not occur in previous years, when you had some situations where, as I think you just referred to, certain practices had been investigated following information supplied to the TGA and followed up. Why would that not lead you to undertake an unscheduled audit?

Mr Slater—This was a new factory that commenced operations in March 1999. I put it to you that in four years we have uncovered this activity, and that is despite the fact that there was deliberate concealment, fabrication and falsification of records.

Senator FORSHAW—You have uncovered it since the travacalm situation occurred, where you had people who were so seriously ill that they could have died.

Mr Slater—That is why I was saying to you that the reliance on audit is only one aspect of the TGA's risk profiling. The fact of the matter here is that we have, as I said, either the world's leading or, arguably, one of the two leading adverse reporting systems in operation, and we have a whole range of other activities where we get information available to us. It might exercise senators' minds as to exactly how we did uncover the concealment and the deliberate fabrication of results here.

Senator FORSHAW—So you are now claiming a virtue out of all of this?

Mr Slater—No, I am expressing confidence in the way the regulatory system responded at the end of the day.

Senator FORSHAW—I am sure everybody is glad that you uncovered what happened. Knowing what was on the record and what was known to the TGA through previous dealings with this company, the question that people are asking is: why did you not pick it up much earlier? That is the real question here.

Mr Slater—I would like to know when you think this fabrication commenced.

Senator FORSHAW—It is your job to find that out.

Mr Slater—You are suggesting that it was much earlier.

Senator FORSHAW—Certainly there are reports that practices had been going on at Pan Pharmaceuticals for some time.

Mr Slater—In 1992, as I told you, we took action to charge the company. The company went into liquidation and reformed with a totally new company structure and a board in place—it was a publicly listed company with all of the attendant duty of care, discharge of fiscal responsibilities and prudential requirements that are required of a listed company. In the four years since it commenced operation, we have uncovered practices that developed in the company in a new facility.

Senator FORSHAW—You uncovered them in the last six months.

Mr Slater—I guess all of us could sit here and debate when we think it might have started.

Senator FORSHAW—When do you think it started?

Mr Slater—I think that, given the regulatory framework we have, we got onto it very quickly.

Senator ALLISON—Is it the case that, back in July last year, Pan was given a clean bill of health after an audit?

Mr Slater—No, in April 2002. It was not given—

Senator ALLISON—Wasn't it July last year?

Mr Slater—It was not given a clean bill of health. As Mr Gould said, there were 12 deficiencies identified in that April audit. They were not critical deficiencies.

Senator ALLISON—What about the July one, last year?

Mr Slater—No, there was not a July one last year.

Senator ALLISON—So it was April this year?

Mr Slater—April last year. I should say, Senator Forshaw, that there has been much speculation in the financial press over the last six months about the fact that Pan has come under a lot of competitive pressure and their unit costs have fallen. One could surmise that travacalm resulted because of cost-cutting and that corners were cut in normal processes to reduce costs in response to competitive pressures. There is much evidence and discussion in the financial press about the development of a competitive market in this area for contract manufacturers.

Senator ALLISON—I want to go on a slightly different tack. Why was it that, when those big ads went in the papers, they were listed by batch number instead of brand name? Did you

get a lot of complaints from people who were unable to find whatever it was they were using? Why was that decision made?

Mr Slater—The difficulty there was to actually have a system of identifying which products Pan manufactured. So we used, as our index, a registered list that the TGA had. That was the identification on the—

Senator ALLISON—That might make some sense to the TGA, but it would not make any sense to customers, surely.

Mr Slater—Where products had the same name as they did—

Senator ALLISON—I know, but they were not in alphabetical order. You had to wade through very fine print across two big pages of a newspaper ad.

Mr Slater—Certainly for the documents that we provided for retail outlets, we were able to put them into an alphabetical process.

Senator ALLISON—So why was it not done for the ads where you would expect consumers, in the main, to be those interested?

Mr Slater—The key identifier is the register number. I am happy to take that question on notice, Senator, and see if there was a technical reason as to why alphabetical order was not used.

Senator ALLISON—A few people made a comment to me that they gave up. They tried looking for whatever it was they had in their cupboard, and they just could not be bothered wading through all the listed goods.

Senator FORSHAW—Mr Slater, what would be the basis upon which you would decide to do an unscheduled audit?

Mr Slater—As I said, it is where we had a particular reason; where we felt an unscheduled audit was required and would have value added over a scheduled audit. It is where it is suspected that there may be GMP deficiencies that would be covered up if the licence holder received advance warning of a GMP audit; where information is received from external sources—for example, tip-offs; where information is received from other areas of the TGA—for example, from recalls from product regulatory knowledge from the testing done by the laboratories or from our surveillance area. It could also be on the basis of the nature of the deficiencies and the experience we had from the previous audit where the auditors believed that it was necessary to conduct an unannounced audit or, of course, from other audit history.

Senator FORSHAW—You mentioned a moment ago that one possible problem that Pan might have had that led to these practices was competitive pressure. It is interesting because I understand that Pan actually advised the Stock Exchange of their forecast growth—this was in February this year—that sales their were up, earnings were up and they were anticipating a profit of $8.6 million, a five per cent increase. That does not gel with what you are saying. Maybe they were misleading the Stock Exchange—were they?

Mr Slater—I have an article dated 12 February 2003, interestingly enough, and it says that there was a lot of competition. Jim Selim, the chief executive of Pan, said:

Investors should not be in for any surprises when the company announces its interim profit result on 26 February. There is a lot of competition, but we know what we're doing; we know how to produce a good product at a good price.

It goes on to say:

Pan has found itself in a price war in 2002 battling for market share in the capsules market against Asian imports and emerging local competitors.

Senator FORSHAW—Did you read that at the time?

Mr Slater—Yes.

Senator FORSHAW—Did it trigger anything in your mind?

Mr Slater—At that stage, we were already in there, Senator.

Senator FORSHAW—So it fits with your analysis of why these practices occurred, does it? It is an interesting view about competition—it is not such good thing.

Mr Slater—If I could further quote from that, it says:

Investors who have looked closely at Pan had previously questioned the company's operating margins, which some drug makers had said were too high to be maintained over the long term. This concern was compounded last year by the emergence of Lipa as a serious competitor with the scale to take Pan head on. Lipa now claims to employ over 120 people in its new multi-million manufacturing facility.

Senator FORSHAW—Is the performance of companies a matter that the TGA monitors?

Mr Slater—It is certainly not something that we regulate—

Senator FORSHAW—I know you do not regulate it.

Mr Slater—but it is something we are aware of as part of our intelligence. As I said, in terms of risk profiling, we draw on intelligence that might come our way.

Senator FORSHAW—When did you first become aware that Pan may have been suffering some financial difficulties as a result of this price war?

Mr Slater—We were certainly conscious that there was growing competition in the marketplace.

Senator FORSHAW—Yes, but I asked you when you first became aware. You are putting a proposition forward which may have substance. I am not disputing that they were trying to cut corners et cetera in order to deal with a difficult financial position. If this was something that could have, in turn, led to these sorts of practices occurring, when did you or the TGA become aware that the company was in this situation? Was it before January this year?

Mr Slater—Certainly we were conscious from about September on, when the research paper came out from a division of Equity Capital Markets, which did the analysis around how Pan was performing and what its strategy was.

Senator FORSHAW—But at the time you did not link that with the possibility that this might lead to some practices that should not occur?

Mr Slater—It was one thing in the melting pot, yes.

Senator FORSHAW—But you did not link that at that time. While you are mentioning their financial position, when we were discussing earlier today when the recall occurred—this

was the recall of travacalm and, I suppose, it applies to any other products—you said there was a time delay, because you had to get advertisements into the paper and so on, so you took other steps to inform the company that they should move to recall product. Do you recall that discussion this morning?

Mr Slater—Yes.

Senator FORSHAW—I asked you whether or not you notified the Stock Exchange, and the answer was no. Are you aware of the fact that, once the announcement was made or became public knowledge in April this year, there was a substantial impact upon the company's shares on the stock market?

Mr Slater—Yes.

Senator FORSHAW—Was that a matter that crossed your mind at the time the recall was being made—that, given the substantial nature of this recall, that sort of information was pretty critical to shareholders?

Mr Slater—I am not going to offer a personal opinion on that, Senator. It is not the TGA's role. The TGA is not the regulator of Australian financial markets.

Senator FORSHAW—I am not suggesting for the moment that it is. But if you have made a decision that is not publicly announced until a couple of days later, because eventually the advertisements and the story get into the paper—so you use the voluntary recall method in some cases and in other cases it is a mandated recall—there can be a window of time between when the recall decision is made and when it comes to the knowledge of the Stock Exchange, the public or shareholders and in that intervening time,substantial changes can happen on the Stock Exchange: for instance, the sell-off of shares.

Ms Halton—Your assumption is that the first public notification of a recall is the publication of an advertisement. Mr Slater can go to the process. Your contention, as I understand it, is that the two days it takes you to book space, in the process Mr Slater outlined this morning, is an opportunity for activity on the share market. That information is in the public arena prior to the publication of an advertisement.

Senator FORSHAW—You understand the issue I am raising.

Mr Slater—Yes, I understand the issue.

Senator FORSHAW—It could clearly have a major impact on the company and on shareholders.

Ms Halton—Yes.

Mr Slater—All we could do was ensure that at the earliest possible time we gave information to the public. So on the morning of Monday, 28 April we presented to the full board of the company, as due process and procedural fairness would dictate, the findings of our audit and we outlined the action that we were taking and gave them a letter suspending their licence. We then immediately made a public statement to that effect.

Senator FORSHAW—That was by way of a media release?

Mr Slater—That was by way of a media release, and by media statements and a press conference.

Senator FORSHAW—Could you take us through the various recalls that were made and what the TGA did. You put out a media release, you arranged for advertising—

Ms Halton—Are you talking about Pan?

Senator FORSHAW—Yes, we are talking about Pan. It goes beyond Pan, we know that, in context.

Ms Halton—We are talking about products manufactured by Pan.

Mr Slater—I have to start the discussion by giving you a view as to the complexity of the situation, what the TGA's role was and what the roles of sponsors were. The TGA, having mandated cancellation of Pan's licence, was obligated to immediately advertise those products that were affected as soon as practicable. The TGA advertised those on the day after it issued the suspension of licence—the morning immediately after. So within 24 hours of issuing the suspension of licence the TGA notified the public of the 219 products that were implicated.

Senator FORSHAW—Just so we have this on the record sequentially, the licence was suspended on 28 April and on 29 April there were advertisements that the 219 products were cancelled.

Mr Slater—What comes next is a very complex issue to deal with because there are those companies where Pan was the sole manufacturer, but quite rightly those companies needed to be contacted to see whether they had actually supplied any Pan products. They would have been justifiably angry and maybe litigious in fact if we had nominated them as having products subject to the recall if we had not had advice from them of what batches were implicated. As we had set the date of the recall back to the last satisfactory audit, which was the correct thing to do, we also needed to know whether they had actually had any products supplied in that period. They may well have had them prior to that. Then there was a group of sponsors where Pan was one of many manufacturers. In fact, again, for the very same reasons that I talked about, we needed to get information from them as to whether they had any products that were caught up in the recall.

The TGA's obligations here were to have the sponsors initiate those recalls under the uniform product recall processes. But, as a public service, the TGA was quite conscious that consumers going through potentially 400 or 500 individual advertisements would have been justifiably annoyed and confused. So the TGA, as a public service in asking for the information from those two sponsor groups, said, 'If you get the information back to us within 48 hours, we will advertise it as a public service.' Unfortunately, the response rate was less than impressive: we had had around about a 50 per cent response rate at that stage. Again, we ran what we had on 1 May, as we promised, which was 449 products. We undertook to do another public service the following day when we advertised another 700 products. Because there was still a large number of products coming in, for the very same reasons that consumers would have had to go through multiple advertisements to try to find a potential product, we did a further advertisement on 6 May. That was 386 products with 40 different sponsors.

Senator FORSHAW—That was on what date?

Mr Slater—That was Tuesday, 6 May—386 products and 40 different sponsors. The number of products was 386.

Senator FORSHAW—They were not all Pan products, were they?

Mr Slater—Yes, they were all products manufactured by Pan. I think what you are getting to—

Senator FORSHAW—I am trying to get it clear because figures are flying around everywhere.

Mr Slater—Let me make it even more complicated for you. Not surprisingly, in people's haste to comply—for the very great majority, I might say; there were some who did not want to comply and we will come to that a little later—they made mistakes and they gave us lists of products that ought not to have been recalled, and they came along subsequently and said, 'Gosh, these are the ones we should have given you. These other ones, unfortunately, have been recalled when they ought not to have been.' We undertook that the TGA web site was always up to date. So, in total, there are 1,624 products currently that have been subject to recall. If you ask me the question, 'Are there going to be anymore?' I would have to say that the system of competition is working robustly in this country. We are conscious that there are some suppliers who may not have done the right thing and declared batches of products or implicated products, and we are investigating those and will take firm action as that information comes to hand.

Senator FORSHAW—I think it would be helpful if you could provide us with a chronology of the recall, because it is very confusing reading the media releases from the TGA and looking at the ads, as I think you acknowledge.

Mr Slater—I acknowledge that, Senator.

Ms Halton—We are very happy to give you that, and we will give it to you at a level of detail we hope you will find comprehensible. The key thing to understand here and what Mr Slater has tried to outline—and we apologise for the complexity; it is just the nature of the circumstance—is that the first part of this process was the process we were obliged to do in terms of the Pan product: the things that were cancelled. Thereafter—and I accept the fact that there has been some confusion here—what we did was something we were not obliged to do, which was to try to minimise where possible the confusion for consumers. For all those other products, as Mr Slater is trying to explain, we were reliant on sponsors coming in and telling us what they had from Pan and what batches and, therefore, what they should recall voluntarily. We attempted to remove a small amount of the confusion to consumers by providing one place to advertise all of those products. As Mr Slater said, we did that as effectively a public service. It was something that we decided in what was clearly a very big and complicated exercise that we should do to try to assist consumers.

Senator FORSHAW—Let me take you to some of the confusion that I had with this. The media release of 30 April said that Therapeutic Goods added an extra 449 products to the list of medicines affected by the Pan Pharmaceuticals recall. It then goes on to say:

It brings the total number of recalled Pan products to 668.

This is not the final list of products to be recalled. Around 15 manufacturers have requested more time to supply details to the TGA of products that may have been manufactured by Pan.

Therapeutic Goods Administration principal medical adviser Dr John McEwen said it was likely there will be, at the very most, a further 300 products that would be recalled.

That takes it up to 968. There were further media releases. One on 1 May referred to 701 products, bringing the total number for recall to 1,369. Then it says:

If any other affected products come to light after review of records in cooperation with Pan Pharmaceuticals, they may be subject to cancellation and mandatory recall action.

Now we find, as you said, that it is up to 1,624 following further recall today. What was the basis for the first estimate of Dr McEwen's on 30 April that would have taken it up to 968?

Mr Slater—Dr McEwen was basing that estimate on what we thought was the percentage of responses that we had to hand. He did an extrapolation, not unreasonably, on the basis that he thought we had half of the responses in, or whatever the appropriate percentage was. He extrapolated that out. While the TGA had set 48 hours, as Ms Halton said, as a public service to companies to get their responses in, we had a duty of care to get that information out to consumers as soon as practicable because there were public health issues at stake. Rather than waiting, as we could have, to look good perhaps in formulating a recall list, we have taken the pain here of going out as soon as we had information. We have taken a lot of criticism for causing confusion and for the fact that there has been a number of advertisements, but I believe we have discharged our responsibility to get this information to consumers as soon as we could. And we have taken that as a public cost, when we did not have to take it as a public cost—as a public service.

Senator FORSHAW—We could spend a lot of time debating that last point. You might say you are doing it as a public service over and above what you might be required to do, but the fact of the matter is that the TGA is the body right in the middle of this thing and everybody is looking to the TGA to give the advice and manage this whole process openly and in the interests of public safety and security. So it was a public service that you really needed to undertake—

Mr Slater—I agree, Senator, and we did that.

Senator FORSHAW—given your obligations and your mission statement, but we do not have time to go through those. In the earlier recalls at the end of April and early May, you had advertisements and you also put out media releases. Did you issue a media release in respect of the products that have been recalled today by advertisement?

Mr Slater—No.

Senator FORSHAW—Why not?

Mr Slater—These were products that have come forward from two major sponsors who are running their own advertisements and who made mistakes. Both those sponsors had products advertised as part of the public recall, but because of information that has come to hand they have rightly identified the additional information and are advertising it. The TGA cleared the advertisements for those companies on 23 May and we expected that they would have been advertised as soon as practicable. We are a touch disappointed that they have taken

as long as they have to book the advertising space. The other advertisement is a collective advertisement being paid for by the industry association to pick up those companies that have not responded, where the TGA cancelled their products or where the companies are so small or are in a position where they are unable to pay for the advertisement. To its great credit, the industry association has picked up responsibility for those and has organised the advertising of them.

Senator FORSHAW—But, given that you issued media releases on the other occasions and that this is still a large number of products, why did you not think that it would be consistent to put out a media release? Obviously, there are people such as members of parliament who, having looked at your web site—and I will come to that in a minute—and also having gone through the media releases, would have a reasonable expectation that when you do another recall that is associated with this issue, or any issue, you would have a media release as a bit more information.

Mr Slater—There are two reasons for that. One is that the TGA has undertaken and advised with each of its advertisements that it has a web site, which is always up to date. When we ran our final advertisement on 6 May we made it clear that any further advertisements would be undertaken by the individual sponsors but that the TGA web site would always have the current information. The second reason is that potentially we could have had as many as 80 to 90 sponsors here who had to run an individual advertisement. I think it would have been not helpful for the TGA to be setting a precedent by issuing a press release for each advertisement.

Senator FORSHAW—When did the TGA receive the list, Mr Slater?

Mr Slater—Receive what list, Senator?

Senator FORSHAW—The list of products for recall, the ones we are dealing with in today's recall? When did you become aware of that list?

Mr Slater—The TGA cleared the advertisements on 23 May. We did not have the list of products that were involved there that we had agreed with the companies, particularly with the industry association, which was trying to do a clean-up job, if you like, of those matters that were outstanding. With the other companies, we would have had quite positive lists of what was involved. I have to emphasise that I cannot say to you here and now that the very last product that is subject to the recall has been identified. As I said, we are getting intelligence at this point which says that some companies have not met their obligations and have deliberately not responded with accurate information.

Senator FORSHAW—I heard you say that earlier, but what I was asking you was: when was the TGA supplied with the details for the recall that is advertised in today's papers? I think you said you approved the advertisements on 23 May.

Mr Slater—I would have to ask Mr Cesarin for that. Certainly, as they came to hand they were put on the web site.

Senator FORSHAW—That is what I also want to know. When were they put on the web site?

Mr Slater—They were put on the web site as we received them.

Senator FORSHAW—When was the web site last updated?

Mr Cesarin—We have been receiving this material since about 6 May, since the last advertisement the TGA published. They have been coming in in parcels. On the web site we have also identified and published—and I do not know the exact date; I will need to take it on notice—a list of sponsors who would have to do their own advertising and the products that they would need to advertise.

Senator FORSHAW—That was put on your web site. That is what you are saying, isn't it?

Mr Cesarin—Yes.

Senator FORSHAW—I understand that your web site was last updated on 26 May, which was about a week ago. Did that update include the products that are in the advertisements today?

Mr Slater—Yes. I said that. I said we cleared the advertisement on 23 May.

Senator FORSHAW—Yes, but you then went on to say that you were not sure about whether or not you had the full list of products.

Mr Slater—What I am warning you about is—

Senator FORSHAW—I am not talking about what might come down the track. What we have here is that the TGA puts on its web site on 26 May a list of products that are going to be recalled that the manufacturers are going to advertise about. The ads do not go in the paper until today, over a week later, and the TGA does not put out a media release to this effect. Why didn't you put out some media release the day that you also put the significant list on the web site, as you had done on the previous occasions?

Mr Slater—I explained to you—

Senator FORSHAW—I know you did, but I want to know why you didn't do it on this occasion.

Mr Slater—I might need to check with Mr Cesarin here, but I thought we progressively updated that web site and the last ones were put on on 26 May. So the web site did not have a burst of activity on 26 May, but there were web site updates as they came to hand.

Senator FORSHAW—So unless people had actually accessed your web site in this period of time, they were not to know that these products were being recalled until they read today's papers and saw the ads.

Mr Slater—We made it clear in our advertising that the web site would be updated on a regular basis. Secondly, we had a call centre in operation, right up until consumer calls fell to a reasonable level, which was able to point people to the web site for the latest information.

Senator FORSHAW—You will provide us with that chronological summary of all the recalls?

Mr Slater—Yes.

Senator McLUCAS—Madam Chair, I understand the ombudsman needs to catch a plane this evening. There is an agreement amongst those of us here that we are quite happy to put those questions on notice.

Ms Halton—Okay.

Senator McLUCAS—I thank him for being here. We suggest that Medibank Private come on at 6 p.m. and hopefully we can do that in short order. That would allow the people from Medibank Private to catch their plane to wherever. I suggest that as soon as we have finished with the TGA, given that we are going to have that Medibank Private window, we go to the OGTR. I suggest that we do outcome 1, outcome 5 and outcome 3. That will probably take most of the evening. On Friday, the spillover day, I suggest that we start on outcome 8 and then cover outcome 9, outcome 4 and the corporate matters.

Senator Patterson—On Friday I cannot guarantee that I will here. I will attempt to be here, but I have to be back in Melbourne for a medical research function that I do not intend to miss. I will catch an early plane, but if there is fog then you will have to wait.

CHAIR—Equally, I had made arrangements on the basis of guarantees that had been given to me. I have to be back in Perth by one o'clock. I have been able to put an appointment back, but that means that, at the latest, I would have to be on the 11 o'clock out of here which means that I would have to leave here no later than a quarter past 10. This whole thing is just becoming an absolute farce, the way we are going at the moment.

Senator CHRIS EVANS—With all respect though, Chair, the agreement with the government on estimates is that four of the committees may spill over to the Friday, by agreement. That is determined as the committees progress through their work during the week. It is always possible, and we have largely avoided it on this committee by good luck and good management. But on occasions when the workload is a bit larger and there are more areas to be covered, there needs to be that flow over. That is the basis of the Senate agreement.

CHAIR—That is absolutely so; I could not agree more. However, firstly, there has been a long-standing arrangement between the government and the opposition when conferences are on. Both parties have exercised a courtesy to each other that they would not meet on Fridays when conferences are on. I presume all bets on that are off in the future. Secondly, an agreement made in advance—as we did by swapping Senator Patterson and Senator Vanstone around to accommodate the opposition—meant that Senator Patterson was on on Monday and Tuesday and would not have to return on the Friday. There was an agreement sought from Senator Vanstone, because she already had a pre-existing commitment, that if she did swap to Wednesday and Thursday that would not mean that she would have a spillover. So agreement was sought all the way around to try and accommodate the requirements of the opposition. In fact, I think we sought to accommodate your timetable, Senator Evans, with Defence—which is understandable. The arrangements were that Senator Patterson would not have to return and split her time and that Senator Vanstone, if she agreed, would not have to go over to the Friday. So there were agreements made.

Senator CHRIS EVANS—I am not aware of any agreement about national conferences et cetera. To be honest, until I read about it in the paper I was not aware that there was a national conference on. I think I can speak on behalf of all Labor senators when I say the Liberal national conference does not loom large in our considerations.

CHAIR—And nor do your conferences in ours.

Senator CHRIS EVANS—I would, of course, be happy to offer any courtesies if possible. I do not want to debate who said what to whom. There was a swap made, but I do not know that there were any undertakings given in relation to Fridays. Those negotiations were done for us by Senator Ludwig. I am happy to speak to him about that. I presume he did that with Senator Ian Campbell. I am sure they can have another chat if there is a major problem about Friday and work that through. I am happy to offer that as a way of resolving our difficulties. There might be alternative dates or what have you. We are still happy to be cooperative about that, but our understanding was that the Friday was there if we ever ran over and it is looking like Health might be the one that does run over on this occasion. I am happy to get Senator Ludwig to talk to Senator Ian Campbell. They conducted the negotiations. They could have another chat about that, and you, Madam Chair, and the minister could put your particular concerns to Senator Ian Campbell.

Senator Patterson—All I am saying is I will be on the plane, God willing, on Friday morning. If there is a fog I will not be here and you will have to do without me until I arrive. I intend to be at the function on Thursday night in Melbourne. I think that is reasonable.

CHAIR—I think there needs to be agreement by this committee that, in the event that Senator Patterson cannot return, the meeting will proceed. Is there agreement that, if we start at eight o'clock, we can be out of here by a quarter past 10?

Senator Patterson—I will not be here at eight o'clock.

Senator CHRIS EVANS—I do not know that having this discussion in this environment is the best way to resolve this, but certainly my view would be that if Senator Patterson were delayed we could probably start. I have never been terribly fussed; usually, it is the government that is more concerned than the opposition about the minister being here. We work on the theory that public servants get more talkative if the minister is not here. I am not sure whether that is right or not. I think that when we finish et cetera is best left to a discussion with the managers of business about how we might resolve any pressing issues. I am happy to undertake that we would have that discussion. To be honest, in terms of what is left over, I suspect we will not know until 11 o'clock tonight where we are at.

CHAIR—Can I seek Senator Forshaw's comment on how much longer he needs with the TGA, given that we thought it was going to be concluded by 4.30?

Senator FORSHAW—I did not actually say when. I have got not much more to go on the TGA, but I will not be verballed about agreements.

CHAIR—We will go to Medibank Private at 6 p.m.

Senator FORSHAW—I understand that a delegation of Canadian regulators visited Australia in April last year. Do you recall that?

Ms Maclachlan—I can respond to your question. At the moment, the Therapeutic Goods Administration and Health Canada are in negotiations to put in place a mutual recognition agreement for GMP inspections for medicinal products. As part of the development of that mutual recognition agreement, which will actually be a treaty-level agreement, we are undertaking with Health Canada a confidence-building program in our competencies et cetera in relation to our audit capabilities. So a senior officer from Health Canada, our sister agency,

came to Australia and spent three to four weeks here reviewing our GMP processes, and they actually observed one audit that the TGA undertook of a manufacturer. That is the context. It was not a delegation per se; it was one senior GMP auditor from Health Canada that came to Australia.

Senator FORSHAW—So it is just one person?

Ms Maclachlan—Yes, it was. Let me put it this way: the visit from Health Canada was with one GMP auditor. I am not aware of another Canadian delegation, but in relation to our activities it was one GMP auditor from Health Canada.

Senator FORSHAW—Just to clarify that: was there one person from Canada or was there one GMP auditor?

Ms Maclachlan—It was one person from Health Canada, who was a GMP auditor and who attended the audit.

Senator FORSHAW—Where was the audit at?

Ms Maclachlan—The audit was at Pan.

Senator FORSHAW—At Pan Pharmaceuticals?

Ms Maclachlan—Yes, it was.

Senator FORSHAW—When was that?

Ms Maclachlan—That was the 30 April to 1 May audit of 2002.

Senator FORSHAW—Why was Pan chosen?

Ms Maclachlan—Pan was one of the manufacturers chosen. He also observed two other audits. Pan was chosen, I understand, possibly because of the scheduling that we undertake. It just happened to fit in with the Canadian's visit.

Senator FORSHAW—Was that held to be an excellent example, or a good example, of our auditing process?

Ms Maclachlan—No, it just happened to be part of our routine schedule and the Health Canada GMP auditor fitted in with our schedules.

Senator FORSHAW—But if you were endeavouring to show an international visitor how well we do it you would want to take them somewhere you deemed to be a good example, wouldn't you? You said earlier, of course, that we are a world leader in this regard.

Ms Halton—It is important to understand that when we take international colleagues—which we do in a lot of areas in the portfolio—we do not always take them to places which we consider exemplars.

Senator FORSHAW—Which you consider what? Exemplars?

Ms Halton—Good examples of something.

Senator FORSHAW—I would have said exemplary, but that is okay.

Ms Halton—Whatever. Essentially, in a regulatory area our colleagues in Health Canada in this particular instance are interested in the process we follow. As is the case in a number of other areas of the portfolio, we would show our international colleagues how we do things

and what we do. The fact that we took them to a particular service facility, factory or whatever it might be would not necessarily be designed to show off the worst, the best or anything else in between. You are actually showing the process and the regulatory approach.

Senator FORSHAW—Have the TGA taken other people to Pan to look at audit processes or other activities that the TGA has been undertaking at the time?

Ms Maclachlan—I do not believe so.

Senator FORSHAW—What about students? Does the TGA run courses on auditing and testing?

Ms Maclachlan—At times we may run seminars which bring manufacturers up to date on our latest regulatory requirements.

Senator FORSHAW—Does the TGA run training courses on auditing and testing?

Ms Maclachlan—Certainly for international visitors. For example, the TGA is considered to be a leader in GMP and we are asked very often if we will run courses for other regulators. So there are certainly members of other regulatory authorities that come here, or we will go to their particular regulatory authorities and provide courses.

Senator FORSHAW—Do you charge those international visitors and so on for that?

Mr Slater—It depends—

Senator FORSHAW—The answer is yes, you do, in some circumstances.

Mr Slater—The answer is sometimes, for obvious reasons. For developing countries or where we have got a memorandum of understanding for exchange of information and so forth we might not. However, if we advertise for training courses that we are conducting on a full cost recovery basis then we do.

Senator FORSHAW—And have any of those persons been taken through Pan?

Mr Slater—Not to our knowledge.

Senator FORSHAW—Could you check?

Mr Slater—Yes, we will.

Senator FORSHAW—Thank you. Since the recall of the Pan-made products, how many of those products have had adverse drug reactions reports made in relation to them?

Mr Slater—There is quite a number. I will have to ask Dr Hunt for details on that. We have had quite a lot of adverse event reporting on this.

Senator FORSHAW—Is it something you can answer now, or you can take it on notice?

Mr Slater—It may be best to take that on notice.

Senator FORSHAW—How many adverse drug reaction reports has the TGA received? How many products does that involve? I assume you would include travacalm in that—

Mr Slater—No—

Senator FORSHAW—Can you exclude travacalm?

Mr Slater—Yes.

Senator FORSHAW—So I mean those figures since April.

Mr Slater—We are happy to exclude travacalm.

Senator FORSHAW—Also, how many complaints have been proven.

Mr Slater—We have got the stats here if you want them.

Senator FORSHAW—Thank you.

Dr Hunt—Following the recall of Pan, there have been a total of 81 reports received by the Adverse Drug Reactions Unit in relation to the use of complementary medicines. Usually in the time between meetings of the Adverse Drug Reactions Advisory Committee, approximately 15 to 20 reports in relation to use of complementary medicines would be received, but we have 81 reports to review at the next ADRAC meeting. All but seven of these were received in the three weeks following the Pan suspension, 35 implicated recalled products and a further 15 potentially involved recall products. Batch numbers, however, were not available for all of their products that were reported to us as adverse reaction related, and most of these reports have come from consumers.

Senator FORSHAW—How many more are there to be reported on? How many are there still to test? Have you completed the process of following up on these?

Dr Hunt—No. The reports have been received from consumers in many cases, some from health professionals. In the case of each of the reports, further information has been sought if possible by staff of the Adverse Drug Reactions Unit. The reports are now scheduled to be considered by the Adverse Drug Reactions Advisory Committee. The committee may recommend to the TGA that further information be sought, and there may be further testing or other results coming out of consideration of these reports in detail. They are in the process of being investigated by the TGA. That process has not been finalised in all cases.

Senator FORSHAW—Do you have any indication of when it might be finalised?

Dr Hunt—I would expect that we will know considerably more after the meeting of the Adverse Drug Reactions Advisory Committee. However, the recommendations arising from that committee may well be to ask TGA to undertake further investigations. There is some limitation in the amount of information provided. Some of these reports are very scanty and it is very difficult to draw any conclusions from them, and unless further information in those individual cases is obtained it will be very difficult to finalise any outcome from the report.

Senator FORSHAW—In that case, wouldn't the finding be that it was not proven?

Dr Hunt—There are a number of findings that can be allocated—and, yes, that probably will be the case.

Senator FORSHAW—I wanted to get how many reports you have received—I know they come potentially from consumers—how many complaints have been proven and how many you still have left to test now. I heard what you have said.

Dr Hunt—Seventy-four reports were received in the three weeks following the Pan recall. It is uncertain if all of them were connected to the Pan recall. They are being investigated further and they are being referred to the expert advisory committee that deals with adverse drug reactions reports for its advice.

Senator FORSHAW—Is that likely to be finalised before we meet again as an estimates committee?

Dr Hunt—I would expect so.

Senator FORSHAW—Could you take it on notice that when it is finalised we be provided with the findings?

Dr Hunt—Yes.

Senator FORSHAW—Can I just go back to the Corcoran report which you have us a copy of this morning, and obviously you would understand that I have not had a chance to go through it in much detail at all. Mr Slater, from my reading of it so far, it seems to suggest that issues identified by Mr Corcoran cover some of the areas that arose in the Pan Pharmaceuticals saga.

Mr Slater—No. What we are talking about with an audit is a look at the systems.

Senator FORSHAW—I am not trying to trap you.

Mr Slater—No, I am trying to give you a thoughtful answer. GMP auditing today is about looking at the controls and the quality that is built into the system which ensure that we do have processes in place that meet the code of good manufacturing practice and we get quality outcomes. I thought the Corcoran report was quite far thinking in its pointing to adopting world-leading practices around peer review and so forth that would ensure that we do have a better quality outcome and certainly a quality focus as a result of our auditing process. We have given you a copy of how far we have gone with implementation, which will be very helpful to you about our thinking about the Corcoran report recommendations. We are progressing those implementation issues as quickly as practicable.

Senator FORSHAW—I am sure we will have some questions on notice which we will send to you. One of the recommendations that I have noticed talks about the duration and thoroughness of audit as being more important than frequency, but then it says that the quality manager also conducts shadow audits, including review of audit plans, exit reports as well as close-outs. That would seem to go pretty much to the some of the issues that we have been discussing today. You would find it surprising if Mr Corcoran's review did not pick up, if you like, some problems that we now know through the Pan process exist. If he had missed them, you would think. 'Heck, what was going on in the review!'

Mr Slater—While I acknowledge the value of Mr Corcoran's thinking, he did say that the TGA's audit staff was highly competent.

Senator FORSHAW—Yes, I know. I told you all that. I know what he said.

Mr Slater—He said as part of his findings that individual audits were done well and there was a sound risk management framework. So what he has done is what we wanted him to do, which was to review us and make recommendations about how we could improve.

Senator FORSHAW—Was Mr Corcoran previously employed by the department of health?

Mr Slater—Yes.

Senator FORSHAW—What did he do?

Mr Slater—He held a number of positions, but the last position he held was First Assistant Secretary, Population Health Division. He also had auditing experience.

Senator FORSHAW—He had auditing experience.

Mr Slater—I am being advised.

Senator FORSHAW—With the TGA.

Mr Slater—No, not with the TGA. His principal activity was First Assistant Secretary, Public Health Division. He had a very good appreciation of public health issues and risk management in public health.

Senator FORSHAW—How long was he employed by the department?

Mr Slater—I would have to take that on notice.

Senator FORSHAW—Do you know when he left the department?

Ms Halton—He left on retirement is my understanding. Certainly he has not been in the department in the time that I have been back in the department. I understand he left at some point after 1998, but we can confirm that detail.

Senator FORSHAW—Can you advise us? Thank you. We will have further questions on notice in regard to a number of issues that we have not been able to get to today.

Senator McLUCAS—I have a couple of very quick questions to the TGA on BSE. Has the TGA, either as an entity or in conjunction with AQIS or FSANZ, prepared a list of imports containing Canadian beef?

Dr Priestly—My area of responsibility in the TGA is to manage TSE risks associated with therapeutic goods. In this context, I have been working closely with other government agencies, particularly in relation to the recent case reported in Canada. We are currently reviewing those therapeutic goods which may have beef products originating from Canada.

Senator McLUCAS—So you are currently reviewing them. What is the process after that?

Dr Priestly—We will do a risk assessment on individual products. Our general policy is to avoid using material which is sourced from countries which have reported BSE, so we will be investigating the re-sourcing of those materials where we have been able to identify that it has been sourced in Canada.

Senator McLUCAS—You are reviewing a list, but that is not published yet?

Dr Priestly—No, it is not a published list. It is based initially on risk assessments that we did some years ago of products which may have been sourced from other places that had reported BSE. We are working through that particular list of biological products to ascertain whether any of those were sourced from Canada.

Senator McLUCAS—How long will that process take?

Dr Priestly—It is being done quite quickly. I am anticipating that we will have it finished inside the next week or so.

Senator McLUCAS—And what happens next?

Dr Priestly—We will be looking at the risk management options that will be associated with that and working with the sponsors to re-source their materials where it is practical or where it is necessary.

Senator McLUCAS—Do you have a predicted time line? I am trying to get a notion of the time line to the point where we will publish a list of products that should be recalled or should not be imported. That is where I am heading.

Dr Priestly—On previous occasions when we did these sorts of exercises, we did not publish lists of products that had been examined. We have dealt throughout with the Special Expert Committee on TSEs that is looking at the all-government response in this regard. We have advised them of the range of products that we have assessed and the outcomes of those assessments. None of those assessments resulted in the need for a recall. What we had done in some individual cases was to require the sponsors to re-source their materials. That may well be the outcome of the current investigation involving Canada.

Senator McLUCAS—Why would there not be the need for a recall? If there is product that is sourced from cattle in Canada that has been imported, why don't we need to recall that? I suppose I am getting to the point of what the risk assessment is that you go through.

Dr Priestly—On previous occasions when we had looked at products that had been sourced from Europe, where there was a much higher incidence of BSE, in all of those cases the risk associated with those products was so low it did not justify a recall. What it did justify was action to re-source the material.

Senator McLUCAS—So do you have a notion of when that final process, in conjunction with other entities, might be complete?

Dr Priestly—We are obviously still gaining information about the epidemiology of the disease in Canada and related issues. We are working as quickly as we can through our list of pharmaceutical products. It could well be a matter of a week or two. It depends on how quickly we can get through all the information we need to go through. We are prioritising the approach. We have identified those we think to be the highest priority and we are working with those first.

Senator McLUCAS—Thank you, Dr Priestly, for your time.

CHAIR—Thank you, Mr Slater, and your colleagues. We are now moving onto OGTR.

[5.05 p.m.]

Australian Gene Technology Regulator

CHAIR—Mr Slater, you are back. It was a very brief adjournment.

Mr Slater—It was.

Ms Halton—He is a multiskilled and very busy man, Chair, and thoughtful, Senator Forshaw.

Senator McLUCAS—Dr Meek, I want to go through where we are up to with the inspection of research sites. When we talked in February you said that since 21 June the previous year you had issued four licences for dealings involving intentional release and that

there were other dealings that were not involving intentional release. Could you give us an update on the licences since that time?

Dr Meek—Since 21 June we have had 40 applications for dealings involving intentional release to the environment. We have issued 14 of those now, and we have 18 currently under consideration. Eight have been withdrawn, for various reasons. That is the dealings involving intentional releases to the environment. For dealings not involving intentional releases to the environment, we have received 246 applications, of which 173 have been completed.

Senator McLUCAS—In February we talked about the inspection of trial sites for compliance, and you said that it was too early to comment because those licences had only been recently issued. Have you had any direct inspections since we spoke in February?

Dr Meek—There certainly would have been inspections since then, yes.

Senator McLUCAS—Can you tell me how many you have undertaken?

Dr Meek—Yes. I think we will have to answer that one on notice.

Senator McLUCAS—Could you answer this now: have there been any breaches in that time?

Dr Meek—There have been no problems at all.

Senator McLUCAS—You told us in February that you have a minimum target of 20 per cent of all trials to be inspected on a rolling annual basis. Has that been achieved?

Dr Meek—Our targets have always been exceeded.

Senator McLUCAS—Exceeded by what?

Dr Meek—Again, we are always above that minimum of 20 per cent or minimum of five per cent per quarter. All that detail comes out, as you probably know, in our quarterly report, and we have always been able to report that we are in excess of our minimum target. That applies to contained facilities as well.

Senator McLUCAS—Do you still have 10 inspectors?

Dr Meek—Yes.

Senator McLUCAS—Do you have any plans in the 2003-04 year to change the number of inspectors?

Dr Meek—We do not have any immediate plans to look at a restructure in that sense, no.

Senator McLUCAS—But you will retain those 10?

Dr Meek—We will certainly retain at least that level, yes.

Senator McLUCAS—This year, on 1 April—an unfortunate date—

Dr Meek—A number of people say that.

Senator McLUCAS—you said in relation to the Bayer application for commercial release of GM canola that the public consultation would be for eight weeks, which would have finished on 26 May.

Dr Meek—That is correct.

Senator McLUCAS—Did that time line remain the same?

Dr Meek—Yes. Indeed, it did close on 26 May.

Senator McLUCAS—Have you ceased taking submissions?

Dr Meek—We have not said that we will absolutely not consider any further submissions. What we say is that we will analyse in detail and prepare some form of response to applications that have been received prior to the end of the consultation period. However, we have had people ringing up and saying, 'We can't make the deadline,' and we have said, 'Well, get them in as soon as possible.' Obviously, we will do our very best to analyse anything that comes in at any stage, but the commitment that we have is in response to submissions received by 26 May.

Senator McLUCAS—How many have you received to this point?

Dr Meek—In total, we had about 1,100 responses. However, it is worth bearing in mind that a very significant proportion of those were in the form of petitions. There were about 500 signatures on petitions and about nearly 400 campaign letters of various kinds. We had about 250 individual public submissions.

Senator McLUCAS—How do the public get access to those submissions—or do they?

Dr Meek—What we do is provide a breakdown of the submissions we receive, de-identified, in the risk assessment and risk management plan. Of significance obviously are the issues raised in connection with risks to human health and safety and the environment. So we provide an analysis of the information we have received and an indication of where, in the risk assessment and risk management plan, those risks have been addressed.

Senator McLUCAS—So, essentially, you are telling me that submittees to the process remain confidential?

Dr Meek—Yes.

Senator McLUCAS—So my next question, which was to ask you for a list of those individuals, cannot be complied with?

Dr Meek—It is not a normal process. We identify down to the level of the sort of organisation it comes from, but it then becomes a matter of privacy in that sense for people who have provided that information. We have never asked them whether we could do that. I think it would not be a fair thing to do.

Senator McLUCAS—I will have some discussions with colleagues and we may put that on notice, if it is appropriate. When will you make your final announcement as to the licence conditions for the Bayer application?

Dr Meek—As you can appreciate, we have had a reasonably significant response from 26 May. Some of the submissions are lengthy. We are in the process of analysing them at the present time. It will depend on whether any new risks are identified through the submissions we have received or whether our attention is drawn to additional information that we may have been unaware of when we made our first risk assessment as a management process. If nothing else comes up which requires us to do additional work that will require information

from the applicant, the 170-day statutory time frame expires on 19 June. So, at the current time, that would be the date by which I would have to have made a decision.

Senator McLUCAS—If you do identify new risks, can that statutory time be extended?

Dr Meek—The clock could be stopped on the application and extended further. It really does depend on whether anything new comes up through the consultation process.

Senator McLUCAS—Can you update us on the Monsanto application?

Dr Meek—We are still awaiting the information we requested from the company. In that context, the clock remains stopped on that application.

Senator McLUCAS—That is basically the evidence you gave us last time.

Dr Meek—Yes. There is no change, in that sense.

Senator McLUCAS—Moving to the licences for the importation of genetically modified grain to Hunter Grain Pty Ltd, in January you issued two licences for that importation.

Dr Meek—Yes. They were licences for dealings not involving intentional release to the environment. They are significantly different from the dealings involving intentional release.

Senator McLUCAS—How many shipments and of what types and tonnage of grain has Hunter Grain brought into Australia?

Dr Meek—We would have to take that on notice.

Senator McLUCAS—Is there any expiry date on those licences?

Dr Meek—Yes.

Senator McLUCAS—Which is?

Dr Meek—There are two different expiry dates. We can give you that on notice. They are limited in their extent.

Senator McLUCAS—What is the difference between the two licences?

Dr Meek—The difference is that a dealing involving an intentional release to the environment means precisely that.

Senator McLUCAS—No, the two licences issued to Hunter Grain.

Dr Meek—One is for GM corn and the other is for GM soya bean. I should clarify that further. They are actually not shipments of GMOs per se; they are shipments from places like the United States, which do not segregate between GM and non-GM. Therefore, the assumption was made that they may contain GM. So we treated them as if they were GM imports.

Senator McLUCAS—What is your inspection regime?

Dr Meek—Essentially, the inspection regime is closely linked with the Australian Quarantine and Inspection Service. Because these shipments present a disease risk to Australia, the Australian quarantine inspection requirements are that the shipments are downloaded under tight constraints and they are taken to a processing plant where they are heat treated and milled. Therefore, the reason that our licences are for dealings not involving an intentional release to the environment is that effectively the viability of the genetically

modified organisms that may be present in the shipments is destroyed by the requirements of the inspection service. Essentially, the AQIS quarantine requirements are the ones that are covering the management of any risk to human health and safety and the environment associated with those imports.

Senator McLUCAS—So AQIS manage that essentially closed system?

Dr Meek—Exactly, yes—which is why, as I said, they are dealings not involving intentional release to the environment licences.

Senator McLUCAS—Have there been any breaches by Hunter Grain of their licence conditions?

Dr Meek—You would have to check that with AQIS. I am aware—and it was in the press—that there was one minor issue that was reported which was quickly dealt with by AQIS themselves.

Senator McLUCAS—So you are saying that they may have breached AQIS's but we need to talk to AQIS.

Dr Meek—That is right.

Senator McLUCAS—But, in terms of the licence condition that you have provided, have there been any breaches?

Dr Meek—Conformance with the AQIS certification requirements for disease control meets our licence condition, effectively.

Senator McLUCAS—So potentially they have breached your licence?

Dr Meek—Not that we are aware of, no.

Senator McLUCAS—What is the process by which AQIS would tell you that there may or may not have been a breach?

Dr Meek—They would advise us if that was the situation. I have just had a clarification in relation to the situation that we are aware of. There was a spillage in the importation and it was cleaned up, and that is what was required under our licence condition.

Senator McLUCAS—Did your officers inspect part of that spillage?

Dr Meek—My colleague Elizabeth Flynn is closer to this than I am. Perhaps she could answer that question for you.

Ms Flynn—The AQIS inspectors inspected the spillage and ensured that it was cleaned up and we liaised with AQIS on that.

Senator McLUCAS—But you did not physically attend?

Ms Flynn—We did not go out there, no.

Senator McLUCAS—Where was the spillage?

Ms Flynn—I would have to take that on notice. I think it was Brisbane, but I will confirm that for you.

Senator McLUCAS—Thank you. Are there any further importation applications under consideration by the office?

Dr Meek—No.

Senator McLUCAS—Moving to cost recovery: in response to a question, you provided us with the Acumen Alliance report. Thank you for that. In one of the conclusions it basically says that the burden of cost recovery would rest largely with research institutions and as a result of that could have negative impacts on the levels of gene technology researching undertaken in Australia. Is it still the intention—I suppose this is really a question to the minister—to pursue a full cost recovery regime in relation to running OGTR from 1 July?

Mr Slater—The government's stated policy here is that there will be cost recovery for gene technology regulation, but its implementation of that policy is clearly affected by whether it is practicable or not. As you point out and the report that we released to you pointed out, the incidence would fall on research institutions very heavily. However, if the climate were to change where there were a lot of commercial releases and it was viable for a cost recovery system to be put in place—and, for that matter, a 100 per cent cost recovery system was to be put in place—that certainly would be in line with the government's policy.

Senator McLUCAS—I understand the policy framework was that we would be at full cost recovery by 1 July this year. Are you telling me that that possibly is not going to occur?

Mr Slater—I do not think that was ever stated as definitely as that. I think the government, in announcing its intention in the first instance to put in place a regulatory framework for gene technology, said that the cost of regulation would be 100 per cent cost recovery. When the Office of the Gene Technology Regulator was created—and there would be some senators here who will remember the Senate discussions around that—it was clearly not practicable to implement that policy and the government, given the very point you are making about the impact on research institutions, decided to fund that 100 per cent from the budget. It said it would review that after two years. It did not say it would implement cost recovery after two years. It did have that review, and you have a copy of that review report. It has provided 100 per cent funding from the budget for the following two years.

Senator McLUCAS—Do you have any direction or understanding of what will occur after that two years?

Mr Slater—Sorry, Senator?

Senator McLUCAS—Are you telling me now that from 1 July 2003 you have been funded 100 per cent by government? What happens after two years?

Ms Halton—I think the government took a decision that two years of funding was appropriate in this particular instance, given the maturity of the area. Essentially, there would have to be another look at the issue in a reasonable time frame. Obviously this is not something you can decide at close of business on 30 June that year. Our expectation is we will be taking that issue back to government in an appropriate time frame.

Senator McLUCAS—In the report from Acumen Alliance there were seven models of cost recovery that could have been adopted. Has OGTR or TGA suggested which one is the one that should be pursued or, given what you have just said about the delay again, is that not a question that you are considering?

Mr Slater—That was a consultant's thinking. At the time, the government's response to that report was to recognise that the Gene Technology Regulator would be funded from the budget again for the following two years; there would be a further review and, as Mr Halton said, that review would have a look at how things stood at that time and make recommendations to government.

Ms Halton—And that will take account of the circumstances at that time. I think it is far too early to be indicating any preference for those or, indeed, any other option at this point.

Senator McLUCAS—So OGTR has not come down in support of any of the seven of those models. Thank you.

[5.24 p.m.]

CHAIR—We will now move on to Medibank Private.

Senator McLUCAS—I would like to go to a specific question that has been raised with me on behalf of a helicopter rescue organisation called CQ RESQ. Do you know the organisation?

Mr Savvides—No, I do not.

Senator McLUCAS—I have been advised that CQ RESQ, which is a non-profit private company limited by guarantee, operates a community based helicopter rescue service based in Mackay in North Queensland. Medical work is the considerable part of their operations. Essentially, the issue goes to recouping funds from insurance companies and the process by which they do that. I am advised that they bill health insurers when the patient has private health insurance that covers aeromedical ambulance insurance—that is, usually, people with the highest cover. They advise me that, in all cases where they invoice private insurers, with one exception—and that is why I am raising it—those insurers pay. You can imagine that the reason I am talking to you is that Medibank Private is the one that does not. Do you have any knowledge of the correspondence between CQ RESQ and Medibank Private?

Mr Savvides—No, I do not have any knowledge of that complaint. I can take it on notice and investigate it.

Senator McLUCAS—That is unfortunate, because it would have been nice to get some answers to this. Maybe it would have been better if I had given you some notice that it was going to occur. But, just so that you are aware, they tell me that they have written to you on many occasions since November 2002 and that has included a debt collection letter—that was on 18 November last year. There is an enormous list of alleged correspondence to you. I understand that Mrs Kelly, the member for Dawson, wrote to the minister about this in January 2003 and has not received a reply. I am advised that, on 21 May, they had a phone call from Medibank Private asking them to apply for a provider number. Can you explain that need for a provider number?

Mr Savvides—Normally, the providers that can claim from Medibank Private have already prequalified themselves by showing proof of their ability to meet the compliance requirements for that particular medical service. Upon meeting those criteria, they would then be provided with a number that would legitimate their ability to claim.

Senator McLUCAS—They seem a bit confused about what this provider number does. Have you sent them a form or something?

Mr Savvides—I am not familiar with the particular incident that you are referring to, but the usual procedure would be that, to engage a provider, we would have to prequalify them and make sure they met the requirements.

Senator McLUCAS—What are those requirements?

Mr Savvides—That they are accredited, that they are a legitimate service, that the personnel they employ have whatever health or medical qualifications that are required for that kind of service, and whether they have got the right insurance to protect the people that they carry. Depending on the kinds of services being provided, there is a whole host of requirements before—

Senator McLUCAS—Have you given provider numbers to other aero rescue-type organisations?

Mr Savvides—I would have to take that on notice, but I would expect that we would have and that we would not normally pay any claims unless the provider who was making those claims on behalf of members was approved by the fund. It would be a standard procedure.

Senator McLUCAS—It just seems that it has been going on for quite some time without any resolution. The amount that is owed to CQ RESQ is in the vicinity of $32,000. You can understand that that is quite an enormous amount of money for a voluntary organisation to carry. Coming back to the provider number, how is the provider number different from the Health Insurance Commission provider number? Is it quite a separate thing?

Mr Savvides—I would expect that there would be commonalities when it came to a hospital being given a provider number, for example, but with these ancillary services or special rescue services it may be a very different code. I would have to follow that up on notice.

Senator McLUCAS—Do CQ RESQ get the provider number you are asking them to obtain from you or the HIC?

Mr Savvides—It would be from us. We would establish an accreditation with that provider.

Senator McLUCAS—That is what they are not clear about, although actually I think that they are clear about it but that maybe someone in your office is not. I might look at pursuing this matter further once I get the information back from you on notice.

Mr Savvides—I would be happy to follow that up.

Senator McLUCAS—Thank you. In 2002, Medibank Private announced a loss of about $180 million due to the rising costs of health services. For the period September 1999 to September 2002, can you tell me what the costs for management salaries were on an annual basis? I have a range of questions here, and you might be able to provide some answers to me now. Can you tell me what the costs were for the Canberra and Melbourne headquarters? Do you have that data with you, Mr Savvides?

Mr Savvides—The aggregate rentals for the leases for the headquarters for our staff in Melbourne—around 700 employees—came to about $3.2 million when we last reviewed it. That is aggregated—it is the two leaseholds at Bourke Street in the Melbourne CBD and the facility at 59 Collins Street. Those three towers, about 12 floors in total, account for that rental. I am sorry, but I do not have at the top of my mind a breakdown of the Canberra lease charges. They would be very small, and those leases have been exited now as a result of the transfer to Melbourne. I can follow up the Canberra charges on notice.

Senator McLUCAS—That would be good. Over what period was that $3.2 million incurred?

Mr Savvides—They would only be affected by CPI over the last three or four years so they would be annualised.

Senator McLUCAS—Thank you. What was the cost of the fitout for the Melbourne headquarters?

Mr Savvides—I would have to take that on notice. I do have those but they are in a file back in the office.

Senator McLUCAS—There were a number of staff in Canberra who did not move to Melbourne.

Mr Savvides—Correct.

Senator McLUCAS—How many were there that redundancy payments had to be found for?

Mr Savvides—That was before my time. I would have to take that on notice and investigate those costs.

Senator McLUCAS—I would be interested in knowing the total cost for those employees for whom, because of the relocation, redundancy payments had to be found. There was a period, I understand, when some of the staff were based in Canberra and some of the staff were based in Melbourne. I daresay there was movement between those locations. Can you identify the costs—the travel, accommodation costs and TA, or whatever—for that period when you had staff identified in two locations above other regular travel? Is that identifiable?

Mr Savvides—Yes. I can take that on notice and come back with those numbers.

Senator McLUCAS—Thank you. Regarding Mr Burrows' completion of his time with Medibank Private, were any bonus payments paid to Mr Burrows as part of ending his tenure with Medibank Private?

Mr Savvides—The nature of the payments made to Mr Burrows was reported in the annual report for the financial year 2002. About 50 per cent of the sum that is represented in the report is made up of his full year's salary, because that period was captured in the reporting period. His separation makes up the balance. The process was consistent with his entitlements that were presided over by the Remuneration Tribunal and the board complied with that. The details about the makeup of that package are part of a confidential settlement that was made with the former managing director and the lawyers between the two parties.

Senator McLUCAS—So the quantum is available but not the items?

Mr Savvides—That is correct.

Senator McLUCAS—I think that is all we need.

ACTING CHAIR (Senator Humphries)—We will now move back to outcome 1. We will deal with drugs when the officer is available.

Senator McLUCAS—When will the new schedule for childhood vaccinations be implemented?

Mr O'Donoughue—The ATAGI recommendations are with the NHMRC as we speak and they will be considering it at their meeting in June.

Senator McLUCAS—When did ATAGI finalise that set of recommendations?

Mr O'Donoughue—The period of public consultation was completed and the recommendations went to NHMRC in November of last year.

Senator McLUCAS—How long was the period of public consultation?

Mr O'Donoughue—I am advised approximately six weeks.

Senator McLUCAS—The technical advisory group make a set of recommendations. They go to ATAGI—or is it the other way round?

Mr O'Donoughue—ATAGI stands for the Australian Technical Advisory Group on Immunisation, so that is the technical group.

Senator McLUCAS—They go through the process.

Mr O'Donoughue—They create a work plan and a series of working parties, and then ATAGI makes recommendations to the NHMRC for inclusion on the Australian standard vaccination schedule.

Senator McLUCAS—I understand those recommendations were finalised almost a year ago.

Mr O'Donoughue—No. The advice is that they were actually forwarded to the NHMRC in November of last year. That has been a rolling work plan that ATAGI began as early as 2000. A series of working parties have been looking at target vaccines over that entire period of time, but the process really came to fruition in November of last year.

Senator McLUCAS—What is the net effect of the delay in getting out the new schedule?

Mr O'Donoughue—I would not describe it as a delay. The working groups have been expeditiously trying to provide expert advice to the NHMRC to complete the process. The NHMRC's act and requirements specify the need for public consultation, so really it has been done in an expeditious way.

Senator McLUCAS—I do not know if that view is shared by everybody. When will the 8th edition of the Australian Immunisation Handbook be finalised?

Mr Sam—The finalisation process rests with final endorsement by council and, as Mr O'Donoughue has outlined, it has another deliberation for final approval. The 8th edition of the handbook was approved by the Health Advisory Committee in May. The next step is for it to be forwarded for consideration by council, so it is possible that it will be approved within

the next month or so. Then it will be able to be published and made available subsequent to that.

Senator McLUCAS—How will providers of immunisation be informed of changes in the recommendations and the available vaccines in the changeover period?

Mr Sam—The national immunisation program operates between the Commonwealth and the states and territories. It basically covers those vaccines that are provided free of charge. That system extends to include a number of ongoing promotion, information and education campaigns to do with the schedule that those vaccines cover. For example, the meningococcal C vaccination program that commenced this year had a separate education promotion to providers about the use of that vaccine. Similarly, any implications for collection of data through the Australian Childhood Immunisation Register also provides direct feedback to individual general practitioners. States and territories also undertake direct interaction with their providers, both public and private, through the process of supplying and distributing vaccines. So the handbook as an NHMRC document is not the primary source of information for vaccines under the national immunisation program.

Senator McLUCAS—What time frame do you expect that process of information dissemination from the point of the adoption of the handbook to take?

Mr Sam—The main information that providers will require is in relation to the those vaccines provided under the national immunisation program as currently stands. Any subsequent changes to those vaccines would be promoted and education and information campaigns would fall behind that as the programs were rolled out. With regard to any announcements from the outcomes from NHMRC, there would be at the time those announcements were made that the handbook had been revised information and education given directly to providers to explain the difference between the changes in the NHMRC handbook and the vaccines provided under the national program.

Senator ALLISON—Who actually wrote the eighth draft?

Mr Sam—The draft was put together by the Australian Technical Advisory Group on Immunisation.

Senator ALLISON—Was the draft endorsed by NHMRC?

Mr Sam—That is the process that is currently being finalised.

Senator ALLISON—So the draft was not endorsed as a draft; it gets to be the final handbook if it is endorsed by NHMRC. Is that correct?

Mr Sam—That is correct.

Senator ALLISON—Is there a list of submissions to the eighth draft available? And are those submissions available?

Mr Sam—That would be available through the NHMRC.

Senator ALLISON—Are they on the web site?

Mr Sam—I would have to take that on notice and check.

Senator ALLISON—If they are not, is it possible to at least get a list of them and an indication that they are available on request?

CHAIR—I am sorry to interrupt, Senator, but it is my understanding that are no questions for Food Standards Australia New Zealand. Thank you to those witnesses from that organisation who may have been sitting here patiently waiting; you may leave.

Senator ALLISON—The draft makes some fairly significant recommendations with regard to particularly pneumococcal vaccine and meningococcal C conjugate vaccine. If this were agreed, would it be likely to make a difference to the current program for meningococcal C vaccination?

Mr O'Donoughue—The recommendation in respect of meningococcal C vaccination was already, in a sense, adopted by government and implemented. The NHMRC had already included it on the Australian standard vaccination schedule of January this year, and that program is in the process of being implemented as we speak.

Senator ALLISON—I understand that, but pneumococcal was not?

Mr O'Donoughue—I am sorry; I heard you say meningococcal. The recommendations in relation to pneumococcal go both to pneumococcal polysaccharide vaccination for people 65 years of age and older and pneumococcal conjugate vaccine for infants. Those recommendations obviously will remain under consideration for funding by government under the national immunisation program.

Senator ALLISON—Just on meningococcal C, the recommendation is a single dose at 12 months of age and for all adolescents at the age of 15 years. How does that vary from the current program?

Mr O'Donoughue—At the same meeting at which ATAGI made those recommendations, they also recommended that, in the best-case scenario, vaccination for meningococcal C disease be made available to all Australians from 12 months of age to 19 years, and it was actually that more expansive program that government has decided to implement.

Senator ALLISON—I am looking at a draft of that section of the handbook and I do not see any reference to the broader application. Can you draw my attention to where it is?

Mr O'Donoughue—As we discussed at a previous estimates hearing, a series of recommendations came out of the July 2002 ATAGI meeting, and one of those was, in the best of all scenarios, for vaccination of all Australians from 12 months of age to 19 years of age. So, in a sense, there was a sort of minimum program which would be prospectively 12 months of age onwards, plus a catch-up dose for the older cohort, and then there was a best-case scenario presented to government which was that one should immediately move to vaccinate all Australians from 12 months of age to 19 years.

Senator ALLISON—But, again, this does not appear in the handbook—the proposed draft No. 8 handbook.

Mr Sam—It may be, without pre-empting the outcome of the NHMRC process, that the final schedule just lists meningococcal C from 12 months in recognition of the accelerated catch-up program. The initial recommendation was predicated upon the fact that a catch-up from 12 months to those older cohorts would take a number of years. Under the national

meningococcal C program, that will in fact occur much more rapidly. So it is possible that the final schedule will only list meningococcal C from 12 months of age as a routine ongoing recommended vaccination.

Mr O'Donoughue—I will try to clarify that. Normally, when a vaccination program is introduced, a particular cohort is selected and then, as that moves through the community, all Australians become vaccinated. In the first set of recommendations, ATAGI was suggesting that there be a catch-up dose in the first year for another age cohort that is at higher risk—that is the older group of kids—but, even better than that, if you could move more quickly and vaccinate all children, you would be quickly covering the whole community rather than waiting for the cohort of year-old kids to work their way through. So, in a sense, it is an expedited or an enhanced implementation of a whole community vaccination program.

Senator ALLISON—But that program, as currently scheduled, is not expected to be completed within four years, is it?

Mr O'Donoughue—Yes. Within four years all Australians from 12 months to 19 years of age should have completed the program.

Senator ALLISON—Is it ATAGI's view that the meningococcal C vaccination program should be completed for all those age groups in that four-year period without consideration of pneumococcal?

Mr O'Donoughue—Their best-case scenario was that meningococcal C vaccination be provided to that cohort of kids between 12 months of age and 19 years, yes. That was the immediate priority. The health ministers have asked ATAGI to consider meningococcal C as a priority.

Senator ALLISON—And now ATAGI's priority would be what?

Mr O'Donoughue—They regard all the vaccines they have recommended for inclusion on the schedule as being of significant benefit. They have passed the threshold, if you like, of being worthy of inclusion on the schedule.

Senator ALLISON—Even meningococcal C in Western Australia. Are you saying that is still a priority for all age groups?

Mr O'Donoughue—ATAGI regarded it as of significant benefit or greater. There is an overall trend, internationally and in Australia, towards the increasing prevalence of type C meningococcal disease. So, even in states where the prevalence is currently lower, it is worrying that it could well increase in prevalence in those states. In a way, it is a timely intervention to vaccinate children as a preventive.

Senator ALLISON—I am still not clear. This is your recommendation. ATAGI has written this document which does not say—unless you can draw my attention to where it does—that there should be a broader range of age groups for meningococcal C and which does include pneumococcal. Would you expect, nonetheless, despite this handbook, there to be no recommendation to change the current program which is for four years for a larger group?

Mr O'Donoughue—Mr Sam was making a distinction between the national immunisation program, which is the government funding program for vaccinations, and the NHMRC standard vaccination schedule, which is, if you like, a description of clinical best practice.

These are vaccines that have been approved and recommended for use by clinicians in Australia. They are not always congruent with what is funded through the national immunisation program.

Senator ALLISON—But you would expect at some stage for them to be congruent, surely. What is the point in having a priority list and world's best practice when our actual practice is something quite different?

Mr O'Donoughue—The practice of this government has certainly been to try and make the two things as congruent as possible. That is what has been delivered, by and large but not always, in recent history. Now that those vaccines have been recommended by ATAGI for inclusion on the schedule, they will be considered for funding by government under the national immunisation program.

Senator ALLISON—When will that consideration take place?

Ms Murnane—If you look at vaccines in Australia since 1940, the availability of vaccines and the funding of vaccines, you will see that there has been a steady increase. I was shown a table the other day by the National Centre for Immunisation Research and Surveillance—I do not have it with me, but I could make it available to you—and it showed that a lot more vaccines have become available since the mid-1990s and have gone onto the Australian standard vaccination schedule. All of the countries to which we compare ourselves have a practice of incrementally adding to the number of vaccines included as part of a national program. This is what the US have done, this is what the UK have done and it is what the Netherlands are doing. This is what we have done here with ATAGI recommendations—that is, consider them in a sequential way. The reason that meningococcal was plucked out first was that there was a manifest concern within Australia and there was a vaccine that was available and that was efficacious in terms of one strain of the vaccine. If you start to look at the complications of diseases, you will see that the meningococcal C infection has a rate of complication, particularly neurological complication, that exceeds the complications of other diseases, such as pneumococcal infection, chickenpox or varicella. These other recommendations are still there on the table and will be considered within processes.

Senator ALLISON—It is my understanding that pneumococcal meningitis has a much higher fatality rate and can lead to long-term disabilities such as cerebral palsy, epilepsy, blindness and deafness and, Ms Murnane and Mr O'Donoughue, that it has been well known for some time—ask any paediatrician—that the problem of pneumococcal has been with us for some time. But it appears that we have had a fairly massive increase for the meningococcal program which would not appear to be as warranted as you are suggesting.

Ms Murnane—I quite deliberately said 'pneumococcal infection'; I did not talk about pneumococcal meningitis. I have been informed and advised that that is very serious, but it is also pretty rare. I do not know if Professor Mathews feels up enough on this to come in, but we could assemble some expert evidence on this and put it to you. The issue is that in the course of last winter there was a steady increase in the number of meningococcal infections and meningococcal deaths. It was of considerable public concern. It was something for which we had recommendations in draft form. It was something that, a year previously, health

ministers had discussed and had asked for a further report on. In my view, it stood out as warranting attention if money were to be made available.

Senator ALLISON—Is it or is it not the case that ATAGI recommended that pneumococcal be part of the program last year at, as I understand it, about the same time or not long after the government decision to proceed down this path?

Ms Murnane—They made a number of recommendations. Of the sequencing of those, you will get different opinions amongst experts.

Senator ALLISON—The NHRMC seems to be the one we rely on—or at least their reports which are effectively your reports. Isn't it the case that the NHMRC recommended that there be a $45 million program targeting meningococcal, including only some states, and that $60 million would be spent on pneumococcal?

Mr O'Donoughue—As we were saying earlier, the consideration of the broader set of recommendations for ATAGI is yet to be considered by the NHMRC. The inclusion of meningococcal vaccination on the schedule was completed in January of this year. I also point out that there is in fact a vaccination program for pneumococcal disease for children most at risk—

Senator ALLISON—It is not on the 'free list', is it?

Mr O'Donoughue—Yes, it is. It is a funded program.

Senator ALLISON—And that is for Indigenous communities and—

Mr O'Donoughue—It is for Indigenous children of less than five years of age and for all children under two years of age living in Central Australia. In addition, it is for all children under five years of age with medical risk factors.

Senator ALLISON—That is, those exposed to smoking?

Mr O'Donoughue—Professor Mathews might assist me there.

Prof. Mathews—It is true that passive smoking is a risk factor for pneumococcal disease in children as it is for other infections, but it would not by itself qualify as putting a child in a situation where they would be eligible for the free vaccine. That is my understanding—unless it was an Indigenous child or a child with chronic disease. But it is true, as Mr O'Donoughue was saying, that the majority of pneumococcal disease is borne by the Indigenous population; they are already covered by the conjugate vaccine. How far to extend the free vaccine to other children—that is, the conjugate vaccine—is something for government to consider in the future.

Senator ALLISON—Has there been a review of the coverage of pneumococcal in Indigenous children? I understand there are some serious problems with actually getting it to those children and identifying Indigenous children. Has that now been resolved and has there been a review of its effectiveness?

Prof. Mathews—I am sure Mr Sam could comment upon the effectiveness of delivery, and a question in relation to that was addressed to OATSIH last night, but there are records coming through the immunisation register.

Mr O'Donoughue—There are some inherent difficulties in identifying children of Aboriginal and Torres Strait Islander decent on the Australian Child Immunisation Register which are being worked through. We do have some data in relation to the provision of pneumococcal vaccine. As of 20 February 2003, a total of 28,737 children had received a dose of vaccine and of these 36 per cent, or 10,282, had consented to being identified as an Aboriginal and Torres Strait Islander person.

Senator ALLISON—I am sorry, the statistics do not mean much to me. I am really talking about the difficulties, as I understand there were. They may have been resolved now. All I am looking for is some assurance that the distribution problem has been sorted. So the statistics do not mean anything to me.

Mr O'Donoughue—Obviously we are trying to achieve a higher coverage rate of the groups most at risk. Given that Indigenous status is one of the risk factors, it is important to actually have the data to assess whether you are doing well or not. We could improve the data, and in that case we would have even greater confidence that we were doing well, but the data in front of me suggests that we are already making significant inroads to getting good coverage in most states and territories.

Senator ALLISON—Can I then put the question in a slightly different way. As I understand it, there is good coverage where Aboriginal community health centres are operating. So in the more remote areas it is okay but there is still a problem with some mainstreamed, if you like, health services. Is that right? Professor Mathews, you are nodding. Are we on to something here?

Prof. Mathews—I think it is true there may still be delivery issues but, as Mr O'Donoughue said, the childhood register is working effectively. It may be that some of those difficulties are in fact not as great as they might appear. It may just be that the identification of children as Indigenous may not be on the register, and that is why we were referring to the difficulties of recording, as opposed to the difficulties of delivery, and it is not totally clear in all jurisdictions whether you can separate those two dimensions of difficulty.

Senator ALLISON—When will we have some idea of the impact of the vaccination program for Indigenous children? When can we start to measure the effectiveness?

Prof. Mathews—My understanding is that, as you pointed out, in places where we know there has been a big problem in the past, such as the Northern Territory and Central Australia, and where there has been very effective delivery through Aboriginal health services, there have already been reports of a decline in pneumococcal disease in young children, and that is the group at greatest risk in that early period of life.

Mr Sam—If I may add, the National Centre for Immunisation Research and Surveillance has been commissioned to undertake a study on immunisation coverage in Indigenous children, and I believe they have just commenced that process.

Senator ALLISON—And when will it be completed?

Mr Sam—In 12 months time. Just adding to the earlier point about uptake, in addition to the childhood register, we require states and territories to provide us with data as part of their acquittal for vaccines. And, as I think was also alluded to by the Office of Aboriginal and

Torres Strait Islander Health last evening, the reports we have received are that in the Northern Territory 96 per cent of eligible children have received a first dose; in North Queensland, 70 per cent; in Queensland overall, 60 per cent; and in Western Australia, 70 per cent.

Senator ALLISON—Just looking at some figures, Ms Murnane, you said that pneumococcal is rare, but it is my understanding that the data from Communicable Diseases Australia showed that there were 573 cases of meningococcal infection and 2,354 cases of invasive pneumococcal disease reported in 2002. Mr O'Donoughue, does that accord with your data as well?

Mr O'Donoughue—Would you mind repeating that; I will just check the figures as you read them through.

Senator ALLISON—There were 573 cases of meningococcal infection and 2,354 cases of invasive pneumococcal disease.

Mr Sam—I can update those figures. The data that I have available based on the national notifiable diseases system for 2002 is that the total for meningococcal is 676, of which 206 were group C, and for pneumococcal—that is, all pneumococcal infection—2,350.

Senator ALLISON—So it is hardly rare, one would say. When will consideration of pneumococcal in the funded program next take place? Perhaps, Minister, that is a question for you.

Ms Murnane—Sorry, who were you asking the question to?

Senator ALLISON—It is probably your decision, Minister. It is the question of when pneumococcal will be considered. It is now included in the draft, at least, of the *Australian Immunisation Handbook* by ATAGI, which is being considered currently by NHMRC. We have a budget projection of four years. Does that mean that pneumococcal will not be considered within that period, or is it possible it will be considered after NHMRC endorses, or otherwise, this handbook?

Senator Patterson—As you have been told, the pneumococcal program has now been extended to Indigenous children and other children at risk—that is, children who mix with Indigenous children in the Northern Territory communities. Isn't that right?

Mr Sam—In Central Australia.

Senator Patterson—And it has been extended for people aged over 65. It is on the PBS.

Senator ALLISON—I understand what is in the current program.

Senator Patterson—There are enormous demands on the budget from health, and one has to weigh up all the competing demands and all the technical advice. As Ms Murnane said, on some of these issues there is competing scientific advice about the various immunisations and conflicting advice about the various medications—it sometimes requires the wisdom of Solomon to sort it out. We will be looking at the ATAGI advice in the light of the future budget context, but we do have a program for those most at risk.

Senator ALLISON—I am not sure that answered the question, Minister. This is due to be endorsed, or otherwise, within the next few days. I understand NHMRC meets on the 4th and the 5th. Is there a process by which these recommendations—

Senator Patterson—Senator, as I said, there are these huge competing demands. There are medications that are lined up that cost millions of dollars; we have a series, as Ms Murnane said, of vaccines that are already through the process; we have got others which are lining up. There is one on genital warts about to go into final clinical trials, where there is some suggestion that we should not vaccinate every sexually active young person when that comes through. There are all those competing things that I have to try and weigh up, given all the technical advice and the conflicting opinions.

Senator ALLISON—There are some, Minister, who would suggest a lot of savings could be made on unnecessary meningococcal C vaccines. As I understand it, the NHMRC's original recommendation was, as I said a little earlier—you may not have been listening—

Senator Patterson—I was listening.

Senator ALLISON—that the original proposal was for targeted meningococcal type C, and only in some states, and for pneumococcal more broadly. I am not necessarily suggesting to you that the recommendations will result in an extra cost.

Senator Patterson—There are always different views. The meningococcal C, we believe, protects young people for a lifetime, or for at least a significant time during the high-risk period. Young people who live in Queensland do not always stay in Queensland as they grow up and you would have a complication about who had been vaccinated and who had not, so there are also differing views about that. It seemed as if there was an increase in the incidence. There was also a pressure because at that time there was a limited amount of vaccine, and a decision was made that we would vaccinate all the children because they would be protected.

Senator ALLISON—On what advice did the decision rely, to shift from vaccinating only 12-month-olds and 15-year-olds to all children aged 12 months to 19 years?

Mr O'Donoughue—ATAGI, at its July 2002 meeting, did give a series of recommendations in relation to meningococcal C, including a best-of-all-worlds option for vaccinating all children from 12 months of age to 19 years of age.

Senator ALLISON—Is that recommendation available?

Mr O'Donoughue—I think we have already indicated in previous answers to questions on notice that the working party reports have been used by government in the consideration of budget and policy advice and they are not traditionally on the public record. The NHMRC schedule which has the outcome of, in part, the ATAGI process is on the public record.

Senator ALLISON—So we have got two reports, one of which recommends pneumococcal immunisation and limited meningococcal C, but the government releases a decision which is otherwise and we are not entitled to look at the argument that was put to do that?

Mr O'Donoughue—As Mr Sam indicated earlier, the handbook would focus on vaccination of 12-month-old children, prospectively, as an ongoing vaccination program. It is possible that it may also refer to the older cohort of teenagers as well, in a best-practice

model, but in a sense that has been overtaken by the government decision to expedite an accelerated program—

Senator ALLISON—Indeed.

Mr O'Donoughue—and that decision was based on an ATAGI recommendation, in a best-case scenario, for all those children to be vaccinated.

Senator ALLISON—What else is in a best-case scenario? How many other vaccines would you include in a best-case scenario, leaving aside the question of what is currently on the schedule?

Mr O'Donoughue—The ATAGI work program which was formulated in 2000 looked at all the candidate vaccines that were thought to be best candidates at that time. Obviously, as time moves on there will be other vaccines that are emerging—

Senator ALLISON—That was not my question, Mr O'Donoughue. What other vaccines would be regarded as best-case scenario now which are not included currently on the government's free list?

Mr O'Donoughue—I think you are asking me a theoretical and hypothetical—

Senator ALLISON—I am asking you what the status of the best-case scenario is—whether this gives it a high priority or whether it is just what, if you had loads of money, you would use the money for. I am trying to understand the status of your recommendation about best practice.

Mr O'Donoughue—As I indicated before, ATAGI has indicated that, to reach the threshold of inclusion on the schedule, each of these vaccines would be of significant benefit or greater. So in a sense there is already a best-case scenario that one would envisage if one had all the money one would want to fund all those vaccines immediately.

Senator ALLISON—Perhaps you could take on notice the question of what best-case scenario vaccines are currently not on the list. Is it possible to do that?

Mr O'Donoughue—It seems—

Senator Patterson—Mr O'Donoughue has answered the question, Senator.

Mr O'Donoughue—I am not sure whether you are asking me to be speculative about what vaccines might be in prospect.

Senator ALLISON—No. I have asked you what vaccines, in your view, are best-case scenario that are currently not funded.

Senator Patterson—It is not Mr O'Donoughue's position to say what, in his view, is the best-case scenario.

Senator ALLISON—He has offered a view that meningococcal C, broadly applied, is best-case scenario. My question is: how many other vaccines are best-case scenario but do not make it to the free list? It is a fairly clear line of questioning, I would have thought.

Mr O'Donoughue—The phrase I used was a paraphrase of words that ATAGI used. They gave a minimalist recommendation around meningococcal C but they also chose to indicate that, subject to available funds, in the best of all possible worlds—or whatever the phrase may

have been—it would be great to vaccinate all children 12 months to 19 years of age. That was the only case in which they made that kind of reference.

Senator ALLISON—Do they say the same about pneumococcal vaccine now?

Mr O'Donoughue—They have said that each of the vaccines they are recommending for inclusion on the schedule would be of significant benefit or greater.

Senator ALLISON—And does that put them in the same category as the best-case scenario?

Mr O'Donoughue—No. As I said, they actually used that phrase, or that description, singly for meningococcal C, even though they were prepared to recommend all the vaccines for consideration, particularly for inclusion on the schedule.

Senator ALLISON—So meningococcal C has a higher status or a lower status by virtue of its broader spread?

Mr O'Donoughue—I think Ms Murnane and the minister have indicated the series of circumstances, including the concern from all health ministers, the emergence of type C disease in Australia and the particular circumstances around the shortage of vaccine, that led to the government making that expedited decision.

Ms Murnane—A document on vaccinations was put out a couple of years ago—in 2001, I think—in our communicable diseases information document series. We will provide Senator Allison with a copy of the document, because what it shows, among other things, is the complexity: the number of factors that are considered. It is very difficult indeed, from this sort of analysis, to pluck out something and say, 'This is absolutely and clearly scientifically what you would go for.'

Senator ALLISON—Thanks for that. Has there been a cost-benefit analysis done of the broader application of meningococcal C?

Mr Sam—Yes.

Senator ALLISON—Is that available?

Mr Sam—As part of the ATAGI recommendations, that cost-benefit was done.

Senator ALLISON—Has a similar exercise been done for pneumococcal?

Mr Sam—That is correct.

Senator ALLISON—How do they compare with regard to cost and benefit?

Mr Sam—I cannot give you a direct comparison. What I can say, to support what Mr O'Donoughue has said before, is that the process for the ATAGI making a final referral to NHMRC on a particular vaccine relates to the fact that it is found to be cost-effective in addition to a range of other factors which make it suitable for use on a population basis—for example, its safety profile, the total cost of the intervention, the certainty of the public health outcome, and that relates to its uptake, and the short- and long-term benefits.

Senator ALLISON—Surely this can all be factored into a cost-benefit analysis?

Mr Sam—That is correct.

Senator ALLISON—Are you able to provide that to the committee?

Mr Sam—It has the same status as the reports that Mr O'Donoughue referred to.

Senator ALLISON—So that is before the NHMRC?

Mr Sam—The NHMRC looks at the cost-effectiveness data and the assumptions that the ATAGI has used.

Prof. Mathews—The complexities you are alluding to in terms of the value of each of the vaccines are addressed in quite some detail, without the detailed cost-benefit analysis, in the new draft handbook which will be considered by NHMRC shortly. So it is our understanding the description, in generic terms, about the value of each of those vaccines is very likely to be considered and approved by NHMRC.

Senator ALLISON—I want to look at the stats for various states. I think I mentioned earlier that Western Australia has at the present time no cases of meningococcal C infection. Is that correct?

Mr Sam—I do not have those stats before me.

Senator ALLISON—Mr O'Donoughue, would you be familiar with that?

Mr O'Donoughue—I would be happy to take it on notice to confirm that. I have not got the information in front of me.

Senator ALLISON—Professor Mathews, is that your understanding too?

Prof. Mathews—I understand that the rates in Western Australia are lower than elsewhere, but I was not aware that there were no cases.

Senator ALLISON—Is it possible to get a state by state analysis in terms of incidence and prevalence of communicable and preventable diseases?

Mr Sam—Yes. The Communicable Diseases Network and the department will shortly release a report on surveyance of meningococcal infection. That should be available at the end of this month.

Senator ALLISON—Okay. That is good.

Senator Patterson—Senator, as I was saying to you before, one of the issues is that young people who live in Western Australia do not stay in Western Australia; they travel. I stand to be corrected, but I think there was a young basketballer—this was two years ago—who came across to Victoria and contracted meningococcal. I cannot remember. I think it was a girl from Western Australia. They travel. They travel to sporting events. I think that person may have been a rower—Senator Knowles remembers. They do not stay in one place. They are much more mobile than we were. They travel to sporting events, they travel here to Parliament House, they travel to various events. You cannot isolate them now like you used to be able to and say, 'Well, Western Australia has a lower rate, or such and such has a higher rate, and this protects them, we believe, for their whole period for when they are at risk, right up to their mid-20s,' when they are travelling.

Senator ALLISON—Perhaps I can ask what the rate of pneumococcal infection is in Western Australia.

Mr O'Donoughue—I think we would have to take that on notice and come back to you, but those data are available.

Senator ALLISON—Yes, and it is the case that there are numerous cases of infection in Western Australia, is it not? You would not find that there are no cases of pneumococcal in Western Australia?

Senator Patterson—There are also children at high risk in Central Australia in Indigenous communities, so whether they are Indigenous children or not they are part of the targeted program for children with pneumococcal.

Senator ALLISON—I am just trying to understand the reason for moving away from what was an original recommendation to a broad one. I am just trying to flesh that out, with some difficulty.

Senator Patterson—We indicated to you that there was an issue about getting the vaccine.

Senator ALLISON—There is still an issue, as I understand it, for meningococcal C vaccine.

Senator Patterson—No, it is available, and that is one of the reasons why we were able to speed up the program.

CHAIR—Given that it is now 6.30, I call a halt to proceedings for an hour.

Proceedings suspended from 6.30 p.m. to 7.32 p.m.

CHAIR—I call the meeting to order and call on Senator Allison.

Senator ALLISON—Just for the record, Minister: I have had a chance to look back at my notes on pneumococcal meningitis versus meningococcal. I notice that Ms Murnane is not here, but I refer to her comment about pneumococcal disease being rare. I think we should put it on the record that in the year 2001 across Australia there were 1,650 cases of pneumococcal disease, and in 2002 there were 2,354. So it is not rare. That compares with 679 cases of meningococcal infection in 2001 across Australia and 573 in 2002. So it is something around five times as high. When Ms Murnane comes back, perhaps we will ask her what she meant by rare. It is also my understanding—perhaps, Mr O'Donoughue, you can confirm this—that pneumococcal meningitis has a higher fatality rate than meningococcal.

Mr O'Donoughue—I might ask Professor Mathews to comment on that.

Prof. Mathews—Yes, I think you are correct. When pneumococcal bacteria get into the blood, its pneumococcal septicaemia, or meningitis in an infant, is very often life threatening. Unfortunately one of the difficulties with the pneumococcal vaccine is that a number of those life-threatening infections in very young infants occur before the age at which an infant could be vaccinated.

Senator ALLISON—What proportion would you say?

Prof. Mathews—I would not like to put a figure on it, but it is a significant problem in some populations.

Senator ALLISON—Could you be more specific? Is it the Indigenous populations where this is the case?

Prof. Mathews—As we know, the take-up rates and the availability of the pneumococcal conjugate vaccine for Indigenous communities at high risk are now pretty good and the evidence of efficacy is starting to come through, but one of the significant potential causes of 'vaccine failure' would be when an infant gets septicaemia or meningitis before the age at which they could be vaccinated.

Senator ALLISON—Could I ask a question of you, Mr O'Donoughue, or Mr Sam, about the draft Australian Immunisation Handbook No. 8? Who was the author of the clinical features section which appears under meningococcal infections?

Mr Sam—I cannot give you that information on the moment, I am sorry. I do not know.

Senator ALLISON—There are a number of people on the advisory committee, obviously, who would typically do the authoring?

Mr Sam—In most cases it is a member. The chair of the meningococcal C working party was Dr Robert Hall.

Senator ALLISON—Can I read out one of the sentences from this features description. It says:

As a result of all these factors, this disease causes widespread community alarm and generates significant media interest.

Is that typical of a clinical features statement—a comment about the media and community alarm?

Mr Sam—I think that is at the discretion of the author.

Senator ALLISON—I understand that, but I am asking you how common that kind of language is in clinical features. If I was to look at the clinical features of measles, for instance, would I find a description of that sort?

Mr O'Donoughue—In assessing the impact of any disease, gauging community concern is one of the variables that experts would want to consider because it does go to community confidence.

Senator ALLISON—I can understand that, Mr O'Donoughue, but would you necessarily find it in clinical features? Aren't clinical features, by definition, clinical?

Mr O'Donoughue—I guess that is a question of definition, but it certainly seems characteristic of meningococcal disease that it has the potential to cause a great deal of anxiety and concern in the community.

Senator ALLISON—I do not know whether Professor Mathews can contribute to this. I am sorry to interrupt. I was commenting, Professor Matthews, on the clinical features of handbook No. 8—the draft version—which includes the statement:

As a result of all these factors, this disease causes widespread community alarm and generates significant media interest.

Do you think that is appropriate for a section on clinical features in this document?

Prof. Mathews—Aspects of public communication are very important, because with something like meningitis—

Senator ALLISON—I am not saying you should not say there is media interest or that it has generated alarm, but I am asking you whether it is appropriate under a heading described as clinical features.

Prof. Mathews—I was about to try, in perhaps a hyperbolic way, to address that. The positive rationale for community concern is community awareness. Because the diagnosis of meningitis is not commonly seen by a general practitioner, you have to have mechanisms to alert everyone in the community—the doctors, the parents and relatives. From that point of view, it is very hard to draw a fine line between awareness and concern. From that point of view, yes, there is a rationale for linking those two dimensions together in a clinical description.

Senator ALLISON—If we tell doctors that this is causing widespread community alarm, they will be in a better position to diagnose the disease. Is that what you are suggesting?

Prof. Mathews—No, I am not defending that particular line. But I think there is an issue that the positive side of community concern and alarm is awareness, which is the biggest single problem in diagnosing rare diseases. You have to think of it and, because most people see common conditions most of the time, you have to have enough concern out there so that the family or the neighbour or somebody thinks: 'Is this meningitis? Let's get them into the best possible hands. Let's get them to someone who could diagnose it.' I am not necessarily defending that particular sentence, but there is—

Senator ALLISON—Would you?

Prof. Mathews—No, I guess I would not defend that particular sentence as it is worded.

Senator ALLISON—What about:

The capacity of meningococcal disease to have a fulminant and rapidly fatal course in previously healthy (and usually young) individuals causes it to be greatly feared.

Would you regard that as a fairly non-clinical approach too?

Prof. Mathews—Again I think it is part of the issue of alerting this generation of clinicians to something which they may not see in their professional lifetime. When they see it, it is very important that they think of the right answer. If you do not occasionally perhaps step over line in terms of alerting clinicians, you may not get the prepared mind that gets the diagnosis right. Some doctors are lucky—they train in a good paediatric hospital, they work in the emergency department where the meningitis cases will come in—and those ones will be very prepared, because they have seen cases in the past, to make the right diagnosis.

Senator ALLISON—I understand the importance of alerting doctors, but perhaps there needs to be another heading called 'social implications' or 'fear out there in the community' rather than describing it as a clinical feature. The Technical Advisory Group on Immunisation recommended pneumococcal should be provided to children at two, four and six months in the Australian standard schedule. Is it possible to say where that recommendation is at at the present time?

Mr Sam—You are referring to the universal program for all children. That is with NHMRC.

Senator ALLISON—That is the one we have been talking about. Is there public consultation in that process? How does that work?

Mr Sam—A round of public consultation has been completed.

Senator ALLISON—We have been there, haven't we? You were going to examine whether the submissions can be made available. That is all the questions I have on meningococcal.

Senator McLUCAS—I would like to go over this ground again just so I am clear in my mind. It was on 5 September 2002 that ATAGI made recommendations about childhood pneumococcal conjugate vaccine—is that correct?

Mr Sam—No. The September recommendation was for the pneumococcal polysaccharide for over-65s.

Senator McLUCAS—That also recommended pneumococcal conjugate vaccination at two months, four months and six months of age as being of significant benefit. Is that correct?

Mr Sam—That recommendation was progressed with a suite of other ATAGI recommendations as being suitable for recommending to NHMRC.

Senator McLUCAS—When was the meningococcal C recommendation made?

Mr Sam—It was finalised in July 2002.

Senator McLUCAS—From ATAGI?

Mr Sam—Yes.

Senator McLUCAS—Was that the same style of recommendation as the September meeting?

Mr Sam—That was a finalisation of ATAGI's report in preparation for forwarding to the Health Advisory Council of NHMRC to have that recommendation endorsed.

Senator McLUCAS—Was that in the normal process of vaccinations going to ATAGI for assessment and analysis?

Mr Sam—I am not sure I understand your question.

Senator McLUCAS—There must be a process. When vaccinations become available, how are they then recommended to ATAGI—what happens there?

Mr O'Donoughue—As we indicated earlier, ATAGI formed a work program at the beginning of August 2000 and meningococcal C vaccination was part of the candidate vaccines they were considering. Through the process that we have described, beginning with the July meeting and culminating in the September meeting, the suite of recommendations was put forward to NHMRC for consideration for inclusion in the schedule.

Senator McLUCAS—Are you telling me that it was after that 5 September meeting that meningococcal C was included in the suite of recommendations?

Mr O'Donoughue—No. The recommendation for meningococcal C was fully formed, if you like, at the July 2002 meeting of ATAGI.

Senator McLUCAS—What other vaccinations did they look at at the July meeting?

Mr Sam—They also considered the issue of diphtheria-tetanus and pertussis (acellular) vaccine for adolescents and the childhood conjugate pneumococcal vaccine.

Senator McLUCAS—But those recommendations were not fully formed at the July meeting; is that what you are saying?

Mr O'Donoughue—It was a work in progress, as it were. At the July meeting, meningococcal C, conjugate pneumococcal for children and DTPa were considered. At the September meeting, polysaccharide pneumococcal for over-65-year-olds was formulated. At the November meeting it was varicella and finally, as I understand it, in December there was in-principle approval for IPV. That concluded the suite of recommendations.

Senator McLUCAS—I thought varicella was recommended on 5 September as well?

Mr Sam—There are two steps. Firstly, there is the point at which ATAGI completes its reports; and, secondly, the September point was in relation to the presentation to the NHMRC for that particular recommendation. In September-October 2002 it was meningococcal C. Varicella had previously gone to the NHMRC on—sorry, it has not gone.

Senator McLUCAS—Can I ask on notice that you provide me with a time line that shows when each of these vaccinations was, shall we say, processed through the system, including varicella, diphtheria-tetanus and pertussis for adolescents, childhood pneumococcal conjugate vaccination and meningococcal C?

Mr O'Donoughue—Yes, we can do that.

Senator McLUCAS—I want that from where it enters the system to where it comes out. If we can get that on notice, it might clarify some of the questions we have got. That is all I want to talk about on meningococcal. On inactivated polio vaccine, ATAGI has recommended that we need to replace the oral polio vaccine with the inactivated polio vaccine. That has not been taken up by government, and I understand the minister's comments about the bucket being only so big. What is the potential disbenefit to the community of not funding the change from oral polio to vaccinal polio?

Prof. Mathews—You would be aware that there have been two forms of polio vaccine. OPV—oral polio vaccine—has obviously got the advantage of not needing an injection and has been used for many years in Australia. The only complication with that is that, once polio itself has virtually disappeared, as it has now almost entirely around the world, there is a very small risk that some of that polio vaccine, which is a live virus, circulates in the child who is vaccinated—they excrete it for a time in the faeces—and in some countries that vaccine virus has mutated back to become paralytic. That has not happened in Australia. It has tended to happen more often in countries where the vaccination programs have not been fully effective and have not had complete coverage.

Senator McLUCAS—Such as where?

Prof. Mathews—I recall that there has been a report of an outbreak in the West Indies and also in the Philippines where the vaccine virus has mutated back and become paralytic. So that is the complication which can arise. It is for that reason that the United States, for example, have now decided that, from their point of view, that risk justifies going back in time in a sense and using the injectable polio vaccine—what used to be called the Salk

vaccine. That is also of course why ATAGI has made that similar recommendation. From the government's point of view, that is where you would want to go, but the unfortunate thing is that IPV is more expensive to produce than OPV because it is an injectable vaccine. So that essentially encapsulates the issues.

Senator McLUCAS—Just to clarify, I understand that the estimated cost in the first year was $20.2 million. Is that the total cost or is that the replacement cost, given that you would not have to purchase the oral polio vaccine?

Mr Sam—That is the replacement cost. That is predicated on the availability of an injectable form of the vaccine in suitable combinations, not as a single dose.

Senator McLUCAS—You would want to put it in with other vaccinations the child is having.

Mr Sam—That is correct.

Senator McLUCAS—And we have not got to that technology yet?

Mr Sam—That technology is currently available.

Senator McLUCAS—I do not understand. What was the point you were making then?

Mr Sam—That the cost of $21 million per year is the cost of introducing IPV in a suitable combination.

Senator McLUCAS—And you say that is a replacement cost, so that is the net cost?

Mr Sam—That is correct.

Senator McLUCAS—That is all I have on vaccinations.

Senator Patterson—While we are on the subject of vaccinations, I might remind people that we have gone from 53 per cent of our children being vaccinated with those vaccinations for which we do have subsidy, when we came to government, to over 90 per cent—93 per cent, I think—of children vaccinated. You can have the vaccines on, but unless you have a policy which drives the uptake, you can be back at—I think we were—68th in the world.

CHAIR—Are there any further questions on outcome 1?

Senator GREIG—Minister, I would like to ask some questions about HIV-AIDS strategy and policy. I received information from AFAO—the Australian Federation of AIDS Organisations—last Thursday, indicating that Australia is witnessing significant rises in HIV infections, particularly in Victoria and Queensland where there was a 20 per cent increase, and in New South Wales, where I understand they are anticipating an eight per cent increase. In the context of that, I am wondering what is the Commonwealth's response. There was a committee review and report which, I understand, you have been considering for six months. I am wondering—as are the HIV-AIDS community and their carers and advocates—what direction we are going to see from the Commonwealth, in terms of a revitalisation or renewal of strategy, and when we might see this.

Senator Patterson—The review was undertaken in advance of the current strategy coming to an end at the end of June 2004. I have received those reports, I have read them and I will be providing a whole-of-government response in due course. It is a very serious reminder—and I

said this the other day on radio—of the need to refocus and most probably revisit and re-look at the way in which we are approaching the issue. We have a new generation of young people and a new generation of people who have now had access to treatment and, therefore, that changes the perception of some young people who have not seen the ravages of HIV. But we do have a current strategy and this review was to be done well in advance of the end of the next strategy. In due course I will be releasing our response to the review. There are a number of reviews—there are, I think, five or six sections of it.

Senator GREIG—Can you be more definitive than 'in due course'? Are we looking at a matter of weeks?

Senator Patterson—No, I cannot. At the moment, as you may have noticed, I do have a few things on my plate, and I want to give it absolutely appropriate consideration. I read it in depth over Christmas. It requires a whole-of-government response. We still have a current strategy before us. It is to inform the next strategy and it was done early in order to do that. But it does remind us that we need to refocus and there is a very serious message, to people who engage in unprotected sex, from the data that is now appearing in Queensland and Victoria.

Senator GREIG—Has there been any recent analysis of why we are seeing the rise in infection rates that we are? As I understand it, some of the rises, particularly in Queensland, are such as we have not seen since about 1994. Has there been any kind of research into why we are seeing a return to these levels of infection?

Mr O'Donoughue—We are yet to see those data. We are awaiting the HIV surveillance report, which is published on a quarterly basis, and we are still to see the confirmation of these data. When there were previous indications of rises in infection in Victoria, there was some research done along the lines that the minister has already indicated. People have hypothesised that, when the fight against such an epidemic is sustained for a long period, the risk assessment changes over time, especially in young people entering the gay community. The availability of highly effective therapies has also changed the risk equation. People now—perhaps wrongly—perceive HIV to be a chronic disease that can be managed with medication. Also, people make more sophisticated choices about how to protect themselves. Whereas in the early days of the epidemic it may have been simple enough to say that one should always use a condom, now there are more complicated equations of risk and protective behaviours that people choose. There is always a challenge to educators to continually refine their preventive messages. Some of the research centres that are funded through the national strategy look specifically to those social and behavioural risks that might be changing over time, and they provide the data that can inform our preventive strategies.

Senator GREIG—Are we still finding that transmission is principally through sexual intercourse? How are we coping, as a nation, with transmission through IV drug use?

Mr O'Donoughue—Our record there still stands remarkably well. By far the majority of cases are transmitted sexually, and by international standards we have managed to avert an epidemic among injecting drug users. That performance stands up very well, although obviously we cannot be complacent about it, and new cases are overwhelmingly attributable to sexual transmission.

Senator GREIG—You have said—I am paraphrasing—that one of the reasons for apparent complacency, particularly amongst the young, is a sense that HIV is now much more manageable than it once was. And it is. I caught some TV news tonight on the issue of an AIDS vaccine. Can you tell us a bit about what is happening there, in terms of Australian research?

Mr Sam—The AIDS vaccine trial that was announced tonight is the result of an Australian consortium, led by Professor Cooper, which won an NIH contract to develop this. It is ready to trial. I am not sure whether Professor Mathews has any more details on that, but it has been under development for the last two years in terms of preparing to commence a trial.

Senator GREIG—Is this a trial of the possibility of a preventative vaccine?

Mr Sam—It is therapeutic.

Senator GREIG—So it is for those people who have HIV already?

Mr Sam—Yes. To follow on from Mr O'Donoughue, could I say in relation to the reported rise in the Victorian rates, particularly over 2001 and 2002, that under the current strategy each state and territory health department, as part of the funding that the Commonwealth provides, has to provide and implement a revised strategy within that state or territory. The Victorian department of health, as part of that process, launched a revised Victorian action plan in response to those reported rises. As you alluded to, the priority for that action plan was in relation to gay men, particularly young gay men.

Senator GREIG—Minister, are you able to indicate, in relation to a strategic review—or a revitalisation, as it has sometimes been termed—whether the ongoing educative campaign in this area will maintain a broad focus or will it be more in terms, perhaps, of niche education of constituencies and higher risk groups about the disease?

Senator Patterson—Senator Greig, as I said to you, we currently have a strategy. We currently work in conjunction with the states. As Mr Sam has indicated, it is the third year in an row that Victoria has had an increase, and they have responded to change their advertising and the way they approach it. We currently have that strategy in place. We have funded part of this current strategy. The reviews, as I have said, were done very early, to give sufficient time to inform the next strategy. I am not going to pre-empt at this stage what approach we have taken. There is a suggested restructure of ANCARD, and I am working my way through that. There are, as I have said, a number of other issues that focus my attention, but I am focussed, first of all, on the restructuring of ANCARD and then responding to the review.

Senator GREIG—The history of HIV-AIDS prevention policy and action in Australia has historically been one of good corporation with the Commonwealth and the states. Are you confident that that corporation is maintained and still there?

Senator Patterson—I cannot see any reason why it would not be. It is in all of our interests to maintain that cooperation.

Senator GREIG—Is it reasonable for me to suggest, though, about your commitment to the current strategy that we can reasonably say that it is not working as well as it might, given that we have seen significant increases in infection rates in some states over last financial year?

Senator Patterson—It has been more than the last financial year. Obviously, Victoria has responded at that level. As I said to you, I am responding to the suggestion that we restructure ANCARD. Once I have done that, I will then move to the next phase of responding to the reports. I think it is much better to start in a thoughtful, responsive way than in a knee-jerk way that maybe does not give us the outcomes plus the required discussion with the states.

Ms Halton—Can I make the observation that we actually do enjoy excellent working relationships with our colleagues in the states. There are many issues on which we work with them in a very considered way, particularly on issues in relation to public health. I can assure you that in ensuring those issues are addressed vigorously Commonwealth and state officers do literally work shoulder to shoulder.

Senator GREIG—There were dire warning some years ago about HIV breaking out in Indigenous communities. Have we witnessed that?

Mr O'Donoughue—No, we have not, fortunately. You are right: as far back as the review by Richard Feachem, there have been warning signs about the potential for the outbreak of HIV infection in Indigenous communities but, fortunately, as yet we have not seen any evidence of that emergence. Again, it is something we cannot be complacent about. But, undoubtedly because of the timely response by the Commonwealth and the states and territories in partnership with non-government organisations and the medical and scientific community, we have so far managed to avert that epidemic.

Senator McLUCAS—I want to go to the issue of SARS.

Senator Patterson—Senator Greig, I have had discussions Minister Aagaard about a couple of situations in the Northern Territory. We discussed that very cooperatively. Some of that may require changing legislation in the Northern Territory, but we have at that level discussed the issue in the Northern Territory. So it is not something that I have left on the backburner. Because I am not out there talking about it all the time, that does not mean that I am not dealing with it. We had an appointment to discuss that very issue in the Northern Territory. Ms Halton is saying that she discussed it with WA Health.

Ms Halton—Recently.

Senator Patterson—It is high on the radar. It is a constant reminder that we have to be vigilant and we need to—as I think you said—revitalise and refocus. Maybe the message needs to be different, because young people's experiences are different now.

Senator McLUCAS—I notice that in the PBS there is an allocation of $1.7 million currently in this budget essentially for placing nurses at airports; that is essentially what you are doing. Is that the extent of the initiative that the Commonwealth is undertaking with respect to SARS?

Mr O'Donoughue—No, it is not. Since the first cases of atypical pneumonia became noticed in the world, and more recently since WHO issued a global alert on 14 March, the Commonwealth and the states have been actively engaged in, first of all, watching and actively surveying to see whether we saw any emergence of SARS in Australia. The budget measure is really just a part of the border protection measures that we have put in place to, if possible, avoid the importation of cases of SARS into Australia or at least to get early

warning, should any people arrive with symptoms of SARS. In addition to that, we have also been working closely with states and territories, for example, to update our infection control guidelines to ensure that people can be safely managed in the health system. It has really been a day by day and—as the secretary alluded to—a shoulder to shoulder cooperative effort with all state and territory health authorities and, in particular, the Communicable Disease Network of Australia and New Zealand.

Ms Halton—Just adding to that, this one is not just the question of our relationship with the states and territories; this is also a kind of whole of Commonwealth government exercise. I had no sooner established in the department an incident room to enable us to respond to some sort of issue, when we discovered that we had to activate it to deal with the SARS issue. Exactly as Mr O'Donoughue said, we are working with the communicable diseases people and a range of other people across the states. But we are also working with our colleagues in Transport, in AQIS—and I could go on—to ensure that not only is our domestic response appropriate but our response at the border is appropriate too.

Senator McLUCAS—The states are bearing costs in that process; for example, you hear stories of rooms being quarantined, just in case. Has the Commonwealth had any discussions about who is going to bear that cost or have the states said that they will happily pay for it?

Mr O'Donoughue—The specific budget measure relates to the additional costs that are borne by the states in respect of putting health personnel actually at the border, at airports—and that is an unusual impost upon them. We have been monitoring closely with the states the existing capacity within the public health system to manage cases of infectious disease. In a sense, that is a longstanding set of arrangements that we have had with the states and territories to make sure that there are appropriate facilities available. Obviously, in the face of a modern, emerging epidemic, we have needed to make sure that those facilities are actively available and could be deployed, but they are really part of the existing armoury of the public health system. So, at this stage, there have not been any additional costs incurred by the states, fortunately, because so far we have actually had no detections of people with SARS in the country, other than the people who fit the WHO case definition, who have been reported to WHO.

Ms Halton—Professor Smallwood is also on the record as talking about the need for practising health professionals to be particularly alert because, whilst we have not actually had a case, the reality is that anybody who is suspected may actually be a case. I think Professor Smallwood—working with his colleagues across the profession, across the states and territories—has been at pains to point out and to ensure that our approach to infection control is of the highest standard.

One of the things that we have been at pains to do is to inform ourselves about what has happened in those countries that have had experience of SARS. Professor Mathews in fact attended a conference in Taiwan—which was brave—to make sure that we fully understand the experience overseas and can bring that experience back domestically to ensure that our health professionals are not only informed but continually vigilant.

Senator McLUCAS—At the last estimates we talked about the stockpile of drugs that we had and there was reference to anti-flu drugs in that stockpile. Are those drugs of any use to us with SARS? The stockpile of drugs was mainly to do with antiterrorism.

Prof. Mathews—The particular drugs that work for flu do not work for SARS. It has been suggested that another drug, ribavirin, might work for SARS, but in fact the evidence that it does is not good. There has been some overseas publicity about other drugs which do work in the test tube against the SARS virus, but it would be many months, if not years, before those were available for use.

Senator McLUCAS—I want to go now to advice that may have been provided by the department to GPs. How do you talk to GPs about detection of SARS?

Prof. Mathews—We have had some detailed discussions with doctor organisations. In the first instance, before SARS came, we were talking about some of the other biosecurity preparations. We have met with both the leading medical organisations and the Australian Nursing Federation to brief them and make plans to consolidate the means by which we have distributed educational materials. Of course, our work with the states on the SARS initiative has meant that we have developed in partnership with the states the packages of information about infection control. So the messages are going out through the states and coming back through their networks, to doctors working in hospitals, in particular—and they have got communication networks with their divisions of general practice. We are going through the professional organisations and there is very close cooperation.

Of course, we all struggle with the obvious: as there is so much material going to doctors—it comes through the letterbox, it comes through the Internet—how do you actually draw it to someone's attention? We have got the very strong support of the professional bodies to do that. We have also worked with the medical media. There is a very strong public health media network which has been running for a number of years. That has close connections with the media people who work with the professional medical organisations. It also has close connections with the medical publications. A lot of doctors read those throwaway journals much more than they read the real academic literature. So we are going through all those pathways and consolidating the same messages.

Senator McLUCAS—Was specific advice given to GPs about what would happen if a patient presented at their surgery?

Prof. Mathews—Yes, there is specific advice about infection control. We had that out on the web site very early. We had information available through the 1800 number as well, letting worried people as well as doctors know that they should, if possible, alert the general practice or the hospital emergency department if they thought they might be infectious with SARS, rather than just turning up unannounced. The advice about infection control, wearing masks, hand washing and precautions that should be taken was distributed at a very early stage. It is being updated constantly in the light of feedback from the states, professional groups and, obviously, from overseas. Senators would be aware, of course, that one of the very tragic things about the SARS epidemic is that health workers themselves have been at very high risk if they have not taken the appropriate precautions. We have just been in the

fortunate circumstance of being able to learn from what has happened overseas without yet, we believe, having had a genuine case or any transmission in Australia.

Senator ALLISON—Am I right in assuming that the budget documents do not indicate that there are extra funds for anti-smoking programs? It remains $2 million, as it was in the previous budget?

Ms Hefford—That is correct.

Senator ALLISON—The budget does, however, show that $255 million more is being raised from tobacco revenue. Is that correct?

Ms Hefford—That is a matter you would have to take up with Treasury.

Senator ALLISON—I understand Treasury will collect it, but there is no suggestion in any way that part of that extra revenue would be used for anti-smoking campaigns?

Ms Hefford—No.

Senator ALLISON—I do not suppose we know how much of it would be used for the enhanced enforcement on which the revenue depends. That is not your business either, is it?

Ms Hefford—It is not, I am sorry. I am not in a position to answer questions about taxation, excise or revenue.

Senator ALLISON—In 2001 an extra $400 million in revenue was raised when we changed the rate of taxing cigarettes from weight to stick. That also attracted $400 million a year in extra revenue. Is that correct?

Ms Hefford—Again, I am not in a position to comment on the amounts. I do know that there has been some discussion on these matters in Treasury. The questions would have to be directed to them.

Senator ALLISON—Minister, were you concerned about the fact that half a million dollars was provided to improve tobacco storage at Myrtleford not very long ago? There was an announcement, I think, by Ms Worth.

Ms Hefford—I am advised that that was something announced by Senator Coonan and it was to do with—

Senator ALLISON—I beg your pardon. That is correct. Minister, did it worry you to think that tobacco storage in one small place in Victoria would be effectively handed one-quarter of the budget for anti-smoking measures?

Senator Patterson—I do not know every single skerrick of this portfolio since Senator Coonan announced it, but I believe that it was to do with the illegal sale of chop chop. I think Ms Hefford might be beware of that.

Senator ALLISON—So that might be assisting us in gathering the extra $255 million in revenue from excise?

Senator Patterson—Not assisting us; reducing the sale of illegal tobacco.

Senator ALLISON—Precisely, so that we can net $255 million extra in revenue?

Senator Patterson—That is not the reason. Ms Hefford—

Senator ALLISON—So excise evasion is not the reason for more secure storage arrangements in Myrtleford, costing half a million dollars? I do not think it is a question for Ms Hefford; I think it is for you, Minister.

Senator Patterson—No, it is an issue that Ms Hefford can answer, and she is prepared to answer it.

Ms Hefford—It was about storage containment of illicitly produced and illicitly available tobacco, which there are no health warnings with and no health protections around, and which is therefore of concern.

Senator ALLISON—I see. So it is $500 million for health related issues. Does that mean that your department was instrumental in initiating this project?

Ms Hefford—I think I have already said that it was announced by Senator Helen Coonan. It was an initiative around controlling illicit tobacco.

Senator ALLISON—I understand that, but you have given me an argument based on health—that this tobacco does not come with health warnings. I am simply asking whether the department was involved, since that is one of the reasons.

Ms Hefford—No.

Senator ALLISON—Thanks. Minister, Dr Wooldridge in February 2000 announced a review of the current health warnings on tobacco packaging. He said:

The first stage of the review currently underway is a research project to evaluate the current Australian health warnings.

Was that prepared?

Ms Hefford—That project is still under way. We have in fact conducted some of the research. We have developed a range of warnings, which we have narrowed down with a series of focus testing. We are at the stage now of another round of testing, which involves packet prototypes, allowing us to test consumer reactions to the size of print and the use of either diagrams or printed messages—and that research is almost completed. It is quite complex because we are testing a range of different things.

Senator ALLISON—That sounds like it is more than Dr Wooldridge was talking about three and a half years ago. It was described as evaluating the current health warnings—but you say it is bigger than that?

Ms Hefford—It has gone on from there to an evaluation of the—

Senator ALLISON—Was the evaluation ever produced?

Ms Hefford—Yes, it was produced; it is available on the department's web site.

Senator ALLISON—I looked and I could not find it. How does one navigate towards it?

Ms Halton—Senator, we will get you a copy.

Senator ALLISON—Thank you very much. In the same announcement Dr Wooldridge said:

Public consultation on options for change is planned for later this year.

He meant later in 2000. Was there consultation at that time?

Ms Hefford—There was and there has been ongoing consultation as we have moved towards a narrowed down group of warnings that we might use and as we have tried to go through a process of deciding what form the warnings should take—whether they should be pictorial, graphic or simply print warnings.

Senator ALLISON—With whom did you consult over that process?

Ms Hefford—Our usual process is to contract a social marketing or research company. They undertake focus group testing and one on one interviews with people to test the types of warnings we are using, in a range of different settings.

Senator ALLISON—Is focus group work the only form of consultation?

Ms Hefford—Are you asking if we use professional advice or expertise?

Senator ALLISON—I understand this to be 'public consultation on options for change'. That does not sound like focus group work. I am sure you would put that in a package.

Ms Hefford—There has been a combination of those things, and the work is overseen by an expert advisory group that includes representatives from across the academic and community sector.

Senator ALLISON—Is it possible to get a list of those people involved in that consultation process?

Ms Hefford—Yes, we can do that for you.

Senator ALLISON—Thanks. The web site still says that a discussion paper will be available by the end of 2002. What is the status of that discussion paper?

Ms Hefford—We have a final draft. We are still working on it. It is quite a complex document. Again, it is being produced by an expert advisory group who have done the principal drafting. It has involved work across a number of different portfolios. Tobacco advertising is something which impacts on the department of communications and on the ACCC. It also involves the trade practices legislation, and we have had to take legal advice on a whole range of issues. We are very close to having that discussion paper finalised and we have began talking about the way in which we might disseminate it, which we believe will be very broadly.

Senator ALLISON—I would suggest that you could perhaps correct the web site, so that it indicates when it is due. The advisory group which was, I guess, anticipated as part of Dr Wooldridge's announcement in January or February 2000: when did that first meet?

Ms Hefford—I am sorry. Which advisory group are you talking about?

Senator ALLISON—The advisory group that was part of that announcement.

Ms Hefford—To do with the TAPA?

Senator ALLISON—To do with the labels on cigarette packs.

Ms Hefford—Health warnings, or advertising?

Senator ALLISON—Health warnings.

Ms Hefford—Is the question the date of the first meeting of that advisory group? I will take that on notice.

Senator ALLISON—Perhaps you can advise whether that group has met often.

Ms Hefford—It is an ongoing process, yes.

Senator ALLISON—Roughly how often would it have met?

Ms Hefford—On five or six occasions, Senator.

Senator ALLISON—So it did start to meet in September last year, as expected?

Ms Hefford—Senator, when you began asking about the group, were you asking about the health warnings advisory group?

Senator ALLISON—Yes.

Ms Hefford—It has been going longer. It was going well before 2002. Its first meeting would have been sometime earlier than that. The tobacco advertising act group was the one that began in 2002.

Senator ALLISON—Can we start that again? Is that called the expert advisory panel?

Ms Hefford—There are two expert groups: one working with us on health warnings, and another helping to draft a discussion paper on the Tobacco Advertising Prohibition Act.

Senator ALLISON—Okay. So how is that going? How is progress on it?

Ms Hefford—On which one?

Senator ALLISON—The review of the act.

Ms Hefford—I think I answered an earlier question, assuming that that was the one you meant. We are close to a final product, and that is the paper that has involved us testing the assumptions in the paper on a number of different Commonwealth government departments and taking a wide range of legal advice. We would expect that paper to be out within the next few weeks.

Senator ALLISON—The answer that you gave in April to one of my questions, Minister, was that it would be available 'shortly'. Again, we seem to be missing a lot of timelines.

Ms Hefford—Yes. The legal issues particularly are quite complex. For example, the issues being canvassed in the paper are about things like whether or not we could seek to control advertising that occurs on web sites on the Internet and advertising that occurs in imported products, such as movies. These are very difficult and complex issues that involve us looking at a whole range of legislation.

Senator ALLISON—There was mention made of analysis of the submissions. I think there was a date put in the answer to my question, but I am not sure what that was. Do you expect to put out an analysis of those submissions at some stage, or is it already available?

Ms Hefford—No. We would expect that once the discussion paper has been released there will be submissions from a wide range of organisations and that we would have a process of analysing those submissions and produce some assessment or report of that analysis.

Senator ALLISON—I see: the issues paper comes first and then the submissions, and that paper is due out in two or three weeks; and then there will be consultation for how long?

Ms Hefford—I imagine that we would want to allow about six weeks. It is one of the issues that we are discussing at the moment. It is quite a complex paper and there are quite complex issues, and so organisations that will want to make submissions will probably also want to get legal advice about the nature of their submission.

Senator ALLISON—So the review itself will be finalised by the end of the year, or sometime sooner?

Ms Hefford—I expect that it will be finalised by the end of the year.

Senator ALLISON—Minister, could I turn to the question of exemptions from tobacco advertising. Can you explain why it was that you wrote to the European Union health ministers before their December 2002 meeting, urging them to not adopt the earlier date of 2005 for removing those exemptions altogether?

Senator Patterson—I believe that I have answered that same question from you in the Senate at question time.

Senator ALLISON—You answered the question but you did not tell me why.

Senator Patterson—I did.

Senator ALLISON—Can you remind me?

Senator Patterson—You have asked the question and I have answered it.

Senator ALLISON—I have the question here. You do not answer the question; as I understand it, you only provided a copy of the letter.

Senator Patterson—An agreed date was set. When people are trying to make plans, it is appropriate that they have that information.

Senator ALLISON—This did not affect Australia's position, so why should you take up the case on behalf of the—

Senator Patterson—There was a date which we had all agreed on. I am not going to go into it any further.

Senator ALLISON—What response did you receive to that letter?

Senator Patterson—There was no response.

Senator ALLISON—It was treated with some disdain, perhaps?

Senator Patterson—I do not think I asked for responses.

Senator ALLISON—The government announced some time ago that the exemption from the act would be phased out by October 2006. What is meant by the phrase 'phasing out' by 2006—as opposed to just stopping?

Ms Hefford—Existing agreements were in place, and the term 'phasing out' referred to the fact that no new agreements would be entered into and that existing agreements—for example, the Grand Prix arrangement—would cease at the date set in the legislation.

Senator ALLISON—So we could not expect anything by way of further restrictions between the announcement of that decision and 2006? It is not phasing out in the sense of slowly reaching a stop, but simply means no new agreements?

Ms Hefford—There is no growth; there are no new organisations able to come forward.

Senator ALLISON—'No growth' does not suggest phasing out to me.

Ms Hefford—There were existing contracts which it was agreed would be acknowledged up to and including October 2006, but beyond that there would be no further opportunity.

Senator ALLISON—I understand, though it is hard to see how that could be described as phasing out. Could I ask about the Formula One event in particular.

Senator Patterson—I will stand corrected, but I think there were some agreements that finished earlier and were phased out. The last one is the Grand Prix, which finishes in 2006. From memory, there were others that finished along the way, so they were phased out; they did not begin again. I think the Grand Prix is the last one—in 2006.

Senator ALLISON—Is that phasing out or are they just dropping off the perch?

Senator Patterson—Whatever language you like to use, they will not exist any more after 2006. We could be in here all night with these semantics.

Senator ALLISON—I do not think you could say that the Ladies Masters Golf was phased out. They found somebody else to sponsor them and they are quite happy with that.

Senator Patterson—We are talking about the advertising—not the event—being phased out.

Senator ALLISON—Do you agree that the advertising is being phased out?

Ms Hefford—Yes.

Senator ALLISON—In what sense?

Ms Hefford—It is the advertising which is to be phased out. There are three events that are still able to apply for an exemption and use advertising.

Senator ALLISON—I understand that.

Ms Hefford—They are the Australian Formula One Grand Prix, the Australian Motorcycle Grand Prix and the Indy 300. There was another event, which has ceased because they have managed to find alternative sponsorship.

Senator ALLISON—Yes, that is the Ladies Masters Golf. That is what I meant.

Ms Hefford—That has been phased out, because they—

Senator ALLISON—Sorry, it has not been phased out. They have chosen voluntarily to withdraw.

Ms Halton—I think the point being made here is that people understand that there is a drop-dead date—if you will pardon the appropriate pun—of 2006. People with these events are on notice that at that date this will cease and, essentially, they are encouraged to phase out their dependence on cigarette advertising in that time period. As Ms Hefford has indicated, one of those events has chosen, has found—however you wish to put this—an alternative

sponsor. One might hope that the other three events would be in the same category. In the event that they are not, they will cease being able to use advertising sponsorship money from tobacco firms in 2006. So we are encouraging them to cease this, to phase out their reliance on tobacco sponsorship. In any event, in 2006 it must cease.

Senator ALLISON—And this encouragement is the knowledge that by 2006 it finishes?

Ms Halton—Correct. And in the event that—

Senator ALLISON—Okay, that is fine, although it is hardly what I would call phasing it out. I understand that for the Formula One race in Melbourne there was a reduction in the number of tobacco branded cars at the exhibition; it went from eight to four.

Senator Patterson—Maybe it is being phased out—to use a phrase.

Senator ALLISON—Perhaps, then, you can answer this, Minister. Was that a condition imposed by the government, or did the organisers just offer that up?

Senator Patterson—They had heard you speaking at estimates! I do not know. By the end of 2006 they have not got to use tobacco advertising or have sponsorship from tobacco companies.

Senator ALLISON—Is it correct to say that the government could, if it wished, progressively restrict some of the conditions which are applied within this legislation?

Senator Patterson—We have put the major event organisers on notice that they will not be able to use tobacco sponsorship—sponsorship from tobacco companies—beyond October 2006.

Senator ALLISON—The government, nonetheless, has the capacity to apply restrictions. It restricts the number and the size of the advertising signs; it restricts who can wear them and who they are. This is the case, is it not?

Ms Hefford—In each case the government would stipulate through a gazettal notice what is able to take place. But when you are talking about the number of cars, in effect the tobacco sponsorship is not of the event; it is between, for example, individual competitors. Individual cars that are entering seek sponsorship for their particular entry. So it is not up to the individual Grand Prix organiser but the individual competing companies, or cars, in terms of the labelling that those cars carry. And they have sponsorship by tobacco companies. Is that clear, that it is the competitors that seek sponsorship from tobacco companies?

Senator ALLISON—Yes, I understand that. Nonetheless, they do it within a framework of restrictions that the government agrees to.

Ms Halton—Essentially, we can specify certain conditions; that is right.

Senator ALLISON—The government has chosen not to progressively limit those restrictions? That is my question.

Senator Patterson—Senator, we have put—

Senator ALLISON—The government has chosen, Minister, not to reduce the size, for instance.

Senator Patterson—event organisers on notice that they will not be using sponsorship from tobacco companies after October 2006.

Senator ALLISON—I raise the question of handouts of free cigarettes—and I think there is a cigarette tent or marquee, or several of them—at the Melbourne Grand Prix.

Ms Hefford—Not that I am aware of. One of the things that we would always do for these events is ensure that somebody from the department monitored that the advertising and so on was correct. I have never seen a report indicating that free cigarettes were being given out or that there was a free cigarette tent.

Senator ALLISON—Would you check the record on that and ask whoever it is who inspects these things.

Ms Hefford—Yes.

Senator ALLISON—It is my understanding that that is commonplace and that there are people wandering around all the time offering cigarettes in and outside the marquee.

Ms Hefford—As I said, we always send a staff member. They always write a report. I will check the reports.

Senator ALLISON—Presumably the handing out of free cigarettes is not part of the agreement with the race organisers?

Ms Hefford—No, that is not part of the gazettal conditions.

Senator ALLISON—Minister, I asked you a question recently about the basis on which the government was satisfied that failure to specify the event would be likely to result in the event not being held in Australia. In fact, the Senate agreed to a return to order in May and you responded to that, saying that the return to order was still being examined and that you needed an extension of time until 16 June. Can you explain why it was that that extension was needed and whether the documents are now available?

Ms Hefford—The contractual agreement with the Grand Prix has other subcontractual arrangements attached to it and therefore the documentation is not necessarily all easily accessed by us. We have asked the Grand Prix Corporation to seek agreements from the other cosignatories and we have had our lawyers looking at the paperwork. There will be an answer by 16 June.

Senator ALLISON—What do you mean 'not easily accessed'? Surely this is a document you need to assess in terms of whether you are satisfied that tobacco sponsorship is necessary for the viability of the race.

Ms Hefford—That is true. At the time that we made that assessment, the documentation was provided to us with a confidentiality clause by that organisation. We have had to go back to that organisation and say, 'Are there parts of this documentation which we could release to a wider audience?' We are just waiting on that advice.

Senator Patterson—I was not on top of this. If it was said that it would be there by the 16th, I will do everything I can to make sure we have the return to order by the 16th. I was not aware there was a delay.

Senator ALLISON—I am just interested in why it is not immediately available. I can understand that you might want to ask some questions. It is hard to know without looking at the document, but you say there are some subcontracts attached to it—why not just remove the subcontracts?

Ms Hefford—That may be what we do.

Senator ALLISON—We look forward to the 16th. What progress is being made on the part of the organisers to negotiate alternative sponsorship arrangements? Is part of your process to inquire as to the efforts being made by organisers in this respect?

Ms Hefford—I do not believe so. I think that a number of people have made it reasonably clear that these organisations know they have until October 2006 to find alternative sponsorship. I do not believe that we have a role within the department to assist them in that or to monitor their progress in doing that. The legislation has a 'drop dead' clause. They are aware of that. They are a commercial operation. It would be in their interest to be actively seeking alternative sponsorship, but it is not a concern for us.

Senator ALLISON—I think it comes out of the statement made by perhaps not this minister but the one before, to do with encouragement—that the government encourages the organisers to negotiate alternative sponsorship. But you do not take an active role in that encouragement?

Ms Hefford—We do not take an active role in monitoring that. I am sure those organisations are actively seeking alternative sponsorship.

Senator Patterson—They know the date.

Senator ALLISON—Minister, your letter to the Australian Grand Prix Corporation in July last year said:

I would request your support to encourage the cooperation of all merchandise promoters to agree to restrict sales of their merchandise to persons 18 years of age and over.

Isn't it against the law to do otherwise?

Senator Patterson—I think merchandise could mean a T-shirt with an advertisement on it and it is not illegal to sell a T-shirt.

Senator ALLISON—I see. So it does not refer to cigarettes; it refers to caps and the like?

Senator Patterson—Merchandise.

Senator ALLISON—A number of details were requested in the letter that I have just referred to. I will not go through them all, but one is:

... details of all countries staging a round of the Championship in 2003 and the type and levels of restriction on tobacco advertising imposed by each of these countries—

There are four points altogether. Were those details provided? For instance:

detailed plans for the proposed Formula One Exhibition, including dimensions and a list of items proposed to be included in the Exhibition ... details of all participants in the 2003 Championship including the number of competitors, the name (both individual and team name) of each competitor, the proportion of competitors with any form of tobacco sponsorship, the proportion of competitors with tobacco naming rights, and the tobacco branding of all competitors with tobacco sponsorship ...

and so on. Was that routinely provided?

Ms Hefford—All of the issues that they were asked to respond to in the assessment process they have in fact responded to. I understand that they met all the conditions.

Senator ALLISON—Has the department had a chance to analyse the incidental advertising which comes through these events in daily papers and television?

Ms Hefford—No, we have done no systematic analysis of any incidental advertising that would result from, for example—

Senator Patterson—Somebody wearing a T-shirt.

Ms Hefford—a photograph at the Grand Prix.

Senator ALLISON—So if it is not systematic there is no other form of analysis or concern about it? You are not looking at trends, perhaps?

Ms Hefford—I think it is fair to say that we would be concerned about it, which is why we have the 'drop dead' clause and why we are seeking to move away from this type of activity altogether. That said, there are only a small number of events remaining. I am not sure that there would be a lot of value in us doing a systematic analysis of incidental advertising which may occur as result of the very small handful of events remaining under this provision.

Senator ALLISON—So at no stage have you looked at possible options for limiting incidental advertising?

Ms Hefford—I am sorry, can you ask the question again?

Senator ALLISON—I am just wondering whether—I know there are not many years to go—it has been suggested that there might be ways in which you can obscure some of the advertising which is reproduced in newspapers, for instance, or require editors to remove the insignias and names and so forth?

Ms Hefford—The Tobacco Advertising Prohibition Act—which we were talking about a few moments ago, where we are currently finalising the discussion paper—has provisions which make incidental advertising of that type illegal, so we would be expecting that it would not occur that often and that we would be able to monitor it.

Senator ALLISON—Do you have anything further to add?

Ms Hefford—We would be monitoring, but it is an offence where somebody complains that they believe it was more than incidental, in which case we could take action.

Senator ALLISON—Are you saying that it is possible to take action if it is more than incidental now?

Ms Hefford—Yes.

Ms Halton—I think what Ms Hefford is trying to say is if it is not genuinely incidental, if it is orchestratedly incidental—if that is not too convoluted a term—in other words, you have manufactured the supposedly incidental circumstance. Of course, proving that would probably be a trifle tricky. It is essentially if it were manufactured—in other words, something you set out to do, even though it looked 'incidental'.

Senator ALLISON—Would an inducement to place a photograph, say, with Marlboro all over it in a magazine constitute it being 'deliberate'?

Ms Hefford—The act is phrased around whether or not you would receive a benefit. So if you would receive a benefit from the large signage over and above what you would normally receive from a photograph of a car crossing a finish line the act then gives us the opportunity to look at that taking advantage, in effect.

Senator ALLISON—You are not suggesting that Marlboro would not derive a benefit from handing their Marlboro car on pages 1, 3, 5 and 8 and on television throughout the race season?

Ms Hefford—We are talking at cross-purposes. Now that you use the word 'Marlboro', I understand where you are coming from. We are talking about where it was incidental advertising and the benefit accrued to the publisher, so where the newspaper or the magazine achieved some benefit—

Senator ALLISON—Yes.

Ms Hefford—not the tobacco company.

Senator ALLISON—So none of the incidental advertising led you to suggest there should be an investigation about whether inducements—

Ms Hefford—No.

Senator ALLISON—In Ms Worth's letter to the Grand Prix organisers, she said the government will:

... maintain restrictions at the current level or be seeking to tighten restrictions on the display of tobacco advertising at all future exempted events.

Has an application been made for 2004 yet? If so, is there any plan to tighten restrictions?

Ms Hefford—We have not yet received an application for 2004.

Senator ALLISON—By this time last year it was already in for this year, wasn't it?

Ms Hefford—I am not aware.

Senator ALLISON—I go back to Dr Wooldridge's comments. In 2000 he announced that there would be a national best-practice model to prevent the sale of tobacco to minors. Can you advise of where that best-practice model is at and what it is?

Ms Hefford—I cannot answer that at the moment. I will try to get an answer for you.

Senator ALLISON—Thanks. If you could you also find out what the effectiveness of that model is, that would be useful.

Ms Hefford—Yes, I will do that.

Senator ALLISON—Your officer has some advice.

Ms Hefford—It was before my time in this area, but the explanation is that the model was developed. It takes the form of a report, which again is available on our web site. It is a model for application by state and territory governments, because the sale of tobacco products is regulated and monitored by state and territory governments where minors are concerned. This

report talks about best practice and steps and guidelines that the state and territory governments can elect to implement. As I said, it is available on our web site.

Senator ALLISON—Have you updated that study to show what state governments have picked up by way of the recommendations in place? Did those recommendations include higher penalties—because they are quite low in most states at present, are they not?

Ms Hefford—I will just take advice on that. The document has not been updated since it was finished. It was put up on the web site and, as I said, state and territory governments were asked to look at it and implement it where it was appropriate for them. It is not something we have reviewed since that time, but it is something we would be planning to review over the next few months in building the next national tobacco strategy. The current national tobacco strategy ends at the end of June 2004 and we would be looking over the next few months to—

Senator ALLISON—So this particular model will not be reviewed before that time?

Ms Hefford—No, we would review it in the lead-up to that time. We would look at what the pick-up rate was, we will talk to state and territory governments about how useful they found it, look at to what extent they have implemented it and look at whether or not that is something worth repeating or whether we would need to go somewhere else.

Senator ALLISON—I think the last survey showed that almost 300,000 secondary students are smoking at present. In November the new per stick method of calculating excise was introduced and that was, at the time, said to provide further price disincentives to price sensitive smokers. Has there been an evaluation of the success of that, given that the number of smokers is increasing, particularly of young women? Does that suggest that it did not work or that it was not high enough? What sort of review or evaluation have you done?

Ms Hefford—Australia's smoking prevalence is one of the lowest in the world and has been decreasing in recent years. In fact, while 19.5 per cent of the population in general smoke, only 18 per cent of women are smokers.

Senator ALLISON—I am referring to young people, particularly school aged children. The surveys would indicate an increase rather than a decline in that age group.

Ms Hefford—The advice I have is that daily smoking rates have declined significantly with no significant change for the young age group that you are talking about. There is no increase in the prevalence of smoking among teenagers in Australia according to the research that we conducted.

Senator ALLISON—Some surveys suggest that at least girls are smoking more. It has been in the news in the last couple of weeks. My point was that the per stick method of calculating excise was to provide further disincentives, particularly for young people. If the smoking prevalence has stayed the same, then that would suggest that it is not working. Would you agree?

Ms Hefford—What I have been saying is that I think smoking prevalence has been declining. I also want to suggest that it would be very hard to attribute that decline to any particular issue. We run national advertising campaigns, we promote the use of quit lines and we do a lot of other things. Whether any one individual factor is particularly influential in reducing the prevalence of smoking is more difficult to say, but we do have figures showing a

decline in smoking. You were talking a moment ago about information on women smoking. There was a report in the papers earlier this week or late last week about the incidence of cancer among women. That report was actually talking about the take-up of smoking by young women in the seventies and early eighties. So they are people who have been smoking for more than 20 years and amongst whom we now see a rising incidence of smoking related cancers.

Senator ALLISON—I recall that study, but I think there have been others that have looked at young women in particular. We will move on. On 31 May 2000 Dr Wooldridge said:

> ... the Federal Government is currently negotiating with the tobacco industry on an agreement that will provide information on the actual ingredients of cigarettes currently for sale in this country.

What is the status of those negotiations?

Ms Hefford—Those negotiations were completed and agreements with tobacco companies have been entered into voluntarily. The ingredients listings are, again, provided on the department's web site.

Senator ALLISON—Is there any suggestion that they should be put on the cigarette packs themselves?

Ms Hefford—It is one of the things that we have considered in the health warnings review that we were talking about earlier. One of the issues is that there are enormous listings of ingredients. They are a page long; there are 20 or 30 ingredients, sometimes. It would be very difficult to fit it onto the cigarette pack, and you have to think about the issues that, when we test them in focus groups and in awareness campaigns, resonate best with young people. Ingredients listings do not come out that highly. People are not necessarily influenced by ingredients listings.

Senator ALLISON—Does the department have a clear understanding of what those ingredients mean, particularly in terms of the effect they have on health?

Ms Hefford—Does the department have a clear understanding or do the people who are accessing that information—smokers or potential smokers?

Senator ALLISON—The department. I just wonder if there has been an analysis of the carcinogenic qualities of particular ingredients or any substances there that perhaps the government might argue should not be there.

Ms Halton—We do not regulate cigarettes as a therapeutic good, probably for fairly obvious reasons. I think it fair to say—

Senator ALLISON—A therapeutic good that kills 19,000 people a year, yes.

Ms Halton—We have just had a rather lengthy discussion, I think, Senator Forshaw being at the front of it, about the way we regulate therapeutic goods, which went to the content and the claims made about content of particular—

Senator FORSHAW—I have seen what goes into cigarettes sometimes, too, in cigarette factories. I won't go into that!

Ms Halton—The reason I make the comparison with the TGA is that there we have a particular responsibility in respect of the particular content, the active ingredient, in a number

of products. We look at those and have a great deal of scientific expertise brought to bear. In this particular area, as the department, we have medical expertise in the department, we have a range of medical advice internally available to us and we have obviously access to a much broader range of scientific advice externally. But whether we commission particular studies in relation to particular components other than—to use an example, knowing that you asked me—something that is not a component you put in cigarettes, the answer is no. I do not know whether Professor Mathews would like to add to that.

Prof. Mathews—It is 50 years since smoking and lung cancer were linked. In fact, it is longer, because the data actually appeared in Europe in the 1930s but did not get widely publicised because of World War II. It is still true to say that we know benzpyrene is the principal carcinogen that comes out of tobacco smoke, but we do not know the relative importance of all the others, nor do we know from very good studies what the additives that are put into the cigarette with the tobacco do. There is some evidence on that and, as the secretary said, we watch the data that comes from the International Agency for Research on Cancer and we are ready to respond to new information as it appears. But, as I mentioned earlier, we are part of an international group and we have to live off each other's research. We cannot duplicate everything in Australia. It is not cost effective to do so.

Ms Halton—And it does not go to our fundamental message, which is that smoking kills you and you should not do it.

Senator ALLISON—Is the World Health Organisation, or some other global body, looking at those additives to cigarettes to determine what impact they have on health?

Prof. Mathews—Yes. The International Agency for Research on Cancer in Lyons is the WHO agency that has principal responsibility for pulling all that international information together.

Senator ALLISON—Is there a time line on doing that? When can we expect to see something?

Prof. Mathews—They publish regular monographs. I have to confess that I have not read the most recent monograph that would cover this from IARC, but I could pull it off the shelf and answer any questions you have, on notice, if you wish.

Senator ALLISON—It just seems to me that, having gone to the trouble of requiring additives to be disclosed, oughtn't we be doing something about that, either by advising consumers of what this means in terms of the impact on them or by getting them to choose products that have one or the other? What is the point of doing it if you do not actually do something with the data?

Ms Hefford—The original thinking behind it might have been that the listing of the ingredients would in itself serve as a deterrent to smokers. I guess that one of the things that we have to consider in the lead-up to reviewing the national tobacco strategy is how effective that kind of message is for smokers.

Senator ALLISON—But how can you know that? If it is not on the pack, how can you judge it? Are you just relying on smokers looking up your antitobacco web site to find out? Isn't that a bit unlikely?

Ms Hefford—We do a lot more research than that. We actually regularly—

Senator ALLISON—No. I am talking about how it gets to consumers, and how smokers get to understand this.

Ms Hefford—That is what I was talking about. We do a lot more research through discussions with consumer focus groups, testing their understanding of particular products, labelling and other issues of that kind. That is one of the things we would take into account in trying to decide whether keeping the ingredients listed on the web site was an effective strategy.

Senator ALLISON—Or having it on the pack?

Ms Hefford—Or having it on the pack; or picking out a smaller number of ingredients and listing those and highlighting them more in some way; or listing a smaller number of ingredients on the pack. There are a range of other options and we need to think about all of them.

Senator ALLISON—There has been a lot of criticism about, and in fact some attempts at quantifying, the damage which is done through fires—whether they be domestic household fires or bushfires—through an additive to the paper surrounding the cigarette, an additive which causes it to keep burning for much longer periods than it would otherwise. What progress is being made within your department to look at this question? Can you see there being an argument for banning this additive?

Ms Hefford—I understand that the issue of fire-safe cigarettes is currently being considered by the National Expert Advisory Committee on Tobacco. They are gathering evidence on the available research and will report back to the department in due course.

Senator ALLISON—That is part of the general review, not part of the Tobacco Advertising Prohibition Act, presumably? That is another kind of review?

Ms Hefford—No. NEACT is the National Expert Advisory Committee on Tobacco and works on a range of different issues around smoking and tobacco control, and this is one of their current projects.

Senator ALLISON—When will that be finished?

Ms Hefford—I understand that we have asked for advice back from NEACT by around October.

Senator ALLISON—Will that committee look at other ingredients in cigarettes which might promote the uptake of smoking, particularly by young people? I understand that there is some sweet element within either the tobacco or the way it is put together which is more palatable, particularly to young people. Is that also a matter for consideration by this committee?

Ms Hefford—It is not something that we have looked at or done any work on at the moment. It is something that we could consider in the future as we work on the development of the next national tobacco strategy.

Senator ALLISON—You may not be able to answer this, but in looking at the NHMRC material recently I noticed that it was agreed to refer the question of a policy regarding

provision of research funds to institutions in receipt of sponsorship by tobacco companies to the research committee for consideration and advice. Has there been a policy developed on this question?

Ms Halton— Ms Hefford is not able to answer questions about the National Health and Medical Research Council.

Senator ALLISON—Fine. Minister, on 30 May, your parliamentary secretary put out a release for World No Tobacco Day 2003 about smoking and the fashion industry. In fact, the campaign for World No Tobacco Day 2003 was also about the film industry. Is there some reason why the parliamentary secretary did not mention anything to do with film and smoking?

Ms Hefford—We have had the opportunity, particularly in recent months, to work with the fashion industry in Australia. The parliamentary secretary participated in events for the Smoke Free Fashion initiative at the recent Mercedes Australian Fashion Week—

Senator ALLISON—Yes, I know that; that is what I said.

Ms Hefford—and that has been an opportunity to work with that industry and send a good message. We have not yet found a similar opportunity to work with the film industry. Issues about smoking in films are canvassed in the Tobacco Advertising Prohibition Act discussion paper, which we talked about earlier. One of the issues we need to think about is that a lot of films shown in Australia are produced overseas. The discussion paper raises questions about that and whether or not people, in making submissions to that review paper, might want that issue to be taken up. The theme of World No Tobacco Day 2003, film and fashion, was not set in Australia; it is an international event and the theme is set overseas.

Senator ALLISON—Yes, I understand. I just thought it was interesting that there was no statement about film, not even anything supportive. As I understand it, the tobacco advertising act is unclear as to whether smoking or smoking product placement in films would constitute a criminal offence if inducements were taken for that placement. How much work has the department done on this question?

Ms Hefford—It is the one of the issues that is raised in the review and canvassed in the discussion paper. We will be very interested to see the submissions that come into the department as a result of that discussion.

Senator ALLISON—So the department has not at any stage considered taking some kind of court action, such as prosecution, or investigating whether inducements have been taken?

Ms Hefford—I think it is a more complex issue than that. There are issues for us about who you would take to court, particularly if the movie is made overseas—the cinema screening the movie? There are issues about how you would prosecute something like that and how you would prove whether or not a person in a movie actually showed the packet brand or the cigarette in some way, incidentally or otherwise. I think it is a far more complex issue than simply saying, 'We will legislate to take action against behaviour type X.'

Senator ALLISON—My question was not so much about further legislation as about the application of the current legislation. Presumably, you would need to do some investigation before knowing if you had a case or not. All I am asking is whether the department has

considered going down that path or embarked on any inquiries or investigations about inducements.

Ms Murnane—We have realised that one of the marks of the effectiveness of the legislation that we have is that tobacco manufacturers are finding other and—Ms Hefford used the word 'subtle'—more subtle ways to get their message across.

Senator ALLISON—Indeed.

Ms Murnane—You could go down all sorts of dry gullies trying to prove somebody had taken an inducement. We are looking at what we might do in the long run about these more sophisticated, more subtle and more subliminally appealing actions that they are taking. We are looking at that in the review. Most recently, as Ms Hefford mentioned, we have taken this Smoke Free Fashion initiative to get a countermessage across in an industry whose protagonists we know—young women in particular—are very susceptible to smoking. While there might not be blatant advertising of smoking, there is an incidental use of cigarettes that could be captured. The success of that initiative was that in Fashion Week there was not one public image of any of the protagonists in the fashion shows smoking.

Ms Halton—And, in fact, the year before, cigarettes were actually used as a prop. So I think the fact that we have gone from a situation where smoking was being glamorised and used explicitly as a prop to a situation where, to our knowledge, there was not one public image coming out of that event is a very major achievement.

Senator ALLISON—Just getting back to film, you would understand that product placement provides a great deal of revenue for the film industry, which is why they do not want to give it up. It is a formal process that the film producers go through. Whether it is placing a particular brand of car or whatever, a wide spectrum of opportunities for revenue comes to film-makers this way. The reason I want to pursue this is that there is plenty of evidence to show that the number of scenes in which smoking is used has risen over time. There is no doubt that it has climbed since the time of tobacco advertising being banned in cinemas. I find it difficult to believe that you would not consider that there might be an inducement being provided or see any need for any form of consideration or investigation into that.

Ms Halton—I think we are conscious that there are many avenues that we need to pursue, and film is one of them. Ms Hefford and I have actually had a conversation in the last three or four weeks about the need to look at film as one of the next areas that we might work in.

Senator ALLISON—That is all right; I just needed an answer that said, 'We have not bothered to do it and we haven't considered it, but we might in the future.' That was all I was asking for.

Ms Halton—It is not that we have not bothered. It is just that we have had a particular opportunity with fashion, which we have taken up. We have actually now had a conversation about the success of this particular initiative and the opportunity that we may have to spin off from this and look at film. So we have actively had the conversation about the need to do something about film. The question is how one does it.

Senator ALLISON—It is not exactly new, Ms Halton.

Ms Halton—I am not saying that it is new. I am saying to you that we have been focusing our attention on fashion. We will now explore actively the opportunities with film.

Senator ALLISON—There is just one other area. The United States seems to be concerned about the advertising of tobacco products on the Internet and suggests that particularly underage people are purchasing cigarette products through the Internet. Is there any evidence of that in Australia so far?

Ms Hefford—Young people being exposed to product advertising, including tobacco product advertising, through the Internet is one of the things that is canvassed in the discussion paper. We will be very much looking for community comments on that. Again, it is a very complex issue and it will be interesting to see what kinds of suggestions people have about how you might seek to influence that behaviour or to control the access.

Senator ALLISON—Finally, in this review, will the question of the amount of money that is invested in antismoking campaigns be touched on? Will recommendations be included, for instance?

Ms Hefford—This is a review of the Tobacco Advertising Prohibition Act. It is a review of the legislative framework around which we control access to tobacco. It is not a review of the department's expenditure on particular activities.

Senator ALLISON—As I understand it, the tobacco strategy group—I think that is what it is called—has made some comments in the past that the $1 you spend on an advertising campaign returns twice as much in savings. Firstly, has the department updated that work in the context of the current Australian program? Perhaps you could let me know what the states are doing as well. Secondly, has a comparison been made with other countries that might be doing well in reducing the number of people who smoke? I am thinking of Canada in particular. I think they have increased their funding fivefold on antitobacco efforts. It is now up to $110 million a year, Minister. Is that work being done at present?

Ms Hefford—I am not sure that I understand the first part of your question where you talked about dollar returns. Is there a particular report or piece of research that you are referring to?

Senator ALLISON—It is not on a web site—or at least I could not find it—but it has been quoted extensively. The body was called a strategies committee—for anticancer or something.

Ms Halton—Does it mention return on investment?

Senator ALLISON—Yes.

Ms Hefford—The return on investment study has only recently been completed and made available. Was your question about whether or not we are about to review that? I think it is relatively recent and therefore not something we would be seeking to review at this stage.

Senator ALLISON—So my comment about getting $2 back from $1 invested is accurate?

Ms Hefford—Yes, that is accurate, and reasonably contemporary. On how we compare with other countries like Canada, I have not looked at what other countries spend on antitobacco or antismoking campaigns compared with us. We usually compare ourselves in

terms of prevalence rates, and we compare very favourably. We are one of the leading countries in the world, with a smoking prevalence rate of 19.5 per cent.

Senator ALLISON—We banned advertising ahead of most other countries, so that has probably given us a headstart. So there is no intention of doing that study to look at other countries. California, for instance, has brought its rate down below 19 per cent, has it not?

Ms Hefford—Yes.

Senator ALLISON—Does the study which shows the $2 gain for the $1 invested lead you to suggest that Australia's expenditure of $2 million a year is inadequate? I know that the states of course add their own funds to it, but what does that suggest?

Ms Hefford—It is one of the things that we would need to review in the coming months. There are several issues intertwined there. We know that, through things like advertising campaigns, we can have an impact on young people who may be thinking about taking up smoking, but we have less of an impact on committed smokers through activities of that kind. You would need to balance where you wanted to make the biggest impact and how you wanted to direct your dollars.

Senator ALLISON—I am talking quantum, though.

Ms Hefford—It is something that we would want to review.

Senator ALLISON—Thank you.

Senator MOORE—Senator Denman has a large number of questions on your portfolio area. In view of the time, I am not going to throw all of them at you; I will put them on notice. There were two in particular that she did want asked this evening. One relates to a previous question on heroin dependency and the other to retractable needles. So that is the area I want to cover. Senator Denman had asked a question last June about the proportion of heroin dependent Australians estimated to be receiving some form of drug treatment that were treated since the commencement of the Tough on Drugs policy. She asked whether stats were kept on the number of people receiving treatment. The answer back from the department was that, no, those stats are not kept. She is wondering why that is so, considering the policy process of Tough on Drugs and its focus on heroin dependency. Why aren't stats kept on what number of people are being treated—why haven't they been kept?

Ms Hefford—People who have an opiate dependency and who have sought treatment are on a range of different—I am assuming you are talking about pharmacotherapy? Sorry, I am not aware of the question—was it pharmacotherapy?

Senator MOORE—It referred to a question she asked last June. It just says, 'The proportion of heroin-dependent Australians estimated to be receiving some form of drug treatment'. It did not specifically mention the treatment.

Ms Hefford—Drug treatment. So, those on methadone or buprenorphine?

Senator MOORE—I would think so, yes.

Ms Hefford—Usually this is something which is done at a state or territory level. State or territory government health organisations would have some data collection about the number of GPs who are treating opiate-dependent clients. It is not the kind of information we would

normally collect and I am not sure what it would tell us exactly. There are indications in some states that there is some movement to increased use of buprenorphine over methadone, but I would not have data and I am not quite sure why we would want to collect data of that kind.

Senator MOORE—So it is possible that if she did seek that information it could be through state health, alternatively.

Ms Hefford—State health authorities would—

Ms Halton—I actually recall that question being asked. I think Senator Denman's question went essentially to what proportion of people with an opiate dependency are actually in some form of treatment program. I can remember her being interested in that. It is a perfectly reasonable question. The problem that we have, as Ms Hefford says, is this: assuming that you have a statistical estimate—which of course is all you can have—of people with an opiate dependency or who use some form of opiate, then trying to work out what proportion of those are actually in for some form of treatment. My memory is—and maybe this is incorrect—that she was aware that some other countries can quote a figure that 63 per cent, or 54 per cent, or whatever, of people with a dependency are in some form of treatment program. I think, as Ms Hefford says, one of the basic statistical counting problems we have here is that we have multiple opportunities for treatment—different sorts of treatment banalities—and actually (1) having a uniform statistical collection and then (2) working out that you have not double-counted someone, is actually quite hard.

Senator MOORE—Then the figures would be meaningless anyway.

Ms Halton—I think that is the point. It is not that we do not understand the issue that she is going to; we have every sympathy for it. I think it is a practical question.

Senator MOORE—Now, retractable needles in syringes. The portfolio budget statement on page 67 states that $8.7 million over 2003-04 and 2004-05 will be redirected away from the funding for retractable needles in syringes due to:

a significant increase in the number of commercial providers developing this technology.

What was the justification for withdrawing such a significant amount of funding from the initiative—the background to that decision—and has a decision been made about which commercial provider will be selected to provide this technology?

Mr O'Donoughue—The original budget measure which was announced in 2002-03 envisaged a considerable investment in research and development for this technology. The department undertook an expressions-of-interest process with industry and a national consultation phase in implementing the measure. Through that we discovered that there had actually been some significant developments in private industry in the development of this technology which really obviated the need for that government investment in research and development. So consequently the refined measure of $17.5 million will still be able to meet the original aims of the original measure in introducing this technology, but without the government investment in research and development. The funds have been redirected to emerging priorities in the illicit drugs area, especially comorbidity and psychostimulants, and the maintenance of a research fund and better access for treatment services in rural and regional Australia.

Senator MOORE—Has a decision been made about a preferred commercial provider?

Mr O'Donoughue—No. The process will still go forward in terms of the consultative phase and further consultation and no single provider has been identified at this stage.

Ms Halton—As Mr O'Donoughue says, essentially the market has moved on. There are now a number of commercial providers. In fact, the TGA, who often receive these products for a preliminary examination, actually brought a whole selection of them into my office recently. Essentially, we would expect that a number of those products would probably be trialled for their acceptability and functionality in terms of the particular objectives we would set for a product that we might introduce more broadly. At this point, as Mr O'Donoughue said, we have to have a process not only of consultation but basically of trialling such product. It is far too early to say which commercial provider might be in the trial process or, of course, would ultimately be successful. We have been quite pleased to see that the commercial market is actually responding to that kind of interest, including some—

Senator MOORE—What about Australian developed products?

Ms Halton—Yes. I was just about to say: including a couple of Australian developed products. If one wanted to be a tiny bit patriotic, you would hope that one of those would be suitable for the purpose; so we will see.

Senator MOORE—I am hoping for the Queensland products.

Ms Halton—We hope for an ACT product but, hey, the east coast at least!

Senator MOORE—So the trials that will be done and that activity will still be funded through the department?

Ms Halton—Yes, absolutely.

Senator MOORE—I am sure that was Senator Denman's concern: that the money was still coming from that portfolio.

Ms Halton—Absolutely. Essentially, we believe we have kept ourselves enough money to enable that process to occur, to enable it to be properly evaluated and then to assist with roll-out.

Senator MOORE—Thank you. I will put the other many questions I have in that portfolio area on notice.

CHAIR—Are there any more questions on outcome 1?

Senator MOORE—I will put this on notice as well, but I just have a quick comment. Three particular reviews were mentioned at the end of the section. I would like information on all of them but three in particular. The first one is the evaluation of the bowel cancer screening pilot. I would like to know how that is going and updates on that. I am particularly interested in the evaluation of the National Q Fever Management Program and how that is going. In the budget paper it says, 'Whilst the program is going for another year or so, it is now been evaluated midstream,' and I would like to get information on that as it goes through. The third one is the national injury prevention plan. I put those things on notice.

Ms Halton—In a couple of cases we may not be finished, but I am very happy to give you information about process, timetable et cetera.

Senator MOORE—Also, in relation to the one for older people, which we talked about at previous estimates, it was said that the review will be commencing in May 2003. Has that kicked off?

Ms Halton—Is this falls prevention?

Senator MOORE—National falls prevention in older people. Has it started?

Ms Halton—Yes.

Senator MOORE—Perhaps 'kicked off' was the wrong term, but nonetheless it has started.

Ms Hefford—Yes, we have begun a process.

Ms Halton—We are happy to give you a work in progress.

Senator MOORE—I would like to know how it is going.

CHAIR—Any other questions are on notice. We are now moving to outcome 5, Rural health.

Senator MOORE—Our questions are on notice.

CHAIR—Senator Allison, do you have any questions on outcome 5?

Senator ALLISON—No.

Ms Halton—I indicate that yesterday we said we would table the release from the World Health Assembly which went to the elimination of avoidable blindness. We now have copies of that and are happy to table it.

CHAIR—Thank you.

[9.41 p.m.]

CHAIR—Are there any comments on outcome 3, Enhanced quality of life for older Australians?

Senator MOORE—It would not be the aged care section if we did not start out by asking for statistics. These questions follow on from previous ones, so you will know the sequence. We are asking questions about the latest figures for operational and allocated residential aged care places and Community Aged Care Packages, by regional planning areas. I notice that we asked for these figures last time—by state and electorate. You went away to see whether you could do that. You gave us that data by state, and you advised that you keep it by regional planning areas which do not match with electorates, which makes a lot of sense anyway. We would now like the December 2002 allocated and operational figures in the high, low and Community Aged Care Packages, by aged care planning regions.

Ms Podesta—We do not keep the information by planning regions as a regular report. We would have to take that on notice.

Senator MOORE—How long will it take to get them?

Ms Podesta—It is relatively straightforward.

Senator MOORE—So that would be relatively fast? We are very keen to get these, because we are looking at planning processes. We will follow that up with you as quickly as

you can. We were advised that there would be upcoming stocktakes on the processes—we talked about how the stocktake process operated. We believe that one has just happened midyear on the allocated places; is that right?

Ms Podesta—The next stocktake is due on 30 June.

Senator MOORE—What we would like, post the stocktake, are the figures—high, low and Community Aged Care Packages—by aged care planning regions up to 30 June. Is that possible? Can we get those?

Ms Podesta—Yes, we will take that on notice.

Mr Mersiades—We will be happy to.

Ms Podesta—As of 30 June?

Senator MOORE—Yes, as of 30 June, and for the same kind of thing. Would that be easy to get?

Ms Podesta—It is an enormous amount of data to collect for a stocktake. It will not be immediately after 30 June. We collect the data as of 30 June. We then check the veracity of the figures and finalise it. So it is a period of time following 30 June.

Senator MOORE—Could you refresh my memory about how that data is collected? We throw figures around, and talk about data collection and make demands for figures. Do each of the regions collect their own data and put it into a computer system?

Ms Podesta—State offices maintain monitoring of places and, depending on the status of that place, it will be calculated in a different way. So, for example, a place may be offline on one day but online the next day due to a restructuring proposal. That is why we take the stocktakes as of a particular date: so that we can accurately report from one day, because there is constant movement in aged care places.

Senator MOORE—And that is a matter of someone providing a figure and entering it in—it is a matter of data entry?

Ms Podesta—It is a matter of officers checking the status of places; for example, the progress of a sale or a transfer or the progress of making operational a provisional allocation. It is not a matter of just looking at numbers; it is also a matter of checking with approved providers, in some cases, the particular progress of a provisional allocation or a sale and transfer.

Senator MOORE—So in terms of the complexity of the task, and that is what I am trying to get my head around—we ask for these things and I think it is important that we know how it is fed in—at a state office level there would be people who would be allocated regions and be responsible for those; is that right?

Ms Podesta—I do not believe it is undertaken by regions. Most of the states treat their states as a state.

Senator MOORE—That is novel!

Ms Podesta—The data is collected and I think it is more a case of officers with particular responsibility for aspects of aged care program management bringing together their data and

cross-checking it. So, for example, the people in a state who are responsible for transfers and variations bring their data to the table and the people in a state who are responsible for provisional allocation bring that data to the table. It is a fairly large and complex task.

Senator MOORE—How many people would be involved in doing it?

Ms Podesta—I would have to take that on notice.

Senator MOORE—That would be another lot of figures to ask for; I hardly think that is worthwhile. We asked last time about the outlay that had been in the system the longest. We talked about the delays and the differences. In response to question on notice E03-097 the answer was:

(d) The longest-standing provisional allocation is one for a special needs group for 30 places that was allocated on 22 December 1988. The service is expected to open in June 2003.

Do we still have that hopeful expectation?

Ms Podesta—No. I would like to update that response. Since we prepared that information we have been advised, in response to question on notice E03-097, that the opening date for this service for a special needs group is expected to be August 2003, not June 2003. We are advised that the building works in a metropolitan area of a state are now almost complete. This information has only just become available to the department. The approved provider have assured the department that it will be open. They have had an enormous amount of difficulty in securing land and planning permission.

Senator MOORE—Can we get a special notification under a departmental letterhead when this one finally does open?

Ms Halton—Can I say that there are two former first assistant secretaries and one current first assistant secretary at the table and we all remember this project, so we will be taking as much interest in its eventual opening as you.

Ms Murnane—In 1988 I think it was me.

Ms Halton—Yes, and then I got to follow it up when I got there.

Ms Podesta—I think we should invite you all to the opening.

Senator MOORE—And it really was 1988?

Ms Podesta—It was indeed.

Senator MOORE—Was one of you a former assistant secretary in that position at the time? Did one of you sign that document?

Ms Murnane—I was, but I do not know if I actually signed the document. It was given ministerial approval.

Senator MOORE—I am trying to think who would have been the minister at that time.

Ms Halton—It would have been Peter Staples.

Ms Murnane—Yes, it was Peter Staples.

Senator Patterson—I might have been the shadow minister at the time. I most probably asked a question in estimates about it.

Senator FORSHAW—I can recall that.

Senator Patterson—You were not even here; you most probably were not even born then!

Senator FORSHAW—Thank you, Minister.

Ms Halton—The trouble is that we can recall it.

Senator MOORE—We are trying to get an idea of the full extent. My next question—and I am following Senator Forshaw's example on this one—is exactly how many do we have that are over the two years? We talked about the standard process at the last estimates which is for two years and then negotiation and extension. Can we find out how many, as at the end of this financial year when you do your stocktake, will be over the two-year mark? Notably, exhibit A should then be almost open, which is the one that will be open in August. We would also like to know which one then moves up to be the oldest one after that one opens. I am dying to know what was the next one after 1988.

Ms Halton—We will have to find out which former first assistant secretary was there when that one got approved.

Senator MOORE—That information should be part of the answer. That would be good. We got the one that was over two years old, and we should get that after the stocktake. We talked last time about how allocations are revoked—the process that is gone through to decide that an allocation has been revoked. Can we get the data on how many allocations have been revoked in the last 12 months?

Ms Podesta—Once again, that is information that will be updated in the stocktake. I can give you the information that I gave you at the last Senate estimates in regard to the number of revocations. Would you like that again?

Senator MOORE—That would be good, just for the record.

Ms Podesta—There have been 161 provisional allocations revoked, lapsed or surrendered in the 12 months up until 31 December.

Senator MOORE—Come the stocktake, some of those will not be in that 12 months but we will get that. In your stocktake, what exactly are you taking stock of? It could be easier, and save a lot of things, if we just asked to see your stocktake—a bit like David Jones!

Ms Podesta—This stocktake reports to the department on the status of allocated places. It is a stocktake of places allocated through the program.

Senator MOORE—So the data that we always ask for—which is the number of high, low and community placements, how many have been revoked and what stage they are at—is all in the snapshot of the stocktake?

Ms Podesta—That is all data that can be derived from the stocktake.

Senator MOORE—And they happen twice a year, you tell me?

Ms Podesta—They happen on 31 December and 30 June each year.

Senator MOORE—In terms of ease, it would be good if we could get the stocktake. Is it possible for us, instead of asking for bits of it, to get what you get? Is there anything in the stocktake that we should not have?

Mr Mersiades—I would not have thought so, but we will take that on notice just in case.

Senator MOORE—Instead of us asking for bits of data, which we ask for all the time, if there were a snapshot to find the information that we were seeking, it might be an easier way of doing it. Then we could ask questions that stand out from that, as opposed to going through the whole process.

Mr Mersiades—We will take that on board.

Senator MOORE—The last estimates were very soon after the minister's announcement of the new allocations—there had been the media release and the celebration of the new allocations—and we could not get information in response to some of our questions then because it was very new. We asked, but we could not find out until after the June 2003 stocktake, about how many beds had become operational since that announcement. Is there no kind of sneak preview of that figure? Do we still have to wait for the stocktake?

Ms Podesta—For consistency, we deliberately count everything as of a particular day. It is similar to a census.

Senator MOORE—We are going to be asking for the standard information, as we have already done. We are particularly interested, as you would expect, in the changes since the ministerial announcement. The ministerial announcement came out saying that there was going to be this greater increase. Is it possible to have any of the new allocations since the ministerial announcement in November brought out into high, low and community care packages?

Mr Mersiades—Do you mean in terms of those that have become operational in that time?

Senator MOORE—Yes.

Mr Mersiades—Because the operational figures are a moveable feast—they can change from day to day—it would not be a very efficient use of our time to try to track it on a day-to-day basis. Unfortunately, our systems have not been designed to track places in that way. That is why we instead choose to get a set on a particular day, twice a year. It would be very difficult to try to keep a record of how those movements take place on a day-to-day basis.

Senator MOORE—Okay. We are interested in what has happened subject to the ministerial announcement, because that came as a result of a great deal of lobbying across the industry. The minister said in his media release—this is in December, after his first media announcement—that he expected that 713 of the 5,579 beds allocated in November to be operational before the end of 2002, and a further 1,511 beds to be operational within 12 months. That was the public announcement of his expectation. Naturally, we would like to see how the reality and the expectation match. If it is difficult to get those figures, how are you then able to confirm to the minister that there has been success?

Ms Podesta—The figures are counted in the stock-take.

Senator MOORE—So you would be able to see the ones that have come on since November?

Ms Podesta—We are able to report on operational as a result of any particular aged care approvals round on, but only through the stock-take program.

Senator MOORE—That is what we are after. We are wanting to track the 713 and the 1,511. We always ask about the gap between the beds that have been allocated and the ones that are not yet operational. How much progress has there been to actually meet the gap with the ones that have been allocated but are not yet operational? We believe that there were over 20,000 as of December 2002 that had not been operational.

Ms Podesta—As of December 2002, there were 18,564 provisional allocations, but the vast majority of these were still within the two years to be made operational.

Senator MOORE—There were 18,564?

Ms Podesta—Provisional allocations. As we have indicated before, of those 18,564 only 1,302 were more than two years old; so they were well within the requirements of the act to be made operational.

Senator MOORE—So it is still the basic monitoring, as long as people keep within the act's requirements?

Ms Podesta—Yes, Senator. There is a very strict monitoring process in place now, regarding the provisional allocations. As I think I reported last time, approved providers are now required to give three-monthly reports and there have been strengthened conditions of allocations, including milestones; and approved providers are required to provide evidence to the department regarding their capacity to meet their milestones and evidence that they have. Failure to do so may well lead to revocation.

Senator MOORE—Similarly to the 161 that have been revoked, surrendered or—what was the other term?

Ms Podesta—Lapsed.

Senator MOORE—Or lapsed in the last period.

Ms Podesta—Precisely.

Senator MOORE—You also went through with us last time the process of the regular warning, the encouragement, and all that kind of stuff.

Ms Podesta—Yes. The state offices now meet with approved providers every three months as necessary regarding their reports and give feedback and information but also primarily monitor their progress, basically looking at whether any of those are at risk of not becoming operational within the two years and basically providing approved providers with an opportunity to show cause to the department why their places should not be revoked. It is a very stringent monitoring regime.

Senator MOORE—The funding for the beds is allocated when they are provided. It does not actually click in until they are operational?

Ms Podesta—That is correct. When an approved provider is ready to provide care, they apply under section 15.1 of the act, for a determination to take effect so that the places take effect. After that date, subject to them meeting their ongoing accreditation requirements, they attract residential subsidy.

Senator MOORE—Okay. So the funding keeps sitting there, waiting for them to become operational?

Ms Podesta—The funding is attached to the provision of care and so, when an approved provider is in a position to provide care, they are able to attract funding for that place.

Senator MOORE—What about the capital works stuff?

Ms Podesta—Funding for capital works is provided through a deed of agreement that specifies milestones that an approved provider is to meet; and payments are made upon completion of stages of work, as specified in the deed of agreement.

Senator MOORE—So in the case of exhibit A, which has been in the system since 1988 and hopefully will be open in 2003, has the money allocated for that particular exercise just been kept there? Notionally, it would have been allocated in 1988, because that was when that expectation was there.

Ms Podesta—The expectation would have been two years afterwards. They had two years to make it operational.

Senator MOORE—1990?

Ms Podesta—Yes.

Mr Mersiades—The subsidy payment does not flow until a resident takes occupancy in an approved place. In how the budget is constructed, there are certain estimates drawn in the special appropriation based on an expectation that a certain number would be coming on at a certain rate. We do not actually sit down and look at each particular home and say, 'This is going to happen here,' or 'That is going to happen there.' It is an overall estimate which is updated on a regular basis as well, depending on how the operational places are coming onstream. So there would not have been a funding allocation for that particular home going back to 1988.

Senator MOORE—It would have been in the estimate of what was allocated in that period?

Mr Mersiades—Yes. It would have been a global estimate, which would not have had regard to particular facilities.

Senator MOORE—How much room is there to move within a global estimate? I am interested in how the money allocation is organised. I can see that you look at a certain number, and certainly the concept is that you are, or will be, providing beds for a number of people. It is not beds; it is people. How do you actually get a handle on the money?

Mr Mersiades—We discuss it with the Department of Finance and Administration and we arrive at an estimate for budget purposes. But that estimate is not a capped figure. It can go over or under. But, obviously, we aim to try and calculate a figure which is as close as possible to what we think the outcome is going to be. As I say, we do reappraise that during the year. There is in a formal opportunity at additional estimates to reflect it in the appropriation estimates.

Senator MOORE—So that is how you actually trace it. If there has been undue delay, large numbers or whatever, do you monitor that on the three-monthly basis we were talking about, where you talk to people about three monthly?

Mr Mersiades—It is more often than that, isn't it?

Ms Hart—The two main points where the estimates appear in published budget figures are with the budget papers and at additional estimates, as Mr Mersiades indicated. But there are regular updates of estimates as part of the process between us and the Department of Finance and Administration to have the most accurate estimate of outlays. As we said earlier, those estimates are adjusted for information that is provided through the aged care payment system on the number of places that have come online and other payment parameters to do with numbers of places and the profile of residents. It is a process of constantly adjusting an estimate and making sure that the residential care subsidies reflect people who are in places.

Senator MOORE—And making sure that the warning bells are responded to when things are getting out of kilter.

Ms Hart—There is certainly continuing adjustment because of information that is flowing from the payment systems and from the data we collect about our resident population.

Senator MOORE—I will not be asking about waiting periods this time—I cannot do it. But we will be in contact about that, because we are still trying to get our heads around exactly how you determine that. My understanding is that some time in the last year there was a census done of people in hospitals to see how many people in a particular age group were waiting for alternative kinds of service delivery. Has there been such a census or study or survey?

Ms Hart—There has been a project.

Senator MOORE—A project, okay.

Ms Hart—Or a study, yes.

Senator MOORE—Everyone has got different titles for these things, but this is a project.

Ms Hart—That is right. It is one of a suite of projects commissioned by the Health Ministers Advisory Council to have a look at the care of older Australians. The study that you referred to is one that looked at older Australians who were in hospital on a given night and had a look at their situation and transit through the system three weeks later. That is part of one of four areas that is being examined that is currently with all Commonwealth, state and territory health ministers for their approval for release.

Senator MOORE—I know that this is an almost impossible question to answer when you have so many ministers sitting together around a table—and I note that ours is not here—but is there any kind of time frame on how long it will take? That would be fascinating data, I would think.

Ms Halton—You would know that the minister has talked at some length about the need for reform in the hospital sector. She is scheduled to meet with ministers—there is a regular meeting of the AHMC, which is the Australian Health Ministers Conference—and, essentially, we are anticipating that that whole reform agenda, which encompasses this particular piece of work, will be discussed at the end of July. I think it is fair to say that the question of what happens with older people and their experience of hospital and discharge—and we could go back to the two former first assistant secretaries here—has been an issue on the agenda for many years. I think the interesting thing about the study is that, whilst some of the traditional prejudices may have been in part proved, a number of them have in fact been

disproved. I think the minister is keen to work with our colleagues—as, indeed, we are—to find ways to reform the system to give people better care outcomes. I would anticipate that that broad area will be discussed at the end of July.

Senator MOORE—Within this particular project, are older Australians a certain age? What constitutes an older Australian in this project?

Ms Hart—For the purposes of that study, it was non-Indigenous Australians over 65 who were—

Senator MOORE—So it fell into an age pension type category, apart from the race—the age is over 65?

Ms Hart—Yes, the age is over 65. It also included a small sample of Indigenous people who were aged over 50 and in hospital on a given night.

Senator MOORE—Was this particular study taken in all hospitals or a certain hospital?

Ms Hart—I would have to take on notice the exact number of hospitals, but it was public hospitals and I believe it was a sample size of around 16,000 from the census.

Senator MOORE—That was part of the health advisory group and the state and federal governments looking at a whole range of issues, but this particular snapshot was on older Australians?

Ms Halton—Yes. As I said, this is an area that has been difficult between us and the states for many years. We agreed that we should try and do some collaborative work to at least get a shared benchmark—if you like, an understanding of the facts—so that we could then go on to discuss the policy and other issues that flowed from those. So the work has been auspiced by AHMAC, which is the combined CEOs of the health departments, and as a group we have been taking a great deal of interest in the various components of this work. We have a group of officers, largely deputy secretaries, who have been working on the reform agenda. In our case, Dr Morauta, who has already been in and answered some questions about health care agreements, has been taking the lead. We would imagine that this particular study would be one of the things that we will go to when deciding what next on reform.

Senator MOORE—And that data is confidential until the next meeting?

Ms Halton—It has not been released publicly. You would understand that there are sensitivities between individual jurisdictions. The notion is that it will be released at the one time with the understanding and knowledge of all of the ministers.

Senator MOORE—We look forward to the release and possible discussion on those figures at the next round of estimates. We do believe, and we continue to believe, that there are ongoing waiting lists for people to get into aged care facilities across the country. We are interested that, in the budget papers, there was no new funding to increase aged care places. We are wondering why we could not find new aged care places in the budget papers.

Ms Murnane—Aged care places do not increase every year—they increase with population.

Ms Hart—Funding for new places and the release of new places is driven by the Bureau of Statistics population projections for people over 70. As that number continues to grow, places

are released in line with the projections of people in that age group. The reason why there does not need to be a budget appropriation or an annual appropriation bill as part of the budget for funding for new places is that residual aged care subsidies and subsidies for CACPs are appropriated through a special appropriation—a kind of standing appropriation—so, as places increase and additional funding is required to support residence in those places, the funding flows through the special appropriation.

Senator MOORE—Is the special appropriation published?

Ms Hart—Yes. If you refer to page 137 of the portfolio budget statements, which has on it a resource summary for the aged care program, you will see that the two relevant figures are under the heading of 'Administered Appropriations'. You will see the figure of $3,834,476 as the total special appropriations budget estimate for 2003-04. That is the special appropriation for residential care subsidies. Under the heading 'Administered Item 2: Community Care and Support for Carers' you will see a total special appropriation item there for community care subsidies.

Senator MOORE—$292,618,000?

Ms Hart—Yes. In addition, under the heading 'Administered Item 3: Ageing Support and Strategies' there is a special appropriation for flexible care subsidies as well.

Senator MOORE—That is $60,103,000.

Ms Halton—This is actually much like the arrangements for, for example, the MBS. So, when we are discussing that item, we would not see a measure in relation to this. You will see large numbers of measures—we have discussed a good number of them so far—but this is, as has been explained, something that flows as an algorithm, if I can describe in that way, with the increase in the population. It is not published as a separate measure. It is not something which we go into in every budget process and make an argument for. It comes with the growth in the population.

Senator MOORE—Automatically.

Ms Halton—Yes.

Ms Podesta—On 13 April, for example, the minister announced 1,624 places for allocation through the aged care approvals around, which was advertised this month.

Ms Hart—In addition, not listed in our portfolio budget statements but in those of the Department of Veterans' Affairs is the funding appropriated for veterans' residential subsidies.

Senator MOORE—Veterans' homes, yes. And it is the same kind of process, isn't it?

Ms Hart—That is right—exactly.

Senator MOORE—I have seen that. At the last estimates we talked about the planning ratio and that it had not been revised since 1992. There was some discussion about whether there was any consideration of revising that planning ratio—the 100 per 1,000 which was then broken down. Has there been any further consideration of that?

Mr Mersiades—It is not an issue that is under active consideration in the way of a formal review, but it is an area that we are conscious of. Depending on what comes out of the pricing

review, for example, there may be an opportunity to have a closer look at it as well. But there is not an active—

Senator MOORE—That is the first time the pricing review has been mentioned tonight. We mentioned the pricing review lots in the last estimates, and that is the first mention of it this time. Are we are still waiting for the pricing review?

Ms Halton—Yes. It is not due yet.

Mr Mersiades—It is still on schedule.

Senator MOORE—It is on schedule?

Mr Mersiades—Yes. It is to report at the end of this calendar year.

Ms Halton—The government has not indicated that it intends to review the ratio. The ratio was established, as you say, in 1992 and was based on a range of academic and statistical advice. There was a review at the time as to the best method of ensuring that there was a regular flow of resources to ensure increasing supplier of care places. We have had some change over the years in the balance between the number of beds and places, which actually reflects, we believe, community requirements such as a greater expectation that people might be able to stay at home, and those places have been very enthusiastically embraced by the community. But at this point the government has not indicated an intention to actively review that ratio.

Senator MOORE—We understand how the funding process works, but we are trying to find out whether there was any consideration of extra funding in the budget. So, beyond the ongoing ratio, was there an understanding that more money was needed in the budget?

Ms Halton—No. What you see allocated in the budget reflects the funding arrangements as they currently apply and the places that will come on stream according to the arrangements that we use for calculating, which I think have been explained.

Senator MOORE—I received your figures for the RCS reviews in response to the last estimates questions about what had gone up, what had gone down and what was unchanged. What we got previously, though, was actually a calculation of the funding involved. We can work that out with the data, but we would like you to tell us what the funding implications are. We have the state by state data for July 2002 to December 2002 that you gave us on the number of beds, how they had been reclassified—some unchanged, some upgraded and some downgraded—and the totals. What we would like to know absolutely clearly so that we are talking the same language is how much funding was recovered through the RCS reviews for the period 1 July 2002 to 30 June 2003, which coincidentally would be the same as the stocktake period, I imagine.

Ms Bailey—We can certainly provide that. At present, we obviously do not have that.

Senator MOORE—It will be an ongoing question, Ms Bailey. So, in terms of the questions we ask and the little data set that you send us back, can we get the next column put into it? You have carefully given us the states, the places and the totals, and we would like to have the money total added to that. I am sure that is something that is available. I think that is the last of my questions on numbers—I hope it is the last of my questions on numbers! Yes, that is it.

Senator FORSHAW—Could I turn to the reports about the Tangerine Lodge nursing home in Victoria and the Collaroy Nursing Home in Sydney. The results of the assessments made of these two nursing homes were pretty appalling, weren't they?

Ms Bailey—They did show a number of problems, yes.

Senator FORSHAW—The reporting of what had occurred in those locations identified some very serious failures and breaches. Is it true, for instance, that the Tangerine Lodge in Victoria failed to meet 33 of the 44 accreditation standards?

Ms Bailey—That was the finding of the agency side audit in March—that is right, yes.

Senator FORSHAW—They last had an accreditation audit in June 2000. At that time, I understand it was called the Abalene Private Nursing Home. Just remind me: when was the latest report done on that nursing home?

Ms Bailey—The side audit was conducted on 25, 26 and 28 March 2003.

Senator FORSHAW—So we are talking about a gap of over two years. Were any spot checks undertaken in that nursing home in the intervening period?

Ms Bailey—From the department's perspective, it had achieved three years accreditation and we had no reason to visit the home, I understand.

Senator FORSHAW—You had no reason?

Ms Bailey—No. There was no strong complaints history; as the records show, we had no reason to link with it. But the agency might have another view.

Ms Vesk—At the accreditation audit in 2000 of the former Abalene Private Nursing Home, the home was found to be compliant with all 44 expected outcomes. There were two support contacts in 2001 and then the accreditation audit in 2003. There were no indicators present prior to that to—

Senator FORSHAW—Would you say that last bit again?

Ms Vesk—There were no indicators that the agency was aware of to cause concern.

Senator FORSHAW—When was that?

Ms Vesk—In December 2001.

Senator FORSHAW—And that was based upon what?

Ms Vesk—Previous support contacts and the history of the home. It had a history of being completely compliant.

Senator FORSHAW—Can you tell us why it went so bad?

Ms Vesk—I do not think that I could really speculate. I would observe that the ownership did change in December 2002. I am advised that there was some change in staff.

Senator FORSHAW—What do you mean by change in staff?

Ms Vesk—I mean that people who had worked there previously were replaced by other people. But, as I said, I do not think it would fair for me to speculate but simply to make those observations that—

Senator FORSHAW—We are not asking you to speculate at all. I am asking you what you know, and you obviously know that there was some change in staff. Are you saying that the new staff that came on were not qualified or that there were not sufficient staff? Can you expand a bit more on why a change in staff would have led to such a serious decline in such a reasonably short period?

Ms Vesk—No, I do not think I can, except to say that the knowledge that people have who work in an aged care home is very important in the ongoing running of that home, as it is in any organisation. If you have a high turnover of staff—I am not suggesting here that there was a high turnover of staff, because I do not know that—it can sometimes be that some of the knowledge might go with some of the people. That is why systems are very important, and that is why continuous improvement and the need to have those sorts of systems in a home are really important so that it is not so dependent on individual people.

Senator FORSHAW—Have you endeavoured to follow that through to try and find out some more details, to see whether your assumptions are valid?

Ms Vesk—Again I have to say it was not an assumption of mine; it is one thing that might be an indicator. The assessment team did give the home a very detailed report of their assessment, the agency gave the approved provider a list of what improvements they needed to make, and the obligation is really on the approved provider not only to comply with the accreditation standards but where they do not to put in place the improvements that they need in order to achieve compliance and I guess really, where it is relevant, for them to explore the reasons why to ensure that it is not repeated. Certainly the agency has provided a lot of advice to the home to assist them in that regard.

Senator FORSHAW—I want to come back to that staffing issue in a moment, but first I will go back to spot checks. In February 2002 we sought information on notice about how many spot checks had occurred in facilities that had had some problems in meeting their accreditation standards. We have been told that the department and agency undertook over 900 spot checks nationally in 2002. I can give you the question reference if you like, but that is what you have said. How many spot checks have you done this year, in the 2003 calendar year? I assume that 2002 was the calendar year, not the financial year.

Ms Vesk—Without seeing it, I would assume the same thing. I cannot speak on the part of the department, but for the agency to the end of April we had carried out 67 spot checks.

Ms Bailey—Would you like the departmental number too?

Senator FORSHAW—Yes, please.

Ms Bailey—Our number is to June, so it is slightly later, and it is 265.

Senator FORSHAW—So the figures are 265 and 67. I can add the numbers, but they are not directly comparable in time. So we are talking about 300-odd checks up until now.

Ms Bailey—The agency's numbers are slightly behind ours.

Senator FORSHAW—Yes. Do you have a target? I appreciate that there might have been some more checks earlier on when homes were seeking accreditation and some had problems, but what is your policy position here?

Ms Bailey—We do not have a target as a number; we have a policy setting that says we try to respond appropriately to information that comes to our attention about individual homes. Sometimes that will require a spot check. Sometimes it may require a different approach. Basically we deploy all of our resources to establish information that comes to our attention. We do as many spot checks as we feel necessary to respond to the information that has come to our attention.

Senator FORSHAW—Could I just clarify that we have both the department and the agency doing spot checks.

Ms Bailey—That is right.

Senator FORSHAW—On different locations, I assume. You are not doubling up, are you?

Ms Bailey—If we are case managing a home we usually communicate very closely to ensure that we are not doubling up on any given day. A home that is being closely managed might get a spot check or a visit from the department and the agency on alternate days.

Senator FORSHAW—Can you explain to me what the difference, if any, is between the nature of the spot checks done by the department as distinct from the agency?

Ms Bailey—The process for the department is usually that information comes to our attention that requires some verification or an establishment of the facts. That usually involves a Commonwealth nursing officer making a visit to the home without notice or at short notice to gain further information about information that has come to our attention. Following that, we decide whether that requires a more thorough assessment by the agency, who have the quality assessors who do thorough assessments. A spot check from the department could result in a referral to the agency for a more thorough visit or assessment.

Ms Vesk—The agency's spot checks can be either review audits, which are comprehensive assessments against all 44 outcomes of the accreditation standards, or support contact visits under the legislation. Within the agency, at least 10 per cent of those visits are done as spot checks—that means without previous notice. Also, in the context of this year, we have been doing a large number of accreditation audits because of the cyclical nature of accreditation. To the end of April, we had done about 1,200 visits to homes and more than 800 of those were site audits for accreditation.

Senator FORSHAW—They would be with notice?

Ms Vesk—Yes.

Senator FORSHAW—How much notice do you give for those?

Ms Vesk—That is determined in the legislation; it is done after receipt of the application and once a team is appointed. I do not remember off the top of my head. It depends how it is calculated, but basically the site audit would occur between two or three months after they had made their application.

Senator FORSHAW—They are making an application for reaccreditation—is that what we call it?

Ms Vesk—That is right—for a further period of accreditation.

Senator FORSHAW—So they know it is coming at some point in time.

Senator MOORE—They have done their self-assessment before that, haven't they?

Ms Vesk—They have.

Senator MOORE—They have recorded their own services and submitted that to you before you go into the audit?

Ms Vesk—That is correct.

Senator FORSHAW—You mentioned the support contacts. Could you explain what that actually means.

Ms Vesk—It is the name given in the legislation. Generally, that is a visit which would last between a half and one day, with an assessment team looking at an overview of expected outcomes. Say, for example, following an accreditation audit the agency identified some outcomes as noncompliant. In particular they would follow up progress on those outcomes to see what improvements had been made, but if there are no improvements to be monitoring it would be looking at a variety of expected outcomes in a general overview. I should add that we do both random and targeted spot checks. So the agency might do a spot check with no indicators for that where it is a perfectly compliant home. Then we also do targeted spot checks where we are monitoring a home for improvements it has been required to make.

Senator FORSHAW—You referred to the legislation. I recall wading through the initial legislation. I am sure the minister remembers it from estimates some years ago. Getting back around it is not something I have had to do until more recently. There have been just over 300 spot checks so far this year. Can we deduce anything from that as to what you would expect the total to be for the rest of this calendar year?

Ms Bailey—It would be speculation. We would do spot checks as we feel necessary to follow up information, but I really cannot predict a number. It is just driven by the information and level of monitoring that we are doing of homes. So we will do as many as we have to.

Senator FORSHAW—How many homes—by homes, I mean all aged care facilities, not just nursing homes—are you monitoring?

Ms Bailey—We have six homes with sanctions in place, and they would be at the top of our case management list. Other homes that the agency might identify then have follow-up visits. A lot of our spot checks are generated from information that comes to us, perhaps through a complaint and so on. But we have a process that sets out what we do for each home, depending on their compliance record with the agency and their compliance record with the other responsibilities. The process is quite detailed and is set out in the legislation. We follow that process for each home.

Senator FORSHAW—You mentioned Tangerine Lodge. Tell me about the history of the Collaroy Nursing Home.

Ms Vesk—I will give you the agency's knowledge of it. They were accredited for three years in December 2000. Subsequent to that, there were a number of support contacts and a review audit was conducted from 25 to 28 March. The team identified seven noncompliant outcomes and serious risk in one outcome, which was infection control. A report of that serious risk was sent to the Department of Health and Ageing, and sanctions were imposed on

3 April. The agency continued to make visits to the home, prior to making the decision on the review audit. The service engaged an administrator straightaway as a result of the sanctions and they had sought consultants' advice for the infection control issues and to provide training to staff. There were some pretty immediate changes to their practices and procedures in the home, and that minimised the risk in infection control. When the agency made its decision on 16 April, the decision was to vary the period of accreditation by reducing it so that it expires in October—

Senator FORSHAW—October of this year?

Ms Vesk—October of this year. At that same time, it advised the Department of Health and Ageing that there was no longer serious risk present. We continued to visit the home regularly. I think we were there just over a week ago, and a number of improvements have been made. We are scheduled to go there again this week. The home needs to apply for a further period of accreditation in July of this year. Then it will have to have another full audit for accreditation.

Senator FORSHAW—It will have to have another full audit. When is that likely to be—some time between now and October?

Ms Vesk—Probably August-September.

Senator FORSHAW—I want to go back to the Tangerine Lodge issue. You said that it was sold in 2002, and the ownership changed.

Ms Bailey—It opened as Tangerine Lodge in December 2002.

Senator FORSHAW—Yes. I was right, wasn't I, that it was previously called Abalene?

Ms Bailey—Abalene Lodge, yes.

Senator FORSHAW—What role did the department have in the transfer of licences et cetera at the time of the sale? I assume there had to be a transfer.

Ms Bailey—That is right. There is set out in the legislation a transfer process that all providers need to put before the delegate and the department. Ms Podesta can give you the full detail.

Ms Podesta—An approved provider may acquire transfer places, and the secretary or the delegate approves the transfer in accordance with the requirements of the act. The transfer of places usually involves a transaction between parties but takes place outside the act. Only operational places may be transferred. A new approved provider may operate the places from the same site or relocate some or all of the places. An approved provider proposing to transfer places must submit an application plan, a justification and a timetable; and the approved provider receiving the places must also complete such forms. A range of criteria is applied by the department in making a decision regarding the transfer of a place. Would you like me to outline the criteria?

Senator FORSHAW—That would be very good. You are telling me what the criteria are generally. I want to focus as well on what happened in the case of Tangerine Lodge.

Ms Podesta—I will go through the criteria. There are a number of criteria that need to be considered in regard to any transfer. The first is whether the transfer meets the objectives of the planning process. The objectives of the planning process are to provide an open and clear

planning process, to identify community needs, particularly in respect of people with special needs, and to allocate places in a way that best meets the identified need of a community. That is the first criteria that needs to be considered. The second is the suitability of the transferee—that is, the approved provider wishing to take possession of the places—to provide care. The third is the financial viability of the service to and from the transferee. Another is whether the care needs of residents will continue to be met appropriately, and another is the suitability of premises—and a range of other matters under the allocations principles.

Senator FORSHAW—Would the range of other matters include staffing levels?

Ms Podesta—They include matters such as the capacity to repay bonds, for example.

Senator FORSHAW—Would it include maintaining staffing levels?

Ms Podesta—I would have to take that on notice. I do not believe so, but I can check that.

Senator FORSHAW—Yes, if you would not mind. When the sale of Tangerine Lodge occurred and the licence was transferred, did the department or the agency do any physical inspection or checks, or is it all done just as an exchange of paperwork, if you like? I appreciate that it has already been accredited, but I am interested to know how thoroughly you pursue the issue of ensuring that what has already been established for the current provider will be taken on board by the new one.

Ms Bailey—As Ms Vesk pointed out, there is a monitoring regime by the agency following accreditation, and support contacts. Relocation to a new building is quite a frequent occurrence. Where a transfer takes place, all those matters about the plan and how people are going to do it are looked at. I am not familiar with it, but I do not believe there is a routine inspection of buildings before they open. But I would have to take advice on that.

Ms Podesta—There are approximately 150 to 200 transfers each year and it is the responsibility of the approved provider to set out their plans and timetables for the relocation of residents. As part of the process by the department to consider a transfer, it is very usual that there is a series of meetings between the approved provider and the parties to discuss those things and satisfy the department that they understand their responsibilities. The onus of responsibility is on the approved provider to continue to meet the obligations as an approved provider under the act.

Senator FORSHAW—I understand that one of the observations that has been made is that there were some serious staff shortages at the Tangerine Lodge nursing home. Do you have any comments to make about that? Some comments about staffing were made earlier.

Ms Bailey—Clearly the Aged Care Act sets out a very clear responsibility for approved providers to have adequate and properly skilled staff to meet the care needs of the residents. That is a most serious undertaking by an approved provider. That is a responsibility they have to meet.

Senator FORSHAW—I assume that, following the checks, you have gone back to check the file on this home. Has it shown that there were staff shortages?

Ms Bailey—I think that the agency's report pointed to issues that related to staff skills and training—not directly to numbers but issues about the demonstrated skills and training of staff. That is an observation this agency often makes, and clearly it is the agenda for approved

providers everywhere to look at ways to enhance the skills and training of their staff. We have been very highly involved in this home since it had sanctions applied to it. The staffing there is something that we are looking at very frequently. We have been asking the approved provider questions about staffing, how he is atttracting staff and how that is being managed. We are vitally interested in that while there is a sanction. That is for all homes, but right now at his home.

Senator FORSHAW—I would assume, and I would ask whether you would agree, that if you had a reduction in staff numbers and/or a reduction in the level of skills, qualifications and training of staff, particularly if existing staff leave or are terminated and replaced, that is the sort of thing—and I am making an assumption now, Ms Vesk—that could lead fairly quickly to some serious problems arising such as the ones that occurred at this nursing home?

Ms Bailey—I think, on balance, you would imagine that was an element of what has been happening.

Senator FORSHAW—It would be one of the first things you would want to look at, wouldn't it?

Ms Bailey—As I said, we are extremely concerned about staffing and have raised that with the provider upon almost every visit.

Senator FORSHAW—You are concerned, but have you actually done anything about the monitoring of staffing?

Ms Bailey—It is not our position to advise the approved provider how to run the business, but it is our position, on our visits to the home, to ask them how they are meeting the care needs of the care recipients. That includes whether they have adequate staffing with appropriate skills. So we ask them, on our visits, whether they have people on shift who can care for the residents. That is the level of monitoring that we are doing, I suppose, at the moment.

Senator FORSHAW—What is the current position with the Tangerine Lodge nursing home?

Ms Bailey—As Ms Vesk said, there was a site audit in March and the agency notified the department that there was a serious risk at Tangerine Lodge. The department imposed a sanction on the home for six months, requiring them to appoint an administrator with nursing experience and they could not have any further residents for, I think, six months. Following that, on 5 May I understand the agency made a decision not to accredit the home. The home's accreditation expires on 20 June. On 19 May the home applied to the agency for a reconsideration of the decision not to accredit. On 21 May the approved provider appointed receivers.

The agency is currently in the process of processing the request for reconsideration in accordance with the legislation and a site order is being conducted now. I understand that it will conclude perhaps tomorrow. After that, the approved provider has up to 14 days to give the agency a written response to the findings of the audit. I should say that, since April, both the department and the agency have been there probably over 40 times. Given that the process of reconsideration is incomplete, we really cannot speculate much further. But it is important,

I think, to note that the department has been communicating very closely with the residents and their families and keeping them up to date.

Senator FORSHAW—You covered quite a few things there. Can I just take you back to one of them. Did I hear you say that the home, or the company that is the approved provider, has been placed in receivership?

Ms Bailey—Yes. The approved provider company is in receivership—that is right.

Senator FORSHAW—Which company is that?

Ms Bailey—Marnotta Pty Ltd.

Senator FORSHAW—What impact does that have on your processes?

Ms Bailey—We have obviously met with the receivers and they are working closely with the department. They become, I guess, key personnel of the approved provider company now. They carry out a key management role at the home now. So we have established an open line of communication. We have given them, I believe, a very thorough briefing about what it is they need to do to bring the home up to the standard that will be required.

Senator FORSHAW—Were the department or the agency aware that there were some financial problems with the company; and, if so, when?

Ms Bailey—We do not have a direct interest in the financial affairs of the provider. They are a company like every other company, but—

Senator FORSHAW—You do not?

Ms Bailey—In this case, our interest was in the care of the residents. In looking for the causes, questions were asked and people brought information to us. But the decision to go into receivership and those matters are ones that the company makes.

Senator FORSHAW—You said earlier, Ms Podesta, that financial viability is one of the things you look at when you determine the suitability of the transfer, as in this case, of a licence to another approved provider. Is that it? Don't you continue to at least keep some focus on their continuing financial viability?

Ms Bailey—Their financial capacity to pay to deliver the care to the residents is our primary concern. From that angle we are certainly interested and discuss that. In this case, it was I think clear just before the receivers were appointed that the home may have been in financial difficulty. There were anecdotal stories of people not being paid, of suppliers not being paid, but it was at that level—any information coming to the department was anecdotal. But we were concerned and we spoke to the approved provider on a number of occasions, setting out our extreme concerns and making it clear to them, especially when the sanction was implied that they had to appoint an administrator, that they would need to make available the funding to that administrator to help her to remedy the problems.

Senator MOORE—So some of the sanctions that are applied mean that people cannot take more patients or more clients. Is that correct?

Ms Bailey—There are a range of sanctions, but in this case the two that we imposed were no new residents for six months and that they must appoint an administrator, in this case with nursing experience, to help them get the home, hopefully, back up to the standard required.

Senator MOORE—If the home is not able to take more clients, and beds become empty, that is actually part of the whole spiral in continuing to operate.

Ms Bailey—That is a possibility, although if things are serious enough that we impose a sanction it is usually not appropriate to allow new residents to enter into that scenario.

Senator MOORE—Absolutely.

Ms Bailey—In 99.9 per cent of the 10 to 12 sanctions that we typically apply each year most providers act very quickly and release the resources to remedy matters very quickly, so they can either apply to the department to have the sanction lifted or work their way through that to get themselves back on track. It could be seen as that, but mostly it is really to protect new people and to give the provider a chance.

Senator FORSHAW—It seems that something went horribly wrong in this process. The nursing home business was sold in December last year. The licence was transferred. There was supposed to be a check on their financial viability and planning suitability, amongst other things. And three months later they have got one of the most scathing reports you could ever read—what was happening was atrocious—and the company is in receivership. All that happened in three months. It just has not worked, has it? Something has gone horribly wrong. How did this happen? How did this get through?

Ms Bailey—Clearly the current situation is unacceptable, and it is unacceptable for any provider not to meet the care standards. But I am not able at this stage to give you a full analysis of how this happened. I have been dealing with it since it happened, and I think it needs to be looked at in context. At the moment, my efforts are focused on what has happened since it happened. I am not aware of the arrangements. As I said, Abalene was never a home that was drawn to our attention for any other reason. So this has happened in three months without any—

Senator FORSHAW—Excuse me, I am focusing on the fact that it was transferred—apparently it was sold—in what we can only assume was full compliance and that everything being fine. A check was done on the purchaser, Marnotta Pty Ltd, and somehow they got through okay. Three months later, you have got this terrible situation and the company being placed in receivership. I would like to know how that occurred. This regime is supposed to stop that. It should not happen, should it?

Ms Bailey—I think what it did stop was that as soon as this was brought to our attention—

Senator FORSHAW—Yes, but it was three months.

Senator Patterson—About three nursing closed down in that time, as I remember it, but about 190 came in.

Senator FORSHAW—So you think it is okay, Minister—

Senator Patterson—No, I am not saying it is okay. What I am saying is—

Senator FORSHAW—for me to ignore that. Is that what you are asking me to do?

Senator Patterson—I am not saying it is okay. I am saying that you should go back and have a look at your record. There were nursing homes that should have been closed down that were left open. It was appalling.

Senator FORSHAW—I am not going to sit here and debate this at five to 11 and, frankly, waste the valuable time of the officers at the table. I am not going to ignore the situation either, just because you sit there and say, 'Let's have a look at what happened X number of years ago.'

Senator Patterson—I am not saying that—

Senator FORSHAW—You are saying that. I would like to know—

Senator Patterson—I am just saying that Labor's record on nursing home standards is nothing to be proud of.

Senator FORSHAW—We are debating your government's performance and the performance of this department and the agency—

Senator Patterson—Something is being done about it.

Senator FORSHAW—We are not in debate; I am asking questions about it.

Senator Patterson—Something is being done about it.

Senator FORSHAW—It is no answer to just point back to what may or may not have happened in the past.

Senator Patterson—I just reminded you.

Senator FORSHAW—You can remind me all you like, but it is not going to stop me from asking the question, which is: how is it that a sale is allowed to go through, a licence is transferred and everything is supposed to have met the tests that are laid down in your act and then, within three months, you have got the most outrageous situation and a damning report and you have got the company in receivership? That is the issue you have to address, Minister, not what might have happened X number of years ago.

Senator Patterson—I am just saying that your party's record was appalling.

Senator FORSHAW—I would like an answer to the question.

CHAIR—Can we proceed or shall we adjourn?

Senator FORSHAW—I have asked the question and I have tried to explain—

CHAIR—Let us proceed or adjourn, Senator. You have already mentioned that four or five times. Let us proceed or adjourn.

Senator FORSHAW—Would you, Chair, do your job and stop the minister from interrupting and going back and discussing issues that might have occurred under previous governments?

CHAIR—Sorry, I have to stop both of you interrupting each other.

Senator Patterson—It is just that I have got a very long memory.

Senator FORSHAW—I would have thought you might have tried to improve things, Minister.

CHAIR—Senator Forshaw, do you want to proceed?

Senator FORSHAW—I have asked a question and I am waiting for an answer. How was this allowed to happen?

CHAIR—It is the only answer you are going to get.

Ms Halton—Senator, can I make a comment about this.

Senator FORSHAW—Yes, please.

Ms Halton—We will give you an answer on notice about the process. I am happy for us to do that. I would say to you that at the end of the day a company's financial health at a particular point in time may be able to be tested—and that is what we understand to have been done—but we will come back to you on notice as to the process that has been followed. Of course, what we cannot say is what they actually did inside that company using that company's resources in the three months after this was transferred. At the end of the day we as a department have certain obligations under the act which we attempt to discharge, and we are able to ask certain questions, which again we attempt to ask and attempt to satisfy ourselves in relation to. We all know that there are occasions on which companies make decisions which are unrelated to the material business which they largely conduct. They may relate to the individuals in that company et cetera—

Senator FORSHAW—Ms Halton, you are speculating. I am sorry to interrupt.

Ms Halton—I suppose my point to you is that we will come back to you on notice about the process that has been followed here. If there is some deficiency in that process we will most certainly identify it. All I am saying to you is that I think you are jumping to a conclusion that there is a deficiency in the process. There may be a number of reasons that this occurred and it is probably better for no-one to speculate. We will go and have a look at the process and come back to you on notice as to what we believe has occurred.

Senator FORSHAW—I am seeking to find out what happened in such a short period of time within this nursing home and within this company that it went from a position of being approved to hold a licence on the basis that it had passed the tests, including financial viability, and then a mere three months later—

Ms Halton—I think that is a perfectly reasonable question to ask.

Senator FORSHAW—Exactly. That is what I have been trying to find out.

Ms Halton—That is fine.

CHAIR—Order! It is 11 o'clock. I have a procedural question. Are there any questions for PHIAC on Friday under outcome 8? Will they be needed here?

Senator McLUCAS—Can I advise the secretary of the answer to that question tomorrow?

Senator Patterson—I think the officer will have to come from Sydney, so please do that tomorrow so we know.

Senator McLUCAS—There are issues but the questions may be able to be placed on notice.

CHAIR—I thank the minister and the officers present. We will reconvene the hearing with the Department of Health and Ageing on Friday.

Senator McLUCAS—We have had two days to do a lot of work in Health. The agenda we face has required that and requires our having to reconvene on Friday. We as senators do appreciate that this is a long but an important process, as I am sure the officers and the minister agree, and it is a process that we hold very highly in this parliament. Whilst we recognise that it is a long process, that is an explanation for why we have to reconvene on Friday, and I look forward to seeing the officers then.

Committee adjourned at 11.01 p.m.